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Correlations Between Management Behaviors and Financial Indicators with FDA Compliance Leading to Medicine Shortages

Francisco Gutierrez-Perez
Walden University

Walden University

College of Management and Technology

This is to certify that the doctoral dissertation by

Francisco Gutiérrez-Pérez

has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

Review Committee
Dr. Richard Schuttler, Committee Chairperson, Management Faculty
Dr. Thomas Spencer, Committee Member, Management Faculty
Dr. Mohammad Sharifzadeh, University Reviewer, Management Faculty

Chief Academic Officer
Eric Riedel, Ph.D.

Walden University
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Abstract

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Francisco Gutiérrez-Pérez

MBA, Universidad de Puerto Rico, 1992

MS, Massachusetts Institute of Technology, 1976

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Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

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Management

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Abstract

In the first 3 years of the Obama Administration, 2009–2011, the number of warning letters issued to pharmaceutical firms for manufacturing and quality issues increased by 81% to 49 letters. Only 9 letters were issued in the last 3 years of the George W. Bush Administration. Shortfalls in compliance and product quality led to medicine shortages that affected patients' treatment and health. This quantitative study sought to learn to what extent, if any, the independent variables, management behaviors and financial indicators at pharmaceutical firms in the United States, correlated with, or predicted, the dependent variable, compliance with the FDA regulations. FDA's enforcement actions on the firms were the treatment event. A shift in the relationship between the variables occurred after the FDA interventions, which highlighted a new level of compliance. Of the 1144 SurveyMonkey invitations sent to the members of the International Society of Pharmaceutical Engineers, only 21 completed the survey's 133 questions. Three research questions were addressed using correlations and linear regressions. The theory of planned behavior was applied to correlate behavioral constructs with the compliance of the firms leading to the rejection of the null hypothesis. By establishing an inverse relation between financial indicators and the firms' level of compliance, the study offers awareness and insight to senior leaders regarding their behaviors and the decision-making process. Enhancing managers' decision-making processes in light of their beliefs, along with their control over financial indicators, could reinforce the presence of effective quality systems among pharmaceutical manufacturers minimizing medicine shortages.

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Dedication

I dedicate this work to my wife and children that supported my passion for this adventure during the past six years. Their love and motivation allowed me to achieve this dream.

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As a mentor and professor, Dr. Richard Schuttler provided enthusiasm and guidance to a dream that made a profound difference in my life. Dr. Thomas Spencer contributed to my critical thinking skills throughout my analysis of the study. My gratitude and appreciation to these gentlemen who shared their knowledge and wisdom with me during the past six years.

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Chapter 1: Introduction to the Study

Since 2009, interventions and enforcement actions against U. S. pharmaceutical manufacturers by the Food and Drug Administration (FDA) have increased. Many of the interventions were due to a lack of compliance with current good manufacturing practices (CGMP). In short, patented or generic pharmaceuticals sold to the public were not available or were substandard in quality. Attitudes and behaviors of management in pharmaceutical firms with an over-commitment to financial results have led to the lack of the expected compliance with regulations, thus declining organizational performance. This performance has a direct impact on internal and external stakeholders, which needs to be addressed to achieve the desired positive social change of avoiding shortages of medicines. Pharmaceutical management consists of all individuals that have the authority to make-decisions that could impact compliance with the FDA regulations and to direct financial decisions within the pharmaceutical firms. According to Pollack (2013), the drug shortages were caused by (a) pharmaceutical management decisions to limit investments in enhanced quality systems and (b) insufficient manufacturing capacity.

To project the complexity of addressing the change process, management decision-making processes, and possible theoretical frameworks need to be implemented by pharmaceutical management. The essential change process to avoid medicine shortages has to evolve through the typical change cycle of what, how, and why (Kezar, 2001). The potential impact on stakeholders, especially drug shortages, constituted the "why" for conducting this study. Influencing the organizational performance, by

modifying management behaviors and financial indicators, is expected to minimize or eliminate the impact on stakeholders, leading to positive social change.

Chapter 1 includes the background of the study, the specific details of the problem statement, and the purpose of the study. Then, the impact on social change by the study was followed by the theoretical framework of the study, the research questions and hypotheses, and the design that guided this quantitative study. Chapter 1 concludes with the definitions, scope of the study, assumptions, limitations, and delimitations in this study.

Background of the Study

A series of FDA interventions and enforcement actions against pharmaceutical manufacturers in the past 5–6 years led to medicine shortages in the United States (Nguyen, Seoane-Vazquez, Rodriguez-Monguio, & Montagne, 2013). Manufacturing shortfalls made essential medicines unavailable for the treatment of patients (FDA, 2013). Manufacturing shortfalls implied that quality management and manufacturing systems were not empowered or properly staffed to adequately support the critical functions of the pharmaceutical firms (Woodcock, 2012). The loss of sales, penalties, and cost of remediation directly influenced the profit, and thus affected the worth of the stockholders and the firms' market value.

In this dissertation, I promoted positive social change by influencing the elimination or minimization of medicine shortages. Medicine shortages placed the patients' health in significant danger (FDA, 2011). Also, medicines that are substandard in quality, purity, strength, and identity do not address the intended health treatment

(Woodcock, 2012). Given that the firms' revenues were affected, both the patients and the stockholders could be perceived as the victims of management decisions. Pharmaceutical manufacturing management's attitude towards limited compliance and based on extreme control over the cost of goods presented the challenge and disconnect in the management decision-making process. Burd and Chrai (2004) challenged the attitudes and behaviors of pharmaceutical management, as well as their drive for financial results. For pharmaceutical firms, lack of compliance with FDA regulations could be devastating. The results could include loss of the market value of the firms, loss of sales, diminished reputation, and increased expenses to recover or achieve remediation. If an FDA intervention were to evolve into a consent decree, which is a legal agreement to resolve the shortfalls in compliance by the firm, the magnitude of all these elements could multiply and become an unacceptable historical benchmark within the industry.

Problem Statement

The general problem investigated in this study was a significant increase in the number of pharmaceutical firms cited for noncompliance with federal quality guidelines during the past 5-6 years. In the first 3 years of the Obama Administration, 2009 through 2011, the number of warning letters issued for manufacturing and quality issues increased from 9 letters (in the last 3 years of the George W. Bush Administration) to 49 letters (Nguyen, Seoane-Vazquez, Rodriguez-Monguio, & Montagne, 2013), for an increase of about 81%. This percentage reflected FDA's emphasis on assuring compliance by the pharmaceutical companies. The lack of compliance with CGMP led to pharmaceuticals

manufacturing facility closures, loss on revenues, unavoidable penalty fees, loss of reputation, and significant investments to address remediation of their non-conformances to the FDA regulations (Asotra, Cossin, & Yacobi, 2012). The FDA, in a letter, dated October 31, 2011, to pharmaceuticals manufacturers, indicated that about 54% of drug shortages were a result of manufacturers' quality issues (Food Drug Administration [FDA], 2011). Collectively, the evidence suggested that the number of FDA interventions and enforcement actions, against pharmaceutical manufacturers, have increased in the recent years.

The specific problem addressed in this study related to shortfalls in compliance performance and product quality leading to medicine shortages that affected patients' treatment and health. According to Pollack (2013) the shortfall in investment decisions for enhancing quality systems and the limited manufacturing capacity caused the medicine shortages. Price competition to attain market share, financial benefits on market value, and management incentives skewed against investing in plant improvements drove pharmaceutical manufacturing leaders' decisions and behaviors away from compliance (Asotra, Cossin, & Yacobi, 2012). Senior leaders' attitudes towards the lack of focus on quality systems prevail in their management decision-making process (Woodstock, 2012). Mehta (2013) suggested that implementing the principles and guidelines developed by the International Conference on Harmonization could be a significant step in facilitating senior leaders' understanding of the compliance expectations. Correcting CGMP violations by the pharmaceutical manufacturing leaders implies that productivity-

financial indicators need assessment and that management behaviors require modification.

Purpose of the Study

The purpose of this quantitative study was to determine to what extent, if any, management behavior and financial indicators at the pharmaceutical firms were correlated with their compliance with FDA regulations. From the review of the literature, the gap consisted in the limited research that would create awareness and offer guidance to managers in their decision-making process and risk assessment process regarding their (a) FDA compliance responsibility, (b) corporate financial mandate, and (c) stakeholders' expectations. This research was driven by the limited information on what are the interdependencies or correlations between the need to grow revenue and the behaviors within the pharmaceutical management decision-making process.

Management's resolve to meet the firms' intended quality, integrity, strength, and purity influences the level of compliance. Other factors include the pressures to enhance productivity, fund research, support marketing plans, and reduce the cost of goods. FDA's enforcement actions were used as the treatment event to reestablish the expected level of compliance. A shift in the relationship between the variables was expected after the FDA intervention, thus highlighting the new level of compliance. The resulting level of compliance is expected to enhance the financial performance of the pharmaceutical firms and minimize drug shortages.

Significance of the Study

This research study was directed to address an area of limited research on the management behaviors and financial decision-making of senior management in pharmaceuticals companies. Management behaviors and financial decision-making could have led to significant shortages of medicines in the last 5-6 years. Drug shortage events increased from 61 in 2005 (Barlas, 2014) to 251 in 2011 (FDA, 2013). According to Woodcock (2012), many of these medicine shortages were caused directly by shortfalls in compliance with FDA regulations. The outcome of the study provided insight to the management decision process on what senior leaders' behaviors should be considered and accentuated the need to modify financial drivers, which limit the presence of effective quality systems in pharmaceutical manufacturing companies.

For pharmaceutical firms, lack of compliance with the FDA regulations could be devastating. Lack of compliance could impact sales and reputation, and could increase in the level of expenses to recover or achieve remediation. These performance indicators also correlated to the market value of the firms. If the FDA intervention escalates into a consent decree, the magnitude of all these elements could multiply and become an unacceptable historical benchmark within the industry. Legal actions against pharmaceutical firms' leadership could be inevitable. This study pursued the potential to highlight the undesired behaviors in management and accentuated the concept that compliance is a competitive business advantage for the pharmaceutical companies.

This study could raise the awareness of pharmaceutical management about how their decisions, based on their attitudes and behaviors, could avoid interruptions in the

supply of some essential patented or generic drugs. The social responsibility of the organization would be perceived to be non-existent and detached from the mission of providing quality medicines for the treatment of patients. Some examples of the experienced shortages are Tylenol for cold symptoms in 2011, Doxil for ovarian cancer in 2012, and Levoxyl for thyroid hormone replacement in 2013 (FDA, 2013). The goal of this study was to provide clarity about the desired behaviors to management. The findings of the study are expected to transform leadership tactics to meet the organization goals and mission, while sustaining compliance with the CGMP regulations.

The target of the study, as previously described, was directed to avoid placing the patients in danger with medicine shortages (Hensley, 2011). In their study, Becker et al. (2013) found that the number of oncology drug shortages affecting patients' treatments increased from 2010 to 2011. Also, stockholders' equity could be affected if management does not recognize the detachment from their mission leading to the costs associated with the FDA intervention and high financial penalties. The effectiveness of this study depended on the degree of honesty in the participants' responses and on how well the responses represented the actual behavior or intended future actions of the participants. Secret agendas were not detected. Unscrupulous managers could have presented an obstacle to enhance quality systems and compliance as indicated by Woodcock (2012). The actual performance could continue with old practices and behaviors, leading to poor product quality and further medicine shortages, while increasing the risk to patients and the losses to stockholders.

The study has implications for positive social change directed to encourage managers of pharmaceutical organizations to operate and behave in compliance with the FDA regulations. The main potential social change was to avoid having medicine shortages, due to decisions about non-compliance by pharmaceutical manufacturing management. Avoiding shortages of patented or generic medicines would minimize or eliminate the risk to patients' health.

Research Questions and Hypotheses

In this quantitative study, I sought to determine the correlation, if any, between the management behaviors and financial indicators of pharmaceutical firms that have been impacted by FDA enforcement actions. The compliance present in the pharmaceutical firms prior to the FDA intervention were compared to the compliance after the FDA intervention to better understand its influence on the firms' compliance with the CGMP regulations. The independent variables that could lead to enforcement actions by the FDA were the behavior of the pharmaceutical managers and the firms' financial indicators. The dependent variable was the level of compliance of the pharmaceutical company.

- Correlations between management (independent variable) behaviors and compliance (dependent variable):

  Research Question 1 (RQ1): To what extent, if any, does management behaviors correlate to compliance with FDA regulations at the pharmaceutical firms in the United States?

$H1_0$: $r = 0$. There is no difference in management behaviors towards compliance at pharmaceutical firms, as a result of FDA enforcement actions in the United States.

$H1_1$: $r \neq 0$. There are differences in management behaviors towards compliance at pharmaceutical firms, as a result of FDA enforcement actions in the United States.

- Correlations between financial indicators (independent variable) and compliance (dependent variable):

  Research Question 2 (RQ2): To what extent, if any, do financial indicators correlate to compliance with FDA regulations at the pharmaceutical firms in the United States?

  $H2_0$: $r = 0$. There is no difference in compliance with FDA related to financial indicators at pharmaceutical firms, as a result of FDA enforcement actions in the United States.

  $H2_1$: $r \neq 0$. There are differences in compliance with FDA related to financial indicators before and after the FDA enforcement actions in the United States.

- Financial indicators (independent variable) impact on compliance (dependent variable):

  Research Question 3 (RQ3): To what extent, if any, do financial indicators impact compliance with FDA regulations at the pharmaceutical firms in the United States?

H3$_0$: $\beta_1 = \beta_2 = \ldots = \beta_7 = 0$. There is no impact in compliance with FDA related to financial indicators at pharmaceutical firms, as a result of FDA enforcement actions in the United States.

H3$_1$: At least one $\beta_1 \neq 0$. There is an impact in compliance with FDA related to financial indicators before and after the FDA enforcement actions in the United States.

The βs in Hypothesis 3 were the regression coefficients of the following multiple regression equation:

$$Y = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \beta_4 X_4 + \beta_5 X_5 + \beta_6 X_6 + \beta_7 X_7 + \varepsilon \qquad (1)$$

Where,

Y= FDA related compliance

X_1 = Cost of goods

X_2 = Investment

X_3 = Process compliance

X_4 = Change in sales

X_5 = Change in revenues

X_6 = Change in market value of the firms

X_7 = Change in stockholders equity

ε = Error of the regression

Theoretical Framework

The purpose of a theoretical framework is to identify a theory that could relate the independent and the dependent variables (Creswell, 2009). Creswell indicated that a deductive approach should apply when selecting the theoretical framework for a quantitative study. Frankfort-Nachmias and Nachmias (2008) suggested that a systematic link between the conceptual and operational definitions is needed for a practical approach to the theory. In this study, the theory before research approach was applied as written by Frankfort-Nachmias and Nachmias (2008). This systematic approach allowed assessing and predicting the interrelation between the selected variables.

The theory of planned behavior (TPB) was developed by Ajzen (1991). In this study, it was used to assess behaviors of the pharmaceutical managers. The central point of TPB is that there is a direct relationship between intention and actual behavior. TPB highlights that any behavior could be explained and that behaviors are not difficult to predict. For this study, the intention of the pharmaceutical industry management to comply with the regulations of the FDA, as well as the financial limitations and complexity, created an excellent scenario to assess with TPB.

As presented by Langham, Paulsen, and Härtel (2012), the relationship between intention and actual behavior is essential to the understanding of the willingness to comply and of the actual action of non-compliance. Consequently, predicting intention to comply is as important as predicting the actual compliance behavior. TPB also evaluates the topic of behavioral control, including the concepts of perceived behavioral control and actual control. Perceived behavioral control consists of the individual's ability to

control behavior and willingness to apply the required behavior. Actual control is essential for investigating behaviors that require the individual to overcome performance hurdles. Attitudes and values are specific elements in this approach. Understanding the factors that led to the unwillingness to comply or drive to ignore compliance facilitate the probable prevention measures accompanying any FDA intervention. TPB provided mechanisms of comparison, correlation, and prediction to understand how to reinforce the intention that could modify future compliance.

Nature of the Study

The nature of the study intended to address the research questions to raise management's awareness avoiding interruptions in the supply of some essential patented or generic pharmaceutical drugs. The study highlighted that (a) avoiding FDA actions provides business sustainability and (b) compliance is a competitive advantage for pharmaceutical companies. The design of the research sought to predict the outcome of the dependent variable, that is, compliance with FDA regulations.

Selection of Study Methodology

The comparison between experimental methods could be centered in two foci, either in an exploratory study of a new topic (qualitative) or on the degree of achieving or understanding the causation relation between variables (quantitative). The quantitative research method predicts, investigates relationships between variables, or assesses possible impacts or influences on outcomes. The qualitative research method is an approach to study the implicit, as well as the explicit of the targeted study or phenomena. The qualitative method evaluates personal perceptions and people's experiences as their

reality (Patton, 2002). Typically, the qualitative data interprets words during the quantitative data analyzes numbers. The significant difference is that qualitative research is inductive and quantitative research is deductive (Colorado State University, 2012). Both research strategies consider research questions and purpose of the study. However, in qualitative research, a hypothesis is not used. Quantitative research method requires hypotheses to predict or direct the study (Creswell, 2009).

To address the research question and test the hypotheses of this quantitative study, a deductive approach was adequate to confirm the correlation between the variables. The responses from the participants were the input to the data analysis. Based on the correlations between management behaviors and financial indicators on the compliance with the CGMP regulations, I was able to determine the firms' compliance before and after the FDA intervention with the pharmaceutical company. Management attitudes and financial metrics required statistical instruments and probability methods to predict the mindset of management and the financial indicators about the outcomes of compliance with FDA regulations.

Study Design and Variables

The study consisted of a correlation design including the application of statistical tools. This approach allowed making comparative statistical analysis to establish correlations and make predictions after a treatment, the FDA intervention. The variability in this study and the goal to predict outcomes also led to the application of regression line analyses. For this study, the compliance conditions prior to the FDA intervention were the scenarios that led to enforcement actions by the FDA. The independent variables or

predictors were management behaviors and financial indicators. The treatment event was the application of the enforcement action by the FDA. The level of compliance of the firms was the dependent variable or outcome.

Other quantitative methods were evaluated for the study but found not appropriate to test the research questions and hypotheses of the study. The concept that the FDA intervention could create a change in behaviors was the primary design parameter. The control over the extrinsic and intrinsic factors was very limited about companies' sizes, organizational structures, and the portfolio of products. Consequently, a classical experiment design did not apply in this study. Considering cross-sectional design, the independent variable cannot be typically manipulated to establish before and after comparisons. As stated by Frankfort-Nachmias and Nachmias (2008), there is a need to incorporate control and manipulation over the independent variables to be able to infer causation from them. The cross-sectional design did not apply to the study since the focus was in the influence generated between the variables by the FDA intervention.

Since a pre-experimental design is the weakest in the validity of the design (Frankfort-Nachmias & Nachmias, 2008), it did not applied. The causation could not be easily defined. Time implementation of treatment was not applicable since the FDA intervention tends to occur in one instance, while pursuing the desired compliance. The target was to study the correlation in the variables with emphasis driving towards the compliance outcome from the FDA intervention. Comparison of the compliance conditions pre-intervention of the FDA (pre-FDA) and post-intervention of the FDA

(post-FDA) in the pharmaceutical organization were evident because of the outcome of the FDA intervention.

Definitions

Definitions for the study were aligned to the FDA definitions of the corresponding regulations or guidance. Terms like *management* and *medicine* are associated with the relevant FDA definition. Citations from the FDA documents allowed assurance that the definitions' terms were clear for the intent of the study.

CGMP Regulations:

> The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations make sure that a product is safe for use, and that it has the ingredients and strength it claims to have. (Food Drug Administration [FDA], 2012, "Drug Applications and Current," para. 1).

Compliance with CGMP:

> Decisions regarding compliance with CGMP regulations are based upon inspection of the facilities, sample analyzes, and compliance history of the firms. (FDA, 2012, "Drug Applications and Current," para. 2).

FDA Form 483:

> An FDA Form 483 is issued to firms' management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act

and related Acts. (Food Drug Administration [FDA], 2013, "Frequently Asked Questions," para. 1).

High management agent (management):

> …(A) an officer or director of a corporation or an association, (B) a partner of a partnership, or (C) any employee or other agent of a corporation, association, or partnership, having duties such that the conduct of such officer, director, partner, employee, or agent may fairly be assumed to represent the policy of the corporation, association, or partnership, and (2) includes persons having management responsibility for - (A) submissions to the Food and Drug Administration regarding the development or approval of any drug product, (B) production, quality assurance, or quality control of any drug product,… (FDA, 2012, "FD&C Act," p. 35).

Warning Letter:

> …a correspondence that notifies regulated industry about violations that FDA has documented during its inspections or investigations. A Warning Letter is one of the Agency's principal means of achieving prompt voluntary compliance with the Act. (Food Drug Administration [FDA], 2012, "Regulatory Procedures Manual," p. 5).

Scope of the Study

The scope of the study addressed the process to determine to what extent, if any, pharmaceutical management's behaviors and financial indicators correlated to compliance with the FDA regulations at the pharmaceutical firms. Shortfalls in

compliance with FDA regulations have led to significant shortages of medicines to patients in the last five years (FDA, 2013). Pollack (2013) indicated that these medicine shortages have been a direct consequence of shortfalls in compliance with the FDA regulations. The population for the study consisted of the pharmaceutical firms that were been impacted by FDA enforcement activities due to manufacturing violations. All listed members of the International Society of Pharmaceutical Engineers (ISPE) in public U. S. pharmaceutical firms were invited to participate in the survey: executives and operational managers who had the authority to make compliance and financial decisions.

The survey instrument consisted of a four-section survey, structured as a Likert-type scaled questionnaire. Two sections focused on the behavior of the participants and the financial indicators of the pharmaceutical firms in the pre-FDA and post-FDA interventions. The third section collected demographical information from the participants. The fourth section focused in the firms' historical compliance.

The TPB questionnaire guidelines developed by Fishbein and Ajzen (2010) were modified for the behavioral section of the survey instrument. Ajzen (2002) suggested the essential elements for the construction of a survey for a TPB questionnaire, including the use of a pilot study to set the potential drivers of the behaviors. The conducted pilot study enhanced the level of clarity, content validity, and feedback on the questions in the instrument as indicated by Creswell (2009). The financial indicators' sections of the intended survey instrument were based on typical indicators that could be impacted by the expenses needed to support remediation from FDA interventions. The validity and

reliability of the intended survey instrument were essential to allow for the trustworthiness of the data as explained by Frankfort-Nachmias and Nachmias (2008).

For the sampling size determination of completed surveys, three approaches were followed to address the three research questions and hypotheses. For research questions one and two, the sampling size determination of completed surveys considered Krejcie & Morgan (1970) equation and Cohen's power (1992) as the basis for calculation. The sample size of completed surveys for RQ3 was established by using G*Power software (Faul, Erdfelder, Lang, & Buchner, 2014).

The study population consisted of pharmaceuticals firms that have been impacted within the last 5–6 years by enforcement activities from the FDA in the United States. This population was estimated to be about 272 pharmaceutical manufacturing firms based on the FDA information (FDA, 2015). The sampling size of completed surveys indicated by Krejcie & Morgan (1970) to be considered was about 160. The intended survey participants were selected from executives and operational management levels of the firms. These participants, based on their self-disclosed position titles in the ISPE database, had the authority to make compliance and financial decisions for their firms.

SurveyMonkey was the electronic survey applied to estimate the optimum sample size assuming a normal distribution. For a target of 160 completed questionnaire, the SurveyMonkey sampling estimator initially indicated that the number of potential participants should be about 400 at a 90% confidence level and a 5% margin of error. This sample of 400 participants projected about 162 completed surveys with a 90% probability that the sample of participants could reflect the attitudes of the intended

population. Also, the margin of error of 5% intended to minimize the deviation from the true value at the selected confidence limit of 90%. For this scenario, the expected response rate based on SurveyMonkey sampling estimator implied a participation of 40.5%.

A response rate of 40.5% was initially considered too optimistic. The expected response rate was set at 20% to ensure the probability of attaining the targeted 160 completed surveys. This scenario required about 800 participants at 20% response rate. The SurveyMonkey sampling estimator indicated that for 800 targeted participants at a 90% confidence level, the margin of error could be expected at 6%. As a precaution, 1144 members in the directory of the International Society of Pharmaceutical Engineers (ISPE) were invited to complete the survey. These participants had an e-mail address and meet the participants' criteria.

Assumptions of the Study

The assumptions included elements related to participants and financial indicators. In this study, I made the following six assumptions:

- The responses to the pilot study and the main survey were honest.
- The participants were not to expect any repercussions from their supervisors or senior officials of the pharmaceutical company for participating in the study.
- The participants were assumed to have the same definition of the compliance elements as presented in the definitions section based on the FDA.

- Also, the survey participants, based on their position titles, had the authority to make compliance and financial decisions within the pharmaceutical firms.
- Financial information provided by the participants was based on the complete financial disclosure by the pharmaceutical firms and not in their perceptions.
- The financial responses provided by the participants was accurate illustrating the financial indicators of the firms, before and after the FDA intervention.

Limitations of the Study

Limitations that were not controlled by the researcher included accessibility by intended participants to the Internet or the presence of a firewall on the Internet. Access to participants' e-mails was obtained from the International Society of Pharmaceutical Engineers (ISPE), a professional organization related to pharmaceutical firms under the FDA regulation. The managers of the targeted pharmaceuticals firms were expected to be members of the professional organizations.

The length of the main study proved to be a major limitation. The pilot study had about 40 questions. The main study had 133 questions. The number of participants that initiated the survey was about 90 of which 45 progressed through all the questions. Only 21 participants provided completed surveys for the study. This low participation had a significant impact to the completeness of the study.

The low level of participation limited the study depth and significance of the findings. The rationale for the low participation could have been to the sensitivity of the topic in the pharmaceutical industry for the shortfall of quality product to the patients. Also, the participants could had personal concerns on the confidentiality of the survey,

despite the consent form with the IRB endorsement. In the technical side of communications, the internet firewalls in the pharmaceutical firms limiting e-mails to reach the participants. The limited participation was a major obstacle for the assessment of the financial indicators.

Timely access to FDA reports about a particular firms might be limited by the time to process the information. By using the FDA public database for all intervention with pharmaceutical firms in the last 5–6 years provided a reasonable level of completeness and minimized the constrained by the complexity of the FDA interventions to the pharmaceutical firms. Typically, FDA information from a given intervention to a pharmaceutical firms could take 6–8 months before publication or post on the FDA web page.

Delimitations of the Study

Privately owned and international pharmaceutical sites that had received FDA interventions were not part of the study. The financial results of privately owned pharmaceutical firms are not available. The focus of the research study included only pharmaceutical companies in the United States. Personal interviews were not performed due to participants' limited accessibility.

Any new FDA intervention or medicine shortage that might occur concurrently to this study was not be included. Concurrent FDA interventions might not have triggered remediation expenses at the time of the study through 2015. Changes in behaviors of the pharmaceutical management might not have occurred concurrently with the FDA

intervention. The time required to develop a remediation plan by the affected firms, and the actual execution of the plan, makes concurrent FDA interventions inaccessible.

Summary

By conducting this quantitative experimental research study, the findings allowed me to determine to what extent, if any, management behaviors and financial indicators correlate with compliance with FDA regulations at pharmaceutical firms. Chapter 1 included the background of the general problem and the specific area of study. The purpose and the significance of the study led the discussion into the positive social change to patients, managers, and stockholders of the pharmaceutical firms. The section on the nature of the study allowed me to highlight the justification for a quantitative approach to the research and data analysis. The three research questions and the hypotheses to address the problem statement were listed. The assumptions, limitations, and delimitations of the study were presented to clarify the scope of the study.

The gap was addressed in this study by providing awareness and guidance to managers on their behaviors, decisions, and risk assessment processes, when considering their FDA compliance responsibility, corporate financial mandate, and stakeholders' expectations. The expected managers' modified behaviors could lead to a reduction in the number of FDA interventions and enforcement actions, against pharmaceutical manufacturers, resulting in fewer medicines' shortages to patients.

Chapter 2 includes the literature review conducted to identify existing research on the dependent variable, the independent variables, and the theoretical framework. The gap in the literature is discussed in Chapter 2. The section on the theoretical framework

presents the theory of planned behavior utilized to develop and execute this quantitative study. Also, in Chapter 2, an analysis of issues, trends, and concepts formalize the literature review for what needs to change, the how to change, and the why to change.

Chapter 2: Literature Review

Chapter 2 contains an in-depth review of the literature on the problem statement revealing the gap in the literature, which was addressed by this study. The discussion about the independent variables and the dependent variable emphasized the expected correlations. The FDA strategy of enforcement since 2009 and its relation to drug shortages was summarized from the literature (Roman, 2014). The theory of planned behavior and the approach to change management were detailed, and the implication of the study discussed. In the last sections of Chapter 2, change models, continuous improvement strategy, and managing change resistant or impediments are presented.

Strengths and weaknesses of the variables, as found in the literature, facilitated the introduction to the literature discussion. I analyzed issues, trends, and concepts to manage the review of the literature. Details of the influence of the independent variables and their correlation with the level of compliance were analyzed. The theoretical framework literature review provided the basis for the research tools supporting the selected research methodology. The relevance of the study and its impact on social change was presented to address the research gap in the literature and clarify what needed to be changed.

Interventions and enforcement actions against pharmaceutical manufacturers by the FDA are due to the lack of compliance with CGMP (Woodstock, 2012). The correlation between attitudes and management behaviors with an over commitment to financial results lead towards a lack of the expected compliance with regulations. This performance needs to be modified to achieve the desired positive social change of

avoiding medicine shortages. As presented by Asotra, Cossin, and Yacobi (2012), focus on financials with low CGMP compliance also leads to an undesired financial performance, which has a direct impact on stockholders.

The required change process to attain the desired state of avoiding medicine shortages has to evolve through the typical life change cycle of what, how, and why (Kezar, 2001). Management trends and possible theoretical frameworks were presented to project the complexity of addressing the change process. The future impacts on the stakeholders were the "why" to conduct the study, delineating the required attributes that influenced the organizational performance to achieve positive social change.

Literature Search Strategy

Research databases, associated with management and business, were used. ABI/Inform Global and ProQuest were the most used databases in the literature search process. Walden University's library and Goggle Scholar were the main search engines in this effort. A search log, in ReadCube® and in Word, provided indexing of the literature by creating clusters of relevance by topic. The search log included article information and comments on significant ideas. The search log served as the vehicle to review, reflect, and plan the direction of the next stage of the literature search strategy. The process was repeated to reinforce the link between the selected literature pieces, emphasizing each specific topic and accentuating the interrelations of the variables.

In Table 1, the span of the references that were evaluated and researched is presented. Potential articles from the databases search and the keywords applied to the Goggle Scholar were over 700 sources. The total of references included in this study was

101. A total of 39 peers reviewed articles, 26 professional organizational articles, 13 Internet pages, and 12 government documents constituted the platform of the literature review for this study. A total of 11 books were also consulted to enhance the theoretical basis of the study, especially in the areas of behaviors, change management, and motivation. The focus of the literature search was based mainly on current sources. The reference list consists of 62% of sources less than five years for the current situation, and of 38% older references. About 21% of the references are from the last year 2014, 2015, and 2016. The references focused in the description of the problem statement, the variables of the correlation, subject matter experts, the theoretical framework for the study, and management topics. The totals in Table 1 include the referenced articles in this study.

Table 1

Evaluated and Research Literature

	Peer- Reviewed Articles	Professional Organizational Articles	Books	Internet Pages	Government Documents
Problem Statement	5	17	0	6	9
Dependent Variable	5	2	0	1	1
Independent Variables	2	4	1	0	2
Theory (TPB)	8	2	2	2	0
Change and Management Theories	19	1	8	4	0
Totals	39	26	11	13	12

Table 2 presents the list of the keywords used in the research. Keyword alerts were set to maintain a continuous search the keywords with emphasis on *FDA, change,* and *medicine shortages*, *theory of planned behavior* and *CGMP compliance*. Google Scholar's listing was frequently revised to ensure updates for the literature review. The independent variables, management behavior and financial indicators as related to the study presented limited options.

Table 2

Keywords Used for Research

Problem Statement	Dependent Variable	Independent Variables	Theories Framework	Management Theories/Method
Warning Letters FDA	CGMP Compliance	Behavior	Theory of Planned Behavior	Change
Medicine Shortages		Financial Indicators		Organizational Structure

Background of the Literature Review

The number of FDA interventions and enforcement actions against pharmaceutical manufacturers has led to several medicine shortages. The lack of compliance with CGMP has resulted in facility closures, loss of revenues, unavoidable penalty fees, and significant investments to address remediation of the violations of the FDA regulations (Burd & Chrai, 2004). In addition, the loss of sales, penalties, and cost of remediation influence directly the profit line, impacting the worth of the stockholders and the firms' market value. Achieving and maintaining FDA compliance makes business sense and provide a competitive advantage as discussed by Smart (2013). The primary

social impact is that essential patented drugs or generic pharmaceutical drugs, provided to the general public, could have been substandard for quality, purity, strength, and identity, placing the patient health in significant danger and probably not addressing the intended treatment.

The purpose of this quantitative dissertation research study was to determine to what extent, if any, management behaviors and financial indicators correlated to compliance with FDA regulations at the pharmaceutical firms that have been impacted by FDA enforcement actions in the United States. This quantitative design was directed towards correlations and regression analyses. The conditions before to the FDA intervention in the pharmaceutical firms were compared to the conditions after the FDA intervention to predict compliance with the CGMP regulations. The independent variables that could lead to enforcement actions by the FDA were behaviors of the pharmaceutical managers and the firms' financial indicators. The level of compliance of the pharmaceutical company was the dependent variable.

In Figure 1, a conceptual map is presented to illustrate the interrelations between the variables, management behaviors, and leadership skills, leading to the need for change management to drive the expected behaviors and compliance with the FDA. The problems affecting pharmaceutical-organizational performance were considered to be attitudes and management behaviors with an over-commitment by pharmaceutical management to financial results, leading to a lack of the required compliance with regulations. The problem statement had a direct impact on stakeholders. The impact on stakeholders needed to be addressed to achieve the desired positive social change of

avoiding medicine shortages. Management trends to address "what is needed" were listed in the bottom-right of Figure 1. Areas that could be studied and possible theoretical frameworks (How is it done) were enumerated in the bottom-center of Figure 1 to project the complexity of addressing the change process. The desired impacts that are listed in the left-bottom of Figure 1 were the "why is it needed" to conduct the study, delineating the attributes influencing the firms' performance to achieve positive social change.

From the concept map in Figure 1, the use of change management and adaptability emphasized the need and reinforced the notion that ethical behaviors need to be modified. The benefit from the concept map structure (Novak & Cañas, 2006) was obtained by the hierarchical flow from the initial problem position to the outcome in the concept map. The concept map provided a means to capture the transition from the problem ("as is") to the outcome ("desired state"). By addressing the problem statement to achieve social positive change, leaders of pharmaceutical organizations, who are involved with FDA interventions, should modify their behaviors and financial metrics, avoiding medicine shortages to patients and minimizing risk to stockholders.

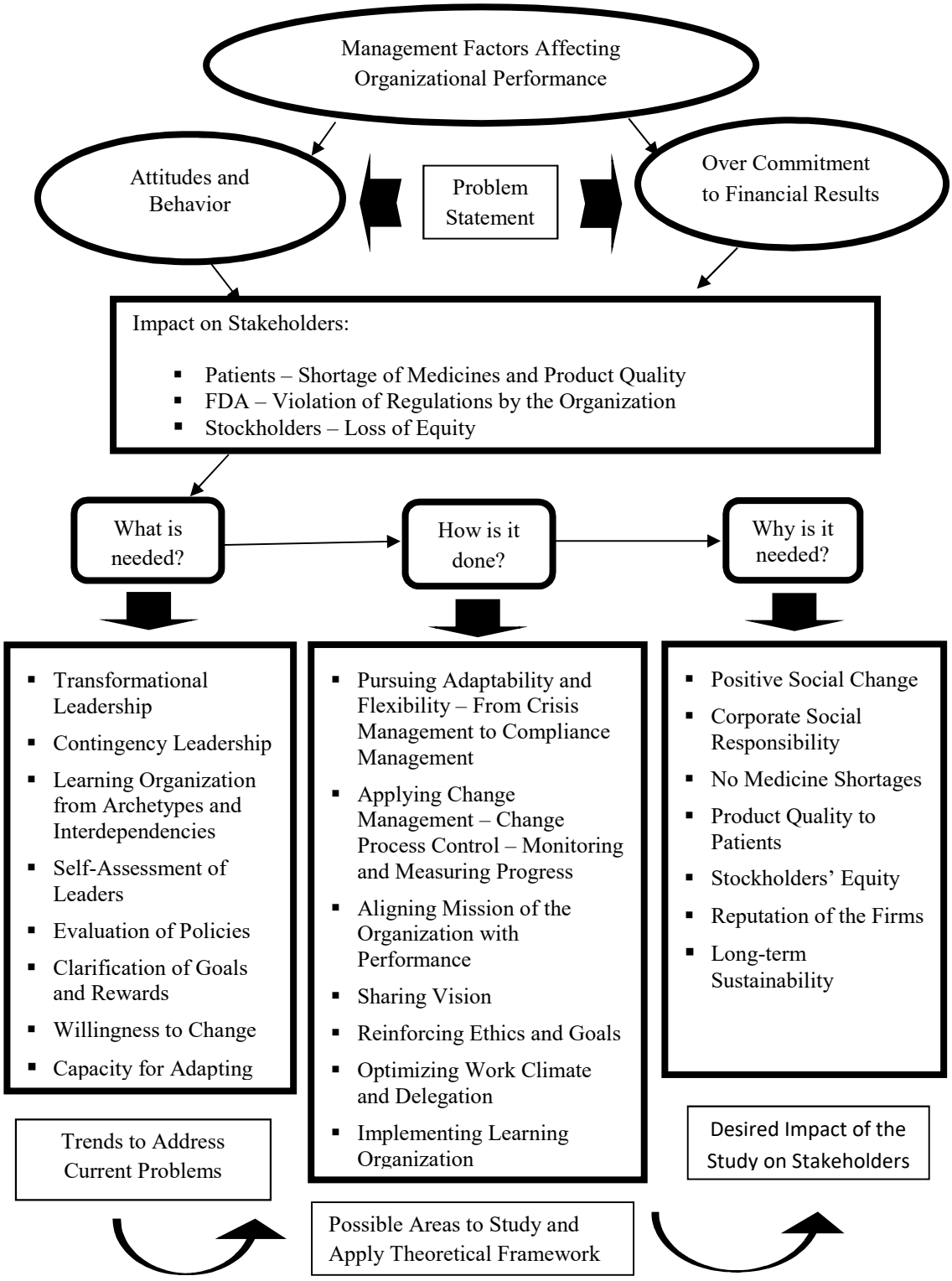

Figure 1. Conceptual map of the problem statement and the change process elements to influence the sustainability of the change.

Gap in the Literature

From the review of the literature, the gap was the lack of research providing awareness and guidance to managers in their decision and in their risk assessment process, regarding their FDA compliance responsibility, corporate financial mandate, and stakeholders' expectations within the pharmaceutical manufacturing industry. The approach to determine the gap to prompt the research was based on the limited information available on what drives non-compliance decisions in pharmaceutical organizations that have experienced FDA interventions. The limited published data on the interdependencies between the need to grow revenue and the intent to behave within senior management decision process in the pharmaceutical manufacturing industry drove the development of this research. The short-term financial pressures, the high costs of innovation, and the firms' reputation have been identified as causes, but no direct research on the correlation with behavior has been published that can be directly associated with the pharmaceutical industry.

The avoidance of medicine shortages drove the need to understand what motivated or distracted management from compliance behavior. There are published studies in behavior related to tax evasions (Langham, Paulsen, & Härtel, 2012), academic misconduct (Stone, Jawahar, & Kisamore, 2009), digital piracy (Yoon, 2011), and Sarbanes-Oxley (Hess, 2007). These studies were used in this dissertation study as templates for approaching the study in the pharmaceutical organizations by also applying Ajzen (1991)'s theory of planned behavior. This study addressed a gap in the literature related to the limited direct studies providing awareness and guidance to pharmaceutical

manufacturing industry managers in their decision and risk assessment processes. The study specifically addressed the gap in regards to the pharmaceutical manufacturing industry managers' FDA compliance responsibility, corporate financial mandate, and stakeholders' expectations.

Dependent Variable

The selected statistical tools, correlations and regression analyses, provided clarity in the relationships between the variables. The purpose of the study was to predict the outcome of the dependent variable, compliance with the FDA. Linear regressions provided the assessment between the pre-FDA conditions and the post-FDA conditions focusing on the scenarios before and after of the FDA intervention. With the selected study design, the correlations and linear regression method were applied twice, pre-FDA and post-FDA interventions. All variables were considered continuous in the pre-FDA and post-FDA interventions.

Compliance by pharmaceutical management with the FDA regulations in the production of medicines pursues the intended integrity, purity, and quality of the products for the expected medical treatment of the patients' conditions (FDA, 2013). Management decision-making in the manufacturing processes within the pharmaceutical organization need to demonstrate alignment to the expectations of the FDA regulations. The trust of the public in both the FDA and the pharmaceutical firms can be considered as a "given" fact as perceived by the patients, the medical community, and the investors in the pharmaceutical company.

The manufacturing of medicines follows a very intensive process of research for a given disease cure: discovery of a molecular entity, clinical trials in animals and human volunteers, and approval process by the FDA. Once the medicine is defined and as part of the development, a production process is defined and validated to manufacture the medicine always to the same level of the approved-intended integrity, purity, and quality. FDA regulations (FDA, 2013) indicated to the pharmaceutical organizations to always follow the same validated manufacturing processes and systems. The execution by the pharmaceutical management of production processes and systems is obliged to follow the CGMPs. The pharmaceutical organization and its management are expected to apply, implement, and follow the CGMP at all times.

Manufacturing of medicines requires significant investment in facilities, personnel know-how, equipment, active medicine ingredients, and other raw materials. The investments in these factors in addition to on-going operational manufacturing expenses, as energy and distribution mechanisms represent cash flow, which is not recovered until the medicine is sold to the end users, the patients. The CGMPs expectations require a significant level of documentation as evidence of compliance. Procedures, training records, and data integrity in the laboratories demand precise and current documentation (Dutton, 2014). Computerized systems have also become a significant investment and operational expense in the production operations to demonstrate compliance to achieve the intended product quality as indicated by the FDA announcement (FDA, 2016).

The operational cash flow for manufacturing is typically represented by the idea of the cost of goods, including the depreciation of capital investment and inventory cost of material in the process. Allocation of funds to achieve the manufacturing of medicines is added to the cost of sales and other significant accounting entries in the pharmaceutical company's income statement and balance sheet. Controlling the cost of goods is an established operational practice to achieve an acceptable competitive financial position by the firms. Management reward programs and employees' performance is based on continuous improvements that are typically biased towards cost improvements, besides improvement in processes and systems. The general assumption is that the product quality and quality systems that warrant consistency are not to be impacted by the improvement changes. Removing process variability like in Lean-6-Sigma initiatives is promoted to improve consistency and reduce cost (Longo, 2012). The principles are reasonable, but the rewards to the incumbent managers are typically based on dollars saved in production. Compliance with CGMPs is promoted as non-negotiable, but not necessarily, a high factor for the basis of the rewards and performance recognition from the business improvements.

Pharmaceutical management also has to achieve a balance between cost of sales, like promotion and sales personnel, and the cost of goods to maintain products competitiveness at adequate pricing strategy, especially in a global platform. Medicine pricing practices around the world receive pressure from local governments and competition. Except for Medicare practices, these pricing pressures are usually not a strong influence (Graham, 2012). In addition, the financial market expectations of a

return on investment to stockholders augment the financial pressures on the pharmaceutical management. The decision on where to use the cash flow between these business pressures and the cost of goods requirements has led to scenarios in which quality systems and production capacity have been second priority, as concluded by Pollack (2013) and Woodstock and Wonsinka (2013).

The purpose of compliance and the written policies, directing the conduct to the best decision for the patient, has been expressed in pharmaceutical companies' vision and mission statements. These statements and policies have been deployed with the internal stakeholders, like employees, and with the external stakeholders, such as patients and stockholders, to gain trust and credibility (Pfizer, 2015; Johnson and Johnson, 2015; Bristol Myers-Squibb, 2015). The challenge, to maintain a balance to assure compliance with CGMPs and with the business expectations, creates a relationship influencing actual management behaviors and quality systems' robustness in pharmaceutical companies.

Compliance with FDA regulations, CGMPs, requires commitment and firmness in management in front of financial pressures (Asotra, Cossin, & Yacobi, 2012). The balance between intended behavior and actual behavior by management in the pharmaceutical organizations, in which FDA has initiated regulatory intervention, needed to be better understood. The information about which FDA interventions have impacted pharmaceutical organizations can be found in the FDA web page and through the Freedom of Information Act. For those companies that are public financial firms, the financial reports are public. These financial reports include the cost of goods, as well as other essential elements in their published profit statements and balance sheet. Public

press releases are also available from the management of these firms, addressing their approach to correct and align with the CGMP regulations as stated by the FDA interventions (Impax, 2014; Novartis, 2012; Ben Venue, 2011). The firms' reaction to the FDA observations about the lack of conformance leads to corrective action with significant financial impact typically documented in the firms' financial reports.

The level of sustainability of the corrective actions by the pharmaceutical organizations that has been impacted by FDA regulatory interventions depends on the degree of change that management embraces and accepts (Asotra, Cossin, & Yacobi, 2012). The compliance history, following the initial FDA regulatory intervention, allowed measuring the effectiveness of the change in behavior. Financial indicators from the published financial reports could also provide the information of the new level of cost of goods and investment in manufacturing to attain the desired state of operations in compliance, indicating a more robust level of quality systems in the production of the medicines. For this study, I depended on the participants' knowledge and recollection of the information regarding financial indicators in their forms.

The interrelation of the degree of compliance with the predictors, behaviors and financial indicators, caused changes in the correlations and the regression analyses in this study. The intent of the study was to predict the outcome of the dependent variable, compliance with the FDA. Considering that there was a logical expectation that the FDA intervention was going to force a change in management attitudes, the changes in correlations and linear regression analyses were not a surprise. The analysis of the TPB questionnaire responses allowed to compare the relationships before and after the FDA

intervention. Concurrently, the financial indicators information collected in the survey provided the financial environment of the firms before and after the FDA intervention. Also, establishing the regression line, between the variables after the treatment, could assist on assessing the long-term effect in compliance, allowing for follow-ups and self-corrections by the firms.

An electronic survey was be the vehicle utilized for management attitude assessment, due to the limited accessibility to the participants (pharmaceutical management). The cost of remediation and financial indicators from the survey assisted in determining the financial correlations. Figure 2 illustrates the interrelations and expected outcome between the independent variables, the dependent variable, and the FDA intervention.

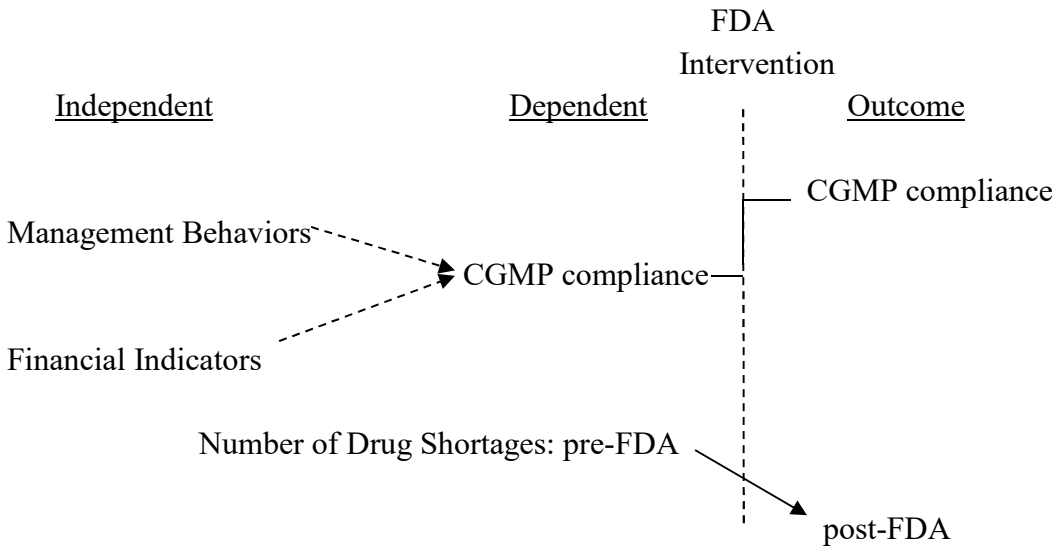

Figure 2. Interrelations of variables and outcome as a reaction to the FDA intervention in the pharmaceutical firms.

As discussed by Woodcock (2012), manufacturing shortfalls implied that quality management and systems were not empowered or properly staffed to support adequately the critical functions within the pharmaceutical company. Many of the drug shortages events have been associated with manufacturers issues (Woodcock, 2012). Historical trends of drug shortages represent an increase from 61 shortages in 2005 (Barlas, 2014) to 251 shortages in 2011 (FDA, 2013). The FDA issues warning letters if the pharmaceutical firms has not addressed the violations observed during FDA audits to the manufacturing establishments or facilities. These violations, listed on Form 483 of the FDA audit, indicate that the quality management and systems in the audited pharmaceutical firms were below expectations, implying low CGMP compliance. From 2009 to 2010, the FDA's observed violations in the operations of medicine manufacturers increased from 550 to 646 (Huitt, 2014). In the first three years of Obama's administration, 2009 through 2011, the number of warning letters issued for manufacturing and quality issues increased to 49 letters versus nine letters in the last three years of George W. Bush's administration (Nguyen, Seoane-Vazquez, Rodriguez-Monguio, & Montagne, 2013). In a brief look over the past 15 years, the previously referred FDA interventions through a Warning Letter can be summarized in the timeline shown in Figure 3.

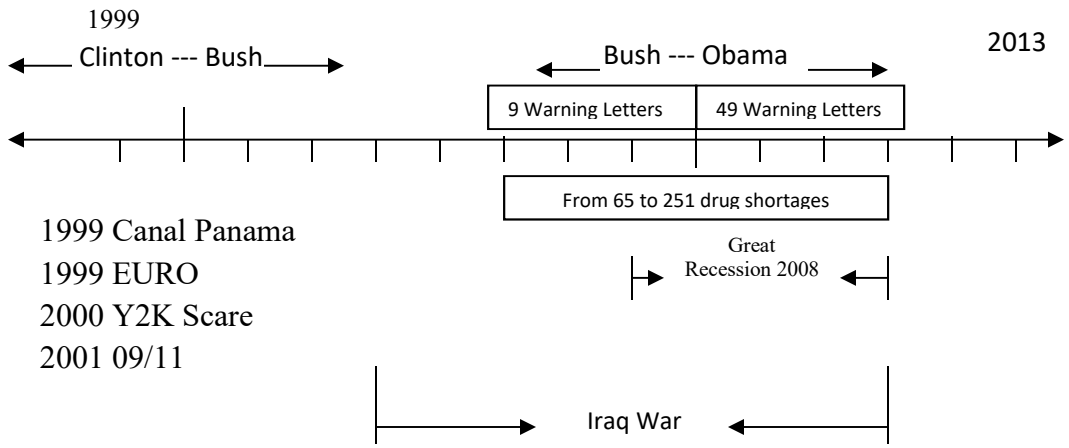

Figure 3. Time line between 1999 and 2013 illustrating the trend of warning letters and medicine shortages in comparison to significant global events.

Independent Variables

The approach to determine the gap for the research was based on the limited information available on what drives non-compliance in the pharmaceutical organizations that have experienced FDA interventions. The limited data that prompt this study consisted on what are the interdependencies between the need to grow revenue and the intent to behave within the management decision process. The factors of financial short-term pressures, the high costs of innovation, and the firms' reputation have been identified as causes of non-desired behaviors (Hess, 2007; Langham, Paulsen, & Härtel, 2012; Yoon, 2011). No direct research on the correlation with behavior associated with the pharmaceutical manufacturing has been published.

The purpose of this study was to determine to what extent, if any, the independent variables, pharmaceutical management's behaviors and financial indicators correlated to compliance, the dependent variable, with the FDA regulations at the pharmaceutical

firms. Compliance with CGMP regulations has led to significant shortages of medicines to patients in last five years (FDA, 2013). These medicine shortages have been signaled as a direct consequence of shortfalls in compliance with the FDA regulations (Woodstock, 2012; Pollack, 2013). Significant efforts to generate risk assessments and action plans have been created by organizations like the Parenteral Drug Association (PDA) (Technical Report No.68, 2014) and the International Society of Pharmaceutical Engineers (ISPE) (Prevention Plan, 2014). These documents addressed several topics like FDA role, supply and demand, and culture for quality systems. The concern from Woodcock (2012) that manufacturing is sometimes managed as a second citizen falls into the category of management's decision-making and not on shortfalls in intention or intended behavior.

The study's potential influence on positive social change was based on the intent to encourage managers of pharmaceutical organizations to operate and behave with a sound mental model or thinking pattern. Managers should optimize the financial performance of the firms while considering the availability and quality of the medicines that they produce. The avoidance of medicine shortages was the key positive social change pursued by this research study.

Management Behaviors

In the U.S., corporations are directed legally to pursue profits for their stockholders (Bakan, 2004). Bakan addressed the legal implications around the fact that the corporations are set to maximize the returns to the stockholders. The legal concept implies that it is illegal for a corporation to divert revenues to social responsibilities

without considering the financial implications to the stockholders. Sfeir-Younis (2009) discussed that the current compensation systems for management are mainly focused in rewarding for profit results. There is no mechanism to link society justice and environmental sustainability to the success of the corporations. In the interview by Tavanti, Sfeir-Younis (2009) indicated that efforts towards Corporate Social Responsibility could be perceived as being accompanied by a background of insincerity.

Considering the corporation, Bakan (2004) discussed that the corporations could be considered manipulative, superficial, and self-interested. Lack of empathy, non-social considerations, refusal of responsibility, and lack of remorse could be associated with corporations when setting priorities in front of society's interests. Bakan (2004) introduced the need for being skeptical when looking at social responsibility in the annual reports and management messages. These documents are based on the self-interest of the corporation that has to be meet financial expectations before any social consideration.

About members of the management team, Bakan (2004) discussed the concept of double personality or dual moral lives. The corporate manager was expected to behave in favor of the firms' stockholders. Once at home, the personal values and interests prevailed and were focused on the well-being of the community or society. The ability to navigate in this contradiction in morals, between corporate and personal behaviors, could be considered a type of schizophrenia, as presented by Bakan.

Even if Maslow's (2000) Hierarchy of Needs drives the leaders' motivation to achieve a self-actualization state, the conflicting pressures of attaining compliance with CGMP regulations present opposite-directional vectors to personal motivation between

rewards and personal values. Considering Adler's (as cited by Boeree, 2007) theory of complexes and superiority, the leader usually pursue personal motivation by striving for perfection and overcoming complexes. In this endeavor, if the manager cannot achieve a positive lifestyle (being of help to others), it could create the sense of not achieving, leading to personal failure, even in the presence of financial rewards.

The corporation and stockholders' drive for profit projects, which is a perception that prevails in the financial environment. The only change in expectations of these parties could allow the manager to perform and strive for sustainability and balance between financial goals and compliance with regulations. The decision-making process's complexity exponentially grows when considering consumers' expectations, religion beliefs, and cultural diversity.

Management is expected to behave with a high sense of ethics. Ethical behavior is valued and considered as non-negotiable in society. Respect for what others believes and their dignity as human beings, as presented by Resick, Hanges, Dickson, and Mitchelson (2006), is considered as an acceptable definition of ethical conduct and behavior. Leaders' influence is associated with several factors, including the use of power, the projection of authority, and having a balanced behavior in front of employees and society members. Resick et al. (2006) discussed six elements related to ethical leadership. These traits or characteristics were a character with integrity, ethical awareness, community and people orientation, motivating, encouraging/empowering, and managing ethical accountability.

Providing quality pharmaceutical products projects good citizenship. The firms is valued and understood as one of caring for the well-being of the patients. The elements included in this perception range from providing medicine to alleviate the health issues to attaining an effective treatment of the patient's medical situation. The intended behavior to comply with regulations and to manufacture a quality product should lead to the adequate financial outcomes. The intent to do something versus the actual action could accentuate that there is a potential disconnect if the drive is for the financial bottom line and not for compliance.

Making ethical decisions requires values and beliefs that the action taken is the best option. The definition of the best choice requires a balance between desire linked to personal satisfaction and financial rewards. The decision to sustain the status quo or ignore non-compliance behavior by management could create critical impediments to the organization, leading to FDA interventions. Elements consisting of slow information flow, change resistance by personnel, loss of customer loyalty, and inflexibility by leaders in challenging mental models could accentuate the scenario leading to non-compliance. The decision to ignore the current state could be the catalyst for the loss of resilience and adaptability to change. The climate of the organization to allow for a prompt response and active participation, in front of the undesired scenario, requires intensity and transparency to drive the desired behavior at all levels of the organization.

Sharing leadership vision projects a genuine message, which enhances the enrollment and participation of followers (Senge, 2006). Leaders need to share their vision and expose their reasoning to demonstrate an honest approach to share the vision

and sense of urgency, as indicated by Kotter (2007). The management vision should accentuate compliance with the regulations, and provide the right level of investment for compliance. Listening to the employees' opinions should open the dialog towards the adequate priorities to sustain compliance. A dialogue should minimize tension and conflict, allowing for transparency in the flow of information between individuals. Open discussions are required to assess options and make decisions. Sharing the vision is possible and attainable by encouraging inquiry, advocacy, and reflection, as discussed by Senge (2006). The scenario of "us-and-them" does not serve or benefits any party, nor the patients or the stockholders.

Organizational structures can be related to different management theories and the drivers of behaviors. The selected organizational structure and the leaders' style dictate the interrelationships and links within the organization (Morgan, 2006). The organizational structure influences the thinking, defines the learning, and shapes the behaviors. Morgan (2006) presented several examples of organizational structures and the internal interdependencies and expected behaviors using metaphors. "Open-learning" organizations allowed for participation and sharing of knowledge, dictating behaviors and adaptability. The perceived controls by the individual and the opinion of others (including supervisors) according to the TPB were two constructs assessed in this study.

Engle and Nehrt (2011) indicated that when considering emotional intelligence, the behaviors were mainly driven by the leaders' ability to control their emotions, while pursuing maturity and intellectual growth. Elements considered as the base for emotional intelligence are self-awareness, self-control, and social awareness. To control or regulate

behaviors, leaders needs to have a significant maturity to appraise their emotions, understand emotions from others, regulate emotions internally, and take advantage of emotions to drive performance (Engle & Nehrt, 2011). Leaders should have insight into the followers' emotions and feelings, with the corresponding reasons behind them. As per Engle and Nehrt (2011), being self-confident, in their internal assessment and the corresponding conclusions is a critical trait in the leaders.

Providing quality pharmaceutical products projects good citizenship. The firms are valued and understood as one of caring for the well-being of the patients. The elements included in this perception range from providing medicine to alleviate the health issues to attaining an effective treatment of the patient's medical situation. The intended behavior to comply with regulations and to manufacture a quality product should lead to the adequate financial outcomes. The intent to do something versus the actual action could accentuate that there is a potential disconnect if the drive is for the financial bottom line and not for compliance. In this study, thought correlations, linear regressions, and the theory of plan behavior, the researcher linked the independent variables to the dependent variable of compliance with the FDA. A comparison was made between the pre-FDA and post-FDA scenarios regarding the compliance with the FDA regulations.

Financial Indicators

For the pharmaceutical firms, the lost sales, the impact on their reputation, and the significant level of expenses to recover or achieve remediation of the lack of compliance with the FDA could be devastating. This scenario could also impact the firms' market value. If the FDA intervention escalates into a consent decree, which is a legal action

against the company, the magnitude of all these elements could multiply and become an unacceptable historical benchmark within the industry (Asotra, Cossin, & Yacobi, 2012). Furthermore, legal actions by the FDA against the firms' leadership could be inevitable (Burd & Chrai, 2004). This study has the potential to raise the awareness about undesired behaviors in management and accentuate the concept that compliance is a competitive business advantage for the pharmaceutical companies.

The complexity of regulations, price pressures, and compressed time to market contributes to the financial pressures in front of medicine manufacturers (Dutton, 2014; Duffy, 2014). The cost of development a new drug has been noted to be is some cases up to 1 billion dollars (Adams & Brantner, 2010). Management decision-making is typically driven by current cash flow and future opportunities to grow revenue, including decisions on research and development investments (Scherer, 2001). Thus, optimizing fixed assets utilization supports both concepts. Controlling or reducing the cost of goods allows a positive impact on available cash flow to invest in new products research, support marketing-sales challenges, and neutralize price challenges from the competition and abroad.

Organizational knowledge is based on the individuals within the organization. Organizational structure, work climate, and leadership styles have a significant impact on the growth and performance of employees (Morgan, 2006). Investing in training, procedural systems, data integrity systems, and equipment requires determination to continuous improvement while enhancing quality systems (Koberstein, 2014). Also, attaining the proper quality and operational staff within a manufacturing firms provides

consistency and stability of the knowledge base. These elements in pharmaceutical manufacturing enhance the reliability of quality systems. Manufacturing shortfalls implies that quality management and systems are not empowered or adequately staffed to adequate support the critical functions of the pharmaceutical firms (Woodcock, 2012). The concept of empowerment is linked to the leadership style in elements as trust, transparency, and sharing (Senge, 2006). Knowledge, the level of staffing, empowerment, and continuous improvement are essential to attain the level of compliance in front of complex regulations and global business (Koberstein, 2014). As indicated by Woodcock (2012), for some management, these factors imply incremental cost and expenses of the manufacturing systems, instead of continuous improvement in quality systems.

If the attitude to accommodate the investment towards knowledge, facilities, and equipment is not assessed by management, the new launches or expiration of product products could create pressures, postponing critical investments. The technological movement from the traditional chemical manufacturing to cell manufacturing (biotechnology) has also introduced the need for new facilities with different technologies, equipment, and personnel knowledge (Merchuck & Toren, 2013). The minimal education provided by a high school diploma is no longer adequate for understanding fermentation and enzyme process dynamics in product manufacturing. The cost of goods and allocation of overheads requires detailed assessment for decisions in technology, processes, and geographical network strategies (Khinast, Fraser, & Dujmovic 2014). Remodeling an existing facility might not be feasible for the new technology. The

costs of closure of old chemical facilities and severances pay for the long time employees add cash flow pressures on pharmaceutical decision makers.

In addition, high waste from production, low reimbursement on investment, and no proper pricing contracts were some of the inefficiencies driving good-compliance manufacturers away from producing quality low-cost generic medicines as per Woodcock in an interview with Koberstein (2014). Management behaviors' and financial indicators' impact on compliance and product quality require change management, leading to the expected outcome of fewer drug shortages. Woodcock also inferred that pharmaceutical manufacturers that implement high-quality systems could be financial productive by reducing waste, customer complaints, and product recalls (Koberstein, 2014). Financial efficiency implied an adequate cost of goods and proper utilization of resources. Managing financial indicators by attaining financial effectiveness led to a climate of less operational pressure allowing attention to quality systems.

The elements that could affect the quality of products leading to potential FDA intervention and undesired product shortages depend on management decisions. Management decisions that could impact the quality of products are limiting quality systems in manufacturing, avoiding investment in improvements to facility and equipment, lacking proper raw material selection, and accepting inadequately knowledgeable staff. Changes led to reducing operating expenses, even with the intention of lean manufacturing practices, could drive to limited quality systems (Woodcock, 2012). Quality systems should evolve with technology and consistency in procedures. Unfortunate, the enhancement to the quality system typically occurs after FDA

interventions, following evidence that the pharmaceutical company has been operating in a non-compliance scenario in front of the CGMP regulations (Asotra, Cossin, & Yacobi, 2012). Drivers and decisions to reduce the cost of goods without maintaining a balance with quality systems could lead to an unconscious situation of applying procedures without considering all the FDA expectations for a quality product (Woodcock & Wonsinska, 2013). Although CGMPs are common sense, sometimes management assumes that all common sense is CGMPs. This mental model leads to non-compliance and reduction in resources to attain the expected compliance level for product quality and quality systems within the pharmaceutical organization.

Financial factors like loss of sales to competition or new medicines, as well as loss in financial value of the firms in the financial markets, could generate significant financial pressures on the decision makers in the pharmaceutical firms. The reduction in the pipeline of new products, by the loss of patent of blockbusters medicine products, and due to growing pricing practices from the globalization of medicine and generics markets have raised the pressures in the cash flow of the pharmaceutical industry (Duffy, 2014). Even the generic sector of the pharmaceutical industry is subject to these factors and has been subject to FDA interventions for non-compliance in the production operations.

The annual pharmaceutical sales, with no-growth or marginal growth from year-to-year, have influences in the financial market value, impacting stockholders' investment. Reputation of the firms could be significantly affected by FDA interventions, in relation to the perceived management conduct, undesired behaviors, and lack of social responsibility of the pharmaceutical firms (Asotra, Cossin, & Yacobi, 2012). Typically,

operational management changes follow the FDA intervention. The loss in sales could be caused by patients and the medical community looking for treatment options, avoiding inferior quality products, or as a reaction to the medicine shortages. Asotra et al. (2012) indicated that disclosure of these changes influences the credibility and reputation of the firms with suppliers and investors.

In this quantitative study, the financial indicators of the factors discussed were assessed for the pre-FDA and post-FDA interventions, by applying correlations and regression analyses. The pre-FDA conditions are the scenarios (independent variables: behaviors and financial indicators) that led to enforcement actions by the FDA. The treatment event was the application of the enforcement action by the FDA. The level of compliance of the pharmaceutical company was the dependent variable. The post-condition was the outcome after the remediation activity was completed, which could be measured in behavioral attitude (management "decision making" survey), financial results (remediation investments and cost from financial statements), and level of compliance (FDA observations).

FDA Interventions

The FDA interventions examined by this study consisted of an action initiated by the FDA towards a pharmaceutical firms. These actions were based on the FDA's observations obtained during manufacturing facility audits, during assessing of patient complaints, or during medical patients' reactions related to the level of compliance in the manufacturing operations and to the quality of the medicine. The FDA interventions commonly consist of 483 observations (FDA, 2013, "Frequently Asked Questions," para.

1) followed by warning letters (FDA, 2012, "Regulatory Procedures Manual," p. 5) in the case that the pharmaceutical firms continue a non-compliance attitude or not address the observations. In the event that the pharmaceutical firms does not demonstrate commitment and due diligence to address the FDA actions, a consent decree issued by the FDA could follow to force a cease and desist to the senior management of the firms.

Arguments relating the FDA as the driver of medicine shortages has gained strength. The intensity and firmness of the FDA, ensuring that CGMP compliance by the pharmaceutical firms in recent years, are signaled as the cause of the medicine shortages (Graham, 2012; Roman, 2014). Graham (2012) went as far as indicating that the FDA was over-regulating with the increased in inspections to injectable manufacturers. According to Roman (2014), the FDA's approach to enforcing instead of working action plans, especially in critical medicines, promoted shortages of the medicines.

Pharmaceutical manufacturers' decisions have to be based on a balance of profitability and market value of the firms. If the FDA intervention leads to an unstable financial position, the firms could be forced to close and stop manufacturing as in the case of Ben Venue and Hospira in 2013 (Roy, 2012). Closures and discontinuation of manufacturing processes led to interruptions in the supply of medicines. Roy (2012) and Roman (2014) both concluded that the consequence of the FDA intensity and firmness in ensuring the CGMP regulations was a shortage of critical cancer drugs affecting patients with no alternate treatment.

Medicine shortages have been associated in recent years, with FDA interventions to pharmaceutical firms. Roman (2014) indicated that the medicine shortages between

2010 and 2013 resulted from an unnecessary approach by the FDA. The FDA's interventions to assure compliance with CGMPs caused pharmaceutical facilities to remodel facilities, re-train personnel, and change processes, when the manufactured drugs' quality was acceptable and in some cases meeting specifications (Kweder & Dill, 2013). Gottlieb (2013) concluded that the remediation activities led to facility closure and long recovery of the supply of the critical medicines. Roman (2014) insisted that negotiation and tolerance by the FDA with the pharmaceutical firms would have avoided medicine shortages. The interruption in the supply of medicines to patients needs a different approach.

Haninger, Jessup, and Koehler (2011) focused the shortage of medicines in the economics relation between supply and demand and not in the FDA interventions. Manufacturer's capacity, inventory practices by Group Purchasing Organizations (GPO), pricing strategies by pharmaceutical firms, and the FDA approval process of new manufacturer capacity led the rationale in the discussion of this study. Manufacturer's quality shortfalls were assessed as a contributor but not the primary factor in the supply and demand relationship to medicines' shortages. Although the statistics based on Medicare indicators supported the arguments, the fact that 54% (FDA, 2011) of the medicine shortages were associated with manufacturers' quality problems fell as a secondary factor. Haninger et al. (2011) indicated that manufacturer' problems highlighted by the FDA during manufacturer's facility inspections need to be assessed against the risk of affecting the supply of medicines, a message similar to Roman (2014). The causes prompting management behaviors to create manufacturer's non-conformance

issues with the FDA guidelines were not addressed nor recognized as a particular solution by Haninger et al. (2011). Any relation between the FDA interventions in the manufacturer firms' performance remained in the background or as a second theme.

The approach to compliance versus the risk of creating a shortage of medicines was a growing concern. Several recent studies have concluded that the FDA needs to balance between firmness of compliance and the benefits of drugs (Gottlieb, 2013; Roman, 2014; Roy, 2012). In the other side of the argument, Woodcock in an interview with Koberstein (2014) inferred that high waste from production, low reimbursement on investment, and no proper pricing contracts are some of the inefficiencies influence manufacturers away from producing low-cost quality medicines. The cause of the medicine shortages relates to manufacturing quality shortfalls (Fox & Tyler, 2013 and Woodcock, 2012). Enhancing CGMP compliance while avoiding patients' treatments needs high level of attention by pharmaceutical manufacturers.

A survey conducted by the American Hospital Associations (2011) revealed that 82% of the responding hospital had to delay patients' treatment because medicine shortages. The FDA approach towards manufacturing firms that lack compliance or are not focused on the CGMP expectations on quality was a crucial element in the well-being of patients, both from the quality as well as the supply of the medicines (Schweitzer, 2013). A proposal by Schweitzer (2013) directed the efforts by the FDA to grade the manufacturers on a scale from highest quality to unsafe standards. This approach could provide a measurement of when manufacturing practices need attention and the degree of modification to maintain supply to avoid medicine shortages. An action plan, as suggest

by Roman (2014) and Gottlied (2013), might then be implemented to keep supply and allow reasonable time for the remediation plan to meet the non-conformance found by the FDA during an inspection of the manufacturer's facility.

The FDA's new guideline, published in 2013 and based on the Executive Order from President Obama (Exec. Order No. 13,588, 2011) for managing medicine shortages, presented a reasonable approach to address a balance between enforcement, communication, and medicine availability (Barlas, 2014; Roman, 2014). In this new rule, Food and Drug Administration Safety and Innovation Act, the FDA requires that the manufacturing firms have to notify the FDA of upcoming medicine shortages and the FDA specifies the corresponding timing of the firms' notifications (FDA, 2013). Rooney (2014) presented the scenario in which the GPOs have been cooperating with the FDA and manufacturers to mitigate shortages, raise awareness related to the supply chain, and facilitate the understanding of the demand for drugs and generic medicines. From another point of view, Elzawawy (2015) challenged the drivers of the market economics like GPOs and global regulators to focus on enhancing the incentives to manufacturers by addressing pricing strategies. Elzawawy (2015), Rooney (2014), and Ventola (2011) concluded that a reliable supply of essential medicines was the critical responsibility of all involved.

The FDA role continues to be the same: "FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with its Current Good Manufacturing Practice (CGMP) regulations" (FDA, 2012, "Drug Applications and Current," para. 1). The FDA published goals for the five years from 2014 through 2018

that enumerate and emphasize the FDA's role, including minimizing medicine shortages (FDA, 2014). A common theme presented by almost all the sources agreed on the need for communication, coordination, and collaboration. These theme requires commitment by all parties, the manufacturer's management, the GPO's, health providers, and the FDA.

Theory to Support the Change

Theory of Planned Behavior (TPB)

One method of assessing the predictability of behaviors is by applying the theory of planned behavior. Ajzen (1991) developed TPB to provide a model of measuring attitudes and dispositions to predict behavior. TPB infers the existence of a direct relationship between intention and actual behavior. Also, attitudes and norms can explain any behavior following the principles of TPB. This study applied TPB to understand and predict the intention of pharmaceutical management to comply with the FDA regulations.

The structure of the flow diagram supporting TPB is presented in Figure 4. According to TPB, three types of behaviors direct and influence human behavior: beliefs (attitudes), normative behaviors, and perceived behavioral control (Ajzen, 2002). The interrelations between these beliefs influence the intention towards a given behavior. Intentions are the predecessors of behaviors (Ajzen, 1991). The relation between intention and behavior depends on the strength of the attitude from behavioral beliefs, the social pressures leading to subjective beliefs, and the level of perceived control that the person has in front of the decision process. Actual behavioral control results from the

limitations or obstacles to perform the intention. If adequate control exists, an individual's intention predicts the actual behavior, as a direct outcome.

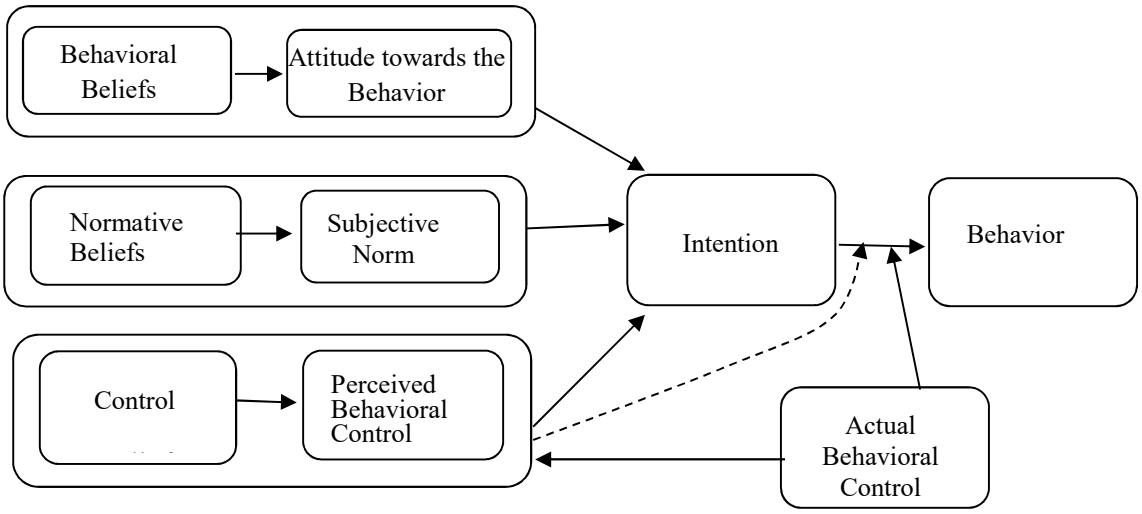

Figure 4. A diagram of process flows according to the theory of planned behavior. Reprinted from "Constructing a theory of planned behavior questionnaire: Conceptual and methodological considerations." by I. Ajzen (September 2002), Constructing a theory of planned behavior questionnaire: Conceptual and methodological considerations. Copyright 2006 by Iczek Ajzen.

Intentions. Ajzen (1991) indicated that motivational elements create the basis for intentions. The willingness of a person to execute a behavior and the level of effort placed in the planning the behavior can be used to infer the probability of the actual behavior (Ajzen, 1991). The performance of a given behavior depends on the level of strength of the motivational factors forming the attitude of the person. Ajzen (1991) emphasized that the intention can only become a behavior if the behavior meets the condition of the volitional control. The person has to be able to decide if the behavior is executed or not. The elements or resources influencing volitional control are for example

time, money, and the cooperation of others (Ajzen, 1985). If these elements are under the perceived control of the person, the intention should transform into the behavior.

Salient beliefs. TPB relies on the dependent connection between behaviors and the person's beliefs (Ajzen, 1991). The beliefs or information relevant to the intended behavior are the predecessors to the attitudes and perceived controls of the person towards a given behavior. Ajzen labels the relevant beliefs or information as salient beliefs. In TPB, intention towards a particular behavior depends on three salient beliefs: "behavioral beliefs produce a favorable or unfavorable *attitude toward the behavior*; normative beliefs result in perceived social pressure or *subjective norm*; and control beliefs give rise to *perceived behavioral control"* (Ajzen, 2002, par. 1). The determinants of behavior depend on the attitudes, perceived social pressures, and the control around the intention. According to TPB, the elements inducing a person to execute or not to execute a desired behavior are the intentions and the perceived controls that are outcomes of the salient beliefs of the person.

Applications of TPB

Predicting intention to comply with regulations is as important as predicting the actual compliance behavior. According to Langham, Paulsen, and Härtel (2012), applying of TPB produces a direct relationship between intention and actual behavior. This relationship is essential to the understanding of the willingness to comply and of the actual undesired action of non-compliance. By applying TPB, the researchers also evaluate the topic of behavioral control including the concepts of perceived behavioral control and actual control. Perceived behavioral control is directed to the intention to

behave. In addition, perceived behavioral control consists of the individual's ability to control their behavior and willingness to apply the required behavior (Ajzen, 1991). Actual control is essential for investigating behaviors that require the individual to overcome performance hurdles. Langham et al. (2012) concluded that attitudes and values are essential elements in the application of the TPB approach.

In an academic setting, Stone, Jawahar, and Kisamore (2009) attempted to demonstrate that academic misconduct seems to be increasing. Stone et al. (2009) also claimed that identification of factors that influence academic misconduct was a significant task due to its potential tie to the workplace later on. The study examined elements that could influence or lead to academic misconduct using TPB (Ajzen, 1991). Stone et al. (2009) concluded that understanding and reducing academic misconduct could dictate behaviors and values in future leaders.

Stone, Jawahar, and Kisamore (2009) applied two mediation regression equations. The population was from a self-selected sample. The data collection was through a survey. In their survey, Stone et al. used Likert-type scales. Relationships between the subscales of attitudes, subjective norms, behavioral control, intentions, justifications, and cheating were analyzed. The Cronbach's alphas for the six subscales were calculated establishing the reliability of the questionnaire. All Cronbach's alpha values were at or above 0.80. Some elements were signaled as "reversed" to obtain the reported Cronbach's alpha values. The Cronbach's alpha values obtained by Stone et al. (2009) indicated that the relations between the variables met the expectations for the application of the TPB questionnaire.

Stone, Jawahar, and Kisamore (2009) presented convergent validity and discriminant validity to address the construct validity of their study. Stone et al. (2009) concluded that the validity of their study was met. Shuttleworth (2013) discussed the difference between convergent and discriminant validity. Convergent validity tests whether constructs that should be related are indeed related. Discriminant validity tests whether believed unrelated constructs are indeed unrelated. In this study, the correlations between the two predictors and the Cronbach's alpha values in the questionnaire were assessed to prove convergent validity. Results of *t*-tests and the confidence interval tests should provide a means to test for discriminatory validity.

In an attempt to better understand and predict the intent of taxpayers to comply with tax regulations in Australia, Langham, Paulsen, and Härtel (2012) used TPB. Langham et al. (2012) demonstrated that TPB could be a predictor of compliance with tax regulations, using their findings to develop a particular model describing this process. For the first equation, multiple regression was performed for the TPB variables (attitude, norms, and behavioral control). For the second equation to predict compliance, a logistic regression was utilized, since the researchers indicated that the assumption of normality was violated. The results presentation and hypotheses discussions were adequate and easy to follow. Finally, a discriminatory analysis was conducted for each scenario, using a Wilks' lambda to establish the correctness of the prediction.

Understanding the factors that lead to unwillingness to comply or drive to ignore compliance should facilitate the probable prevention measures accompanying any FDA intervention. Intention and attitudes were assessed in this study. TPB were used to

identify behaviors to understand better how to predict behavior, reinforce intention, and probably modify future compliance with the FDA regulations.

Criticisms of the Theory of Planned Behaviors (TPB)

Several researchers have criticized the predictability and applicability of TPB. Ajzen (2011) analyzed and addressed criticism related to elapsed time, emotions, habits, personality traits, and background factors. Ajzen concluded that these elements "can expand and enrich our understanding of human social behavior" (Ajzen, 2011, p. 1124).

Ajzen (2011) did not concur, however, with the argument that elapsed time affects the predictive validity of the TPB as raised by Conner, Sheeran, Norman, and Armitage (2000). Ajzen contrasted Conner et al.'s (2000) position with that of Kor and Mullan (2011), who found that intentions were also affected in short time intervals. In relation to past behaviors or habits, Ajzen (2011) explained that the basis in TPB relates to recent beliefs relevant to the intention towards a particular behavior. In contrast, the arguments in favor of habits by Norman and Cooper (2011) inferred that the frequency of executing a given behavior creates stability and influences control over the behavior. Ajzen (2011) concluded the discussion on this topic by indicating that habit's strength over behaviors needs further studies.

Rivis, Sheeran, and Armitage (2011) assessed the role of the "big five" personality traits as a predecessor to intentions and behaviors. Ajzen (2011) judged that the results indicated small effect between the personality's traits and behaviors. Background factors such as demographics and emotions influence beliefs that are

antecedents to the salient beliefs. Ajzen (2011) explained that the origin of these factors affects the beliefs and indirectly the attitudes and control that are already part of TPB.

Change in Behavior (What, Why, How)

The required change process to attain the desired state of avoiding medicine shortages could evolve through the typical life cycle of what, how, and why (Kezar, 2001). Management trends and possible theoretical frameworks presented in Figure 1 project the complexity of addressing the change process. The future impacts on the stakeholders were the "why" to conduct the study, delineating the required attributes influencing the management performance to achieve positive social change.

What Needs to Change

The lack of compliance with CGMP has led to pharmaceuticals manufacturing facility closures, loss of revenues, unavoidable penalty fees, loss of reputation, and significant investments to address remediation of their violations to the FDA regulations (Asotra, Cossin, & Yacobi, 2012). Manufacturing shortfalls implied that quality management and systems are not empowered or properly staffed to support adequately the critical functions within the pharmaceutical firms (Woodcock, 2012). In the first three years of the Obama Administration, 2009 through 2011, the number of warning letters issued to manufacturing and quality issues increased to 49 letters versus nine letters in the last three years of the George W. Bush Administration (Nguyen, Seoane-Vazquez, Rodriguez-Monguio, & Montagne, 2013). The FDA, in a letter to pharmaceuticals manufacturers in October 2011, indicated that about 54% of drug shortages were a result of manufacturers' quality problems (FDA, 2011). Collectively, the evidence suggested

that the number of FDA interventions and enforcement actions against pharmaceutical manufacturers have increased in the recent years. Also, as shared in Anisfeld (2009), the FDA has issued warning letters to international generics firms, establishing import bans of their products into the U.S.

Why the Need for Change

For pharmaceutical firms, the lack of compliance with the FDA regulations could be devastating. The results from the lack of compliance include loss in sales, impact on reputation, and an increase in the level of expenses to recover or achieve remediation. These performance indicators typically also impact the market value of the firms. If the FDA intervention escalates into a consent decree, Asotra, Cossin, and Yacobi (2012) explained that the magnitude of all these elements could multiply and become an unacceptable historical benchmark within the industry.

This dissertation promoted positive social change by eliminating or minimizing medicine shortages. Medicine shortages place the patients' health in significant danger. In addition, medicines that are substandard in quality, purity, and identity probably do not address the intended treatment (Woodcock, 2012). The potential mistrust by the public on companies' lack of commitment towards social responsibilities could be kept to a minimum.

How to Pursue the Change

The gap between the present situation and the desired state was the basis for justifying the need for change. How to pursue the desired change could have several approaches. Market dynamics, survival of the organization, personnel needs, new

technology, regulatory requirements, or a mixed of all the above items is an excellent basis to influence the metrics of how the change is pursued. The FDA proposed the establishing of quality metrics to control operations and change (Koberstein, 2014). Internal and external elements create the scenario of interdependencies and archetypes to be dealt with in the road to the desired state as generalized by Senge (2006). The complexity of designing the strategy of how to pursue change depends on the understanding of the interdependencies and archetypes.

In the area of motivation and inspiration, Ilies, Judge, and Wagner (2006) designed a conceptual model to illustrate the impact of transformational leadership on the motivation of subordinates or followers. The effect of affective and cognitive approach to motivation was presented in three areas: direction of the action, effort intensity, and persistence. Charismatic leadership and motivational leadership were linked to actual followers' reaction. The analysis focused on how leaders should approach team members while considering the diversity in attitude and individual skills. The theory of multiple intelligences, as described by Kornhaber, Krechevsky, and Gardner (1990), could further highlight the need for an individualized approach to teams. Motivation theories like Maslow's (2000) hierarchy of needs could be part of the leaders training.

The organizational goals and working climate drive the change strategy to be selected and implemented by the organization leaders. The flexibility and adaptability of the management decision-making process and the existing environmental factors of the organization create boundaries in the potential change process. As explained by Chadwick-Coule (2011), the effectiveness of the change process and the sustainability of

the outcomes are highly dependable on who sets the target, the approach to the execution of the change, and the impact of the change on stakeholders.

The selection of the change strategy typically depends on leadership style and organizational structure. Peng and Weichun (2011) concluded that leaders have a significant influence on organizational performance. In reference to leadership style, Vroom and Lago (2007) described contingency leadership, and Deluga (1990) studied the impact of transformational, transactional, and laissez-faire leadership. Morgan (2006) compared different organization models, emphasizing that the organizational model set the internal dynamics of operation and change management. For effective change management, Senge (2006) indicated that sharing vision, effective communication, and confirming change effectiveness are essential elements. The effectiveness of the change strategy converse in the integration of all these elements. The implied interdependencies of these elements provide a robust scenario to ensure the execution of the change strategy and hopefully, its sustainability.

Resistance to change is a critical item that needs to be understood and managed. Stakeholders' mental model of "what is in" for me is a sensitive topic driven by motivation, individual psychology, emotional intelligence, and learning style. Maslow's (2000) hierarchy of needs and the pursuit of self-actualization, as well as Adler's theory (as cited by Boeree, 2007) of complex management by striving for superiority, cannot be ignored by leaders when selecting a change strategy and setting the corresponding execution plan. The idea is to engage the stakeholders, and not to apply intimidation.

Motivation and improvement to the self-esteem of the followers could allow leaders to delegate and grant opportunities for participation. As demonstrated by Leana (1987), the climate of participation, as well as the willingness for delegation by the leaders, is associated with the level of trust and the understanding by the leader of the degree of competence demonstrated by the subordinates. Leaders should consider the person's lifestyle to optimize the individual's motivation. Adler's (as cited by Boeree, 2007) concept "of being useful" could be linked directly to the organizational climate. The employee should feel satisfied that is valuable to the team and is in the pursued of the targeted goals.

Change Models

The selected model of change or strategy to be followed typically includes team building, new relationships, and technological support. The geographical characteristics of the organization could also influence the selection of the change model. The systematic approach to change implementation, execution, and measurement should attain the desired transformation as summarized by Kupritz and Cowell (2011).

Deming's Cycle

In the twentieth century, quality and reduction of variability became the backbone of continuous improvement with concepts like Deming's improvement cycle and the 14 quality principles, which were followed by many others like Crosby, Shingo, and Peters (Hussai, 2004). The concept of planning change, for improvement versus purely reacting to external environment factors or internal weaknesses, became a significant trait to attain transformation and long-term sustainability of outcomes. Focusing on Deming's Quality

Management 14 principles, total quality management (TQM) implies a process of continuous improvement, by applying the cycle of plan, do, check, and act to the organizational and leadership transformation to pursue the expected level of compliance with the FDA regulations. Also, leadership's adaptability and flexibility are typically associated with strategic planning and organizational development (Beinhocker, 2006). These changes could be considered both transformational as well as transactional since usually a mix of changes is implemented.

Kotter's Model

Kotter (2007) discussed the critical factors that constitute the model for the change process. The effectiveness of the implementation depended on essential elements, requiring attention and monitoring. The eight phases or *errors to avoid* were integrated to prevent failure in a change process. Kotter's (2007) eight phases or *errors to avoid* consist of

- Establish a sense of urgency
- Create a guiding coalition
- Develop a vision and strategy
- Communicate the change vision
- Empower broad-based action
- Generate short-term wins
- Consolidate gains and produce more change

These eight phases or *errors to avoid* are essential to assure the transformation in behavior to attain the expected level of compliance with the FDA regulations. The notice of violation from the FDA explicitly set the level of urgency to the operational management to avoid and minimize the impact to the supply of the medicines and the revenues of the pharmaceutical firms. The undesired impact on sales and reputation of the firms most likely results from the FDA intervention, raising the urgency and expectations of the management of the firms. The next two phases require senior management to establish a clear guidance and vision on the need to change the behavior from the supervisors to the operational personnel. Strategies and tactics need to be developed, leading to changes in processes, styles, and deliverables.

The fourth stage in Kotter's model is the next critical step: communication. As stated by Senge (2006), sharing the new vision of compliance and desired behavior tends to engage all levels of decision-making and operations. Establishing subject matter experts and delegating to teams should accelerate the transformation, assuming that management can evolve from crisis management into participative leadership.

The next stage is to set clear short-term targets to highlight a clear direction of change and the expected level of compliance. The notice of violation from the FDA sets the general tone. Quality systems need overall review and probably significant changes. Mehta (2013) suggested that implementing principles and guidelines, as developed by the International Conference on Harmonization, could be a significant step in facilitating leaders' understanding of the compliance expectations. To correct the events of CGMP

violations implies that productivity indicators, financial metrics need to be assessed while management behaviors need to be modified.

A systematic review of progress and hurdles during the implementation plan needs to be established to assure measurement of progress. In addition, a time most be set aside to adjust in front of any failure or delay. Sensitivity to the employees' engagement and citizenship to support the overall change process needs to be recognized to ensure effectiveness and sustainability of the change. An overall continuous process should allow management to secure the new compliance behavior and assure sustainability for the long term.

Continuous Improvement Measurement

To assess continuous improvement, a holistic approach is required across all disciplines to measure performance. Chan, Qi, Chan, Lau, and Ip (2003) presented a process-based approach to measuring performance for supply chain management. The measurements cover the traditional supply chain indicators in cost, time, capacity, capability, resource utilization, and reliability. Accurate data could be collected to compare the performance of the two scenarios: before and after the FDA intervention. The application of this type of tool to measure continuous improvement could support the process of managing the change process, allowing for adjustment when the indicators are not as expected. Influencing the change process implies an open flow of information, the share of knowledge, experimentation, and tolerance of autonomy, allowing fast response to adapt and adjust as changes are being implemented.

With the FDA intervention creating new pressures and challenges within the interdependencies of the organization, planning and reassessment become essential to monitor progress and reduce pitfalls. The transformation of the attitudes and behaviors impacts leadership styles and emotional intelligence attributes of the management team. Understanding the evolution of the change stages and links needed to support, the new approach to compliance, demands vision and hands-on knowledge. The change process evolves in stages as the organization learns, accepts, and matures along the implementation of the associated changes in policies and procedures. Finally, the new required level of adaptability, flexibility, and tolerance to change challenges the traditional authority and financial policies of the organization.

Managing Change Resistant or Impediments

The deliverables in this study were compliance behavior to assure medicines availability for patience, adaptability to handle the financial pressures, and transformation into a learning organization. The goal was operational compliance with FDA regulations, which normally in these situations, were well defined by the audits and expectations from the FDA. The plan to transform behavior and to address the financial pressures requires transformational leadership approach and tolerance to change, minimizing pitfalls and resistance to change while sustaining the expected CGMPs regulations from the FDA.

In Figure 5, a concept map representing a Change Implementation Plan is illustrated. Cicmil (1989) developed the structure of this concept map. Cicmil suggested that by mapping the what, how, and why the gaps and the impediments would be exposed, including the vulnerable areas for implementation of the change. The what and

how refer to project deliverables and implementation process, respectively. The elements of the implementation process are the identification of the gap, the development and execution of the implementation of the plan, and the measuring progress.

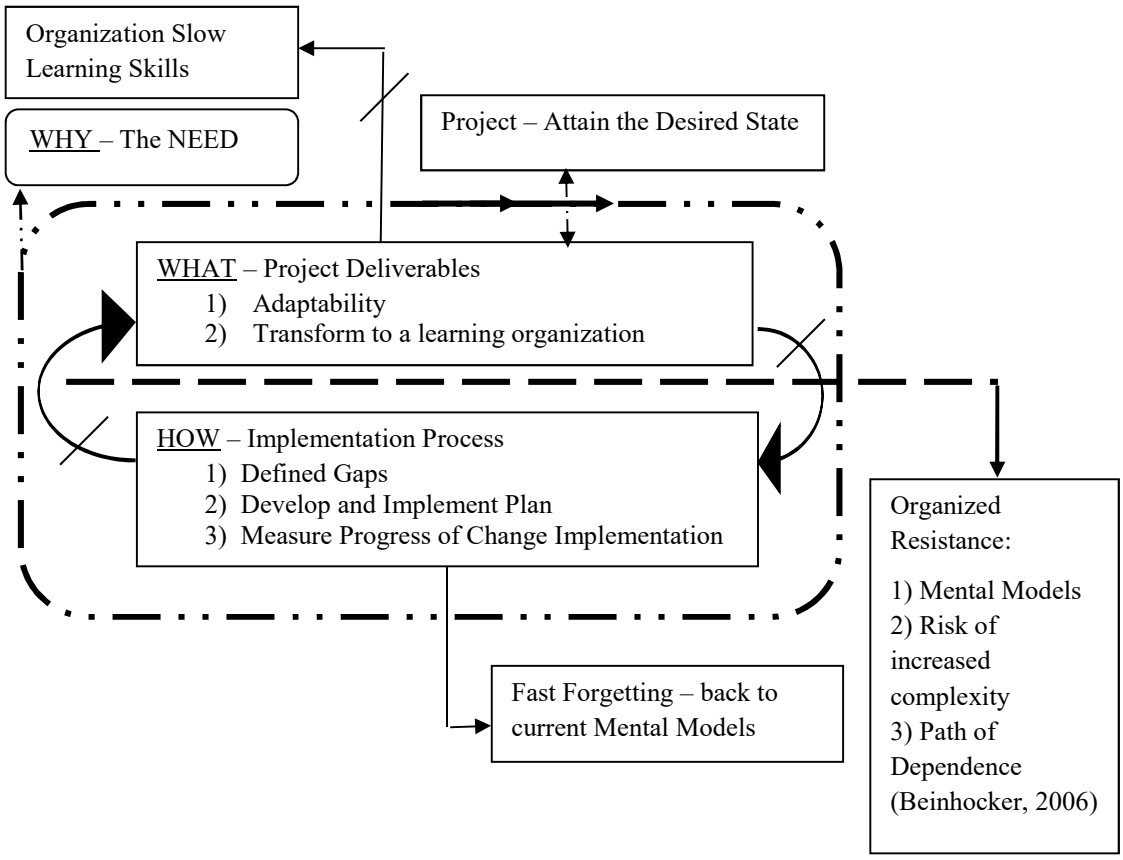

Figure 5. Concept map for a complex adaptive system for the implementation of organizational changes. Source of Concept Map was adapted from "Implementing organizational change projects: Impediments and gaps" by S. Cicmil, 1999, *Strategic Change, 8*(2), page 128. Copyright © 1999 John Wiley & Sons, Ltd.

Summary

Change is an ongoing performance improvement that organizations must examine. There may be many different styles of change models utilized within an organization. The goal is to identify that there is a need for change, develop a plan for

change, implement the plan with effective communication, and evaluate the effectiveness of the change implemented. The "what, how, and why" of change needs to be an ever-rotating cycle. Although some people may not like the concept of change; for leadership, change in behavior is always an opportunity for improvement for long-term sustainability of the organization.

Chapter 2 contained the literature search strategy that was followed. For the quantitative study to be performed, the independent variables, the dependent variable, and the FDA intervention were analyzed. Arguments were presented in which the FDA interventions could be considered as the cause since the FDA showed to have low tolerance with manufacturers in front of the impact to the supply of medicines. The relevance of the study and its impact on social change regarding the research gap in the literature were further discussed.

The literature review on the theoretical framework addressed the theory utilized for this quantitative study. Critics of the theory of planned behavior presented arguments on the weakness of the theory. Counter arguments were discussed from the response of Ajzen (2011). An analysis of issues, trends, and concepts formalized the literature review for what needs to change, the how to change, and the why to change assuring an efficient change management process while managing resistance to change.

In Chapter 3, the research methodology and design are presented in detail. The research tools to be employed are discussed, including the efforts for validity, the trustworthiness of the survey, and the Internet tools. Accessibility of the targeted

participants and the assurance of confidentiality is described. Finally, elements of confidentiality and data protection are enumerated.

Chapter 3: Research Method

This quantitative study sought to learn to what extent, if any, management behaviors and financial pressures at pharmaceutical firms correlated with or predicted compliance with the FDA regulations avoiding interruptions in the supply of some essential patented or generic pharmaceutical drugs in the U.S. In Chapter 3, the research methodology and design were presented in detail. The research tools to be employed were discussed, including the efforts for validity, the trustworthiness of the survey, and the Internet tools. Accessibility of the targeted participants and the assurance of confidentiality was described. Finally, elements of confidentiality and data protection were enumerated.

The study enhanced the understanding that avoiding FDA interventions provided business sustainability by analyzing management behaviors. The study also accentuated the concept that compliance was a competitive business advantage for the pharmaceutical companies. The design of the research allowed the scenario of predicting the outcome of the dependent variable, compliance with the FDA regulations.

Research Method and Design

For the study, the selected quantitative research methodology needed to correlate the variables and predict the outcome. The quantitative research method predicts, investigates relationships between variables, or assesses possible impacts on outcomes (Creswell, 2009). This deductive approach to confirm the correlation between the variables was considered adequate to address the research question and assess the hypotheses.

The quantitative study consisted of a research design including correlations and regression analyses. I applied this statistical tools to make a comparative analysis between the scenarios before and after the application of a treatment, the FDA intervention. The expected variability in the study and the desired to predict outcome led to the application of Cronbach's alpha and regression line analyses. Also, applying simple *t*- test comparisons provided clarity to the correlation. For this study, the pre-FDA conditions were the scenarios that led to enforcement actions by the FDA. The independent variables or predictors were management behaviors and financial indicators. The treatment event was the application of the enforcement action by the FDA. The dependent variable or outcome was the level of compliance of the firms.

The correlations between management behaviors and financial indicators on the compliance with the CGMP regulations defined the quality systems before and after the FDA intervention with the pharmaceutical companies. A multiple linear regressions provided the assessment between the pre-FDA conditions and the post-FDA conditions, before and after the FDA intervention. A regression methods were applied twice, pre-FDA and post-FDA interventions, for comparative statistical analysis to establish patterns before and after the application of the treatment.

For this study, the pre-FDA conditions were the scenarios that led to enforcement actions by the FDA. The pre-FDA conditions represent the situations (independent variables or predictors: management behaviors and financial indicators) that resulted in enforcement actions by the FDA. The treatment event was the application of the enforcement action by the FDA. The level of compliance of the firms was the dependent

variable or outcome. All variables were considered to be continuous at the time. The post-FDA condition represented the outcome after the remediation activity was completed, which was measured in the behavioral attitude (TPB) questionnaire (management "decision-making" survey), financial results [financial indicators section (i.e. cost of goods, investment, and revenue)], and level of compliance with the FDA (level of compliance responded by participants).

Considering that there was a logical expectation that the FDA intervention was going to force a change in management attitudes, an impact on the regression line was expected, at the application of treatment, the intervention of the FDA. The analysis of the TPB questionnaire responses allowed to compare the relationships before and after the FDA intervention. Also, establishing the regression line, between the variables after the treatment, should assist in assessing the long-term effect on compliance, allowing for follow-ups and self-corrections by the firms.

Research Questions and Hypotheses

The focus of this quantitative dissertation research study was to determine to what extent, if any, management behaviors and financial indicators correlated to compliance with FDA regulations at the pharmaceutical firms in the United States. The conditions before to the FDA intervention in the pharmaceutical firms was compared to the conditions after the FDA intervention to predict compliance with the CGMP regulations. The independent variables that led to enforcement actions by the FDA are management behaviors of the pharmaceutical managers and the firms' financial indicators. The

treatment event was the application of the enforcement action by the FDA. The level of compliance of the pharmaceutical company was the dependent variable.

- Correlation between management behaviors (independent) and compliance (dependent):

  RQ1: To what extent, if any, does management behaviors correlate to compliance with FDA regulations at the pharmaceutical firms in the United States?

  $H1_o$: $r = 0$. There is no difference in management behaviors towards compliance at pharmaceutical firms, as a result of FDA enforcement actions in the United States.

  $H1_1$: $r \neq 0$. There are differences in management behaviors towards compliance at pharmaceutical firms, as a result of FDA enforcement actions in the United States.

- Correlation between financial indicators (independent) and compliance (dependent):

  RQ2: To what extent, if any, do financial indicators correlate to compliance with FDA regulations at the pharmaceutical firms in the United States?

  $H2_o$: $r = 0$. There is no difference in compliance with FDA related to financial indicators at pharmaceutical firms, as a result of FDA enforcement actions in the United States.

$H2_1$: $r \neq 0$. There are differences in compliance with FDA related to financial indicators before and after the FDA enforcement actions in the United States.

- Financial indicators (independent) impact on compliance (dependent):

  RQ3: To what extent, if any, do financial indicators impact compliance with FDA regulations at the pharmaceutical firms in the United States?

  $H3_0$: $\beta_1 = \beta_2 = \ldots = \beta_k = 0$. There is no impact in compliance with FDA related to financial indicators at pharmaceutical firms, as a result of FDA enforcement actions in the United States.

  $H3_1$: At least one $\beta \neq 0$. There is an impact in compliance with FDA related to financial indicators before and after the FDA enforcement actions in the United States.

The β in Hypothesis 3 are the regression coefficients of the following multiple regression equation:

$$Y = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \beta_4 X_4 + \beta_5 X_5 + \beta_6 X_6 + \beta_7 X_7 + \varepsilon \qquad (2)$$

Where,

Y= FDA related compliance

X_1 = Cost of goods

X_2 = Investment

X_3 = Process compliance

X_4 = Change in sales

X_5 = Change in revenues

X_6 = Change in market value of the firms

X_7 = Change in stockholders equity

ε = Error of the regression

Pilot Study

A pilot study was conducted to examine clarity of questions to collect feedback on the questionnaire's structure and to identify essential beliefs using Likert-type scales. Ajzen (2002) indicated that a pre-work is required to define the behaviors of interest for the adequate design of the TPB survey instrument. The pilot study clarified management behaviors towards compliance with FDA regulations. The pilot study also collected feedback about financial indicators of the pharmaceutical firms. Demographics of participants, the degree of compliance, and the type of FDA interventions were requested in the next sections of the survey instrument. The pilot study confirmed the effectiveness and completeness of the order of the questions.

To qualify as a participant in the pilot study, participants complied with the same survey population criteria that was also used for the main study. Participants were selected from executives and operational management levels who had the authority to make compliance and financial decisions within pharmaceutical firms, based on their self-disclosed position titles in the ISPE members' database. The number of participants invited to the pilot study was 21. The response rate was 47% for 10 completed surveys. The 10 responses to the pilot study represented about 6% of the initially targeted usable responses for the main study of about 160. The pilot study participants' selection process was based on convenience sampling that is different from the main study. The need to

ensure sufficient and reliable replies from the pilot study made it important to recruit participants who provided usable feedback within 14 days.

The pilot study was conducted similarly to the same intended instrument for the study. The pilot study was administered through SurveyMonkey, an electronic survey tool chosen to collect data and facilitate analysis. Trust and desire to participate depended on the cover letter and personal communication by me with the pilot study's selected participants. Also, the pilot study provided feedback on the effectiveness and completeness related to the message of confidentiality directed to ensure participation later on in the study questionnaire.

Population and Qualifications

The study population consisted of pharmaceuticals firms that had been impacted within the last 5-6 years by enforcement activities from the FDA in the United States, with a specific focus on firms that had experienced FDA interventions related to manufacturing CGMP violations. The FDA interventions consisted of notification of deviations (Form 483) with a rating of official action indicated (OAI), following the FDA's escalation process as a result of the pharmaceutical firms not responding to these FDA communications. Audits with ratings of OAI could lead to warning letters or consent decrees depending on the firms' response and follow-up actions to the FDA notifications. In Table 3, a total of 272 OAI audits was summarized for the pharmaceutical firms between 2010 and early 2015 (FDA, 2015). This number of firms indicated the targeted population for the main study.

Table 3

FDA audits with ratings of OAI

FDA Audit Year	Audits with Official Action Indicated (OAI)
2010	86
2011	73
2012	52
2013	47
2014	13
2015	1
Total Audits	272

The intended survey participants was selected from executives and operational management levels of the pharmaceuticals firms in the United States. ISPE members' data based was used to select the participants. These participants, based on their self-disclosed position titles, had the authority to make compliance and financial decisions for their firms.

Sampling Strategy

The sampling strategy was directed to support the main study in the pharmaceutical firms in the United States. The main criteria for participation were that the executives and senior operational management of the firms were expected to have the authority to make compliance and financial decisions within the firms. The participants' responses were selected from the completed surveys.

The database of potential participants was obtained from the members' directory of the ISPE. Although simple random sampling as suggested by Kanupriya (2012) could

have been an effective sampling strategy for the study, all ISPE members that meet the criteria of participants were invited through SurveyMonkey to participate. The authorization for use of the members' directory of the ISPE as a member is in Appendix D.

For the pilot study, convenience sampling approach was the sampling strategy. This strategy allowed me to select participants based on my personal knowledge. The participants for the pilot study were considered as experts from the targeted population who provided the required information to finalize the study questionnaire (Frankfort-Nachmias & Nachmias, 2008). Based on Ajzen (2002) the pilot study questionnaire provided a stronger selection of the construct elements for the design of the TPB questionnaire for the main study.

Sampling Strategies Not Chosen

Systematic Sampling. Systematic sampling, in which a portion of the population is selected (1/k), was not appropriate for the targeted hypotheses of the main study. The resulting sample could be impacted by the size of the each pharmaceutical firms or the characteristics of the FDA interventions. The financial strength of each pharmaceutical firms could influence the approach to change management to attain the remediation of the deviations from FDA regulations as noted during the FDA intervention because of the firms' manufacturing processes.

Stratified Sampling. Stratified sampling was considered as an alternate when considering that there could be hierarchical levels of internal authority within the sampling units at each firms. Nevertheless, the potential differences in the firms' size and

each particular organizational structure could make it very difficult to have proportional sampling and understand the weight between the decision makers. When comparing different FDA interventions, empowerment to decision makers could depend on the financial resources of each pharmaceutical firms.

Cluster Sampling. Cluster sampling intent was considered not applicable to the main study since the cluster approach was not aligned with the targeted participants' distribution. Although the pharmaceutical industry could be considered as one population, the individual firms does not necessarily create a cluster scenario for sampling. The behavior of management was better substantiated through the approach of including all ISPE members that met the participants' criteria to minimize any risk of biases by the individual firms' financials**.**

Sampling Size Determination

For the sampling size determination of completed surveys, three approaches were followed to address the three research questions and hypotheses. For research questions one and two, the sampling size determination of completed surveys considered Krejcie & Morgan (1970) equation and Cohen's power (1992) as the basis for calculation. The sample size of completed surveys for RQ3 was established by using G*Power software (Faul, Erdfelder, Lang, & Buchner, 2014).

The intended study population consists of pharmaceuticals firms that had been impacted within the last five years by enforcement activities from the FDA in the United States. This population was estimated to be about 272 pharmaceutical manufacturing firms based on the FDA information (FDA, 2015). The sampling size of completed

surveys indicated by Krejcie & Morgan (1970) was to be about 160. The intended survey participants were selected from executives and operational management levels of the firms, and should have the authority to make compliance and financial decisions for their firms, based on their self-disclosed position titles in the ISPE members' database.

Also, an alternate method was utilized to estimate the sample size of completed surveys for research questions one and two. Cohen's power (Cohen, 1992) was assessed as adequate since the population standard deviation is not known. The concept of effect size is based on the difference between population means. Cohen (1992) indicated that the effect size could be selected to be 0.5 if the difference of the means is perceived to be. For the main study, the effect size was not leading to the selection of a smaller effect size of 0.3. Calculation of the sample population with the application of Cohen's effect size *d* was based on a power (1- β) of 0.80, and a confidence level (α) of 0.05. Assuming that the groups' sizes were the same (r =1), the sample population of completed surveys should have been about 121 with the application of Cohen's power.

For the research question and Hypothesis 3, a priori power analysis was applied based on the required expectation of the financial variable impact based on the FDA intervention in the pharmaceutical firms. The values were set for the statistical power (strength of the statistical test), α value (probability of the null), and the effect size (correlation between the variables and the predictor) to determine the sample size. The selected power of a statistical test represented the probability of correctly rejecting the null hypothesis, if applicable (Faul, Erdfelder, Lang, & Buchner, 2007). The sample size of completed surveys for RQ3 was established by using G*Power software (Faul,

Erdfelder, Lang, & Buchner, 2014). Also, the selected statistical power represented the probability that the selected statistical test can find a relationship between the variables.

The G*Power software option for the linear regression study assumed a R^2 that is different from zero for two predictors in a linear regression. The sample size of completed surveys was determined to be about 127, based on the selected values for statistical power of 95%, α of 0.05, and effect size of 0.125. Appendix C presents the G*Power calculations for the sample determination. The power of 95% provided a reasonable position to avoid Type II error of not rejecting the null hypothesis when it was supposed to be rejected. About the effect size, the value of 0.125 was selected to test a reasonably low correlation between the predictors to enhance the regression model likeliness of projecting the outcome.

Based on the three approaches for the sampling size determination, the potential sample sizes of completed surveys were 160 from the method from Krejcie & Morgan (1970), 121 from the Cohn's power (1992), and 127 from the G*Power software (Faul, Erdfelder, Lang, & Buchner, 2014). For the study, the target sample size of completed surveys was about 160 to ensure that the three research questions and hypotheses were adequately addressed. My intent was to minimize Type I and Type II errors in the assessment of the three null hypotheses.

For the intended population, computer accessibility was expected to be high, the typical time navigating and reading e-mails most likely be constant on a daily basis, and the probability of gaining the respondent attention is better than by mail or telephone calls. As explained by Ahern (2005), the benefits of the electronic survey are time

management, accessibility to sensitive/specific population, and easy and comfort to use (user-friendly) while minimizing the missing data. The use of an established electronic survey, SurveyMonkey, facilitated the data management. SurveyMonkey had a reasonable reputation and could add comfort to the participant, driving the overall level of participation.

The SurveyMonkey was applied to estimate the optimum sample size assuming a normal distribution. For the initial target of 160 completed questionnaire, the SurveyMonkey sampling estimator indicated that the number of potential participants should be about 400 at a 90% confidence level and a 5% margin of error. This sample of 400 participants projected about 162 completed surveys with a 90% probability that the sample of participants should reflect the attitudes of the intended population. Also, the margin of error of 5% intended to minimize the deviation from the true value at the selected confidence limit of 90%. For this scenario, the expected response rate based on SurveyMonkey sampling estimator implied a participation of 40.5%.

A response rate of 40.5% was initially considered too optimistic. The expected response rate was set at 20% to ensure the probability of attaining the targeted 160 completed surveys. This scenario represented about 800 participants at 20% response rate. The SurveyMonkey sampling estimator indicated that for 800 targeted participants at a 90% confidence level, the margin of error could be expected at 6%. As a precaution, 1144 members in the directory of the ISPE with an address and meeting the participants' criteria were invited to complete the main survey.

Description of the Survey

The survey instrument consisted of four sections, structured as a Likert-type scale questionnaire. Two sections focused on the behavior of the participants and the financial indicators of the pharmaceutical firms in the pre-FDA and post-FDA interventions. The third section collected demographical information from the participants. The fourth section focused in the firms' historical compliance.

The period of the survey was an important factor. The participants were expected to associate personal assessment of behaviors and financial indicators for both the pre-FDA and post-FDA interventions. The instructions in the survey instrument needed to be precise providing clarity to optimize the number of usable responses.

The TPB questionnaire by Ajzen (2016) was modified for the behavioral section of the intended survey instrument. Ajzen (2002) suggested the essential elements for the construction of the survey for a TPB questionnaire. Consent to apply and modify the TPB questionnaire for this study was granted by Ajzen (see Appendix A). The financial indicators section of the planned survey instrument were based on typical indicators that could be impacted by the expenses needed to support remediation addressing FDA interventions like the cost of goods and investment in facilities or equipment. Sales, Revenues, and stockholders' equity were also be part of the financial indicators.

For the participants, computer accessibility was expected to be high; the typical time navigating and reading e-mails most likely be constant on a daily basis; and, the probability of gaining the respondent attention was better than by mail or telephone calls. The benefits of an electronic survey are time management, accessibility to

sensitive/particular populations, and being easy and comfortable to use while minimizing the potential for missing data (Ahern, 2005). The survey was administered through SurveyMonkey. SurveyMonkey has a reasonable reputation and could add comfort to the participant driving the overall level of participation.

Appropriateness of the Instrument

The questionnaire structure for assessing management behaviors was developed following Ajzen's (2002) guide for constructing a theory of planned behavior questionnaire. Also, the sample TPB questionnaire from Ajzen (2016) was used. The permission to use the TPB questionnaire is in Appendix A. Two surveys from the literature were also used as guides. The first model considered the survey from Stone, Jawahar, and Kisamore (2009) in which academic misconduct was used trying to predict future performance as leaders. The second model was from Langham, Paulsen, and Härtel (2012). In this model, the target was to demonstrate that the TPB could be a predictor of compliance with tax regulations. In the main study, the questionnaire constructs considered beliefs (attitudes), normative beliefs, and perceived behavioral controls.

The questionnaire based on TPB was directed to the elements of salient outcomes and control factors with the objective to obtain direct measurement of the attitudes toward the intended behavior, the perceived norm, and the perceived behavioral control as indicated by Ajzen (2002). The pilot study was be the source of beliefs (attitudes) and control factors used in the main survey instrument. Past behaviors versus current behaviors could depend on background changes like organizational structure and working

climate. A section of general questions was included to help identify future areas of study affecting behaviors of managers as a result of FDA interventions.

For the financial indicators, a Likert-type scale questionnaire was developed to create a clear and direct tool for the participant to provide their responses. The scales were designed to associate in an ordinal relation with each financial indicator's values. The elements included for financial indicators consisted of basic business topics like revenues, the cost of goods and investment in facilities or equipment. The goal was to provide a questionnaire structure that allowed the participants to compare periods before and after the FDA intervention for the financial indicators.

The survey instrument consisted of four sections of questions to assess management behaviors and financial indicators of performance before pre-FDA and post-FDA interventions. The responses to the questionnaire were expected to provide feedback over time while maintaining the participants' responses aligned to both periods, before and after the FDA intervention. The third section of the study questionnaire asked for demographic information of the participants. Section four complied responses about the FDA experience of the firms.

Validity of Measurements

Attempts to neutralize or compensate for measurement errors could be defined as evidence or specific conditions in support of the validity. The objective is to enhance the validity of the instrument about what it is intended to measure (Frankfort-Nachmias & Nachmias, 2008). There are three types of approaches to address measurement errors: content validity, empirical validity, and construct validity.

Content Validity

Content validity is directed to assure that the measurement instrument covers all intended attributes of the study. Face validity (all questions addresses the properties of the variables) and sampling validity (all properties of the variables are considered) are the two areas that need to be considered when addressing concerns around content in the questions validity of a questionnaire (Frankfort-Nachmias & Nachmias, 2008). An important challenge is to ensure that the questionnaire addresses all significant aspects of behavior.

Assessment of the feedback from the pilot study assisted in achieving a significant content validity. Assuming that all participants had the same level of definition of what is compliance was difficult to predict. Maintaining neutrality and not pre-setting responses on the questionnaire by me required neutrality and control over previous mental models.

Empirical Validity

The relationship between the measurement instrument and the actual outcomes requires attention. Addressing empirical validity is very difficult (Frankfort-Nachmias & Nachmias, 2008). Predictions via a pilot study was developed with peers in the pharmaceutical industry to allow comparison of initial expectations with actual measured results. Even establishing a reference base had its challenges, based on potential biases of management (participants).

Construct Validity

Construct validity looks for a theoretical framework that could be related to the intent of the measuring instrument. The TPB (Ajzen, 1991) was used to discuss the

outcome of the measurements. TPB presented the concepts that allowed me in the study to link beliefs (attitudes) with the actual behavior, subjective norms with the behavior, and perceived control over behavior. The correlations and linear regressions provided the basis to assess the data from the TPB sections of the study questionnaire. The attributes and assumptions of TPB could affect the study. Assessment of the survey data allowed defining future research in the topic.

Questionnaire Reliability

Cronbach's alpha tests correlation to determine the reliability of a scale questionnaire (Field, 2009). Cronbach's alpha is not a validity measure. The values for Cronbach's alpha range from 0 to 1. Cronbach's alpha provided the means to assess if the scale items in the study questionnaire impacted the overall total subscale reliability. Either eliminating or reversing the phrasing of a negative scale item were assessed to obtain the Cronbach's values. All subscales of the Likert-type scale structure of the questionnaire were included in this assessment with the Cronbach's alpha tests correlation.

Protection of the Survey Population

The data collected through the electronic questionnaire was protected by the terms provided by SurveyMonkey. An individual codification was used to protect each participant's responses within SurveyMonkey. All lists of the study's participants generated with the SurveyMonkey code will be destroyed by incineration for any printed master list after five years from the approval of the study. SurveyMonkey confidentiality terms will also apply in their databases. The electronic lists from my computer will be

stored in a bank security box for five years on a DVD and in an external memory storage device. Then, the data will be erased and the storage devices destroyed to assure no opportunity for data recovery.

Informed Consent

For both the pilot study and the actual survey questionnaire, consent of participation were sent to the intended participants as part of the electronic method selected following the approved by Walden University's Institutional Research Board (IRB) with approval number 12-28-15-0289564 that expired on December 27, 2016. The participants had to confirm the consent of participation before commencing the questionnaire. The consent form provided an introduction of the intent of the study, clarity that the study was for my Ph.D. program, and informed of the confidentiality of the data to be provided to each participant. There were two consent forms used for this study: one for the pilot study and one for the study questionnaire. These consent forms included the invitation to participate in each survey and were the page of the e-mail electronic survey. Also, SurveyMonkey system provided the option to the participants to opt-out of the survey and any future mailing.

As inferred by Ahern (2005), using electronic surveys have challenges in the areas of confidentiality and in acquiring rights and permission to quote. The use of established survey web pages, like SurveyMonkey, facilitated conveying the academic intent and privacy of the study. An opening statement regarding my academic program, including a reference to the IRB should have provided the opportunity for the participant to feel comfortable in proceeding to the questionnaire. The IRB of Walden University

provided the permission to apply the pilot study and the main study questionnaire. A copy of the study was offered to the participants that completed the main survey and responded to the dateline of the questionnaire. A need for reminder and follow-up were conducted after the IRB concurrence. The pilot study questionnaire provided insight to reinforce the message of confidentiality. In the consent statement, the participants were informed of their rights to stop their participation at any time. Also, after reading the instruction at the beginning of the questionnaires within SurveyMonkey, the participants were given a final option to stop their participation.

Confidentiality

For both the pilot study and the actual questionnaire, the collected data from all electronic questionnaires were received and tabulated with the participant using the SurveyMonkey code to assure confidentiality of the responses. Confidentiality follows the terms provided by SurveyMonkey for their database used. Any printed information or data regarding the names of the participants will be destroyed by incineration, including any printed master list. The electronic data files with names in my computer will be stored on a DVD and in an external memory device. The electronic devices, DVD and a storage memory stick, will be deposited in a bank security box for five years with the list of participants and codification matrix. All this data and information will then be erased, and the storage devices destroyed to assure no means for data recovery.

Data Collection Plan

Data collection is a critical stage in any research study. A data collection plan consists of the strategy and instrument to collect information that could dictate the

validity, success, and impact of the study (Frankfort-Nachmias & Nachmias, 2008). Research data collection should be of having in mind cost effectiveness, confidentiality, ethics, and accuracy. As concluded by Ahern (2005), survey applications that are well-managed and designed through the Internet could provide the expected attributes to some degree. Also, effective time management in the collection and verification of sources and data could be achieved with the application of the Internet.

Data collection from participants in this research study required accessibility to a sensitive population and assuring a high level of confidentiality. However, opportunities for face-to-face interviews with the intended population of pharmaceutical managers were very limited due to participants' accessibility and geographic locations. Mailed questionnaires have advantages like reduced biases and strong protection of confidentiality, as listed by Frankfort-Nachmias and Nachmias (2008). The challenge was to grasp the interest from participants, who have multiple priorities and limited available time.

Managers in this field normally have an assistant who filters the correspondence. As a result, the mail survey receives limited response rate. Based in today's office environment in the pharmaceutical industry for the intended population, computer accessibility was expected to be high; the typical time navigating and reading e-mails most likely be constant on a daily basis; and, the probability of gaining the respondent attention was better than by mail or telephone calls. The survey was administered through SurveyMonkey.

The structure of the electronic survey is complex as explained by Ahern (2005). The weaknesses of using electronic surveys are mainly in the area of confidentiality and privacy, the authenticity of the respondent, and acquiring rights and permission to quote. The introduction to the survey has to be concise while projecting a clear level of protection and comfort to the respondent. Despite these challenges, Ahern (2005) summarized the benefits of the electronic survey as time management, accessibility to sensitive/particular population, easy and comfort to use (user-friendly), and reduces the missing data.

Expected Duration

The expected duration of the data collection activities, consisting of conducting the pilot study and of the actual survey process, was expected to take a total of between 30 to 40 days. The pilot survey with the opening statement, including the confidentiality explanation, was delivered to 21 industry peers. This pilot survey process to gather the data took 12 days. The data review and formatting of the final questionnaire lasted 34 days. The pilot process took a total of 46 days from the first mailing.

The actual survey execution was expected to last an additional 15 to 20 days. Recognizing the need to send a reminder to participants might be beneficial, the projected timeline included reminders through SurveyMonkey every 2-3 days up to 10-12 days. Due to the low initial partition of the 1144 invitees, the data gathering for the main study took 65 days after six reminders including a required second IRB review that lasted 38 days. The net extent of the actual data gathering process was 27 days. The total research lasted 111 days including the pilot study.

Data Acquisition

The data acquisition instruments consisted of the behavioral attitude (TPB) questionnaire (management behaviors survey), the change in financial results [financial indicators section (i.e. cost of goods and investment in equipment and facilities)], and level of compliance with the FDA (compliance observations). A pre-FDA and post-FDA survey questionnaire was the vehicle utilized for management attitude (TPB) and financial indicators. An e-mail approach was employed to reach the participants. The design to the electronic questionnaire was analyzed to ensure an effective data acquisition process. The number of questionnaires that were completed, not completed, and wrongly completed were tabulated to summarize the actual performance of the electronic survey. Some statistics from the Internet survey tool were provided in the data analysis from SurveyMonkey.

Data Analysis Plan

Several steps were taken to ensure the organization, confidentiality, and meeting assumptions of the statistical tests to facilitate the data management process. Morrow (2009) suggested specifics on how to manage the data and to address shortfalls, like missing data and assumptions' requirements. The first step was to develop a data codebook (SPSS template) to store the data for all the variables and sampling details. The database template was created in SPSS from the data transferred from SurveyMonkey. The access to my laptop was password-protected to support confidentiality protecting the access to the collected data and the SPSS data template. Personal references from

participants were cross-coded by SurveyMonkey with reference numbers to enhance privacy and confidentiality.

The second step consisted of the cleaning of the data per the steps outlined by Morrow (2009). Cleaning of the data refers to the process of minimizing biases and calculation errors generated by the quality of the obtained data. A step-by-step approach was followed by utilizing SPSS guides.

1. Outliers' scores were identified to minimize biases and not relevant information. Elimination of these outliers was the first task.
2. Verifying for normality of variables enhanced the review for outliers. Achieving a normal distribution around the mean was an expected assumption.
3. Missing data could impact the results of the analysis. The data was reviewed to assure that the suggested level of not more than 5% missing data was attained. The average of the individual responses was used to fill in the missing data.
4. Transforming the data by means of reversing the Likert-Type scores provided alignment and proper assessment of the Cronbach's alpha to assess the reliability of the scales by section or construct of the TPB.
5. Verifying for multicollinearity was done within the SPSS regression application.
6. The Pearson coefficient was used to assure that the correlations between variables were less than 0.8. In the event of a higher value of the correlation,

the variables were evaluated by either combining them or eliminating one of them.

7. For homogeneity of regression, SPSS was also used.
8. Linearity was verified by visually assessing the graphs of the data.
9. For the completed-usable responses, the participant had to complete over 95% of the questions in either the pilot study or the main study including the demographics and FDA compliance questions at the end.

The application of regression analyses increased the complexity since two TPB scenarios pre-FDA and post-FDA interventions were assessed. Maintaining separation of the data for the two scenarios within the SPSS template was important. The number of the questions within SurveyMonkey provided the vehicle to maintain the separation of the data for the two TPB scenarios pre-FDA and post-FDA interventions. The application of SPSS for the statistical analyses and all the corresponding assumptions of regression analyses was utilized for both scenarios pre-FDA and post-FDA interventions.

Hypotheses Testing Plan

The two predictors used in this study were management behaviors and financial indicators. The three sets of hypotheses related to these predictors were listed below. The outcome variable was the level of compliance with the FDA regulations.

- Correlations between management behaviors (independent) and compliance (dependent):

$H1_0$: $r = 0$. There is no difference in management behaviors towards compliance at pharmaceutical firms, as a result of FDA enforcement actions in the U.S.

$H1_1$: $r \neq 0$. There are differences in management behaviors towards compliance at pharmaceutical firms, as a result of FDA enforcement actions in the U.S.

The null hypothesis, $H1_0$, implies that the value of the correlation coefficient is zero, $r = 0$ indicating that there is no correlation or way to predict compliance from management behaviors. The alternate hypothesis, $H1_1$, considering a two-tailed distribution, is $r \neq 0$ or $r <> 0$ indicating that there is a correlation or way to predict compliance from management behavior. The significance level to test the hypotheses had a value for α of .05%. The number of unique correlations in the correlation matrix were based on the three constructs in the TPB questionnaire.

- Correlations between financial indicators (independent) and compliance (dependent):

  $H2_0$: $r = 0$. There is no difference in compliance with FDA related to financial indicators at pharmaceutical firms, as a result of FDA enforcement actions in the U.S.

  $H2_1$: $r \neq 0$. There are differences in compliance with FDA related to financial indicators before and after the FDA intervention.

The null hypothesis, $H2_0$, indicates the value of the correlation coefficient is zero, $r = 0$ indicating that there is no correlation or way to predict compliance from the seven financial indicators. The alternate hypothesis, $H2_1$, considering a two-tailed distribution, is $r \neq 0$ or $r <> 0$ indicating that there is a correlation or way to predict compliance from the seven financial indicators. The significance level to test the hypotheses had a value for α of .05%. The number of unique correlations in the correlation matrix were based on the seven financial indicators.

- Financial indicators (independent) impact on compliance (dependent):

  $H3_0$: $\beta_1 = \beta_2 = \ldots = \beta_7 = 0$. There is no impact in compliance with FDA related to seven financial indicators at pharmaceutical firms, as a result of FDA enforcement actions in the United States.

  $H3_1$: At least one $\beta \neq 0$. There is an impact in compliance with FDA related to at least one of the seven financial indicators before and after the FDA enforcement actions in the United States.

The seven financial indicators for the test of Hypothesis 3 were the cost of goods, investment in facility and equipment, process compliance, sales, revenues, market value, and stockholder's equity. SPSS was used to generate the models. The βs in Hypothesis 3 were the regression coefficients of the following multiple regression equation:

$$Y = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \beta_4 X_4 + \beta_5 X_5 + \beta_6 X_6 + \beta_7 X_7 + \varepsilon \qquad (3)$$

Where,

Y= FDA related compliance

X_1 = Cost of goods

X_2 = Investment

X_3 = Process compliance

X_4 = Change in sales

X_5 = Change in revenues

X_6 = Change in market value of the firms

X_7 = Change in stockholders equity

ε = Error of the regression

For the TPB data and financial indicators in Likert-type scales, aggregate comparison, factor analysis and Cronbach's alpha were utilized. For the regression analyses, the standard linear regression in SPSS was the approach assessing the models. ANOVA, *t* testing, Durbin-Watson statistics, and collinearity statistics were statistical methods that were applied through SPSS for this study. Durbin-Watson supported the independent assumption. Collinearity statistics provided, through variance inflation factor (VIF) and tolerance, the support to indicate if the assumption was met or not.

Summary

Chapter 3 discussed and described the research method and design. The selection of the quantitative methodology for the study was discussed. The sampling plans were discussed for both the pilot study and the main study. The validity and reliability of the survey instrument were described, and the relation to the variables of the study discussed. The intended population was further defined by the information from the FDA. The size of the sampling units (participants) determination was assessed by three mechanisms.

ISPE member's database was indicated as the source of the participants meeting the criteria for selection. The steps to ensure confidentiality and protection of the participants were enumerated. Plan for data collection and data analysis to address the research questions were described including the statistical approach.

Chapter 4 presents the results of the pilot and the main study. Discussion on the pilot study is used to facilitate key concepts to support the three construct of the TPB for the design of the final questionnaire. The application of three correlations between the three construct of the theory of planned behavior and the FDA compliance addresses RQ1. Analyses through correlations and linear regressions of seven financial indicators provide the insight to the assess RQ2 and RQ3. The findings and the resulting null testing are presented.

Chapter 4: Results

This quantitative study sought to learn to what extent, if any, management behaviors and financial pressures at pharmaceutical firms correlated with or predicted compliance with the FDA regulations avoiding interruptions in the supply of some essential patented or generic pharmaceutical drugs in the U.S. From the review of the literature, the gap consisted on the limited available research providing awareness and guidance to managers in their decision and their risk assessment process, regarding their FDA compliance responsibility, corporate financial mandate, and stakeholders' expectations. This research was driven by the limited information on what were the interdependencies or correlations between the need to grow revenue and the intent to behave within the senior management decision process

The behavior by management, related to the quality of drugs to meet their intended quality, integrity, strength, and purity influences the level of compliance of the firms' operations. The pressures of enhancing productivity, funding research, supporting marketing plans, and reducing the cost of goods also influences the firms' compliance performance. The application of enforcement actions by the FDA on the firms was used as the treatment event to reestablish the expected level of compliance. A shift in the relationship between the variables was expected after the FDA intervention, highlighting the new level of compliance.

The independent variables that could lead to enforcement actions by the FDA were set as management behaviors of the pharmaceutical managers and the firms' financial indicators. The treatment event was the application of the enforcement action by

the FDA. The level of compliance of the pharmaceutical companies was the dependent variable. In the study, the conditions before the FDA intervention in the pharmaceutical firms were compared to the post-conditions after the FDA intervention to predict compliance with the CGMP regulations. The research questions were formulated on three foci:

- Correlations between management behaviors (independent) and compliance (dependent)
- Correlations between financial indicators (independent) and compliance (dependent):
- Financial indicators (independent) impact on compliance (dependent).

Research questions were answered based on the null hypotheses testing in Chapter 4. Despite the low rate of participation in the main study, the null hypotheses were rejected. For RQ1, the theory of planned behavior (Ajzen, 1991) was applied. The three behavioral constructs led to the execution of three correlations with the outcome of compliance with FDA regulations. For RQ2, seven correlations were conducted between the selected financial indicators and the outcome of compliance. For RQ3, some of the assumptions for the regression equations were not met avoiding any generalization from the models.

Chapter 4 contains the data collected and the results of the pilot study and the main study questionnaire. The pilot study elements like population, data collection, and feedback are presented. The outcome and impact of the pilot study on the final

questionnaire are discussed. Regarding the final study questionnaire, the data collection process, the length of the study, the IRB approvals, and the limited participation are presented.

Pilot Study

A pilot study was conducted to examine clarity of survey questions, to collect feedback on the questionnaire's structure, and to identify essential beliefs that were used in the Likert-type scales. Ajzen (2002) indicated that a pre-work was required to define the behaviors of interest for the proper design of the TPB survey instrument. Through the pilot study, I identified essential management behaviors towards compliance with FDA regulations. These management behaviors were incorporated into the Likert-type questions suggested by Ajzen (2016) for the main survey questionnaire. The pilot study also collected feedback about financial indicators of the pharmaceutical firms. Demographics of participants, the degree of compliance, and the type of FDA interventions were requested in the pilot survey instrument.

The pilot study questionnaire confirmed the effectiveness and completeness of the order of the sections. The structure of the pilot questionnaire consisted of four sections. The first and second sections related to the TPB initial assessment of attitudes, social influences, and perceived behavioral controls. This section tested the clarity of the Likert-type questions and the open-ended questions to identify attributes of attitudes, social influences, and controls to finalize the main study questionnaire as indicated by Ajzen (2002). Also, the first two sections included a table to collect financial results of the firms before and after the FDA intervention or action. The intent was to identify information

before and after an FDA intervention in the firms. The third section consisted of the demographics questions. Finally, the fourth section pursued clarification on the outcome of any FDA interventions or actions in the firms in the past five-six years.

The instructions for pilot study questionnaire in SurveyMonkey included an initial question to allow the participant to proceed or stop their participation after reading the instructions to the questionnaire. This question ensured the voluntary participation of the person highlighting the understanding of the level of confidentiality and the positive social benefit if participating in the study. The instructions were part of the SurveyMonkey questionnaire. The number of questions in the pilot study questionnaire were 44. The questions consisted of Likert-type scales, open-ended questions, and tables to select responses.

Pilot Study Population

The pilot study participants, to qualify as a participant, had to comply with the same participants' criteria that applied to the main study. Participants were selected from executives and operational management levels who had the authority to make compliance and financial decisions within pharmaceutical firms. The pilot study participants' selection process was based on convenience sampling from individuals known to me. The number of participants invited to the pilot study was 21.

The need to ensure sufficient and reliable replies from the pilot study required recruiting participants who provide useful feedback within 14 days. The pilot survey commenced on January 5, 2016, and was closed on January 17, 2016.

From the 21 invitations sent by using SurveyMonkey, 20 of the invitations were opened by the intended participants and one was not opened. Of the 20 invitations that were opened to read the consent form, 13 participants accepted the consent form and proceeded to the survey. After reading the instruction, nine of the 13 participants accepted to proceed to the questionnaire and five did not initiate the survey. The participation results attained eight completed surveys and one partial-completed survey. The eight completed surveys provided a response rate of 38%. The eight responses to the pilot study represented about 5% of the initially targeted usable responses of 160 for the main study.

Pilot Study Data Collection

The pilot study was conducted similarly to the same intended instrument for the main study. The pilot study was administered through SurveyMonkey, an electronic survey tool chosen to collect data and facilitate analysis. Trust and desire to participate was pursued by an initial e-mail sent to the selected 21 invitees to the pilot study. Then, a consent form for participation was sent via SurveyMonkey as approved by the Walden University's IRB.

The pilot study also provided feedback on the effectiveness and completeness related to the message of confidentiality. Of the 21 SurveyMonkey invitations sent, 20 invitations were opened, 13 accepted the consent from, but five participants decided not to participate in the survey after reading the instructions. The consent form with the questionnaire instructions provided adequate space for the participants to voluntarily decide if they would participate or not. With the 38% rate of participation in the pilot

study, the participation in the main study was expected to reach the initial target of 160 completed questionnaires out of about 1144 invitations with a projected rate of participation of about 15%.

Pilot Study Demographics

The demographics of the pilot study indicated a reasonable representation of the role of responsibility and area of expertise. The demographics questions where located at the end of the pilot study. Appendix E shows the percentage distribution of the relevant demographics. The decisions makers' titles indicated the participation of directors, vice-presidents, and one executive. The educational level included bachelors and doctorate degrees. The functional areas within the pharmaceutical firms represented covered quality, manufacturing, and others like technical services. The demographics of the pilot study's participants ensured a representative source of essential management behaviors that were incorporated to the Likert-type scaled of the final questionnaire.

Pilot Study Data Treatment

The collected data in the pilot study was initially assessed via the results review section through SurveyMonkey. Then, the data was transferred to an Excel template to facilitate the assessment of the open-ended questions to identify management behaviors related to decision makers through the frequency of words appearance in the responses. The open-ended questions led to essential concepts to support the three constructs in the main study regarding TPB Likert-type questions. The collected data was also transferred to an SPSS data table to facilitate the intended statistical assessments for correlations and regression analyses.

Pilot Study Data Analysis

The data analysis consisted on how to manage the data while addressing shortfalls, like missing data and assumptions' requirements. The first step was to develop a data codebook (SPSS template) to store the data for all the variables and sampling details. The database template was created in SPSS from the data transferred from SurveyMonkey. The access to my laptop was password-protected to support confidentiality by protecting the access to the collected data and the SPSS data template. There was no need to cross-code any personal references from participants since the collected data from SurveyMonkey provided reference numbers to enhance privacy and confidentiality of the participants

The second step consisted of the cleaning of the data per the steps outlined by Morrow (2009). Cleaning of the data refers to the process of minimizing biases and calculation errors generated by the quality of the obtained data. A step-by-step approach was followed when using SPSS analysis.

1. Outliers' scores were initially assessed with the intent to apply Windsorizing. None of the Likert-type scores or financial data tables from the pilot study nor the main study required to apply Windsorizing approach. In the SPSS analysis, for just caution and only when requested a 2 sigma was applied.
2. Verifying for normality of variables enhanced the review for outliers. SPSS Explore function was applied to identify if normal distribution assumption was met.

3. Transforming the data by means of reversing the Likert-Type scores provided alignment and proper assessment of the Cronbach's alpha to understand the reliability of the scales.
4. The data was reviewed for each variable's Likert-type questions in the SPSS template to ensure that the suggested level of not more than 5% missing data was present. If needed for less than 5% of the data, the estimated average of the data was used to fill in the missing data.
5. For completed-usable responses, the participant had to complete over 95% of the questions in either the pilot study or the main study including the demographics and FDA compliance questions at the end.
6. For partial responses, an organized approached was implemented. This approach consisted in the separation of the collected data in the SPSS template by each of the two scenarios: pre-FDA and post-FDA interventions. This process allowed to consider those responses that only addressed the pre-FDA scenario, but the participants decided not to continue to complete the remainder of the questions.
7. Transforming the data by means of reversing the Likert-Type scores provided alignment and proper assessment of the Cronbach's Alpha to assess the reliability of the scales by section or construct of the TPB.
8. For the correlation analyses, Pearson and Kendal coefficients were conducted.
9. Verifying for multicollinearity was done within the SPSS application. The Pearson coefficient was used. In the event of a higher value than .8 of the

correlation values, the variables were evaluated by either combining them or eliminating one of them.

10. For homogeneity of regression, SPSS was used.

11. Linearity was initially verified by visually assessing the graphs of the data.

The application of regression analysis increased the complexity since two scenarios pre-FDA and post-FDA interventions were assessed. Maintaining separation of the data for the two scenarios within the SPSS template was important. The number of the questions within SurveyMonkey provided the vehicle to maintain the separation of the data for the two TPB scenarios pre-FDA and post-FDA interventions. The application of SPSS for the statistical analyses and all the corresponding assumptions of regression analyses were considered in each scenario: pre- and post-FDA intervention.

Open-ended questions. An assessment of the eight open-ended questions was conducted. All the eight responses were read and assessed for common words and time repeated by the respondents. The responses were tabulated in an Excel table to tabulate frequency and categories related to the three construct of the TPB. The responses were anonymous since SurveyMonkey maintained the names of the participants not linked to the responses, as selected by me during the formulation of the questionnaire. SurveyMonkey provided confirmation of the word frequency. The high frequently used words were similar in my tabulation and in the SurveyMonkey's output.

The selected words and topics from the open-ended questions provided the pre-work indicated by Ajzen (2002) to define the behaviors and constructs of interest for the suitable design of the TPB main survey instrument. By applying the words and topics to

the three constructs of the beliefs (attitudes), normative, and perceived behavioral control sections of the TPB questionnaire by Ajzen (2016), the Likert-type questions were modified providing the expected questionnaire structure for the main study.

Through the pilot study, the identified words and topics highlighted relationships, attitudes, and perceived controls to be asked in the main study. In the formulation of the Likert-type questions, I focused on management attitudes, motivation factors, peer influences, and behavioral controls towards compliance with FDA regulations. The questions were formulated to enhance the before and after scenarios regarding an FDA intervention or action. These constructs were incorporated into the Likert-type questions suggested by Ajzen (2016) for the final questionnaire. This process led to a significant increase in the number of Likert-type questions in the final questionnaire from 44 to 133 questions.

Assessment of Likert-type questions. Likert-type scales were used to assess constructs of the TPB liked beliefs (attitudes), normative beliefs, and perceived behavioral controls. To attain an internally consistent scale, the approach to obtain the Discriminative Power (Frankfort-Nachmias & Nachmias, 2008) for the pilot study was considered. Because there were only eight questions covering the TPB constructs for the pilot study, the applicability of the Discriminative Power was considered not adequate to challenge the internal consistency of the Likert-type scales.

The pilot study's Likert-type scales were directed to demonstrate the adequacy of the TPB approach to develop the main study questionnaire. Table 4 presents the constructs, the variables, and the corresponding means and standard deviations

corresponding to pre-FDA intervention. The means are skewed towards the high side of the range of 1 to 7. The standards deviations could be considered homogenous except for q0007_0001 whose standard deviation was above 2.00 while all other values were below 1.30.

Table 4

Pre-FDA Intervention

TPB Constructs	Variable Name	SPSS Name	Mean	Standard Deviations
Attitudes	My compliance with CGMP regulations before the last FDA intervention was	Q0002_0001	6.00	1.118
	My compliance with CGMP regulations before the last FDA made me feel	Q0003_0001	5.89	1.269
Perceived Norms	Most people who are important to me approve me being in compliance with CGMP regulations before the last FDA intervention	Q0004_0001	6.44	0.726
	Most people likes me being in compliance with CGMP regulations before the last FDA intervention	Q0005_0001	6.44	0.726
Perceived Behavioral Controls	I was confident that I was in compliance with CGMP regulations before the last FDA intervention	Q0006_0001	5.89	1.167
	Being in compliance with CGMP regulations before the FDA intervention was up to me	Q0007_0001	5.00	2.345
Intention	I intended to be in compliance with CGMP regulations before the last FDA intervention	Q0008_0001	7.00	0.000
Previous Behavior	Prior to the last FDA intervention I have being in compliance with CGMP regulations	Q0009_0001	6.33	1.000

Table 5 presents the constructs, the variables, and the corresponding means and standard deviations corresponding to post-FDA intervention. The means are skewed

towards the high side of the range of 1 to 7. All the standards deviations could be considered homogenous which is different from the pre-FDA intervention.

Table 5

Post-FDA Intervention

TPB Constructs	Variable Name	SPSS Name	Mean	Standard Deviations
Attitudes	My compliance with CGMP regulations after the last FDA intervention was	Q0022_0001	6.50	0.756
	My compliance with CGMP regulations after the last FDA made me feel	Q0023_0001	6.00	1.773
Perceived Norms	Most people who are important to me approve me being in compliance with CGMP regulations after the last FDA intervention	Q0024_0001	6.25	1.165
	Most people likes me being in compliance with CGMP regulations after the last FDA intervention	Q0025_0001	6.63	0.744
Perceived Behavioral Controls	I was confident that I was in compliance with CGMP regulations after the last FDA intervention	Q0026_0001	6.38	0.774
	Being in compliance with CGMP regulations after the FDA intervention was up to me	Q0027_0001	4.88	1.885
Intention	I intended to be in compliance with CGMP regulations after the last FDA intervention	Q0028_0001	6.75	0.463
Previous Behavior	Prior to the last FDA intervention I have being in compliance with CGMP regulations	Q0029_0001	6.63	0.518

Initially, Pearson's coefficient was utilized to understand the internal consistency of the Likert-type scales by establishing how close the different elements of the scales are to each other. Also, the correlation between each subset of the construct was obtained and listed to establish the dependencies within each construct. Table 6 presents the Pearson

correlation for the TPB constructs for the pre-FDA intervention in the pilot study. The question q0009-0001, regarding perceived behavioral control, had non-significant correlations with any other variables with *p* values from 0.443 to 0.903. Also, question q0005-0001 regarding influence from or by peers was non-significant with the participant beliefs and attitudes (q0003-001) towards compliance with $r = 0.602$, $p = 0.086$.

Table 6

Pearson's Correlation pre-FDA Intervention

		q0002_0001	q0003_0001	q0004_0001	q0005_0001	q0006_0001	q0007_0001	q0008_0001	q0009_0001
q0002_0001	Pearson Correlation	1	.881**	.923**	.769*	.767*	-.048	.c	.894**
	Sig. (2-tailed)		.002	.000	.015	.016	.903	.	.001
	N	9	9	9	9	9	9	9	9
q0003_0001	Pearson Correlation	.881**	1	.874**	.602	.750*	.168	.c	.919**
	Sig. (2-tailed)	.002		.002	.086	.020	.666	.	.000
q0004_0001	Pearson Correlation	.923**	.874**	1	.763*	.803**	.073	.c	.975**
	Sig. (2-tailed)	.000	.002		.017	.009	.851	.	.000
q0005_0001	Pearson Correlation	.769*	.602	.763*	1	.803**	-.293	.c	.631
	Sig. (2-tailed)	.015	.086	.017		.009	.443	.	.068
q0006_0001	Pearson Correlation	.767*	.750*	.803**	.803**	1	.091	.c	.786*
	Sig. (2-tailed)	.016	.020	.009	.009		.815	.	.012
q0007_0001	Pearson Correlation	-.048	.168	.073	-.293	.091	1	.c	.213
	Sig. (2-tailed)	.903	.666	.851	.443	.815		.	.582
q0008_0001	Pearson Correlation	.c	.c	.c	.c	.c	.c	.c	.c
	Sig. (2-tailed)	.	.	.	.	.	.		.
q0009_0001	Pearson Correlation	.894**	.919**	.975**	.631	.786*	.213	.c	1
	Sig. (2-tailed)	.001	.000	.000	.068	.012	.582	.	

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

c. Cannot be computed because at least one of the variables is constant.

Table 7 presents the Pearson's correlation for the TPB constructs for the post-FDA intervention in the pilot study. The question q0027-0001, regarding perceived

behavioral control, had non-significant correlations with all other variables with *p* values from 0.522 to 0.909. In the post-FDA, all variables had at least one Pearson's correlation that was non-significant.

Table 7

Pearson's Correlation post-FDA Intervention

		q0022_0001	q0023_0001	q0024_0001	q0025_0001	q0026_0001	q0027_0001	q0028_0001	q0029_0001
q0022_0001	Pearson Correlation	1	.640	.324	.889**	.889**	.050	.816*	.913**
	Sig. (2-tailed)		.088	.433	.003	.003	.906	.013	.002
	N	8	8	8	8	8	8	8	8
q0023_0001	Pearson Correlation	.640	1	.208	.650	.542	-.171	.870**	.778*
	Sig. (2-tailed)	.088		.622	.081	.166	.686	.005	.023
q0024_0001	Pearson Correlation	.324	.208	1	.453	.700	-.049	.397	.178
	Sig. (2-tailed)	.433	.622		.259	.053	.909	.330	.674
q0025_0001	Pearson Correlation	.889**	.650	.453	1	.806*	.267	.933**	.696
	Sig. (2-tailed)	.003	.081	.259		.016	.522	.001	.055
q0026_0001	Pearson Correlation	.889**	.542	.700	.806*	1	-.064	.726*	.788*
	Sig. (2-tailed)	.003	.166	.053	.016		.881	.041	.020
q0027_0001	Pearson Correlation	.050	-.171	-.049	.267	-.064	1	.123	-.201
	Sig. (2-tailed)	.906	.686	.909	.522	.881		.772	.633
q0028_0001	Pearson Correlation	.816*	.870**	.397	.933**	.726*	.123	1	.745*
	Sig. (2-tailed)	.013	.005	.330	.001	.041	.772		.034
q0029_0001	Pearson Correlation	.913**	.778*	.178	.696	.788*	-.201	.745*	1
	Sig. (2-tailed)	.002	.023	.674	.055	.020	.633	.034	

**. Correlation is significant at the 0.01 level (2-tailed). *. Correlation is significant at the 0.05 level (2-tailed).

Considering the small number of participants, skewness and kurtosis were used to assess the distribution of the variables. In the scenario of pre-FDA intervention, the skewness results were all negative indicating that there was a cluster at the higher end of the scales (Field, 2009). Kurtosis was used to measure the degree to which scores cluster

in the tails of a frequency distribution. Kurtosis' values were both positive and negative. Positive kurtosis values indicate that the distribution tends to peak at the tails due to the high number of scores in the tail. Negative kurtosis values signal few scores in the tails and a flat distribution (Field, 2009). In the scenario of post-FDA intervention, the skewness results were also all negative indicating that there was a cluster at the higher end of the scales (Field, 2009). The kurtosis' values were also both positive and negative.

The non-normal distribution in six out of seven distributions was significant as confirmed by using Kolmogorov-Smirnov and Shapiro-Wilk in SPSS. Table 8 shows the results of the Kolmogorov-Smirnov and Shapiro-Wilk tests for the pre-FDA intervention. For the post-FDA intervention in Table 9, the results for Kolmogorov-Smirnov and Shapiro-Wilk tests are illustrated. In a similar manner, the non-normality is confirmed with seven of eight variables being significant.

Table 8

Test of Normality[b] pre-FDA Intervention

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
q0002_0001	.259	9	.083	.844	9	.065
q0003_0001	.313	9	.011	.795	9	.018
q0004_0001	.333	9	.005	.763	9	.008
q0005_0001	.333	9	.005	.763	9	.008
q0006_0001	.316	9	.010	.792	9	.017
q0007_0001	.248	9	.119	.827	9	.042
q0009_0001	.303	9	.017	.710	9	.002

a. Lilliefors Significance Correction b. q0008_0001 is constant. It has been omitted.

Table 9

Test of Normality post-FDA Intervention

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
q0022_0001	.371	8	.002	.724	8	.004
q0023_0001	.339	8	.007	.668	8	.001
q0024_0001	.365	8	.002	.724	8	.004
q0025_0001	.443	8	.000	.601	8	.000
q0026_0001	.300	8	.033	.798	8	.027
q0027_0001	.225	8	.200*	.908	8	.343
q0028_0001	.455	8	.000	.566	8	.000
q0029_0001	.391	8	.001	.641	8	.000

*. This is a lower bound of the true significance. a. Lilliefors Significance Correction

The distribution of the scores was skewed or non-normal in most cases. The results of Kolmogorov-Smirnov and Shapiro-Wilk tests indicated the non-normality of the data. Kendall's correlation coefficient, τ, was used to understand the correlation between the variables. Kendall's Tau is a non-parametric measure that also applies to a small number of scores that rank in a similar manner.

Despite the non-normal characteristics of the variables, Kendall Tau correlation results confirmed the observation from the Pearson's correlation coefficients for the pre-FDA intervention. Question q0007-0001, regarding perceived behavioral control, had non-significant correlations with any other variables with *p* values from 0.456 to 0.906. However, the correlations were all negative when compared to the Pearson' coefficients. All other Kendall's Tau correlations were significant including participant believes and attitudes (q0005-001) for the pre-FDA intervention. In the case of the post-FDA scenario,

Kendall's Tau correlations maintained the same direction of the Pearson correlation and also signaled q0027-0001 with non-significant correlations with all other variables. Table 10 and Table 11 present Kendall's correlation coefficient, τ, for both the pre-FDA and post-FDA interventions, respectively.

Table 10

Kendall's Correlation pre-FDA Intervention

	Kendall's tau	q0002_0001	q0003_0001	q0004_0001	q0005_0001	q0006_0001	q0007_0001	q0008_0001	q0009_0001
q0002_0001	Correlation Coefficient	1.000	.837**	.867**	.749*	.593	-.105	.	.867**
	Sig. (2-tailed)	.	.006	.006	.018	.056	.726	.	.006
	N	9	9	9	9	9	9	9	9
q0003_0001	Correlation Coefficient	.837**	1.000	.762*	.682*	.453	-.107	.	.762*
	Sig. (2-tailed)	.006	.	.017	.032	.149	.724	.	.017
q0004_0001	Correlation Coefficient	.867**	.762*	1.000	.826*	.736*	-.039	.	1.000**
	Sig. (2-tailed)	.006	.017	.	.012	.023	.901	.	.
q0005_0001	Correlation Coefficient	.749*	.682*	.826*	1.000	.736*	-.232	.	.826*
	Sig. (2-tailed)	.018	.032	.012	.	.023	.456	.	.012
q0006_0001	Correlation Coefficient	.593	.453	.736*	.736*	1.000	-.036	.	.736*
	Sig. (2-tailed)	.056	.149	.023	.023	.	.906	.	.023
q0007_0001	Correlation Coefficient	-.105	-.107	-.039	-.232	-.036	1.000	.	-.039
	Sig. (2-tailed)	.726	.724	.901	.456	.906	.	.	.901
q0008_0001	Correlation Coefficient	.	.	.	.	.	.	.	.
	Sig. (2-tailed)	.	.	.	.	.	.	.	.
q0009_0001	Correlation Coefficient	.867**	.762*	1.000**	.826*	.736*	-.039	.	1.000
	Sig. (2-tailed)	.006	.017	.	.012	.023	.901	.	.

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

Table 11

Kendall's correlation post-FDA Intervention

	Kendall's tau	q0022_0001	q0023_0001	q0024_0001	q0025_0001	q0026_0001	q0027_0001	q0028_0001	q0029_0001
q0022_0001	Correlation Coefficient	1.000	.857*	.400	.807*	.835*	-.049	.770*	.939**
	Sig. (2-tailed)	.	.013	.244	.022	.017	.883	.034	.010
	N	8	8	8	8	8	8	8	8
q0023_0001	Correlation Coefficient	.857*	1.000	.333	.719*	.703*	-.094	.816*	.913*
	Sig. (2-tailed)	.013	.	.322	.038	.040	.770	.022	.010
q0024_0001	Correlation Coefficient	.400	.333	1.000	.588	.703*	.047	.544	.304
	Sig. (2-tailed)	.244	.322	.	.089	.040	.884	.127	.393
q0025_0001	Correlation Coefficient	.807*	.719*	.588	1.000	.700*	.222	.961**	.716
	Sig. (2-tailed)	.022	.038	.089	.	.047	.503	.009	.051
q0026_0001	Correlation Coefficient	.835*	.703*	.703*	.700*	1.000	-.092	.662	.770*
	Sig. (2-tailed)	.017	.040	.040	.047	.	.779	.068	.034
q0027_0001	Correlation Coefficient	-.049	-.094	.047	.222	-.092	1.000	.173	-.155
	Sig. (2-tailed)	.883	.770	.884	.503	.779	.	.611	.649
q0028_0001	Correlation Coefficient	.770*	.816*	.544	.961**	.662	.173	1.000	.745*
	Sig. (2-tailed)	.034	.022	.127	.009	.068	.611	.	.049
q0029_0001	Correlation Coefficient	.939**	.913*	.304	.716	.770*	-.155	.745*	1.000
	Sig. (2-tailed)	.010	.010	.393	.051	.034	.649	.049	.

*. Correlation is significant at the 0.05 level (2-tailed).

**. Correlation is significant at the 0.01 level (2-tailed).

Analysis of Cronbach's alpha to determine the reliability of the scales from the pilot study questionnaire was conducted for both scenarios: pre-FDA and post-FDA interventions. The data was analyzed by applying SPSS and by using Field (2009) as a reference. Cronbach's alpha is not a validity measure. The values for Cronbach's alpha

range from 0 to 1. Cronbach's alpha provides the means to assess if a given scale item impacts the overall total subscale reliability. Reversing the phrasing of a negative scale item improved the Cronbach's values. For the pre-FDA scenario in Table 12, the Cronbach's alpha was .800 which infers good reliability. For the post-FDA intervention, Table 13 presented a Cronbach's alpha with a value of .726.

Table 12

Cronbach's alpha pre-FDA Intervention

Cronbach's alpha	Cronbach's alpha Based on Standardized Items	N of Items
.800	.909	7

Table 13

Cronbach's alpha pre-FDA Intervention

Cronbach's alpha	Cronbach's alpha Based on Standardized Items	N of Items
.726	.887	8

Table 14 presented the SPSS function to identify the effect of the Cronbach's alpha if a given item was deleted for the pre-FDA scenario. The values in the last column in Table 14 have a range from .714 to .953. The question q0007_0001, if removed, could have a significant favorable impact in the overall Cronbach's alpha from .800 to .953. Also, in Table 14, all values for Corrected Item-Total Correlation represented the correlations between each item and the total score. These correlation values need to be at or above 0.3, as per Field (2009). In this subscale, all values are over 0.3 except for q0007_0001. In the event of any value below 0.3, the item should be assessed, including

being eliminated. Item q0007_0001 represented the concept that the person has no perceived control in complying with the FDA regulations in the pre-FDA intervention.

Table 14

Cronbach's Adjustments pre-FDA Intervention

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's alpha if Item Deleted
q0002_0001	36.0000	27.250	.771	.904	.736
q0003_0001	36.1111	25.111	.847	.957	.714
q0004_0001	35.5556	30.028	.872	.998	.750
q0005_0001	35.5556	32.528	.536	.982	.785
q0006_0001	36.1111	26.861	.767	.939	.735
q0007_0001	37.0000	30.500	.058	.500	.953
q0009_0001	35.6667	27.000	.914	.998	.721

Table 15 presented the SPSS function to identify the effect of the Cronbach's alpha if a given item was deleted for the post-FDA scenario. The values in the last column in Table 15 have a range from .649 to .859. The question q0027_0001, if removed, could have a significant favorable impact in the overall Cronbach's alpha from .726 to .859. Also in Table 15, all values for Corrected Item-Total Correlation represented the correlations between each item and the total score. These correlation values need to be at or above 0.3, as per Field (2009). In this subscale, all values are over 0.3 except for q0027_0001. In the event of any value below 0.3, the item should be assessed, including being eliminated. Item q0027_0001 represented the concept that the

person has no perceived control in complying with the FDA regulations in the post-FDA intervention.

Table 15

Cronbach's adjustments post-FDA Intervention

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's alpha if Item Deleted
q0022_0001	43.5000	21.714	.811	.649
q0023_0001	44.0000	17.429	.502	.693
q0024_0001	43.7500	22.786	.347	.713
q0025_0001	43.3750	21.125	.924	.633
q0026_0001	43.6250	21.982	.783	.654
q0027_0001	45.1250	25.268	-.043	.859
q0028_0001	43.2500	23.643	.920	.673
q0029_0001	43.3750	24.268	.679	.688

Financial Indicators. The pilot study collected information regarding the financial indicators of the firms. For comparison, the indicators prior and after the FDA intervention or action were requested to the best recollection of the participants. The requested information focused on the elements of decreased, no change, and increased. The tables in the pilot study requesting the financial information scaled the responses to ensure clarity on the responses.

The responses were collected from seven participants. The overall averages were calculated to allow initial assessment of the clarity of the tables. Table 16 and Table 17

below presents the averages of the responses. The averages projected the trend between the prior and after the FDA intervention and actions.

Table 16

Before FDA: Financial Indicators

FNANCIAL OPERATING INDICATORS	Decreased	No change	Increased
COGS	14.3%	28.6%	57.1%
Investment (Facility & Equipment)	42.9%	28.6%	28.6%
Process compliance	28.6%	14.3%	57.1%
Sales	14.3%	42.9%	57.1%
Revenues	14.3%	28.6%	57.1%
Averages	22.9%	28.6%	51.4%

FINANCIAL INDICATORS	Decreased	No change	Increased
Actual sales (end of year prior to FDA)	0.0%	28.6%	57.1%
Actual revenues (end of year prior to FDA)	0.0%	28.6%	57.1%
Market values (end of year prior to FDA)	0.0%	28.6%	42.9%
Stockholder's equity (end of year prior to FDA)	0.0%	28.6%	57.1%
Averages	0.0%	28.6%	53.6%

Table 17

After FDA: Financial Indicators

FINANCIAL OPERATING INDICATORS	Decreased	No change	Increased
COGS	14.3%	28.6%	57.1%
Investment (Facility & Equipment)	0.0%	0.0%	85.7%
Process compliance	0.0%	0.0%	85.7%
Sales	14.3%	28.6%	57.1%
Revenues	14.3%	28.6%	57.1%
Averages	8.6%	17.1%	68.6%

FINANCIAL INDICATORS	Decreased	No change	Increased
Actual sales (end of year after to FDA)	0.0%	42.9%	57.1%
Actual revenues (end of after prior to FDA)	0.0%	28.6%	71.4%
Market values (end of year after to FDA)	0.0%	42.9%	57.1%
Stockholder's equity (end of year after to FDA)	0.0%	42.9%	57.1%
Averages	0.0%	39.3%	60.7%

Reputation of the Firms and Management Changes. The last two questions in the financial sections of the pilot study questionnaire requested the participants to provide their opinion regarding two potential outcomes from the FDA interventions or actions. These responses projected the impact on the firms' reputation and the change management process resulting from the FDA's intervention or actions. Comparing results in Table 18 and Table 19 allowed to conduct the assessment.

Table 18

Before FDA: Reputation and Management Change

Answer Options	Decrease of -50%	Decrease of -5% to -49%%	No Change	Increase of +5% to +49%%	Increase of -+50%	Response Count
Reputation of the Firm	0	1	5	1	0	7
Management change	0	0	4	5	0	7
answered question						7
skipped question						2

Table 19

After FDA: Reputation and Management Change

Answer Options	Decrease of -50%	Decrease of -5% to -49%%	No Change	Increase of +5% to +49%%	Increase of -+50%	Response Count
Reputation of the Firms	0	2	2	3	0	7
Management change	0	0	5	2	0	7
answered question						7
skipped question						2

FDA Experience. For the FDA experience of the firms, only six of the eight completed questionnaires addressed the last six questions out of 44 total questions. This

questions collected information regarding the firms experience with the FDA in the past six years from 2010 through 2015. The six responders indicated that their firms had FDA audits. The responses were assumed to be based on the best recollection of each of the participants. In all years, the FDA issued 483 observations. In two events, the outcome of the FDA intervention were audits with Official Action Indicated. On one occasion, the FDA intervention consisted of a Warning Letter. To assess the overall result of the responses, in the last two question the participants were asked to compare the firms' compliance position with the FDA's CGMP regulations before and after the FDA's interventions. The overall average reflected a favorable increase from 5.67 to 5.83 for a favorable 2.8% increase in compliance with the FDA regulations.

Regression Analysis. Regression analyses were conducted to understand the relationship between the financial indicators with the firms' compliance position with the FDA CGMP regulations. The financial indicators data were transformed within SPSS to facilitate the linear equation. Seven financial indicators were included in the assessment. Each indicator was considered as separate predictor model within SPSS analysis.

The assessment of the regression analysis was limited to 7 responses that made difficult the analysis of the assumptions. For both scenarios, pre-FDA and post-FDA interventions, multi-collinearity was the only assumption that could be confirmed as met. None of the results for the *F*- ratio, *t*- test or ANOVA were significant indicating that limited effectiveness of the model to predict the impact of the financial indicators in the compliance of the firms. The lack of significance in the above tests could be used to indicate that the model could not be used to generalize the outcome. The limited data

could not be used to establish the heteroscedasticity assumption. The normal probability plots indicated the non-normal distribution of variances for the pilot data.

Outcome from Pilot Study

The main outcome of the pilot study could be summarized in five points. First, the concept of comparing the pre-FDA and post-FDA interventions was possible and understood by the participants. Second, the open-ended questions provided important elements to support the constructs of the TPB Likert-type questionnaire. The third point referred to the effectiveness of the table approach to collect the financial indicators. The table format was effective and led to the execution of the intended regression analysis between these indicators and the dependent variable, compliance with the FDA regulations. Regarding the fourth point, the pilot study data could not be used to finalize a predicting model for the relation between compliance of the firms and the financial indicators. Finally, the time to execute the pilot study was as planned and following the IRB guidance including the approved consent form.

Final Study

The final study questionnaire consisted of four sections. The structure of the final questionnaire although not identical followed the concepts of the pilot study. The first sections related to the TPB initial assessment of attitudes, social influences, and perceived behavioral controls prior to the FDA intervention in the pharmaceutical firms. The first section also included a table to collect financial results of the firms before the FDA intervention or action. The second section related to the TPB initial assessment of attitudes, social influences, and perceived behavioral controls after the FDA intervention

in the pharmaceutical firms including a table to collect financial results of the firms after the FDA intervention or action. The intent of sections one and two was to identify information before and after any FDA intervention in the firms. The third section consisted of the demographics questions. Finally, the fourth section pursued clarification on the experience with any FDA interventions or actions in the firms in the past five-six years.

The instructions for the final study questionnaire in SurveyMonkey included an initial question to allow the participant to proceed or stop their participation after reading the instructions to the questionnaire. This question ensured the voluntary participation of the person highlighting the understanding of the level of confidentiality and the positive social benefit if participating in the study. The instructions were part of the SurveyMonkey questionnaire. The number of questions in the main study questionnaire were 133. The questions consisted of Likert-type scales and tables to select responses. The numbers of questions in the final questionnaire were about three times more than in the pilot questionnaire. The increase in the number of Likert-Type questions was driven by the feedback from the open-ended questions from the pilot participants and the final structure recommended by Ajzen (2016). Table 20 presents the questions distribution in the final questionnaire.

Table 20

Questions Final Questionnaire

Section	Scenario	Number of Questions
First	Before the FDA	61
Second	Before the FDA	61
Third	Demographics	6
Fourth	Experience with FDA	5
	Total	133

The length of the final questionnaire turned out to be one of two major limiting factors in the completeness of the questionnaires that were attempted by the participants that decided to provide their information. Of the 45 participants that initiated the final survey, only 21 completed the sections to the end. Feedback from several of these participants was that the number of questions were too many. In some cases, the pre-FDA and post-FDA scenarios were considered repeatable despite that it was indicated in the instructions that this was part of the questionnaire structure to allow the comparison of the pre-FDA and post-FDA scenarios. This concern of repeatability was highlighted by one out of eight participants of the pilot study and was considered a threat by me. Emphasis to highlight the confidentiality and the intended repeatability of questions in the instruction did not prove to be effective in managing this factor regarding the survey length.

The rate of participation in the final study based on 21 completed surveys was 1.9% from the original 1144 participants selected from the ISPE database following the criteria of participants. If only the 79 participants that accepted to commence the survey

are considered, the rate of initiating the survey on 21 completed surveys was 27.8%. The low initiation rate of the survey was identified as the second major limiting factor for the completeness of the final study where the target was to obtain about 160 versus 21 completed questionnaires for a performance of 13.1%. Although the pilot plant participation was 38%, the final low participation in the final study was not expected.

The low participation and initiation rate impacted the data analysis and the basis for judging the test of the hypotheses and the corresponding decisions regarding the null statements. The data collected is presented and the potential null assessment was based on the low rate of participation. Despite the consent form indicating the steps to protect the confidentiality of the participants, I had no evidence to explain or conclude the low participation and initiation rate at the stage of analyzing the data.

Population

The intended study population consisted of the pharmaceuticals firms that have been impacted within the last five-six years by enforcement activities from the FDA in the United States. The initial target were firms that had experienced FDA interventions related to manufacturing CGMP violations. Since the data collection was directed to the participants, the criteria for the pharmaceuticals firms also consisted in that they had operations and that the firms were public companies.

The main criteria for the selection of participation was that the executives and senior operational management of the pharmaceutical firms were expected to have the authority to make compliance and financial decisions within the firms. The database of potential participants was obtained from the members' directory of the International

Society of Pharmaceutical Engineers (ISPE). Sampling strategy targeted all ISPE members that meet the criteria of participation. The self-disclosed title listed by the members in the ISPE database was used for the determination of executives and operational management.

Participants were selected by pharmaceutical firms, states, and alphabetical order to create the participants' Excel database. The participants' e-mails as listed in the ISPE database by the participants themselves were included in the Excel database. A total of 1144 participants were identified in the pharmaceutical firms within the USA. Finally, all the pharmaceutical firms were confirmed to be public corporations by their participation in a financial board disclosing stock market price to investors.

The survey for the final study commenced on February 12, 2016, and was closed on April 19, 2016. Several reminders were sent in the first two weeks and after a second review of the narratives by the IRB. The IRB second review lasted 38 days or half of the time of the final study. Table 21 lists the message history of the final study regarding the communication with the participants. A total of 5238 messages were sent requesting participation and clarifying the need to have repeatable questions to cover the pre-FDA and post-FDA interventions or actions.

Table 21

Messages to Participants

Messages Sent	Date	Number of e-mails
Initial Invitation	2/12/2016	1144
First Reminder	2/15/2016	1052
Follow-up to Partials	2/17/2016	17
Second Reminder	2/20/2016	1022
Third Reminder	3/31/2016	987
Closure Note	4/13/2016	962
Closure note to Partials	4/16/2016	54
	Total	5238

From the original 1144 invitations sent by using SurveyMonkey, 58 e-mails bounced indicating that these e-mails were never received. An additional 50 participants opted not to participate after reading the consent form. 608 of the invitations were opened by the intended participants and no action was taken regarding their options to participate or not to participate. 428 of the invitations were never opened by the recipients. Of the 608 invitations that were opened to read the consent form, 90 participants accepted the consent form and proceeded to the survey. After reading the instruction, 79 of the 90 participants accepted to proceed to the questionnaire and 11 did not initiate the survey. Of the 79 participants that moved to the first question of section one, only 45 initiated this question. From the 45 participants that initiated the survey and after conducting the missing data assessment, the participation results attained 21 completed surveys and 24 partial-completed survey. The 21 completed surveys provided a response rate of about 1.9% versus the original 1144 invitations. If the 79 participants are only considered, the rate of participation was 27.8%.

Data Collection

The final study was conducted following the same instrument of the pilot study. The final study was administered through SurveyMonkey, an electronic survey tool chosen to collect data and facilitate analysis. A consent form for participation was sent via SurveyMonkey as approved by the Walden University's IRB. Trust and desire to participate was pursued through the narrative presented in the consent form including access by the participant to Walden's IRB office.

Of the 1144 SurveyMonkey invitations sent, 608 invitations were opened and 536 were either not recognized, e-mail bounced back, or the participant opted out of the survey. Only 90 invitations accepted the consent from, but eleven participants decided not to participate in the survey after reading the instructions. In addition, of the 79 participants that proceeded to read the first survey questions, only 45 initiated the questions and 21 completed the survey's 133 questions. The consent form with the questionnaire instructions provided adequate space for the participants to voluntarily decide if they would participate or not. With the 38% rate of participation in the pilot study, the participation in the main study was expected to reach the initial target of 160 completed questionnaires out of about 1144 invitations with a projected rate of participation of about 15%. The actual participation was 1.9% of the 1144 participants selected form the ISPE database meeting the criteria of participants. Of the expected 160 completed surveys, only 21 surveys were completed with an additional 24 partially completed surveys.

The data was collected and initially read through the SurveyMonkey analysis section. I did not conduct any specific statistical analysis within the SurveyMonkey data presentation. This data section was used to track the participation along the survey period. The collected data was exported to SPCC for the data analysis of this final study. The internal codification of SurveyMonkey was used to maintain and protect the confidentiality of the participants.

Demographics

The demographics of the final study indicated a reasonable representation of the role of responsibility and area of expertise within the selected participants. The demographics questions where located on the third section of the final study. Appendix F shows the percentage distribution of the relevant demographics. The decisions makers' titles indicated the participation of managers, directors, vice-presidents, and one executive. The educational level included high school diploma, bachelors, masters, MBA, and doctorate degrees. The functional areas within the pharmaceutical firms represented covered quality, manufacturing, engineering, and others like regulatory. The demographics of the final study's 21 participants ensured a representative source of essential management behaviors that were incorporated to the Likert-type scaled of the final questionnaire while recognizing the overall limited participation.

Data Treatment

The collected data in the final study was initially assessed via the results review section through SurveyMonkey. The collected data was transferred to an SPSS data table to facilitate the statistical assessments from correlations and regression analyses. The

assessment within SurveyMonkey consisted mainly in tracking responses and the rate of participation during the survey period. The SPSS database allowed to organize the responses for the correlations analysis and the execution of the regression analyses of the data for both the pre-FDA and post-FDA interventions and actions.

Data Analysis

The data analysis initial steps consisted on how to manage the data while addressing shortfalls, like missing data and assumptions' requirements. The low level of completed responses limited the overall analysis. The first step was to develop a data codebook (SPSS template) to store the data for all the variables and sampling details. The database template was created in SPSS from the data transferred from SurveyMonkey. The access to my laptop, it was password-protected to support confidentiality protecting the access to the collected data and the SPSS data template. There was no need to cross-code any personal references from participants since the collected data from SurveyMonkey provided reference numbers to enhance privacy and confidentiality of participants.

The second step consisted of the cleaning of the data per the steps outlined by Morrow (2009). Cleaning of the data refers to the process of minimizing biases and calculation errors generated by the quality of the obtained data. A step-by-step approach was followed for the SPSS analysis.

1. For the 45 original surveys that were initiated by participants, 24 surveys were removed from the database since significant number of questions were not completed by the participants.

2. For the remaining 21 surveys that answered questions in all the four sections of the questionnaire, some questions were not answered by each participant. Through SPSS, all missing data in the Likert-type scales were completed with the corresponding average of each question. For the questions related to financial indicators, any missing data was replaced with the response of "no change." The data was reviewed for each variable's Likert-type questions in the SPSS template to ensure that the suggested level of not more than 5% missing data was present for each participant in each of the two Likert-type sections of the survey.
3. The Outliers' scores were initially assessed with the intent to apply Windsorizing. None of the Likert-type scores or financial data tables from the main study required to apply the Windsorizing approach. In the SPSS analysis, for just caution and only when requested a 2 sigma was applied.
4. The data was reviewed for each variable's Likert-type questions in the SPSS template to ensure that the suggested level of not more than 5% missing data was present. If needed for less than 5% of the data, the estimated average of the data was used to fill in the missing data. In the case of more than 5% missing data for a given variable, the data for that participant was not included in the analysis.
5. For completed-usable responses, the participant had to complete over 95% of the questions in either the pilot study or the main study including the demographics and FDA compliance questions at the end.
6. For partial responses, an organized approached was implemented. This approach consisted in the separation of the collected data in the SPSS template by each of

the two scenarios: pre-FDA and post-FDA interventions. This process allowed to consider those responses that only addressed the pre- scenario, but the participants decided not to continue to complete the remainder of the questions.

7. Transforming the data by means of reversing the Likert-Type scores provided alignment and proper assessment of the Cronbach's alpha to assess the reliability of the scales by section or construct of the TPB.
8. Linearity was verified by visually assessing the graphs of the data.
9. Verifying for multicollinearity was done within the SPSS application.
10. For homogeneity of regression, SPSS was used.
11. Linearity was initially verified by visually assessing the graphs of the data.

The application of regression analysis increased the complexity since two scenarios pre-FDA and post-FDA interventions were assessed. Maintaining separation of the data for the two scenarios within the SPSS template was important. The number of the questions within SurveyMonkey provided the vehicle to maintain the separation of the data for the two scenarios pre-FDA and post-FDA interventions. The application of SPSS for the correlations analysis and all the corresponding assumptions of regression analysis were considered in both scenarios: pre-FDA and post-FDA interventions.

Research Question 1 (RQ1). To what extent, if any, does management behaviors (independent) correlate to compliance (dependent) with FDA regulations at the pharmaceutical firms in the United States?

- $H1_0$: $r = 0$. There is no difference in management behaviors towards compliance at pharmaceutical firms, as a result of FDA enforcement actions in the U.S.
- $H1_1$: $r \neq 0$. There are differences in management behaviors towards compliance at pharmaceutical firms, as a result of FDA enforcement actions in the U.S.

One method of assessing the predictability of behaviors is by applying the theory of planned behavior. Ajzen (1991) developed TPB to provide a model of measuring attitudes and dispositions to predict behavior. TPB infers the existence of a direct relationship between intention and actual behavior. Also, attitudes and norms can explain any behavior following the principles of TPB. The study applied TPB to understand and predict the intention of pharmaceutical management to comply with the FDA regulations.

According to TPB, three types of beliefs direct and influence human behavior: salient beliefs or attitudes (b), normative beliefs (n), and perceived behavioral control (c) (Ajzen, 2002). The interrelations between these beliefs influence the intention towards a given behavior. Intentions are the predecessors of behaviors (Ajzen, 1991). The relation between intention and behavior depends on the strength of the attitude from behavioral beliefs, the social pressures leading to subjective beliefs, and the level of perceived control that the person has in front of the decision process. Actual behavioral control results from the limitations or obstacles performing the intention. If adequate control exists, an individual's intention predicts the actual behavior, as a direct outcome. These

constructs were incorporated into the Likert-type questions suggested by Fishbein and Ajzen (2010) for the main survey questionnaire.

All Likert-type scales were selected by me to be unipolar (1 to 7) to avoid potential biases by having a negative implication with ratings in a -3 to +3 scale. The first section of the questionnaire was to assess the overall expected outcome regarding the expected compliance with the FDA regulations pre-FDA and post-FDA interventions. A total of 61 questions were included in this section for each scenario. Table 22 presents the average and standard deviations for these Likert-Type questions for each participant. All averages were skewed to the high side of the 1 to 7 Likert-type scales.

Table 22

Outcome pre-FDA and post-FDA intervention

	pre-FDA intervention		post-FDA intervention	
Participants	Ave. outcome	SD	Ave. Outcome	SD
1	6.7	1.94	7.0	0.00
2	5.6	0.97	6.6	0.97
3	5.0	1.41	5.5	0.97
4	6.9	0.32	6.7	0.48
5	6.4	1.07	4.1	0.88
6	6.4	1.90	6.7	0.95
7	6.8	0.42	6.7	0.95
8	6.2	0.92	5.9	1.10
9	6.6	0.85	6.7	0.84
10	6.5	0.96	6.4	1.26
11	6.3	1.25	6.2	1.87
12	5.7	1.42	6.9	0.32
13	6.3	1.06	6.6	0.97
14	6.4	1.90	6.9	0.17
15	5.6	0.70	5.7	0.67
16	6.7	0.48	6.4	0.70
17	5.5	0.71	5.9	0.32
18	6.0	0.82	6.0	0.82
19	5.8	0.63	5.9	0.74
20	6.4	0.70	6.1	1.45
21	5.5	0.53	6.6	0.52

The overall attitude regarding the beliefs was defined as the sum of the products of the individual beliefs, b, and the corresponding strength, e (Fishbein and Ajzen, 2010). The projected relation was based on $A = \Sigma b_i * e_i$. Letter A corresponds to the overall attitude towards the given behavior. In the study, the overall behavior towards compliance with the FDA regulations was the target. Tables 23 and 24 present the calculation for the overall attitude A for both pre-FDA and post-FDA interventions.

Table 23

Overall Attitude pre-FDA

Beliefs	Ave. b	SD	Ave. e	SD	Ave. be	SD	Max	Min
Cheaper	3.80	2.04	6.57	1.12	24.98	14.76	49	1
Reliable	6.10	0.94	5.38	1.07	33.26	9.86	49	1
Product quality	6.50	0.97	6.24	1.00	40.64	9.34	49	1
Supply	6.38	1.07	6.57	1.33	42.24	11.73	49	1
Competitive	6.00	1.34	6.81	0.51	41.10	10.05	49	1
Accomplishment	6.29	0.96	6.62	0.59	41.76	8.14	49	1
Effective	6.19	0.81	6.95	0.22	43.10	6.15	49	1
Information	6.33	1.02	5.76	0.94	36.67	9.06	49	1
Tension	4.30	2.08	6.67	0.58	29.15	14.98	49	1
Overworked	3.48	2.04	5.95	1.02	20.67	12.34	49	1
				Attitude =	353.56		490	

Table 24

Overall Attitude post-FDA

Beliefs	Ave. b	SD	Ave. e	SD	Ave. be	SD	Max	Min
Cheaper	3.80	1.89	6.76	0.70	25.31	12.59	49	1
Reliable	5.62	1.53	5.71	0.85	32.48	11.15	49	1
Product	6.05	1.43	6.86	0.36	41.71	10.86	49	1
Supply	6.14	1.20	3.95	2.13	23.67	13.27	49	1
Competitive	5.95	1.40	6.52	0.75	39.43	11.70	49	1
Accomplishment	6.19	0.98	6.62	0.59	41.19	8.45	49	1
Effective	6.00	0.95	6.81	0.51	41.05	8.04	49	1
Information	5.86	1.20	5.95	0.92	35.05	9.98	49	1
Tension	4.35	1.71	6.71	0.64	29.26	12.16	49	1
Overworked	3.45	1.86	5.86	1.06	20.39	12.01	49	1
				Attitude =	329.53		490	

The overall normative beliefs, N, was defined as the sum of the products of the individual normative beliefs, n, and the corresponding strength, m (Fishbein and Ajzen. 2010). The projected relationship based on summarized $N = \Sigma n_i * m_i$. Letter N

corresponds to the overall attitude towards the given normative belief towards a behavior. In the study, the overall behavior towards compliance with the FDA regulations was the target. Table 25 and Table 26 present the calculation for the overall normative beliefs N for both pre-FDA and post-FDA interventions.

Table 25

Overall Normative Belief pre-FDA

Normative	Ave. B	SD	Ave. e	SD	Ave. Be	SD	Max	Min
SR MGT	7.00	0.00	6.86	0.48	48.00	3.35	49	1
PEERS	6.81	0.40	5.71	1.62	38.86	11.19	49	1
BUSS ASSOC	6.76	0.62	5.81	1.25	39.33	9.33	49	1
DIRECT/MAN	6.81	0.51	6.86	0.48	46.86	5.60	49	1
SUP	6.86	0.36	6.86	0.48	47.14	5.03	49	1
PARENTS	4.10	2.41	5.48	2.06	25.14	17.80	49	1
FRIENDS	3.95	2.33	5.71	1.62	24.19	16.58	49	1
SR MGT	6.95	0.22	6.86	0.48	47.76	4.35	49	1
BUSS ASSOC	6.67	0.66	5.81	1.25	39.10	10.33	49	1
BUSS ASSOC	6.14	1.56	5.81	1.25	35.86	12.41	49	1
				Normative =	392.24		490	

Table 26

Overall Normative Belief post-FDA

Normative	Ave. n	SD	Ave. m	SD	Ave. nm	SD	Max	Min
SR MGT	6.48	0.68	6.71	0.72	43.62	7.12	49	1
PEERS	6.71	0.46	5.90	1.04	39.82	8.56	49	1
BUSS ASSOC	6.48	1.21	5.43	1.54	35.19	12.40	49	1
DIRECT/MAN	6.71	0.56	6.71	0.72	45.19	6.74	49	1
SUP	6.81	0.40	6.71	0.72	45.86	6.36	49	1
PARENTS	3.81	2.66	4.48	2.44	21.95	19.59	49	1
FRIENDS	4.15	2.22	5.90	1.04	25.09	14.96	49	1
SR MGT	6.95	0.22	6.71	0.72	46.75	5.68	49	1
BUSS ASSOC	6.32	0.78	5.43	1.54	34.74	12.42	49	1
BUSS ASSOC	5.53	1.91	5.43	1.54	30.18	15.06	49	1
				Normative =	368.39		490	

The overall perceived control behaviors, PBC, was defined as the sum of the products of the individual perceived control beliefs, p, and the corresponding strength, c (Fishbein & Ajzen, 2010). The projected relationship was based on PBC = $\Sigma p_i * c_i$. Letters PBC correspond to the overall attitude towards the given perceived behavioral control towards a behavior. In the study, the overall behavior towards compliance with the FDA regulations was the target. Table 27 and Table 28 present the calculation for the overall perceived behavioral control PBC for both pre-FDA and post-FDA interventions.

Table 27

Overall PBC pre-FDA

Control	Ave. p	SD	Ave. c	SD	Ave. pc	SD	Max	Min
KNOWLEDGE	3.14	2.22	3.65	2.17	9.75	8.81	49	1
KNOWLEDGE	6.90	0.30	3.65	2.17	25.12	15.09	49	1
EVENTS	3.29	1.59	6.33	0.86	21.43	11.83	49	1
FEEL	5.50	1.47	6.38	0.97	35.93	12.41	49	1
FAMILY	4.80	1.81	6.29	0.96	31.03	13.51	49	1
GOALS	4.65	1.53	6.05	1.40	27.45	10.55	49	1
BUDGET	4.24	2.14	6.00	1.30	26.10	15.14	49	1
DATELINES	3.29	2.19	6.00	1.30	18.67	13.10	49	1
				Attitude =	195.47	392		

Table 28

Overall PBC post-FDA

Control	Ave. p	SD	Ave. c	SD	Ave. pc	SD	Max	Min
KNOWLEDGE	3.95	2.13	3.48	2.16	12.24	9.37	49	1
KNOWLEDGE	6.71	0.64	3.48	2.16	23.24	14.90	49	1
EVENTS	3.81	1.50	5.62	1.86	22.29	12.02	49	1
FEEL	5.40	1.43	5.75	1.61	31.91	13.52	49	1
FAMILY	5.10	1.73	5.75	1.64	30.10	14.60	49	1
GOALS	3.55	1.77	5.75	1.51	19.07	9.59	49	1
GOALS	4.79	1.75	5.50	1.88	27.09	14.77	49	1
DATELINES	3.19	2.04	5.50	1.88	16.45	11.80	49	1
				Control =	182.38		392	

On Table 29, the summary of the results was listed for both the pre-FDA and post-FDA interventions. The maximum value for each construct was included. Also, the percent of the maximum attained by each construct was listed. Although the average outcome tended to be slightly higher towards compliance from 88% to 90%, the TPB constructs tended to be 3-5% lower for the post-FDA intervention versus the maximum points to be attained in each scale.

Table 29

Overall Results for TPB constructs

	Outcome	A	N	PBC
Pre-FDA	6.16	353.56	392.24	195.47
Post-FDA	6.27	329.53	368.39	182.38
Max	7	490	490	392
Pre-FDA	88%	72%	80%	50%
Post-FDA	90%	67%	75%	47%

This data indicated that the probable effect of the FDA intervention in the participants' behavior was inversed. While the expected outcome of compliance was improved, the impact on the behavioral constructs were negative. Although the participants' beliefs of being in compliance was reduced after the FDA intervention, the lost in influence from peers' opinions and the reduction on the influence of perceived controls provided a final favorable impact on the outcome of enhanced compliance with FDA regulations. These trends allowed for a better compliance expectation after the FDA intervention.

An attempt to assess if a prediction could be obtained from the three constructs of behavior regarding the responses to the outcome of compliance by the participants, correlation analyses were conducted for both scenarios, pre-FDA and post-FDA interventions. Also, following the TPB, a linear regression analysis was performed using SPSS to generate and assess if prediction models could be applied to compare both scenarios. For the regression analysis, the SPSS forced entry approach was used to present the contribution to the model. The order of the constructs followed the TPB order of beliefs (attitudes), normative beliefs, and perceived behavior controls (PBC).

Considering the small number of participants, skewness and kurtosis were used to assess the distribution of the variables. In the scenario of pre-FDA intervention, the skewness results were negative indicating that there was a cluster at the higher end of the scales (Field, 2009). Kurtosis was used to measure the degree to which scores cluster in the tails of a frequency distribution. For the pre-FDA, the kurtosis' values were positive and negative. Positive kurtosis values indicated that the distribution tended to peak at the

tails due to the high number of scores in the tail. Negative kurtosis values signaled few scores in the tails and a flat distribution (Field, 2009). In the scenario of post-FDA intervention, the skewness results were also negative indicating that there was a cluster at the higher end of the scales (Field, 2009). The kurtosis' values were also positive and negative.

The four variables were also assessed for their characteristics as a normal or non-normal distribution. Kolmogorov-Smirnov and Shapiro-Wilk results were obtained in SPSS. The results of the Kolmogorov-Smirnov and Shapiro-Wilk tests for the pre-FDA intervention were all non-significant implying that the distribution of the four variables were normal. See Table 30.

Table 30

Tests of Normality pre-FDA

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Outcome_pre	.180	21	.073	.936	21	.181
Beliefs_pre	.096	21	.200*	.984	21	.972
Normative_pre	.176	21	.089	.922	21	.096
Control_pre	.123	21	.200*	.976	21	.860

* This is a lower bound of the true significance.

a. Lilliefors Significance Correction

For the post-FDA intervention in Table 31, the results for Kolmogorov-Smirnov and Shapiro-Wilk tests are illustrated. Results were non-significant indicating a tendency to normal distribution for three independent variables: beliefs (attitude), normative beliefs, and perceived behavioral control. For the dependent variable outcome of

compliance, the Shapiro-Wilk tests indicated a significant correlation indicating a non-normal distribution different from the pre-FDA scenario.

Table 31

Tests of Normality post-FDA

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Outcome_post	.173	21	.099	.830	21	.002
Beliefs_post	.124	21	.200*	.971	21	.758
Normative_post	.155	21	.200*	.933	21	.160
Control_post	.107	21	.200*	.973	21	.800

* This is a lower bound of the true significance.

a. Lilliefors Significance Correction

Pearson's coefficient correlation was utilized to understand the internal consistency of the Likert-type scales by establishing how close the different elements of the scales are to each other. Also, the correlation between each subset of the construct was obtained and listed to establish the dependencies within each construct. Table 32 presents the Pearson correlation for the pre-FDA intervention. The construct of beliefs (attitudes) had the highest correlation with the outcome of compliance with a value of $r = 0.633$, $p < 0.01$. The other two construct, normative beliefs and perceived behavioral control had non-significant correlations with r values of $r = 0.328$ and $r = 0.183$, respectively.

Table 32

Pre-FDA Correlations

		Outcome_pre	Beliefs_pre	Normative_pre	Control_pre
Outcome_pre	Pearson Correlation	1	.633**	.328	.183
	Sig. (1-tailed)		.001	.073	.213
	N	21	21	21	21
Beliefs_pre	Pearson Correlation	.633**	1	.328	.243
	Sig. (1-tailed)	.001		.074	.144
Normative_pre	Pearson Correlation	.328	.328	1	-.127
	Sig. (1-tailed)	.073	.074		.292
Control_pre	Pearson Correlation	.183	.243	-.127	1
	Sig. (1-tailed)	.213	.144	.292	

**. Correlation is significant at the 0.01 level (1-tailed).

Table 33 presents the Pearson's correlation for the post-FDA intervention. The construct of beliefs (attitudes) also had the highest correlation with the outcome of compliance with a value of $r = 0.693$, $p < 0.01$. The other two construct, normative beliefs and perceived behavioral control had non-significant correlations with r values of 0.294 and 0.303, respectively. Also, the construct of behavioral beliefs had a significant correlation with the construct of perceived behavioral control with $r = 0.376$, $p < 0.05$. This last significant correlation differed from the pre-FDA intervention where the correlation was non-significant between these two constructs.

Table 33

Post-FDA Correlations

		Outcome_post	Beliefs_post	Normative_post	Control_post
Outcome_post	Pearson Correlation	1	.693**	.294	.303
	Sig. (1-tailed)		.000	.098	.091
	N	21	21	21	21
Beliefs_post	Pearson Correlation	.693**	1	.332	.376*
	Sig. (1-tailed)	.000		.071	.046
Normative_post	Pearson Correlation	.294	.332	1	-.268
	Sig. (1-tailed)	.098	.071		.120
Control_post	Pearson Correlation	.303	.376*	-.268	1
	Sig. (1-tailed)	.091	.046	.120	

**. Correlation is significant at the 0.01 level (1-tailed).

*. Correlation is significant at the 0.05 level (1-tailed).

The correlation data indicated a favorable change in correlation between the outcome of compliance and beliefs (attitude) for before and after the FDA intervention of about 9.5%. The value of *r* increased from 0.633 to 0.693 for the construct of beliefs (attitude) towards compliance by the participants with significances of $p < 0.01$. The other two independent constructs had non-significant correlations. The perceived behavioral control non-significant correlation with the outcome of compliance also increased by about 65% from the pre-FDA ($r = 0.183$) to the post-FDA scenario ($r = 0.303$). From the limited population that participated in the study, the null hypothesis was rejected for RQ1.

A regression analysis was conducted to establish a model with the TPB constructs as predictors of the outcome of compliance of the firms with the FDA regulations. The regression analyses were performed using SPSS for both scenarios: pre-FDA and post-FDA. All assumptions were assessed to understand the robustness of the models.

For regression analysis, there were several assumptions that needed to be met (Field, 2009). Meeting the assumptions allowed assessing if the conclusions were true for a wider population. For a regression model to generalize beyond the sample population, assumptions have to be met. The assumptions were assessed for each scenario: pre-FDA and post-FDA interventions. The assessment was as follows:

1. Variable types: All predictor variables were quantitative or categorical (with two categories), and the outcome variable was quantitative: continuous and unbounded.
2. Non-zero variance: The predictors should had variation in value. They did not have variances of 0.
3. Sample Size: The ratio of predictors to cases was expected to be significant because of its impact on the value of R. This assumption was not met.
4. No perfect multicollinearity: There was no perfect linear relationship between two or more of the predictors. The predictor variables did not highly correlated.
5. Predictors are not correlated with external variables: External variables could be present. In the model, not all contribution that could significantly influence the outcome was identified. This assumption was not met.

6. Homoscedasticity: At each level of the predictor variable(s), the variance of the residual terms were constant. The SPSS graphs supported this assumption.
7. Independent errors: For any two observations the residual terms should be independent. This assumption tested whether adjacent residuals are correlated. The test statistic was allowed to vary between 0 and 4 with a value of 2 meaning that the residuals were uncorrelated.
8. Normally distributed errors: This assumption indicates that the differences between the model and the observed data are most frequently zero or very close to zero. The SPSS graphs did not support this assumption.
9. Independence: All of the values of the dependent variable were independent of each other.
10. Linearity: The mean values of the dependent variable were represented in a reasonable spread indicating a straight line. Assumption met.

The dependent variable was the outcome of compliance as indicated in the main survey by the participants in the Likert-type scales for the TPB section. The values of the behavioral construct variables were the values of the beliefs with the influence of the corresponding strengths. For beliefs (attitude), the average product of b*e was used. For normative beliefs, the average product of n*m was used. For perceived behavioral control (control), the average product of p*c was used. This approached allowed to have a direct relation in the model with the beliefs in each of the three constructs. The values of the variables are presented in Table 34 for the pre-FDA scenario and post-FDA scenario.

Table 34

Pre-FDA and Post-FDA scenario

	pre-FDA behavioral constructs				post-FDA behavioral constructs			
Participants	Ave. O	Ave. be	Ave. nm	Ave. pc	Ave. O	Ave. be	Ave. nm	Ave. pc
1	6.7	36.1	40.8	32.9	7.0	36.8	27.4	25.9
2	5.6	37.1	30.7	24.0	6.6	32.4	32.0	15.8
3	5.0	22.0	22.4	19.4	5.5	21.4	22.1	23.9
4	6.9	37.3	45.2	24.8	6.7	34.9	44.5	21.3
5	6.4	34.9	33.2	9.6	4.1	24.4	27.7	15.5
6	6.4	42.7	42.5	34.0	6.7	35.2	33.1	26.3
7	6.8	44.1	30.5	39.3	6.7	42.0	24.7	29.4
8	6.2	36.9	44.6	15.1	5.9	23.6	34.4	23.4
9	6.6	41.4	49.0	18.8	6.7	38.2	45.5	21.9
10	6.5	33.3	45.2	28.5	6.4	34.4	44.8	30.0
11	6.3	30.5	36.0	20.3	6.2	29.8	32.5	26.3
12	5.7	34.5	41.5	29.6	6.9	32.3	37.8	26.0
13	6.3	31.9	40.0	25.0	6.6	35.8	38.6	24.5
14	6.4	45.5	41.4	20.3	6.9	44.8	40.6	22.8
15	5.6	25.0	33.3	34.1	5.7	25.6	24.6	25.5
16	6.7	31.9	39.3	20.9	6.4	33.7	41.3	20.6
17	5.5	27.7	46.5	12.8	5.9	26.7	48.3	12.8
18	6.0	38.6	42.6	32.5	6.0	40.6	41.7	32.6
19	5.8	28.6	40.1	25.1	5.9	29.8	41.0	17.6
20	6.4	35.5	46.5	21.9	6.1	35.0	44.2	20.9
21	5.5	33.5	47.7	20.9	6.6	34.6	46.9	16.0

In the next step, the possible predicting models were evaluated for both FDA scenarios. A model in a forced order was developed in SPSS for each scenario. Table 35 presents the model for the pre-FDA scenario. The correlation R between the variables and the prediction R^2 of how much of the dependent variable is contributed by each predictor were obtained. Also, the assumption of independent errors was verified with the Durbin–Watson statistic. The value of 2.21 was obtained, indicating that the assumption of

independent errors could be considered as met. About the external variables, the R^2 values of model 1 indicated that the predictors accounted for about 42% contribution to the outcome variable, indicating that there were other external variables not included, violating this assumption.

Table 35

Pre-FDA Model [b]

					Change Statistics					
Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	R Square Change	F Change	df1	df2	Sig. F Change	Durbin-Watson
1	.649[a]	.421	.318	.42625	.421	4.115	3	17	.023	2.210

a. Predictors: (Constant), Control_pre, Normative_pre, Beliefs_pre
b. Dependent Variable: Outcome_pre

The adjusted R^2 provided a way to understand how well the model could generalize the scenario under review. The smallest the difference of the adjustment the better the possibility for the model to represent the population, not just the sample. In model 1, the value of R^2 was 00.421 and was adjusted to about 32% for the contribution of the three constructs. The *F*- ratio indicated the significance of the change with $p < 0.05$.

For the post-FDA scenario, the three TPB constructs were introduced in a forced order as developed in SPSS. Table 36 presents the model for the post-FDA scenario. Also, the assumption of independent errors was verified with the Durbin–Watson statistic. The value of 2.066 was obtained, indicating that the assumption of independent errors could be considered as met. About the "external variables," the R^2 values of model

1 indicated that the predictors accounted for about 49% contribution to the outcome variable, indicating that there are other external variables not included, violating this assumption.

Table 36

Model [b] Summary post-FDA

					Change Statistics					
Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	R Square Change	F Change	df1	df2	Sig. F Change	Durbin-Watson
1	.701[a]	.492	.402	.50620	.492	5.481	3	17	.008	2.066

a. Predictors: (Constant), Control_post, Normative_post, Beliefs_post
b. Dependent Variable: Outcome_post

The adjusted R^2 provided a way to understand how well the model could generalize the scenario under review. The smallest the difference of the adjustment the better the possibility for the model to represent the population, not just the sample. In model 1, the $R^2 = 0.492$ was adjusted to 40.2% representing the adjustment to the overall contribution of the three variables. The *F*-ratio provided the significance of the change, $p < 0.01$.

The ANOVA challenged whether the models were better predictors of the outcome than the guess based on the average means. The *F*-ratio indicated the ratio of the accuracy of the model versus the means (Field, 2009). All values of *F* were lower above one signaling that the model's fits were good predictors than the guess from the means. The models for both scenarios (pre-FDA and post-FDA) had an *F*-ratio that were significant ($p < 0.05$) indicating that the outcome could unlikely happen by chance.

The model parameters were then obtained by SPSS. Table 37 presents the slope values, B, for each predictor (TPB constructs). Only beliefs had a significant value of $p < 0.05$. None of the other construct had a significant ($p < 0.05$) indicating a weak contribution to the outcome. The smallest the significance of the B values the stronger the contribution of the prediction to the outcome (Field, 2009). Regarding the standardized beta (labeled as Beta, β), beliefs (β = 0.568), had the largest impact on the standard deviation of the outcome of behavior towards compliance. The other two standardized beta (labeled as Beta, β) were normative beliefs (β = 0.150) and PBC (β = 0.065).

Table 37

Models' Parameters [a] pre-FDA

		Unstandardized Coefficients		Standardized Coefficients		
Model		B	Std. Error	Beta	*t*	Sig.
1	(Constant)	3.903	.742		5.259	.000
	Beliefs_pre	.049	.018	.568	2.769	.013
	Normative_pre	.012	.015	.150	.750	.463
	Control_pre	.004	.013	.065	.331	.745

To assess how close is the B value of the sample to the B value of the population, a level of confidence of 95% was selected. See Table 38. Only one of the constructs (beliefs) had a spread between the upper and lower boundaries of the confidence limit not crossing the value of zero implying that the construct was strong for the prediction of the outcome of the model. Regarding the Collinearity Statistics, VIF values were all close to

1.0 and tolerances were below 1.0. These results indicated that the models met the assumption of collinearity.

Table 38

Models' Parameters [a] pre-FDA

Model		*t*	Sig.	95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
				Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	5.259	.000	2.337	5.469					
	Beliefs_pre	2.769	.013	.012	.086	.633	.558	.511	.810	1.234
	Normative_pre	.750	.463	-.021	.044	.328	.179	.139	.847	1.180
	Control_pre	.331	.745	-.024	.032	.183	.080	.061	.893	1.119

For the post-FDA scenario, Table 39 presents the slope values, B, for each predictor (TPB constructs). Only beliefs had a significant value of $p < 0.05$. None of the other construct had a significant ($p < 0.05$) indicating a weak contribution to the outcome. The smallest the significance value, the stronger the contribution of the prediction to the outcome (Field, 2009). Regarding the standardized beta (labeled as Beta, β), beliefs (β = 0.614), had the largest impact on the standard deviation of the outcome of behavior towards compliance. The other two standardized beta (labeled as Beta, β) were normative beliefs (β = 0.118) and PBC (β = 0.104).

Table 39

Model Parameters[a] post-FDA

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	3.456	.858		4.031	.001
	Beliefs_post	.065	.023	.614	2.877	.010
	Normative_post	.010	.017	.118	.576	.572
	Control_post	.013	.026	.104	.499	.624

To assess how close is the B value of the sample to the B value of the population, a level of confidence of 95% was selected. See Table 40. Only one of the constructs (beliefs) had a spread between the upper and lower boundaries of the confidence limit not crossing the value of zero implying that the construct was strong for the prediction of the outcome of the model. Regarding the Collinearity Statistics, VIF values were all close to 1.0 and tolerances were below 1.0. These results indicated that the models met the assumption of collinearity.

Table 40

Model Parameters[a] post-FDA

Model		Sig.	95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
			Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	4.031	.001	1.647	5.266				
	Beliefs_post	2.877	.010	.017	.113	.693	.572	.498	.657	1.523
	Normative_post	.576	.572	-.025	.045	.294	.138	.100	.710	1.409
	Control_post	.499	.624	-.043	.069	.303	.120	.086	.685	1.460

To further assess the assumption of collinearity, a diagnostic was performed by SPSS for both scenarios: pre-FDA and post-FDA. In both scenarios, all Eigenvalue were below one. Only Eigenvalues below 1 were considered for the assessment of collinearity. For the pre-FDA, the three constructs had their highest values in different dimensions for the test of Variance Proportions. For the post-FDA, the three constructs also had their highest values in different dimension also meeting the assumption of no multicollinearity.

The next step was to assess if any case had a significant influence or should be considered as an outlier. Using SPSS, the case summary analysis was applied to both scenarios: pre-FDA and post-FDA. The Mahalanobis Distance values did not show any case to be of concerned. The Cook's number expect for one (case 5) were below 1.0. But, the Centered Leverage Values were all within the three times the expected value of 0.57. None of the cases were excluded from the Cook's numbers and DFBeta calculations by SPSS indicating no undue influence from any of the cases in the model. In the post-FDA scenario, all cases were included with values of Cook of +/-1.

All the values of DFBeta except case 5 and case 17 in the post-FDA were beyond +/-1 but less than two implying that all other cases could be considering not having undue influence in the regression models. For case 5 (post-FDA) and case 17 (post-FDA), the Centered Leverage Values were within expectation leading to accept both cases as not having undue influence in the model. Regarding the covariance ration, CVR, the limits of 1.57 and -0.42. All cases were within or not significantly apart from these values. Case 8 had a value of 2.0 but its Cook's and Centered Value were well within expectations. No case was found to have an undue influence in the model.

For the assumptions of linearity and homoscedasticity, the plots assessed under SPSS could be considered as supporting these assumptions. For the residual normality, the graphs for both scenario had a subtle separation form the straight line implying lack of normality. Since not all assumptions were met, the regression model for TPB cannot be used to generalize beyond the sample of the study in either the pre-FDA or the post-FDA intervention.

Research Question 2 (RQ2). To what extent, if any, do financial indicators (independent) correlate to compliance (dependent) with FDA regulations at the pharmaceutical firms in the United States?

- $H2_0$: $r = 0$. There is no difference in compliance with FDA related to financial indicators at pharmaceutical firms, as a result of FDA enforcement actions in the U.S.
- $H2_1$: $r \neq 0$. There are differences in compliance with FDA related to financial indicators, as a result of FDA enforcement actions in the U.S.

Seven correlations were performed with the seven financial indicators to understand the possible correlations between these indicators and the dependent variable outcome of compliance for each scenario: pre-FDA and post-FDA interventions. The seven financial indicators for the test of Hypothesis 3 were the cost of goods, investment in facility and equipment, process compliance, actual sales, actual revenues, market value, and stockholder's equity. The basis of the correlations was the firms' level of compliance as indicated by the participants both before and after the FDA intervention.

The main study collected information regarding the financial indicators of the firms. For comparison, the indicators prior and after the FDA intervention or action were requested to the best recollection of the participants. The requested information focused on the elements of decreased, no change, and increased. The tables in the study requesting the financial information scaled the responses to ensure clarity on the responses.

The financial responses were collected from the 21 participants. The overall averages were calculated to allow initial assessment of the clarity of the tables. Table 41 below presents the averages of the responses for the pre-FDA scenario.

Table 41

Pre-FDA: Financial Indicators

FINANCIAL OPERATING INDICATORS	Decreased	No change	Increased
COGS	14.3%	61.9%	23.8%
Investment (Facility & Equipment)	4.8%	28.6%	66.7%
Process compliance	42.9%	47.6%	9.5%
Averages	20.7%	46.0%	33.3%

FINANCIAL INDICATORS	Decreased	No change	Increased
Actual sales (end of year prior to FDA)	47.6%	47.6%	4.8%
Actual revenues (end of year prior to FDA)	42.8%	52.4%	4.8%
Market values (end of year prior to FDA)	4.8%	42.9%	52.4%
Stockholder's equity (end of year prior to FDA)	14.3%	47.6%	38.1%
	27.4%	47.6%	25.0%

Table 42 presents the responses for the post-FDA scenario. The average response of the participants indicated that the financial indicators increased from the pre-FDA to

the post-FDA intervention. The results showed that the financial operating indicators "increased" from pre-FDA 33.3% to post-FDA 54.1%. The participants also indicated that the financial indicators "increased" from pre-FDA 25 to post-FDA 38%. The averages projected an increasing trend for financial indicators between the prior and after the FDA intervention and action.

Table 42

Post-FDA: Financial Indicators

FINANCIAL OPERATING INDICATORS	Decreased	No change	Increased
COGS	14.3%	52.4%	33.3%
Investment (Facility & Equipment)	9.5%	28.6%	61.9%
Process compliance	0.0%	42.9%	67.1%
Averages	7.9%	41.3%	54.1%

FINANCIAL INDICATORS	Decreased	No change	Increased
Actual sales (end of year after to FDA)	4.8%	47.6%	47.7%
Actual revenues (end of after prior to FDA)	4.8%	47.6%	47.7%
Market values (end of year after to FDA)	14.3%	53.4%	33.3%
Stockholder's equity (end of year after to FDA)	19.0%	57.1%	23.8%
Averages	10.7%	51.4%	38.12%

To understand the distribution of the financial data, within the SPSS calculation, the skewness and the kurtosis were obtained. In both scenarios of pre-FDA and post-FDA interventions, the skewness results were all positive indicating that there was a cluster at the left end of the scales (Field, 2009). Kurtosis was used to measure the degree to which scores cluster in the tails of a frequency distribution. Kurtosis' values were positive for all the financial indicators on both scenarios. Positive kurtosis values indicates that the

distribution tends to peaked at the tails due to the high number of scores in the tail. Negative kurtosis values signals few scores in the tails and a flat distribution (Field, 2009).

The non-normal distribution in all the financial indicators were significant as confirmed by indicated by the calculations for Kolmogorov-Smirnov and Shapiro-Wilk in SPSS. All values for both scenarios were significant [(K-S): $p < 0.001$ and (S-W): $p < 0.005$] confirming that none of the financial indicators had a normal distribution. Table 43 shows the results of the Kolmogorov-Smirnov and Shapiro-Wilk tests for the pre-FDA intervention. For the post-FDA intervention in Table 44, the results for Kolmogorov-Smirnov and Shapiro-Wilk tests were illustrated.

Table 43

Test of Normality pre-FDA Intervention

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
COGS_pre	.322	21	.000	.779	21	.000
Investment_fac_equip_pre	.288	21	.000	.856	21	.005
Compliance_pre	.273	21	.000	.774	21	.000
Sales_pre	.325	21	.000	.749	21	.000
Revenues_pre	.325	21	.000	.749	21	.000
Act_sales_pre	.307	21	.000	.739	21	.000
Act_revenues_pre	.312	21	.000	.742	21	.000
Market_value_pre	.282	21	.000	.827	21	.002
Stockholders_pre	.252	21	.001	.796	21	.001

a. Lilliefors Significance Correction

Table 44

Test of Normality post-FDA Intervention

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
COGS_post	.277	21	.000	.797	21	.001
Investment_fac_equip_post	.377	21	.000	.697	21	.000
Compliance_post	.372	21	.000	.633	21	.000
Act_sales_post	.282	21	.000	.827	21	.002
Act_revenues_post	.282	21	.000	.827	21	.002
Market_value_post	.277	21	.000	.797	21	.001
Stockholders_post	.290	21	.000	.800	21	.001

a. Lilliefors Significance Correction

Despite the non-normal distribution, the Pearson Correlation was performed to understand the possible correlation between the financial indicators for each scenario: pre-FDA and post-FDA interventions. The basis of the correlations was the firms' level of compliance as indicated by the participants both before and after the FDA intervention. The intent was to establish if there was a correlation between any of the financial indicators with the level of compliance of the firms on both scenarios.

Of the seven financial indicators, the compliance of the firms prior to the FDA intervention had a significant correlation at $p < 0.05$ with three of them considering a one-tailed assumption due to the skewness of the data in the responses. Investment in facility and equipment ($r = |-0.468|$, $p < 0.05$), compliance expenses ($r = |-0.558|$, $p < 0.05$), and stockholders' equity ($r = 0.392$, $p < 0.05$) were significantly correlated to compliance. In addition, facility and equipment and compliance expenses were

significantly correlated to actual sales, actual revenues, and market value at $p < 0.01$. Table 45 and 46 present the Pearson Correlation information for the pre-FDA and post-FDA scenario, respectively.

Table 45

Pearson Correlations (pre-FDA)

		q0133_0001	COGS_pre	Investment_fac_equip_pre	compliance_pre	Act_sales_pre	Act_revenues_pre	Market_value_pre	Stockholders_pre
q0133_0001	Pearson Correlation	1	-.259	-.468*	-.558**	-.061	-.199	-.184	.392*
	Sig. (1-tailed)		.129	.016	.004	.397	.194	.212	.039
	N	21	21	21	21	21	21	21	21
COGS_pre	Pearson Correlation	-.259	1	.258	.324	-.019	.103	.112	.174
	Sig. (1-tailed)	.129		.130	.076	.467	.328	.314	.225
Investment_fac_equip__pre	Pearson Correlation	-.468*	.258	1	.824**	.311	.452*	.346	-.261
	Sig. (1-tailed)	.016	.130		.000	.085	.020	.062	.127
compliance__pre	Pearson Correlation	-.558**	.324	.824**	1	.508**	.687**	.522**	-.036
	Sig. (1-tailed)	.004	.076	.000		.009	.000	.008	.438
Act_sales_pre	Pearson Correlation	-.061	-.019	.311	.508**	1	.933**	.703**	.375*
	Sig. (1-tailed)	.397	.467	.085	.009		.000	.000	.047
Act_revenues_pre	Pearson Correlation	-.199	.103	.452*	.687**	.933**	1	.772**	.352
	Sig. (1-tailed)	.194	.328	.020	.000	.000		.000	.059
Market_value_pre	Pearson Correlation	-.184	.112	.346	.522**	.703**	.772**	1	.565**
	Sig. (1-tailed)	.212	.314	.062	.008	.000	.000		.004
Stockholders_pre	Pearson Correlation	.392*	.174	-.261	-.036	.375*	.352	.565**	1
	Sig. (1-tailed)	.039	.225	.127	.438	.047	.059	.004	

*. Correlation is significant at the 0.05 level (1-tailed).

**. Correlation is significant at the 0.01 level (1-tailed).

Table 46

Pearson Correlations (post-FDA)

		q0134_0001	COGS_post	Investment_fac_equip_post	Compliance_post	Act_sales_post	Act_revenues_post	Market_value_post	Stockholders_post
q0134_0001	Pearson Corr.	1	-.024	-.190	-.263	-.059	-.059	.101	.374*
	Sig. (1-tailed)		.459	.205	.125	.399	.399	.332	.047
	N	21	21	21	21	21	21	21	21
COGS_post	Pearson Corr.	-.024	1	.206	.249	.010	.010	-.082	.089
	Sig. (1-tailed)	.459		.185	.138	.482	.482	.361	.351
Investment_fac_equip_post	Pearson Corr.	-.190	.206	1	.829**	.732**	.732**	.423*	.272
	Sig. (1-tailed)	.205	.185		.000	.000	.000	.028	.116
Compliance_post	Pearson Corr.	-.263	.249	.829**	1	.767**	.767**	.394*	.211
	Sig. (1-tailed)	.125	.138	.000		.000	.000	.039	.180
Act_sales_post	Pearson Corr.	-.059	.010	.732**	.767**	1	1.000**	.552**	.387*
	Sig. (1-tailed)	.399	.482	.000	.000		.000	.005	.041
Act_revenues_post	Pearson Corr.	-.059	.010	.732**	.767**	1.000**	1	.552**	.387*
	Sig. (1-tailed)	.399	.482	.000	.000	.000		.005	.041
Market_value_post	Pearson Corr.	.101	-.082	.423*	.394*	.552**	.552**	1	.749**
	Sig. (1-tailed)	.332	.361	.028	.039	.005	.005		.000
Stockholders_post	Pearson Corr.	.374*	.089	.272	.211	.387*	.387*	.749**	1
	Sig. (1-tailed)	.047	.351	.116	.180	.041	.041	.000	

*. Correlation is significant at the 0.05 level (1-tailed).

**. Correlation is significant at the 0.01 level (1-tailed).

The compliance of the firms after the FDA intervention only had a significant correlation with stockholders' equity ($r = 0.374$, $p < 0.05$) considering a one-tailed assumption due to the skewness of the data in the responses. Similar to the pre-FDA scenario, investment in facility and equipment and compliance expenses were significantly correlated to actual sales, actual revenues, and market value at $p < 0.01$. Compliance expenses was significantly correlated to all other indicators except for COGS and stockholders' equity implying the importance of compliance expense between the indicators in both scenarios.

Since the distribution of the scores was skewed or non-normal as supported by the results of Kolmogorov-Smirnov and Shapiro-Wilk tests, Kendall's Tau correlation coefficient, τ, was used to understand the correlation between the variables. Kendall's Tau is a non-parametric measure that applies to a small number of scores that also rank in a similar manner (Field, 2009). The limited number of completed surveys of 21 also signaled the use of Kendall's correlation coefficient, τ.

Of the seven financial indicators and following Kendall's correlation coefficient, τ, the compliance of the firms prior to the FDA intervention had a significant correlation at $p < 0.05$ with two of them considering a one-tailed assumption due to the skewness of the data in the responses. Investment in facility and equipment ($r = |-0.432|$, $p < 0.05$) and compliance expenses ($r = |-0.497|$, $p < 0.01$) were significantly correlated to compliance of the firms. Also, facility and equipment and compliance expenses were significantly correlated to actual sales, actual revenues, and market value at $p < 0.01$. Table 47 presents Kendall's correlation coefficient, τ for the pre-FDA intervention.

Table 47

Kendall's correlation coefficient, τ (pre-FDA)

		q0133_0001	COGS_pre	Investment_fac_equip__pre	compliance__pre	Act_sales_pre	Act_revenues_pre	Market_value_pre	Stockholders_pre
q0133_0001	Corr. Coeff.	1.000	-.253	-.432*	-.497**	-.061	-.201	-.193	.338
	Sig. (1-tailed)	.	.110	.017	.008	.386	.170	.176	.051
	N	21	21	21	21	21	21	21	21
COGS_pre	Corr. Coeff.	-.253	1.000	.235	.308	-.067	.067	.081	.158
	Sig. (1-tailed)	.110	.	.123	.069	.375	.375	.348	.220
Investment_fac_equip__pre	Corr. Coeff.	-.432*	.235	1.000	.816**	.367*	.501**	.406*	-.111
	Sig. (1-tailed)	.017	.123	.	.000	.038	.008	.023	.292
compliance__pre	Corr. Coeff.	-.497**	.308	.816**	1.000	.565**	.713**	.568**	.107
	Sig. (1-tailed)	.008	.069	.000	.	.004	.000	.003	.302
Act_sales_pre	Corr. Coeff.	-.061	-.067	.367*	.565**	1.000	.921**	.731**	.418*
	Sig. (1-tailed)	.386	.375	.038	.004	.	.000	.000	.023
Act_revenues_pre	Corr. Coeff.	-.201	.067	.501**	.713**	.921**	1.000	.815**	.388*
	Sig. (1-tailed)	.170	.375	.008	.000	.000	.	.000	.032
Market_value_pre	Corr. Coeff.	-.193	.081	.406*	.568**	.731**	.815**	1.000	.570**
	Sig. (1-tailed)	.176	.348	.023	.003	.000	.000	.	.003
Stockholders_pre	Corr. Coeff.	.338	.158	-.111	.107	.418*	.388*	.570**	1.000
	Sig. (1-tailed)	.051	.220	.292	.302	.023	.032	.003	.

*. Correlation is significant at the 0.05 level (1-tailed).

**. Correlation is significant at the 0.01 level (1-tailed).

The compliance of the firms after the FDA intervention had no significant correlation with any of the financial indicators considering a one-tailed assumption due to the skewness of the data in the responses. Similar to the pre-FDA scenario, investment in facility and equipment and compliance expenses were significantly correlated to actual sales, actual revenues, and market value at $p < 0.01$. Compliance expenses was significantly correlated to all other indicators except for COGS and stockholders' equity. Table 48 presents Kendall's correlation coefficient, τ.

Table 48

Kendall's correlation coefficient, τ (post-FDA)

		q0134_0001	COGS_post	Investment_fac_equip_post	Compliance_post	Act_sales_post	Act_revenues_post	Market_value_post	Stockholders_post
q0134_0001	Corr. Coeff.	1.000	-.033	-.212	-.248	-.059	-.059	.067	.329
	Sig. (1-tailed)	.	.436	.154	.125	.388	.388	.373	.055
	N	21	21	21	21	21	21	21	21
COGS_post	Corr. Coeff.	-.033	1.000	.227	.269	.015	.015	-.046	.085
	Sig. (1-tailed)	.436	.	.136	.104	.470	.470	.412	.339
Investment_fac_equip_post	Correlation Coefficient	-.212	.227	1.000	.858**	.728**	.728**	.422*	.246
	Sig. (1-tailed)	.154	.136	.	.000	.000	.000	.021	.117
Compliance_post	Corr. Coeff.	-.248	.269	.858**	1.000	.779**	.779**	.420*	.213
	Sig. (1-tailed)	.125	.104	.000	.	.000	.000	.025	.160
Act_sales_post	Corr. Coeff.	-.059	.015	.728**	.779**	1.000	1.000**	.546**	.327
	Sig. (1-tailed)	.388	.470	.000	.000	.	.	.004	.056
Act_revenues_post	Corr. Coeff.	-.059	.015	.728**	.779**	1.000**	1.000	.546**	.327
	Sig. (1-tailed)	.388	.470	.000	.000	.	.	.004	.056
Market_value_post	Corr. Coeff.	.067	-.046	.422*	.420*	.546**	.546**	1.000	.734**
	Sig. (1-tailed)	.373	.412	.021	.025	.004	.004	.	.000
Stockholders_post	Corr. Coeff.	.329	.085	.246	.213	.327	.327	.734**	1.000
	Sig. (1-tailed)	.055	.339	.117	.160	.056	.056	.000	.

**. Correlation is significant at the 0.01 level (1-tailed).

*. Correlation is significant at the 0.05 level (1-tailed).

The null hypothesis, $H2_0$, was rejected for RQ2 in the pre-FDA intervention since several correlations were proven to be significant to at least $p < 0.05$. The Kendall's correlation coefficient, τ indicated that prior to the FDA intervention there were two financial indicators that influence the compliance of the firms with the FDA regulations. Investment in facility and equipment and compliance expenses were significantly correlated to the level of compliance. Also, investment in facility and equipment, as well as compliance expenses, correlated significantly with sales, revenues, and market value with $p < 0.01$.

The test for the null hypothesis, $H2_0$, for RQ2 was difficult to be assessed for the post-FDA scenario. The limited number of participants was also a factor not allowing a definite result. The Pearson correlation indicated that the compliance of the firms had a significant correlation with stockholders' equity ($p < 0.05$). For the Kendall's correlation coefficient, τ, the compliance of the firms had no significant correlation with any of the financial indicators. The stockholders' equity had a p significance value equal to 0.055. The Kendall's correlation coefficient indicated that investment in facility and equipment and compliance expenses had significant correlations with actual sales, actual revenues, and market value at $p < 0.01$. If the interdependencies between the indicators were used to imply that complince expenses impact actual sales and actual revenues, the null hypothesis could be rejected.

Research Question 3 (RQ3). To what extent, if any, do financial indicators (independent) impact compliance (dependent) with FDA regulations at the pharmaceutical firms in the United States?

- $H3_0$: $\beta_1 = \beta_2 = \ldots = \beta_7 = 0$. There is no impact in compliance with FDA related to seven financial indicators at pharmaceutical firms, as a result of FDA enforcement actions in the United States.
- $H3_1$: At least one $\beta \neq 0$. There is an impact in compliance with FDA related to at least one of the seven financial indicators before and after the FDA enforcement actions in the United States.

To address RQ3 and the null test, regression analyses were conducted to establish a model with the financial indicators as predictors of level of compliance of the firms with the FDA regulations. The regression analyses were performed using SPSS for both scenarios: pre-FDA and post-FDA. All assumptions were assessed to understand the robustness of the models.

Assumptions for Multiple Regression Analysis. For regression analysis, there were several assumptions that needed to be met. Meeting the assumptions allowed assessing if the conclusions were true for a wider population. For a regression model to generalize beyond the sample population, assumptions have to be met (Field, 2009). The assumptions were assessed for both scenarios: pre-FDA and post-FDA interventions. The assessment of the assumptions was:

1) Variable types: All predictor variables were quantitative and the outcome variable was quantitative: continuous and unbounded.

2) Non-zero variance: The predictors should had variation in value. They did not have variances of 0.

3) Sample Size: The ratio of predictors to cases was expected to be significant because of its impact on the value of R. These assumption was not met.

4) No perfect multicollinearity: There was no perfect linear relationship between two or more of the predictors in the pre-FDA scenario. The predictor variables did not highly correlated. For the post-FDA, actual sales and actual revenues were perfect correlated, SPSS removed actual revenues in the post-FDA model.

5) Predictors are not correlated with external variables: External variables could be present. In the model, not all contribution that could significantly influence the outcome was identified. This assumption was not met.

6) Homoscedasticity: At each level of the predictor variable(s), the variance of the residual terms were constant. The SPSS graphs supported this assumption.

7) Independent errors: For any two observations the residual terms should be independent. This assumption tested whether adjacent residuals are correlated. The test statistic was allow to vary between 0 and 4 with a value of 2 meaning that the residuals were uncorrelated.

8) Normally distributed errors: This assumption indicates that the differences between the model and the observed data are most frequently zero or very close to zero. The SPSS graphs did not support this assumption.

9) Independence: All of the values of the dependent variable were independent of each other.

10) Linearity: The mean values of the dependent variable were represented in a reasonable spread indicating a straight line. Assumption met.

The dependent variable was the level of compliance as indicated in the main survey. All 21 participants indicated that their firms had at least one FDA intervention in the last 5-6 years. The FDA interventions consisted of No Action Indicated, Voluntary Action Indicated, and Official Action indicated. The predictors or independent variables were seven. Similar to the pilot study, in the main survey, the participants provided to their best recollection the tendencies for the financial indicators regarding the FDA interventions. As indicated in the Data Treatment section, missing values from the participants were noted as no change to avoid influencing the tendencies of the independent variables. The variables were listed in Table 49 and Table 50.

Table 49

Variables and Descriptive Statistics

	Mean	Std. Deviation	N
Level of Compliance pre-FDA	5.9524	.58959	21
COGS_pre	.0952	.62488	21
Investment_fac_equip_pre	.7619	.76842	21
compliance_pre	.6667	.65828	21
Act_sales_pre	.5714	.59761	21
Act_revenues_pre	.6190	.58959	21
Market_value_pre	.5238	.67964	21
Stockholders_pre	.2381	.70034	21

Table 50

Variables and Descriptive Statistics

	Mean	Std. Deviation	N
Level of Compliance post-FDA	6.0476	.58959	21
COGS_post	.1905	.67964	21
Investment_fac_equip_post	.5238	.67964	21
Compliance_post	.5714	.50709	21
Act_sales_post	.4762	.67964	21
Act_revenues_post	.4762	.67964	21
Market_value_post	.1905	.67964	21
Stockholders_post	.0476	.66904	21

The descriptive statistics generated by SPSS provided a correlation matrix for each FDA scenario. The matrix provided three elements: Pearson correlation between the variables, the significance of the correlation, and the number of cases included in the assessment. In Table 51, the correlation matrix lists the results for the pre-FDA scenario of the 21 cases or completed questionnaires. The three variables with a high correlation with the level of compliance of the firms were investment in facility and equipment ($r = |-0.468|$, $p < 0.05$), compliance expenses ($r = |-0.558|$, $p < 0.01$) and stockholders' equity ($r = 0.392$, $p < 0.05$).

Table 51

Variables and Descriptive Statistics

		q0133_0001	COGS_pre	Investment_fac_equip__pre	compliance__pre	Act_sales_pre	Act_revenues_pre	Market_value_pre	Stockholders_pre
Pearson Correlation	q0133_0001	1.000	-.259	-.468	-.558	-.061	-.199	-.184	.392
	COGS_pre	-.259	1.000	.258	.324	-.019	.103	.112	.174
	Investment_fac_equip__pre	-.468	.258	1.000	.824	.311	.452	.346	-.261
	compliance__pre	-.558	.324	.824	1.000	.508	.687	.522	-.036
	Act_sales_pre	-.061	-.019	.311	.508	1.000	.933	.703	.375
	Act_revenues_pre	-.199	.103	.452	.687	.933	1.000	.772	.352
	Market_value_pre	-.184	.112	.346	.522	.703	.772	1.000	.565
	Stockholders_pre	.392	.174	-.261	-.036	.375	.352	.565	1.00
Sig. (1-tailed)	q0133_0001	.	.129	.016	.004	.397	.194	.212	.039
	COGS_pre	.129	.	.130	.076	.467	.328	.314	.225
	Investment_fac_equip__pre	.016	.130	.	.000	.085	.020	.062	.127
	compliance__pre	.004	.076	.000	.	.009	.000	.008	.438
	Act_sales_pre	.397	.467	.085	.009	.	.000	.000	.047
	Act_revenues_pre	.194	.328	.020	.000	.000	.	.000	.059
	Market_value_pre	.212	.314	.062	.008	.000	.000	.	.004
	Stockholders_pre	.039	.225	.127	.438	.047	.059	.004	.

As indicated in the assessment of the financial indicators, the compliance of the firms before the FDA intervention had a significant correlation at $p < 0.05$ with three of the indicators considering a one-tailed assumption due to the skewness of the data in the responses. Investment in facility and equipment, compliance expenses, and stockholders equity were significantly correlated to compliance ($p < 0.05$). Also, compliance expenses were significantly correlated to facility and equipment, actual sales, actual revenues, and market value at $p < 0.01$. Since none of the correlation between different variables was high ($r = 0.9$), the possibility of multicollinearity was considered low (Field, 2009).

In Table 52, the correlation matrix lists the results for the post-FDA scenario of the 21 cases or completed questionnaires. Two variables with a high correlation with the level of compliance of the firms were compliance expenses ($r = |-0.263|$, $p = 0.125$) and stockholders' equity ($r = 0.374$, $p < 0.05$). The compliance of the firms after the FDA intervention only had a significant correlation with stockholders' equity ($p < 0.05$) considering a one-tailed assumption due to the skewness of the data in the responses. Compliance expenses were significantly correlated to facility and equipment, actual sales, actual revenues, and market value at $p < 0.05$. In the case of the post-FDA scenario, two variables had a correlation of $r = 1.0$ generating the possibility of multicollinearity (Field, 2009). As a result, SPSS removed the financial indicator labeled as actual revenues to compensate and improving the possibility of complying with the assumption of multicollinearity.

Table 52

Variables and Descriptive Statistics

		q0134_0001	COGS_post	Investment_fac_equip_post	Compliance_post	Act_sales_post	Act_revenues_post	Market_value_post	Stockholders_post
Pearson Correlation	q0134_0001	1.000	-.024	-.190	-.263	-.059	-.059	.101	.374
	COGS_pos	-.024	1.000	.206	.249	.010	.010	-.082	.089
	Investment_fac_equip_post	-.190	.206	1.000	.829	.732	.732	.423	.272
	Compliance_post	-.263	.249	.829	1.000	.767	.767	.394	.211
	Act_sales_post	-.059	.010	.732	.767	1.000	1.000	.552	.387
	Act_revenues_post	-.059	.010	.732	.767	1.000	1.000	.552	.387
	Market_value_post	.101	-.082	.423	.394	.552	.552	1.000	.749
	Stockholders_post	.374	.089	.272	.211	.387	.387	.749	1.00
Sig. (1-tailed)	q0134_0001	.	.459	.205	.125	.399	.399	.332	.047
	COGS_post	.459	.	.185	.138	.482	.482	.361	.351
	Investment_fac_equip_post	.205	.185	.	.000	.000	.000	.028	.116
	Compliance_post	.125	.138	.000	.	.000	.000	.039	.180
	Act_sales_post	.399	.482	.000	.000	.	.000	.005	.041
	Act_revenues_post	.399	.482	.000	.000	.000	.	.005	.041
	Market_value_post	.332	.361	.028	.039	.005	.005	.	.000
	Stockholders_post	.047	.351	.116	.180	.041	.041	.000	.

In the next step, following the hierarchical method of assessing the independent variables, the predicting model was evaluated for both FDA scenarios. For the seven financial indicators, a total of seven models in a hierarchical order were developed in SPSS. Table 53 presented the model for the pre-FDA scenario. The correlation R between the variables and the prediction R^2 of how much of the dependent variable is contributed by each predictor were obtained. Also, the assumption of independent errors was verified with the Durbin–Watson statistic. The value of 1.53 was obtained, indicating that the assumption of independent errors could be considered as met. In relation to external variables, the R^2 values of model 7 indicated that the predictors accounted for 60.7% contribution to the outcome variable, indicating that there are other external variables not included, violating this assumption.

Table 53

Model Summary[h] pre-FDA

					Change Statistics					
Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	R Square Change	F Change	df1	df2	Sig. F Change	Durbin-Watson
1	.259[a]	.067	.018	.58435	.067	1.361	1	19	.258	
2	.489[b]	.239	.155	.54211	.172	4.076	1	18	.059	
3	.564[c]	.319	.198	.52789	.079	1.982	1	17	.177	
4	.617[d]	.381	.226	.51858	.063	1.616	1	16	.222	
5	.619[e]	.383	.178	.53457	.002	.057	1	15	.815	
6	.622[f]	.386	.124	.55198	.003	.069	1	14	.797	
7	.779[g]	.607	.395	.45868	.220	7.275	1	13	.018	1.528

a. Predictors: (Constant), COGS_pre
b. Predictors: (Constant), COGS_pre, Investment_fac_equip__pre
c. Predictors: (Constant), COGS_pre, Investment_fac_equip__pre, compliance__pre
d. Predictors: (Constant), COGS_pre, Investment_fac_equip__pre, compliance__pre, Act_sales_pre
e. Predictors: (Constant), COGS_pre, Investment_fac_equip__pre, compliance__pre, Act_sales_pre, Act_revenues_pre
f. Predictors: (Constant), COGS_pre, Investment_fac_equip__pre, compliance__pre, Act_sales_pre, Act_revenues_pre, Market_value_pre
g. Predictors: (Constant), COGS_pre, Investment_fac_equip__pre, compliance__pre, Act_sales_pre, Act_revenues_pre, Market_value_pre, Stockholders_pre
h. Dependent Variable: q0133_0001

The adjusted R^2 provided a way to understand how well the model could generalize the scenario under review. The smallest the difference of the adjustment the better the possibility for the model to represent the population, not just the sample. In model 7, the $R^2 = 0.607$ was adjusted to 0.395 or 39.5% representing a reduction of 0.212 or 21.2% of the overall contribution of the seven variables. The stockholder's equity added almost 32.1% in contribution in comparison to the previous six predictors. Investment in facilities and equipment was the second largest contributor with 13.7%.

These two predictors contributed 45.8% of the total 60.7% of all the financial indicators. The *F*- ratio provided the significance of the change. Only model 7 had a significant *F*-ratio of 7.28, $p < 0.05$. For model 2, COGS and investment on facilities and equipment had a significance at $p < 0.59$, but still above the expectations.

For the post-FDA scenario, the hierarchical method of assessing the independent variables was also followed. For the seven financial indicators, a total of seven models in a hierarchical order were developed in SPSS. Table 54 presents the model for the post-FDA scenario. The correlation R between the variables and the prediction R^2 of how much of the dependent variable is contributed by each predictor were obtained. Also, the assumption of independent errors was verified with the Durbin–Watson statistic. The value of 2.18 was obtained, indicating that the assumption of independent errors could be considered as met. In relation to external variables, the R^2 values of model 6 indicated that the predictors accounted for about 30% contribution to the outcome variable, indicating that there are other external variables not included, violating this assumption.

Table 54

Model Summary[g] post-FDA

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					Durbin-Watson
					R Square Change	F Change	df1	df2	Sig. F Change	
1	.024[a]	.001	-.052	.60474	.001	.011	1	19	.919	
2	.191[b]	.036	-.071	.61007	.036	.669	1	18	.424	
3	.271[c]	.073	-.090	.61560	.037	.678	1	17	.422	
4	.362[d]	.131	-.086	.61448	.058	1.062	1	16	.318	
5	.394[e]	.155	-.126	.62573	.024	.430	1	15	.522	
6	.547[f]	.299	-.001	.58987	.144	2.879	1	14	.112	2.175

a. Predictors: (Constant), COGS_post
b. Predictors: (Constant), COGS_post, Investment_fac_equip_post
c. Predictors: (Constant), COGS_post, Investment_fac_equip_post, Compliance_post
d. Predictors: (Constant), COGS_post, Investment_fac_equip_post, Compliance_post, Act_sales_post
e. Predictors: (Constant), COGS_post, Investment_fac_equip_post, Compliance_post, Act_sales_post, Market_value_post
f. Predictors: (Constant), COGS_post, Investment_fac_equip_post, Compliance_post, Act_sales_post, Market_value_post, Stockholders_post
g. Dependent Variable: q0134_0001

The adjusted R^2 provided a way to understand how well the model could generalize the scenario under review. The smallest the difference of the adjustment the better the possibility for the model to represent the population, not just the sample. In Model 6, the $R^2 = 0.299$ was adjusted to -0.001 representing a very significant adjustment to the overall contribution of the seven variables. This adjustment implied that the model did not generalized beyond the sample. The stockholder's equity contributed with 14.4% in comparison to the 15.5% of the previous five predictors. Actual sales were the second largest contributor with 5.8%. These two predictors contributed 20.2% of the total 29.9% of the financial indicators for the post-FDA scenario. The *F*-ratio provided the

significance of the change. None of the post-FDA models had a significance value less than 0.05 affecting the robustness of the models.

The next test performed in SPSS was the calculation of the ANOVA for the seven models. The ANOVA challenged whether the models were better predictors of the outcome than the guess based on the average of the means. The *F*-ratio indicated the ratio of the accuracy of the model versus the means (Field, 2009). For the pre-FDA scenario, all values of F were above one signaling that the model's fits are better predictors than the guess from the means. In Table 55, only model 7 has an *F*-ratio that was significant to $p < 0.048$ indicating the low probability of the outcome could happen by chance. Models 2, 3, and 4 had *F*-ratios that were non-significance at less than 0.09.

Table 55

ANOVA [a] pre-FDA

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	.465	1	.465	1.361	.258[b]
	Residual	6.488	19	.341		
	Total	6.952	20			
2	Regression	1.663	2	.831	2.829	.085[c]
	Residual	5.290	18	.294		
	Total	6.952	20			
3	Regression	2.215	3	.738	2.650	.082[d]
	Residual	4.737	17	.279		
	Total	6.952	20			
4	Regression	2.650	4	.662	2.463	.087[e]
	Residual	4.303	16	.269		
	Total	6.952	20			
5	Regression	2.666	5	.533	1.866	.160[f]
	Residual	4.287	15	.286		
	Total	6.952	20			
6	Regression	2.687	6	.448	1.470	.258[g]
	Residual	4.266	14	.305		
	Total	6.952	20			
7	Regression	4.217	7	.602	2.864	.048[h]
	Residual	2.735	13	.210		
	Total	6.952	20			

a. Dependent Variable: q0133_0001

b. Predictors: (Constant), COGS_pre

c. Predictors: (Constant), COGS_pre, Investment_fac_equip__pre

d. Predictors: (Constant), COGS_pre, Investment_fac_equip__pre, compliance__pre

e. Predictors: (Constant), COGS_pre, Investment_fac_equip__pre, compliance__pre, Act_sales_pre

f. Predictors: (Constant), COGS_pre, Investment_fac_equip__pre, compliance__pre, Act_sales_pre, Act_revenues_pre

The ANOVA for the six models for the post-FDA intervention are presented in Table 56. The ANOVA challenged whether the models were better predictors of the outcome than the guess based on the average means. The *F*-ratio indicated the ratio of the accuracy of the model versus the means (Field, 2009). For the post-FDA scenario, all

values of *F* are below one signaling that the model's fits are not good predictors than the guess from the means. None of the models in the post-FDA scenario had an *F*-ratio that was significant indicating that the outcome could happen by chance.

Table 56

ANOVA [a] post-FDA

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	.004	1	.004	.011	.919[b]
	Residual	6.948	19	.366		
	Total	6.952	20			
2	Regression	.253	2	.127	.340	.716[c]
	Residual	6.699	18	.372		
	Total	6.952	20			
3	Regression	.510	3	.170	.449	.721[d]
	Residual	6.442	17	.379		
	Total	6.952	20			
4	Regression	.911	4	.228	.603	.666[e]
	Residual	6.041	16	.378		
	Total	6.952	20			
5	Regression	1.079	5	.216	.551	.735[f]
	Residual	5.873	15	.392		
	Total	6.952	20			
6	Regression	2.081	6	.347	.997	.465[g]
	Residual	4.871	14	.348		
	Total	6.952	20			

a. Dependent Variable: q0134_0001
b. Predictors: (Constant), COGS_post
c. Predictors: (Constant), COGS_post, Investment_fac_equip_post
d. Predictors: (Constant), COGS_post, Investment_fac_equip_post, Compliance_post
e. Predictors: (Constant), COGS_post, Investment_fac_equip_post, Compliance_post, Act_sales_post
f. Predictors: (Constant), COGS_post, Investment_fac_equip_post, Compliance_post, Act_sales_post, Market_value_post
g. Predictors: (Constant), COGS_post, Investment_fac_equip_post, Compliance_post, Act_sales_post, Market_value_post, Stockholders_post

The model parameters were then obtained by SPSS. For the pre-FDA scenario, the model discussion was focused on model 7 since this model was the only one with significance *F*-ratio in the ANOVA assessment. Table 57 presents the slope values, B, for each predictor (financial indicator). Stockholders' equity was the only B value that was significant ($p < 0.05$) indicating a strong contribution to the outcome. The smallest the significance of the B values the stronger the contribution of the prediction to the outcome (Field, 2009). Regarding the standardized beta (labeled as Beta, β), Stockholders equity (β = 0.760), compliance expense (β = |-0.754|), and market value (β = |-0.624|) have the largest impact on the standard deviation of the outcome, the level of compliance of the firms.

Table 57

Model 7 Parameters [a] pre-FDA

		Unstandardized Coefficients		Standardized Coefficients		
Model		B	Std. Error	Beta	t	Sig.
7	(Constant)	6.065	.166		36.466	.000
	COGS_pre	-.218	.193	-.231	-1.127	.280
	Investment_fac_equip__pre	.365	.269	.476	1.356	.198
	compliance__pre	-.676	.393	-.754	-1.718	.110
	Act_sales_pre	.029	.566	.029	.051	.960
	Act_revenues_pre	.316	.733	.316	.431	.674
	Market_value_pre	-.541	.295	-.624	-1.834	.090
	Stockholders_pre	.640	.237	.760	2.697	.018

Dependent Variable: q0133_0001

To assess how close is the B value of the sample to the B value of the population, a level of confidence of 95% was selected as shown in Table 58. In model 7, only stockholders' equity had a small spread between the upper and lower boundaries of the confidence limit and not crossing the value of zero. Having only one indicator with these characteristics implied that the model was not strong for the prediction of the outcome of the model. Regarding the Collinearity Statistics, actual revenues had a VIF value significantly above 10 (17.732) with a tolerance below 0.2 (0.056). For actual sales, the VIF value was slightly above 10 (10.872) with a tolerance below 0.1 (0.092). These results highlighted a potential problem in meeting the assumption of collinearity.

Table 58

pre-FDA Confidence and Collinearity

		95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
Model		Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
7	(Constant)	5.705	6.424					
	COGS_pre	-.636	.200	-.259	-.298	-.196	.720	1.389
	Investment_fac_equip__pre	-.216	.947	-.468	.352	.236	.246	4.068
	compliance__pre	-1.526	.174	-.558	-.430	-.299	.157	6.376
	Act_sales_pre	-1.194	1.252	-.061	.014	.009	.092	10.872
	Act_revenues_pre	-1.267	1.898	-.199	.119	.075	.056	17.732
	Market_value_pre	-1.178	.096	-.184	-.453	-.319	.262	3.820
	Stockholders_pre	.127	1.152	.392	.599	.469	.381	2.622

Dependent Variable: q0133_0001

Table 59 presents the slope values, B, for each predictor (financial indicator). None of the B values had a significance ($p < 0.05$) indicating that none of the B values had a strong contribution to the outcome. The smallest the significance of the B values was for the stockholders' equity ($p = 0.112$). The smallest the significance value, the stronger the contribution of the prediction to the outcome (Field, 2009). Regarding the standardized beta (labeled as Beta, β), stockholders' equity (β = 0.611) had the largest impact on the standard deviation of the outcome, the level of compliance of the firms.

Table 59

Model 6 Parameters [a] post-FDA

Model		Unstandardized Coefficients		Standardized Coefficients		
		B	Std. Error	Beta	t	Sig.
6	(Constant)	6.266	.202		31.000	.000
	COGS_post	.004	.222	.004	.016	.988
	Investment_fac_equip_post	-.066	.363	-.076	-.182	.858
	Compliance_post	-.433	.546	-.372	-.792	.441
	Act_sales_post	.178	.356	.205	.500	.625
	Market_value_post	-.252	.339	-.291	-.743	.470
	Stockholders_post	.538	.317	.611	1.697	.112

Dependent Variable: q0134_0001[a]

To assess how close is the B value of the sample to the B value of the population, a level of confidence of 95% was selected as shown in Table 60. In model 6, none of the

predictors had a spread between the boundaries not crossing the value of zero. Having no indicator with these characteristics implied that the model was not strong for the prediction of the outcome of the model. Regarding the Collinearity Statistics, none of the VIF value was significantly above 10, and all tolerances were above 0.1 with a tolerance below 0.2. These results implied that there should not be a concern of not meeting the assumption of collinearity for the post-FDA scenario after excluding actual revenues from the predictors.

Table 60

post-FDA Confidence and Collinearity

		95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
Model		Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
6	(Constant)	5.833	6.700					
	COGS_post	-.473	.480	-.024	.004	.004	.762	1.312
	Investment_fac_equip_post	-.845	.713	-.190	-.049	-.041	.286	3.501
	Compliance_post	-1.605	.739	-.263	-.207	-.177	.227	4.412
	Act_sales_post	-.585	.942	-.059	.133	.112	.297	3.365
	Market_value_post	-.980	.476	.101	-.195	-.166	.327	3.060
	Stockholders_post	-.142	1.219	.374	.413	.380	.386	2.591

To further assess the assumption of collinearity, a diagnostic was performed by SPSS for both scenarios: pre-FDA and post-FDA. In both scenarios, the Eigenvalue for

COGS was higher than one. Only Eigenvalues below one were considered for the assessment of Variance Proportions. For the pre-FDA in Table 61, several indicators had their highest value in dimension 8 implying that the model did not meet the assumption of no multicollinearity. For the post-FDA in Table 62, investment in facility and equipment and actual sales had their highest value in dimension 6 implying a challenge to the assumption of no multicollinearity.

Table 61

Collinearity[a] pre-FDA

			Variance Proportions							
Dimension	Eigenvalue	Condition Index	(Constant)	COGS_pre	Investment_fac_equip__pre	compliance__pre	Act_sales_pre	Act_revenues_pre	Market_value_pre	Stockholders_pre
1	5.090	1.000	.01	.00	.00	.00	.00	.00	.00	.00
2	1.125	2.127	.00	.01	.02	.01	.00	.00	.01	.17
3	.995	2.261	.01	.62	.00	.00	.00	.00	.00	.02
4	.376	3.678	.74	.00	.00	.00	.01	.00	.03	.04
5	.219	4.826	.02	.18	.10	.01	.07	.02	.12	.11
6	.112	6.747	.18	.15	.06	.09	.00	.00	.74	.62
7	.067	8.691	.05	.02	.73	.52	.07	.01	.01	.03
8	.016	17.662	.00	.01	.08	.36	.85	.97	.08	.00

a. Dependent Variable: q0133_0001

Table 62

Collinearity [a] post-FDA

			Variance Proportions						
Dimension	Eigenvalue	Condition Index	(Constant)	COGS_post	Investment_fac_equip_post	Compliance_post	Act_ sales _post	Market _value _ post	Stockholders_post
1	3.871	1.000	.01	.01	.01	.01	.01	.01	.01
2	1.424	1.649	.03	.06	.00	.00	.00	.06	.11
3	.881	2.096	.01	.63	.00	.00	.01	.00	.05
4	.415	3.054	.67	.01	.06	.00	.05	.00	.04
5	.190	4.508	.01	.09	.00	.00	.07	.90	.67
6	.149	5.097	.00	.12	.55	.00	.63	.01	.05
7	.069	7.470	.27	.09	.37	.99	.22	.02	.07

a. Dependent Variable: q0134_0001

The next step was to assess if any case had a significant influence or should be considered as an outlier. Using SPSS, the case summary analysis was applied to both scenarios: pre-FDA and post-FDA. In the pre-FDA scenario for two cases, 5 and 18, the Mahalanobis Distance values were 19.05 but the corresponding Centered Leverage Value were within the expected value of 0.36. The two cases were excluded from the Cook's and DFBeta calculations by SPSS indicating the over influence of these two cases in the model. In the post-FDA scenario, all cases were included with values of Cook at or below +/-1 and values of DFBeta in expectations implying that all cases could be considering not having undue influence in the regression model for the post-FDA scenario.

For the assumptions of linearity and homoscedasticity, some of the plots assessed under SPSS could be considered as supporting these assumptions. For the residual

normality, the graphs for both scenario divert from the straight line implying lack of normality. Since not all assumptions were met, the regression models for the financial indicators cannot be used to generalize beyond the sample of the study in either the pre-FDA or the post-FDA intervention.

Reputation of the Firms and Management Changes.

The last two questions in the financial sections of the main study questionnaire requested the participants to provide their opinion regarding the potential outcomes from the FDA interventions or actions. These responses projected the impact on the firms' reputation and the change management process resulting from the FDA's intervention or actions. Comparing results in Table 63 and Table 64 allowed to conduct the assessment.

Table 63

Before FDA: Reputation and Management Change

Answer Options	Decrease of -50%	Decrease of -5% to -49%%	No Change	Increase of +5% to +49%%	Increase of -+50%	Response Count
Reputation of the Firm	0	1	12	6	2	21
Management change	0	1	9	8	3	21
answered question						21
skipped question						0

Table 64

After FDA: Reputation and Management Change

Answer Options	Decrease of -50%	Decrease of -5% to -49%%	No Change	Increase of +5% to +49%%	Increase of -+50%	Response Count
Reputation of the Firms	0	2	10	6	0	18
Management change	0	3	8	6	2	18
answered question						18
skipped question						3

FDA Experience.

For the FDA experience of the firms, only the 21 completed questionnaires addressed the last six questions out of 133 total questions. This questions collected information regarding the firms experience with the FDA in the past six years from 2010 through 2015. The 21 responders indicated that their firms had FDA audits. The responses were assumed to be based on the best recollection of each of the participants. In all years, the FDA issued 483 observations. In five occasions, the outcome of the FDA intervention were audits with Official Action Indicated. None of the 21 participants reported warning letters nor consent decrees. To assess the overall result of the responses, in the last two question the participants were asked to compare the firms' compliance position with the FDA's CGMP regulations before and after the FDA's interventions. The overall average of firm's compliance reflected a favorable increase of 1.7% from 5.95 to 6.05 in a scale of a maximum value of 7.

A dependent-means *t*-test was applied to the two scenarios' means: pre-FDA and post-FDA considering that the same participants took part in both scenarios. Through SPSS, a paired-samples *t*-test was conducted. The Pearson coefficient for the two scenarios was large at $r = 0.870$, $p < 0.01$ implying that the same population was used for the comparison. In Table 65, the results of the paired sample test are shown.

Table 65

Paired Sample Test

		Paired Differences							
					95% Confidence Interval of the Difference				
		Mean	Std. Deviation	Std. Error Mean	Lower	Upper	t	df	Sig. (2-tailed)
Pair 1	q0133_0001 - q0134_0001	-.09524	.30079	.06564	-.23216	.04168	-1.451	20	.162

The sign of the Mean was negative indicating that the mean of the compliance of the firms after the FDA intervention was larger than before the FDA intervention. The standard error was small at 0.066 with a negative *t*- test confirming that the mean of the post-FDA was larger than the pre-FDA scenario. The level of compliance increased after the FDA intervention as indicated by the means of the participants. Since the expected compliance trend was to increase in value, the two-tailed significance was divided by two to obtained a one-tailed non-significance value of $p = 0.081$. The value of *p* represented the probability that the value of *t* of -1.451 could be experienced if the null hypothesis could not be rejected (no difference between these means). The prediction of this test

indicated that the compliance of the firms should increase by the FDA intervention, at $t(20) = -1.451$, $p = 0.081$.

The 95% confidence interval of the differences for this *t*- test indicated the frame within which the true mean difference could be found (Field, 2009). This test's true mean difference lied between -0.232 and + 0.042. The problem with this interval was that it contained zero between the two boundaries implying that the true value of the differences could be zero at 95% confidence limit. I calculated with SPSS at what confident interval limit the true value of the mean difference could be considered as not being zero. At 80% confident interval, the mean differences could be considered as unlikely to be equal to zero.

Inconsistencies Applied to Data Analysis

In the statistical analyses for research questions one and two, the data analysis was consistent with the pilot study. For the financial indicators analysis, the approach was similar for both scenarios: before and after the FDA intervention. No inconsistencies were noted or applied to these analyses. In the case of assumptions, any non-compliance with the regression assumptions was discussed in the data analysis section.

Reliability Analysis of Questionnaire

Analysis of Cronbach's alpha to determine the reliability of the scales from the main study questionnaire was conducted for both scenarios: pre-FDA and post-FDA interventions. The data was analyzed by applying SPSS and by using Field (2009) as a reference. Cronbach's alpha is not a validity measure. The values for Cronbach's alpha range from 0 to 1. Cronbach's alpha provides the means to assess if a given scale item

impacts the overall total subscale reliability. Reversing the phrasing of a negative scale item improved the Cronbach's values.

The main questionnaire was divided into four section for conducting the reliability assessment with the Cronbach's alpha in SPSS. This approach allowed to focus in each major section of the questionnaire depending on the scenario that was under review. The four section were the pre-FDA Likert-type scales, the pre-FDA financial indicators, the post-FDA Likert-type scales, and the post-FDA financial indicators. The four Cronbach's alpha values were above .8. An assessment of the Corrected Item-Total Correlation as well as the Cronbach's alpha if Item Deleted for the four subscales did not provide a substantial improvement to the overall Cronbach's alpha values. Table 66 presents the four subscales and the corresponding Cronbach's alphas.

Table 66

Cronbach's alpha values for the Sub-scales

	Cronbach's alpha	Cronbach's alpha Based on Standardized Items	N of Items
Pre-FDA Likert-type (TPB)	.828	.929	57
Post-FDA Likert-type (TPB)	.855	.939	58
Pre-FDA Financial	.874	.879	9
Post-FDA Financial	.901	.904	9

Research Questions

The two group of predictors used in the study were management behaviors and financial indicators in the two scenarios: pre-FDA and post-FDA interventions. The three

sets of hypotheses related to these predictors were listed below. The dependent variable was the level of compliance with the FDA regulations.

Research Question 1

To what extent, if any, does management behaviors (independent) correlate to compliance (dependent) with FDA regulations at the pharmaceutical firms in the United States?

- $H1_0$: $r = 0$. There is no difference in management behaviors towards compliance at pharmaceutical firms, as a result of FDA enforcement actions in the U.S.
- $H1_1$: $r \neq 0$. There are differences in management behaviors towards compliance at pharmaceutical firms, as a result of FDA enforcement actions in the U.S.

According to TPB, three types of beliefs direct and influence human behavior: beliefs (b), normative beliefs (n), and perceived behavioral control (c) (Ajzen, 2002). The interrelations between these beliefs influence the intention towards a given behavior. Three correlations between the outcome of compliance and the three constructs of the TPB were performed instead of the original strategy of only one correlation. The null hypothesis, $H1_0$, was rejected for RQ1 in the pre-FDA and post-FDA interventions for the three constructs of the TPB. Correlations were found not equal to zero ($r \neq 0$). The significance of the correlations varied and not all met the expectation, $p < 0.05$.

In the Pearson correlation for the pre-FDA intervention, the construct of beliefs (attitudes) had the highest correlation with the outcome of compliance with a value of $r = 0.633$, $p < 0.01$. The other two construct, normative beliefs and perceived behavioral control had non-significant correlations with r values of $r = 0.328$ and $r = 0.183$, respectively. For the post-FDA intervention, the construct of beliefs (attitudes) also had the highest correlation with the outcome of compliance with a value of $r = 0.693$, $p < 0.01$. The other two construct, normative beliefs and perceived behavioral control had non-significant correlations with r values of 0.294 and 0.303, respectively. Also, the construct of behavioral beliefs had a significant correlation with the construct of perceived behavioral control with $r = 0.376$, $p < 0.05$. This last significant correlation differed from the pre-FDA intervention where the correlation was non-significant between these two constructs.

The correlation data indicated a favorable change in correlation between the outcome of compliance and behavioral beliefs (attitude) for before and after the FDA intervention of about 9.5%. The value of r increased from 0.633 to 0.693 for the construct of beliefs (attitude) towards compliance by the participants with significances of $p < 0.01$. The other two independent constructs had non-significant correlations. The perceived behavioral control non-significant correlation with the outcome of compliance also increased by about 65% from the pre-FDA ($r = 0.183$) to the post-FDA scenario ($r = 0.303$). From the limited population that participated in the study, the null hypothesis was rejected for RQ1.

A regression analysis was also conducted to establish if there was a linear model of the three TPB constructs as predictors of the outcome of compliance of the firms with the FDA regulations. For the pre-FDA scenario, the $R^2 = 0.421$ and was adjusted to about 32% for the contribution of the three constructs. The *F*- ratio indicated the significance of the change with $p < 0.05$. For the post-FDA scenario, the $R^2 = 0.492$ was adjusted to 40.2% representing the adjustment to the overall contribution of the three independent variables. The *F*-ratio provided the significance of the change, $p < 0.01$.

Research Question 2

To what extent, if any, do financial indicators (independent) correlate to compliance (dependent) with FDA regulations at the pharmaceutical firms in the United States?

- $H2_o$: $r = 0$. There is no difference in compliance with FDA related to financial indicators at pharmaceutical firms, as a result of FDA enforcement actions in the U.S.
- $H2_1$: $r \neq 0$. There are differences in compliance with FDA related to financial indicators, as a result of FDA enforcement actions in the U.S.

Seven Pearson Correlations were performed with the seven financial indicators to understand the possible correlations between these indicators and the dependent variable outcome of compliance for each scenario: pre-FDA and post-FDA interventions. The basis of the correlations was the firms' level of compliance as indicated by the participants both before and after the FDA intervention. The null hypothesis, $H2_o$, was

rejected for RQ2 in the pre-FDA and post-FDA interventions. Correlations were found that were not equal to zero ($r \neq 0$). The significance of the correlations varied and not all met the expectation, $p < 0.05$.

Pre-FDA Intervention. Of the seven financial indicators, the compliance of the firms prior to the FDA intervention had a significant Pearson correlation at $p < 0.05$ with three of them considering a one-tailed assumption due to the skewness of the data in the responses. Investment in facility and equipment ($r = |-0.468|$, $p < 0.05$), compliance expenses ($r = |-0.558|$, $p < 0.05$), and stockholders' equity ($r = 0.392$, $p < 0.05$) were significantly correlated to compliance. In addition, facility and equipment and compliance expenses were significantly correlated to actual sales, actual revenues, and market value at $p < 0.01$.

Since the distribution of the scores was skewed or non-normal as supported by the results of Kolmogorov-Smirnov and Shapiro-Wilk tests, Kendall's Tau correlation coefficient, τ, was used to understand the correlation between the variables. Of the seven financial indicators and following Kendall's correlation coefficient, τ, the compliance of the firms prior to the FDA intervention had a significant correlation at $p < 0.05$ with two of them considering a one-tailed assumption due to the skewness of the data in the responses. Investment in facility and equipment ($r = |-0.432|$, $p < 0.05$) and compliance expenses ($r = |-0.497|$, $p < 0.01$) were significantly correlated to compliance of the firms. Also, facility and equipment and compliance expenses were significantly correlated to actual sales, actual revenues, and market value at $p < 0.01$. The null hypothesis, $H2_0$, was rejected for RQ2 in the pre-FDA intervention.

Post-FDA Intervention. The compliance of the firms after the FDA intervention only had a significant Pearson correlation with stockholders' equity ($r = 0.374$, $p < 0.05$) considering a one-tailed assumption due to the skewness of the data in the responses. Similar to the pre-FDA scenario, investment in facility and equipment and compliance expenses were significantly correlated to actual sales, actual revenues, and market value at $p < 0.01$. Compliance expenses was significantly correlated to all other indicators except for COGS and stockholders' equity implying the importance of compliance expense between the indicators.

From the Kendall's coefficient, τ, the compliance of the firms had no significant correlation with any of the financial indicators in the post-FDA scenario. The stockholders' equity had a significance value equal to 0.055. The Kendall's correlation coefficient indicated that investment in facility and equipment and compliance expenses had significant correlations with actual sales, actual revenues, and market value at $p < 0.01$. Since the interdependencies between the indicators also indicated that significant correlations between compliance expenses with actual sales and actual revenues, the rejection of the null hypothesis was supported for the RQ2 for the post-FDA intervention.

Research Question 3

To what extent, if any, do financial indicators (independent) impact compliance (dependent) with FDA regulations at the pharmaceutical firms in the United States?

- $H3_0$: $\beta_1 = \beta_2 = \ldots = \beta_7 = 0$. There is no impact in compliance with FDA related to seven financial indicators at pharmaceutical firms, as a result of FDA enforcement actions in the United States.
- $H3_1$: At least one $\beta \neq 0$. There is an impact in compliance with FDA related to at least one of the seven financial indicators before and after the FDA enforcement actions in the United States.

The seven financial indicators for the test of Hypothesis 3 were the cost of goods, investment in facility and equipment, process compliance, actual sales, actual revenues, market value, and stockholder's equity. The regression analyses were directed to test $H3_0$ for pre-FDA and post-FDA. The βs in Hypothesis 3 were the regression coefficients of the following multiple regression equation:

$$Y = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \beta_4 X_4 + \beta_5 X_5 + \beta_6 X_6 + \beta_7 X_7 + \varepsilon \qquad (4)$$

Where,

Y= FDA related compliance

X_1 = Cost of goods

X_2 = Investment

X_3 = Process compliance

X_4 = Change in sales

X_5 = Change in revenues

X_6 = Change in market value of the firms

X_7 = Change in stockholders equity

ε = Error of the regression

The null hypothesis, $H3_0$, was rejected for the pre-FDA and post-FDA scenarios. All indicators had a β value indicating a slope not equal to zero. Since not all assumptions were met, the regression models for the financial indicators cannot be used to generalize beyond the sample of the study in the pre-FDA and post-FDA interventions.

Pre-FDA Intervention. The null hypothesis, $H3_0$, was rejected for the pre-FDA intervention scenario. All indicators had a β value indicating a slope not equal to zero. The $R^2 = 0.607$ was adjusted to 0.395 or 39.5% representing a reduction of 0.212 or 21.2% of the overall contribution of the seven variables. The stockholder's equity added almost 32.1% in contribution in comparison to the previous six predictors. Investment in facilities and equipment was the second largest contributor with 13.7%. The stockholder's equity and investment in facilities and equipment contributed about 45.8% of the total 60.7% of all the financial indicators.

For the ANOVA assessment, all values of *F*-ratio were above one signaling that the model's fits are better predictors than the guess from the means. Also, the model had an *F*-ratio that was significant to $p < 0.048$ indicating the low probability of the outcome could happen by chance. Since not all assumptions were met, the regression model for the financial indicators cannot be used to generalize beyond the sample of the study in the pre-FDA intervention.

Post-FDA Intervention. The null hypothesis, $H3_0$, was rejected for the post-FDA intervention scenario. All indicators had a β value indicating a slope not equal to zero. The stockholders' equity contributed with 14.4% in comparison to the 15.5% of the

previous five predictors. Actual sales were the second largest contributor with 5.8%. These two predictors contributed 21.2% of the total 29.9% of the financial indicators for the post-FDA scenario.

For the ANOVA assessment, all values of *F*-ratio were below one signaling that the model's fits were not better predictors than the guess from the means. None of the models in the post-FDA scenario had an *F*-ratio that was significant indicating that the outcome could happen by chance. Since not all assumptions were met, the regression model for the financial indicators cannot be used to generalize beyond the sample of the study in the pre-FDA intervention.

Regarding the comparison between the pre-FDA and post-FDA scenarios, the contribution of the seven indicators diminished from 60.7% to 29.9%. Other contributors not considered in the initial model impacted the post-FDA scenario like inventory, cost of supplies, and capacity. These potential other financial contributors could have become evident to the participants lowering the model effectiveness after the FDA intervention.

Summary

In Chapter 4, the pilot study, the data collection, the data analysis were discussed. The limited level of participation in the main study was presented with the corresponding demographics. Despite the limited participation, decisions were presented for the three tests of the null hypotheses.

RQ1 considered the three constructs of the theory of plan behavior. The limited participation with 21 completed questionnaires impacted the analysis by limiting the depth of the trends. Considering the correlations of the three constructs of the TPB with

the outcome of compliance, the null hypothesis, $H1_0$, of RQ1 was rejected. Based on the correlation found between the financial indicators with the level of compliance of the firms, the null hypothesis, $H2_0$, for research questions two was rejected for both scenarios: pre-FDA and post-FDA. The slopes in the regression models for RQ3 rejected the null hypothesis, $H3_0$. Both regression models cannot be used to generalize beyond the sample of the study.

Chapter 5 presents the conclusion and potential interdependencies between the different data analyses that were conducted in Chapter 4. Limitations that were found and potential areas for future studies were discussed. The conclusion of the study was presented.

Chapter 5: Discussion, Conclusions, and Recommendations

This quantitative study sought to learn to what extent, if any, management behaviors and financial pressures at pharmaceutical firms correlated with or predicted compliance with the FDA regulations avoiding interruptions in the supply of some essential patented or generic pharmaceutical drugs in the U. S. In Chapter 4, the pilot study, the data collection, and the data analysis were discussed. The limited level of participation in the main study was presented with the corresponding demographics. Despite the limited participation, decisions were presented for the three tests of the null hypotheses. RQ1 focused on the concepts of the theory of plan behavior (Ajzen, 1991). With the available and limited data, the null hypothesis, $H1_0$, of RQ1 was rejected. Based on the correlation found between the seven financial indicators and the level of compliance of the firms, the null hypothesis, $H2_0$, for RQ2 was rejected for both scenarios: pre-FDA and post-FDA. The slopes in the regression models for RQ3 rejected the null hypothesis, $H3_0$. Both regression models cannot be used to generalize beyond the sample of the study.

The nature of the study intended to address the research questions to raise management's awareness avoiding interruptions in the supply of some essential patented or generic pharmaceutical drugs. The study highlighted that (a) avoiding FDA actions provides business sustainability and (b) compliance is a competitive advantage for pharmaceutical companies. The design of the research sought to predict the outcome of the dependent variable, that is, compliance with FDA regulations.

The behavior by management, related to the quality of drugs to meet their intended quality, integrity, strength, and purity influenced the level of compliance of the firm's operations. Also, the pressures of enhancing productivity, funding research, supporting marketing plans, and reducing the cost of goods impacted the firm's compliance performance. The application of enforcement actions by the FDA on the firms was used as the treatment event reinforcing the expected level of compliance. A shift in the relationship between the variables was observed in the correlations and the linear regressions after the FDA intervention, highlighting the new level of compliance.

The independent variables that could lead to enforcement actions by the FDA were set as management behaviors of the pharmaceutical managers and the firms' financial indicators. The treatment event was the application of the enforcement action by the FDA. The level of compliance of the pharmaceutical company was the dependent variable. In the study, the conditions before the FDA intervention in the pharmaceutical firms were compared to the conditions after the FDA intervention to predict compliance with the CGMP regulations. The research questions were formulated on three focus:

- Correlations between management behaviors (independent) and compliance (dependent)
- Correlations between financial indicators (independent) and compliance (dependent):
- Financial indicators (independent) impact on compliance (dependent).

Interpretation of the Findings

The specific problem addressed in this study related to shortfalls in compliance performance and product quality leading to medicine shortages that affected patients' treatment and health. Pollack (2013) expressed that shortfall in investment decisions for enhancing quality systems and the limited manufacturing capacity were the drivers causing medicine shortages. Price competition to attain market share, financial benefits on market value, and management incentives skewed against investing in plant improvements drove pharmaceutical manufacturing leaders' decisions and behaviors away from compliance (Asotra, Cossin, & Yacobi, 2012). Senior leaders' attitude towards the lack of compliance and focus in quality systems seems to prevail in their management decision-making process. Shortfalls in quality systems resulted from extreme control over the cost of goods and a commitment to strong marketing programs. Mehta (2013) suggested that implementing principles and guidelines as developed by the International Conference on Harmonization could be a significant step in facilitating senior leaders' understanding of the compliance expectations. Correcting CGMP violations by the pharmaceutical manufacturing leaders implies that productivity-financial indicators need assessment and that management behaviors require modification. Change management practices as described in chapter two could support the change process, continuous improvement efforts, and deal with potential resistance to change.

The findings despite the limited participation in the study supported the arguments presented in the literature. Behaviors and financial indicators correlated with

compliance with the FDA regulations. The application of the TPB, as well as the correlations and regression analyses between financial indicators and compliance, allowed me to reject the null hypotheses two and three to support the arguments in the literature. Behaviors and approach to financial decisions were different between the pre-FDA and post-FDA interventions. Changes in the trend of the reputation of the firms and changes in management also supported the findings.

TPB developed by Ajzen (1991) was utilized to assess behaviors of the pharmaceutical managers. The central point of TPB is that there is a direct relationship between intention and actual behavior. TPB highlights that any behavior could be explained and that behaviors are not difficult to predict. For this study, the intention of the pharmaceutical industry management to comply with the regulations of the FDA, as well as managing the financial limitations and complexity, was an excellent scenario to assess with TPB.

According to Langham, Paulsen, and Härtel (2012), TPB proposes a direct relationship between intention and actual behavior. This relationship is essential to the understanding of the willingness to comply and of the actual action of non-compliance. Consequently, predicting intention to comply is as important as predicting the actual compliance behavior. TPB also evaluates the topic of behavioral control, including the concepts of perceived behavioral control and actual control. Perceived behavioral control consists of the individual's ability to control behavior and willingness to apply the required behavior. Actual control is essential for investigating behaviors that require the individual to overcome performance hurdles. Attitudes and values are specific elements

in this approach. Despite the limited participation, understanding the findings that lead to the unwillingness to comply or drive to ignore compliance facilitated the assessment of probable prevention measures accompanying any FDA intervention. By applying linear regression to research questions one, TPB approach provided models to understand how to predict behavior and reinforce the intention that could modify future compliance of the firms.

The correlation of the financial indicators with compliance with the FDA regulations prior to the FDA intervention in RQ2 provided insight on the levels of interdependencies including the significance of the findings. Investment in facility and equipment and compliance expenses demonstrated a significant correlation to compliance with the FDA regulations. For the post-FDA scenario, the correlation coefficient indicated that investment in facility and equipment and compliance expenses had significant correlations with actual sales, actual revenues, and market value at $p < 0.01$. If the interdependencies between the indicators were used to imply that compliance expenses impact actual sales and actual revenues, the null hypothesis could be rejected in the post-FDA scenario for RQ2.

The predictors for RQ3 were the seven financial indicators. The outcome variable was the level of compliance with the FDA regulations. The null hypothesis, $H3_o$, was rejected for both FDA intervention scenarios. All indicators had a B value indicating a slope not equal to zero. Of the seven predictors for the pre-FDA intervention, stockholders' equity had an ANOVA value with significance to $p < 0.05$. The influence of all participants (cases) in the regression model for the pre-FDA scenario was verified,

and two were found to be outside the expectation based on the Mahalanobis Distance values. For the post-FDA scenario, the influence of all cases of the regression model was found to be within expectation.

For the assumptions of residual normality, linearity, and homoscedasticity, plots assessed under SPSS could be considered supporting these assumptions in both FDA scenarios. The lack of significance on the characteristics of the regression models indicated that the models were not robust. The findings cannot be generalized and used beyond the sample population since not all assumptions for the two linear regressions were met. The low level of participation limited the precision on the assessment of the assumptions of the regression model.

Research Question 1

To what extent, if any, does management behaviors (independent) correlate to compliance (dependent) with FDA regulations at the pharmaceutical firms in the United States?

- $H1_0$: $r = 0$. There is no difference in management behaviors towards compliance at pharmaceutical firms, as a result of FDA enforcement actions in the U.S.
- $H1_1$: $r \neq 0$. There are differences in management behaviors towards compliance at pharmaceutical firms, as a result of FDA enforcement actions in the U.S.

The null hypothesis, $H1_0$, was rejected for RQ1 in the pre-FDA and post-FDA interventions. Correlations were found that were not equal to zero ($r \neq 0$). The significance of the correlations varied and not all correlations met the expectation, $p < 0.05$.

In the Pearson correlation for the pre-FDA intervention, the construct of behavioral beliefs (attitudes) had the highest correlation with the outcome of compliance with a value of $r = 0.633$, $p < 0.01$. The other two construct, normative beliefs and perceived behavioral control, had non-significant correlations with values of $r = 0.328$ and $r = 0.183$, respectively. For the post-FDA intervention, the construct of behavioral beliefs (attitudes) also had the highest correlation with the outcome of compliance with a value of $r = 0.693$, $p < 0.01$. The other two construct, normative beliefs and perceived behavioral control, had non-significant correlations with values of $r = 0.294$ and r = 0.303, respectively. Also, the construct of behavioral beliefs had a significant correlation with the construct of perceived behavioral control with $r = 0.376$, $p < 0.05$. This last significant correlation differed from the pre-FDA intervention where the correlation was non-significant between these two constructs. This fact implied the influence on individual beliefs and their own perception of controlling behaviors after the FDA intervention.

The correlation data indicated a favorable change in correlation between the outcome of compliance and behavioral beliefs (attitude) for before and after the FDA interventions of about 9.5%. The value of r increased from 0.633 to 0.693 for the construct of beliefs (attitude) towards compliance by the participants with significances

of $p < 0.01$. The other two independent constructs had non-significant correlations. The perceived behavioral control non-significant correlation with the outcome of compliance also increased by about 65% from the pre-FDA ($r = 0.183$) to the post-FDA scenario ($r = 0.303$). The change in the *r* value for the perceived behavioral control construct led to the change in significance with the outcome of compliance after the FDA intervention. From the limited population that participated in the study, the null hypothesis was rejected for RQ1.

A regression analysis was also conducted to establish if there was a linear model of the three TPB constructs as predictors of the outcome of compliance of the firms with the FDA regulations. For the pre-FDA scenario, the $R^2 = 0.421$ and was adjusted to about 32% for the contribution of the three constructs. The *F*- ratio indicated the significance of the change with $p < 0.05$. For the post-FDA scenario, the $R^2 = 0.492$ was adjusted to 40.2% representing the adjustment to the overall contribution of the three independent variables. The *F*-ratio provided the significance of the change, $p < 0.01$. For the ANOVA assessment, the models for both scenarios (pre-FDA and post-FDA) had an *F*-ratio that were significant ($p < 0.05$) indicating that the outcome could unlikely happen by chance.

For the comparison before and after the FDA intervention, the contribution of the three constructs of the TPB increased from 42.1% to 49.2%. This increased in contribution after the FDA intervention represented an overall 16.9% favorable impact on the compliance of the firms with FDA regulations. For the participants of the study, the FDA intervention influenced their behaviors towards compliance with the FDA regulations in the United States. Since not all assumptions were met, the regression

model for TPB cannot be used to generalize beyond the sample of the study in either the pre-FDA or the post-FDA interventions.

Research Question 2

To what extent, if any, do financial indicators (independent) correlate to compliance (dependent) with FDA regulations at the pharmaceutical firms in the United States?

- $H2_0$: $r = 0$. There is no difference in compliance with FDA related to financial indicators at pharmaceutical firms, as a result of FDA enforcement actions in the U.S.
- $H2_1$: $r \neq 0$. There are differences in compliance with FDA related to financial indicators, as a result of FDA enforcement actions in the U.S.

The null hypothesis, $H2_0$, was rejected for RQ2 in the pre-FDA and post-FDA interventions. Correlations were found that were not equal to zero ($r \neq 0$). The significance of the correlations varied and not all met the expectation, $p < 0.05$.

Pre-FDA Intervention

The null hypothesis, $H2_0$, was rejected for RQ2 in the pre-FDA intervention. Of the seven financial indicators, the compliance of the firms prior to the FDA intervention had a significant Pearson correlation at $p < 0.05$ with three of them considering a one-tailed assumption due to the skewness of the data in the responses. Investment in facility and equipment ($r = |-0.468|$, $p < 0.05$), compliance expenses ($r = |-0.558$, $p < 0.05$), and stockholders' equity ($r = 0.392$, $p < 0.05$) were significantly correlated to compliance.

Also, facility and equipment and compliance expenses were significantly correlated to actual sales, actual revenues, and market value at $p < 0.01$.

Since the distribution of the scores was skewed or non-normal as supported by the results of Kolmogorov-Smirnov and Shapiro-Wilk tests, Kendall's Tau correlation coefficient, τ, was also used to understand the correlation between the variables. Of the seven financial indicators and following Kendall's correlation coefficient, τ, the compliance of the firms prior to the FDA intervention had a significant correlation at $p < 0.05$ with two of them considering a one-tailed assumption due to the skewness of the data in the responses. Investment in facility and equipment ($r = |-0.432|$, $p < 0.05$) and compliance expenses ($r = |-0.497|$, $p < 0.01$) were significantly correlated to compliance of the firms. Also, facility and equipment and compliance expenses were significantly correlated to actual sales, actual revenues, and market value at $p < 0.01$.

Post-FDA Intervention

The null hypothesis, $H2_o$, was also rejected for RQ2 in the post-FDA intervention. The compliance of the firms after the FDA intervention only had a significant Pearson correlation with stockholders' equity ($r = 0.374$, $p < 0.05$) considering a one-tailed assumption due to the skewness of the data in the responses. Similar to the pre-FDA scenario, investment in facility and equipment and compliance expenses were significantly correlated to actual sales, actual revenues, and market value at $p < 0.01$. Compliance expenses were significantly correlated to all other indicators except for COGS and stockholders' equity implying the importance of compliance expense between the indicators.

From the Kendall's correlation coefficient, τ, the compliance of the firms had no significant correlation with any of the financial indicators in the post-FDA scenario. The stockholders' equity had a *p* significance value equal to 0.055. The Kendall's correlation coefficient indicated that investment in facility and equipment and compliance expenses had significant correlations with actual sales, actual revenues, and market value at $p < 0.01$. Since the interdependencies between the indicators investment in facility and equipment and compliance expenses indicated significant correlations with actual sales, actual revenues, and market value, the rejection of the null hypothesis was supported for the RQ2 for the post-FDA intervention.

Research Question 3

To what extent, if any, do financial indicators (independent) impact compliance (dependent) with FDA regulations at the pharmaceutical firms in the United States?

- $H3_0$: $\beta_1 = \beta_2 = \ldots = \beta_7 = 0$. There is no impact in compliance with FDA related to seven financial indicators at pharmaceutical firms, as a result of FDA enforcement actions in the United States.
- $H3_1$: At least one $\beta \neq 0$. There is an impact in compliance with FDA related to at least one of the seven financial indicators before and after the FDA enforcement actions in the United States.

The seven financial indicators for the test of Hypothesis 3 were the cost of goods, investment in facility and equipment, process compliance, actual sales, actual revenues,

market value, and stockholder's equity. The regression analyses were directed to test $H3_0$ for pre-FDA and post-FDA. The βs in Hypothesis 3 were the regression coefficients of the following regression equation:

$$Y = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \beta_4 X_4 + \beta_5 X_5 + \beta_6 X_6 + \beta_7 X_7 + \varepsilon \qquad (5)$$

Where,

Y= FDA related compliance

X_1 = Cost of goods

X_2 = Investment

X_3 = Process compliance

X_4 = Change in sales

X_5 = Change in revenues

X_6 = Change in market value of the firms

X_7 = Change in stockholders equity

ε = Error of the regression

The null hypothesis, $H3_0$, was rejected for the pre-FDA and post-FDA scenarios. All indicators had a β value indicating a slope not equal to zero. Since not all assumptions were met, the regression models for the financial indicators cannot be used to generalize beyond the sample of the study in the pre-FDA and post-FDA interventions.

Pre-FDA Intervention

The null hypothesis, $H3_0$, was rejected for the pre-FDA intervention scenario. All indicators had a β value indicating a slope not equal to zero. The $R^2 = 0.607$ was adjusted

to 0.395 or 39.5% representing a reduction of 0.212 or 21.2% of the overall contribution of the seven variables. The stockholder's equity and investment in facilities and equipment contributed about 30% of the total 39.5% of all the financial indicators. For the ANOVA assessment, all values of *F*-ratio were above one signaling that the model's fits were better predictors than the guess from the means. Also, the model had an *F*-ratio that was significant to $p < 0.048$ indicating the low probability of the outcome could happen by chance. Since not all assumptions were met, the regression model for the financial indicators cannot be used to generalize beyond the sample of the study in the pre-FDA intervention.

Post-FDA Intervention

The null hypothesis, $H3_0$, was rejected for the post-FDA intervention scenario. All indicators had a β value indicating a slope not equal to zero. The $R^2 = 0.299$ was adjusted to -0.001 representing a very significant adjustment to the overall contribution of the six variables. The stockholder's equity contributed almost 15% in comparison to the 14% of the other five predictors. Actual sales were the second largest contributor with about 6%. These two predictors contribute about 21% of the total 29.8% of the financial indicators in the post-FDA scenario.

For the ANOVA assessment, all values of *F*-ratio were below one signaling that the model's fits were not better predictors than the guess from the means. None of the models in the post-FDA scenario had an *F*-ratio that was significant indicating that the outcome could happen by chance. Since not all assumptions were met, the regression model for the financial indicators cannot be used to generalize beyond the sample of the

study in the pre-FDA intervention. Comparing the two scenarios, the contribution of the financial indicators decreased from 60.7% to 29.9% indicating that other factors were also perceived as contributing to the compliance model of the post-FDA model that were not part of the initial pre-FDA model.

Limitations of the Study

The length of the main study proved to be a major limitation. The pilot study had about 40 questions. The main study had 133 questions. The number of participants that initiated the survey was about 90 of which 45 progressed through the questions. Only 21 participants provided completed surveys for the study. The participation rate of 1.9% was a major impact to the completeness of the study. The assumptions for the linear regressions in RQ3 were not met. The predicting models could not be generalized beyond the participants.

The low level of participation limited the study depth and significance of the findings. The rationale for the low participation could have been the sensitivity of the topic in the pharmaceutical industry for the shortages of quality product to the patients. Also, the participants could had concerns on the confidentiality of the survey despite the consent form with the IRB endorsement. In the technical side of communications, the internet firewalls in the pharmaceutical firms could had limited e-mails reaching the participants.

The financials results after the FDA intervention in the pharmaceutical firms were limited to the recollection and level of knowledge of the participants. The limited participation was a major obstacle for the assessment of the financial indicators. The

participants, depending on their knowledge and recollection, inferred the financial information of the pharmaceutical firms depending on the type of the FDA intervention.

Recommendations

Overcoming the limitations of participation and completeness of the study is considered as a specific recommendation. Regarding participation, an alternate approach to the use of a professional organization is to recruit and obtain permission directly from pharmaceuticals firms. This approach could provide some level of comfort in the participants considering the direct clearance by the firms.

Completeness of the study depended on the length and number of questions. The questions were perceived as repetitive as the participant assessed the pre-FDA and post-FDA scenarios. This design of repetitiveness is part of the TPB survey structure (Fishbein and Ajzen. 2010). The typical TPB survey provides about 50 to 60 questions to address the three constructs of attitude, normative beliefs, and perceived behavior control. The study targeted two scenarios to assess the research questions: pre-FDA and post-FDA interventions. This design led to double the TPB questions. The remaining 10 to 15 questions were regarding financial indicators, FDA compliance, and demographics.

The total questions in the main study were 133. If the study had focused in just the after the FDA intervention, the number of usable-complete surveys night have been about 45 instead of 21. This number is still well below the initially targeted number of 160 completed surveys. One recommendation is to reduce the number of questions further by focusing only on the construct of belief (attitude) in the study questionnaire based on the correlation results. On RQ1, beliefs (attitude) had the highest value of

correlation with the outcome of compliance for both FDA scenarios: r (pre-FDA) = 0.633, $p < 0.01$ and r (post-FDA) = 0.693, $p < 0.01$. The other two independent constructs, normative beliefs and perceived behavioral control, had non-significant correlations with the outcome of compliance in the evaluation of RQ1. This approach could further reduce the complexity and the length of the questionnaire influencing the number of usable-complete surveys. The concept of the behavior of the decision makers remains as a significant element difficult to predict.

Recommendations for future research topics based on the models of regression analysis from RQ3 with values of $R^2 = 0.607$ (pre-FDA) and of $R^2 = 0.299$ (post-FDA) could include other operational financial variables to increase the predictors' contribution in the models. Other financial predictors to be included in the regression analysis could be the inventory of goods, marketing costs, and cost of distribution. These topics were found in the literature and on-going studies by professional organizations like ISPE. ISPE (2014) in their publication on the shortage of medicines also suggested the topics of inventory control, the supply of raw materials, the capacity of the manufacturing firms, and harmonization of regulations in a global market.

All the 1144 participants that were invited to participate in the study were related to pharmaceutical companies under the FDA regulations based on their self-disclosed information in the ISPE's database. Since every day the pharmaceutical firms are operating in global markets and driving consolidations, future studies could be focused in other major markets outside the United States. New manufacturing geographies have developed in India and China for the supply of raw materials for the manufacturing of

pharmaceuticals products. The literature that I found was mainly focused on the American culture. Also, the regulations in other markets are different and evolving. Lack of harmonization of regulations will add complexity to the future research. Future studies could continue to be segmented by markets and cultures.

Based on RQ2, the financial indicators correlated with the outcome of compliance with FDA regulations. Management decisions regarding these indicators could influence compliance with the FDA interventions. Based on Kendall's correlation coefficient, τ, the compliance of the firms prior to the FDA intervention had a significant correlation with investment in facility and equipment ($r = |-0.432|$, $p < 0.05$) and compliance expenses ($r = |-0.497|$, $p < 0.01$). Also, facility and equipment and compliance expenses were significantly correlated to actual sales, actual revenues, and market value at $p < 0.01$. Assessment of pharmaceutical management's behaviors should be conducted to consider and accentuate the how to address these financial drivers.

In a future study, emphasis should be directed to understand better the influences from normative beliefs and perceived control behaviors in management behaviors as found in RQ1. Considering the trends of the responses, the overall Normative belief indicated to have a stronger influence on the behavior towards the outcome of compliance with 392/368 (pre-FDA/post-FDA) of a total of 490 points versus overall PBC with a value of 195/182 (pre-FDA/post-FDA) of a total of 490 points. When considering the managers' behaviors, the influence of the opinion from supervisors, peers, and relatives on behaviors was stronger than the perceived control in behaviors from business related items like budget goals and datelines.

Implications

This research study could be considered unique as it was directed to address an area of limited research in management behaviors and on financial decision-making in senior management in pharmaceuticals companies which could have led to significant shortages of medicines in last 5-6 years. Drug shortage events increased from 61 in 2005 (Barlas, 2014) to 251 in 2011 (Food Drug Administration [FDA], 2013). Woodcock (2012) signaled many of these medicine shortages as a direct consequence of shortfalls in compliance with the FDA regulations.

The comparison of the correlations of the three construct of the TPB with the outcome of compliance for the pre-FDA and post-FDA scenarios indicated that the FDA intervention had influence in the participants' behaviors. The correlation of the construct of beliefs (attitude) was significant and increased by 9.5%. In the case of perceived behavioral control, the correlation with the outcome of compliance increased by 65% although it was not significant.

These trends implied that the FDA intervention impacted the participants' perception on how could they control and influence their behavior for compliance with the FDA regulations. The normative beliefs regarding others' opinions did not show any change in the correlation with compliance between the pre-FDA and post-FDA scenarios. Peers, supervisors, and quality unit opinions did not alter their influence towards a behavior of pro-compliance in the participants. The level of compliance increased after the FDA intervention as indicated by the means of the participants' responses. A dependent-means t-test was applied to the two scenarios' means: pre-FDA and post-FDA

considering that the same participants took part in both scenarios. A negative sign to the difference of the means indicated that the mean of the compliance of the firms after the FDA intervention was larger than before the FDA intervention. A negative *t*- test confirmed that the mean of the post-FDA was larger than the pre-FDA scenario.

In the regression model following the three construct from the theory of planned behavior (TPB) in RQ1, the contribution of the three constructs increased after the FDA intervention from 42.1% to 49.2%. This increase signaled that the desired behavior to be in compliance with the FDA regulations was favorably impacted. The beliefs (attitude), the normative beliefs (peers), and the perceived behavioral control provided a higher prediction of behavior after the FDA intervention. These models could be used by management to reinforce behaviors allowing a more robust application of the firm's quality systems to minimize drug shortages and to attain a more competitive position for the firms.

In the seven correlations of the financial indicators in RQ2, the significant correlation between stockholders' equity in both pre-FDA and post-FDA interventions signaled the relevance of the firms' compliance with the FDA and the investors' expectations of the firms' reputation. Also, the favorable trend in perception of the firms' reputation from the participants' responses supported the concept that the firms could be considered as having achieved a more favorable image by increasing its compliance with the FDA regulations. In RQ2, the inverse correlation of investment on facility and equipment and compliance expenses with the outcome of compliance could be

considered as strong opinion that low level of compliance requires high level of investment and compliance expenses.

In RQ3, the regression model after the FDA intervention was not robust in comparison to the contribution of the variables in the pre-FDA scenario. The contribution decreased from 60.7% to 29.9% indicating that other factors were also perceived as contributing to the compliance model that were not part of the initial pre-FDA model. Elements like inventory, cost of supplies, and capacity could be further limiting the post-FDA model. This outcome of the study could provide insight into the management decision process on what senior leaders' should consider when dealing with financial drivers that could limit the presence of effective quality systems in the pharmaceutical manufacturing companies.

For pharmaceutical firms, the lack of compliance with the FDA regulations could be devastating. The results from the lack of compliance could include impact on reputation of the firms and an increase in the level of expenses to recover or achieve remediation. These performance indicators typically also impact the market value of the firms as shown in the correlations of RQ2. Regarding the reputation of the firms, the average of the responses from the participants indicated a decreasing trend in the positive ratings from eight to six between the pre-FDA and post-FDA interventions.

In the Pearson correlation for the pre-FDA scenario, investment in facility and equipment ($r = |-0.468|$, $p < 0.05$) and compliance expenses ($r = |-0.558|$, $p < 0.05$) were inversely correlated to complince of the firms. The lower the compliance of the firms implied the higher the need to increase investment in facilities and equipment as the

corresponding compliance. If the FDA intervention escalates into a consent decree, the magnitude of all these elements could multiply and become an unacceptable historical benchmark within the industry.

This study has the potential to highlight the desired behaviors in management and accentuate the concept that compliance could avoid medicine shortages and be a competitive business advantage for the pharmaceutical companies. In RQ1, the Pearson correlation of beliefs (attitude) with the outcome of compliance was increased from r = 0.663 to r = 0.0693 for a 9.5% when comparing the pre-FDA and post-FDA scenarios. The perceived behavioral control non-significant correlation with the outcome of compliance also increased by about 65% from the pre-FDA (r = 0.183) to the post-FDA scenario (r = 0.303). The normative beliefs driven by opinion from others did not shown any significant change between the pre-FDA and post-FDA interventions.

In the regression analysis to the TPB constructs also in RQ1, the R of the models increased from 42.1% to 49.2%. This increase in the contribution of the construct behaviors in the prediction of compliance reinforced the concept that after the FDA intervention, behaviors towards compliance were better recognized by the participants in the study. These model could be used by management to reinforce behaviors allowing a more robust application of the firms' quality systems to minimize drug shortages and to attain a more competitive position for the firms. Management should ensure clarity to subordinates on the expected behavior and influence perceived controls to drive compliance of the firms with the FDA regulations.

Through this study, I was able to influence pharmaceutical management's awareness on how their decisions, based on their attitudes and behaviors, impacted compliance. The inverse relation of compliance of the firms versus investment in facilities and compliance expense should be used to demonstrate that the higher the compliance the lower these financial factors. Avoiding having low compliance with the FDA regulations increases expenses and could lead to interruptions in the supply of some essential patented drugs or generic pharmaceutical drugs. The desired management behaviors should transform leadership tactics to meet the organization goals and mission, while attaining compliance with the CGMP regulations.

The target of the study, as previously described, was directed to the positive social change to avoid placing the patients in danger by not having medicine shortages. Becker et al. (2013) found in their study that the incidents of oncological drug shortages affecting patients' treatments increased from 2010 to 2011. Also, stockholders' equity, as demonstrated in RQ2, could be affected if management does not recognize the detachment from their mission leading to low compliance and the associated costs from the FDA interventions. Considering that any generalization is limited to the sample of participants and is based on the correlations and regression analyses conducted in this study, if management performance continues with old practices and behaviors, leading to poor product quality and further medicine shortages, the risk to patients and the losses to stockholders could be unavoidable.

To project the complexity of addressing the change, change management decision-making processes need to be implemented by the pharmaceutical management.

The required change process to attain the desired state of avoiding medicine shortages has to evolve through the typical change cycle of what, how, and why (Kezar, 2001). The potential impact on stakeholders, especially medicine shortages to patients, constituted the "why" to conduct this study. Influencing the organizational performance, through modification of management behaviors and financial indicators, should minimize or eliminate the stakeholders' impact, leading to positive social change.

The study alignment to obtain positive social change was directed to encourage managers of pharmaceutical organizations to operate and behave with a sound approach to compliance with CGMP of the FDA. The main potential social impact was to avoid having medicine shortages, due to non-compliance decisions by pharmaceutical manufacturing management. The risk of affecting the patient health could be minimized or eliminated by avoiding drug shortages as well as the supply of substandard patented or generic medicines. Also, the inherent mistrust by the public on companies' lack of commitment towards social responsibilities could be neutralized or reduced enhancing the reputation of the firms as indicated in the responses to the study.

Conclusion

This research study could be considered unique as it was directed to address an area of limited research in management behavior and on the financial decision-making of senior management in pharmaceuticals companies, which could have led to significant shortages of medicines in last 5-6 years. Despite the limited participation, the outcome of the study provided insight into the management decision process on what senior leaders' behaviors should consider and accentuated the need to modify the approach to financial

drivers. Emphasis should be directed to better understand the influence of the perceived behavioral control versus normative beliefs. Enhancing decision making processes while considering behaviors and the financial correlations could reinforce the presence of effective quality systems in the pharmaceutical manufacturing companies eliminating or minimizing medicine shortages.

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Appendix A: Permission to Reprint Figure 4 and TPB questionnaire

Gmail by Google

Francisco Gutierrez <francisco.gutierrez@waldenu.edu>

Permission Request TPB

Icek Aizen <aizen@psych.umass.edu> Thu, Feb 5, 2015 at 3:29 PM
To: Francisco Gutierrez <francisco.gutierrez@waldenu.edu>

Dear Francisco Gutiérrez,

The theory of planned behavior is in the public domain. No permission is needed to use the theory in research, to construct a TPB questionnaire, or to include an ORIGINAL drawing of the model in a thesis, dissertation, presentation, poster, article, or book. If you would like to reproduce a published drawing of the model, you need to get permission from the publisher who holds the copyright. You may use the drawing on my website (http://people.umass.edu/aizen/tpb.diag.html) for non-commercial purposes, including publication in a journal article, so long as you retain the copyright notice.

Best regards,

Icek Ajzen

Professor Emeritus

University of Massachusetts – Amherst

http://www.people.umass.edu/aizen

Appendix B: Permission to Reprint Figure 5

Gmail by Google

Francisco Gutierrez <francisco.gutierrez@waldenu.edu>

Permission Request

Wiley Global Permissions <permissions@wiley.com> Fri, Feb 6, 2015 at 12:06 PM
To: Francisco Gutierrez <francisco.gutierrez@waldenu.edu>

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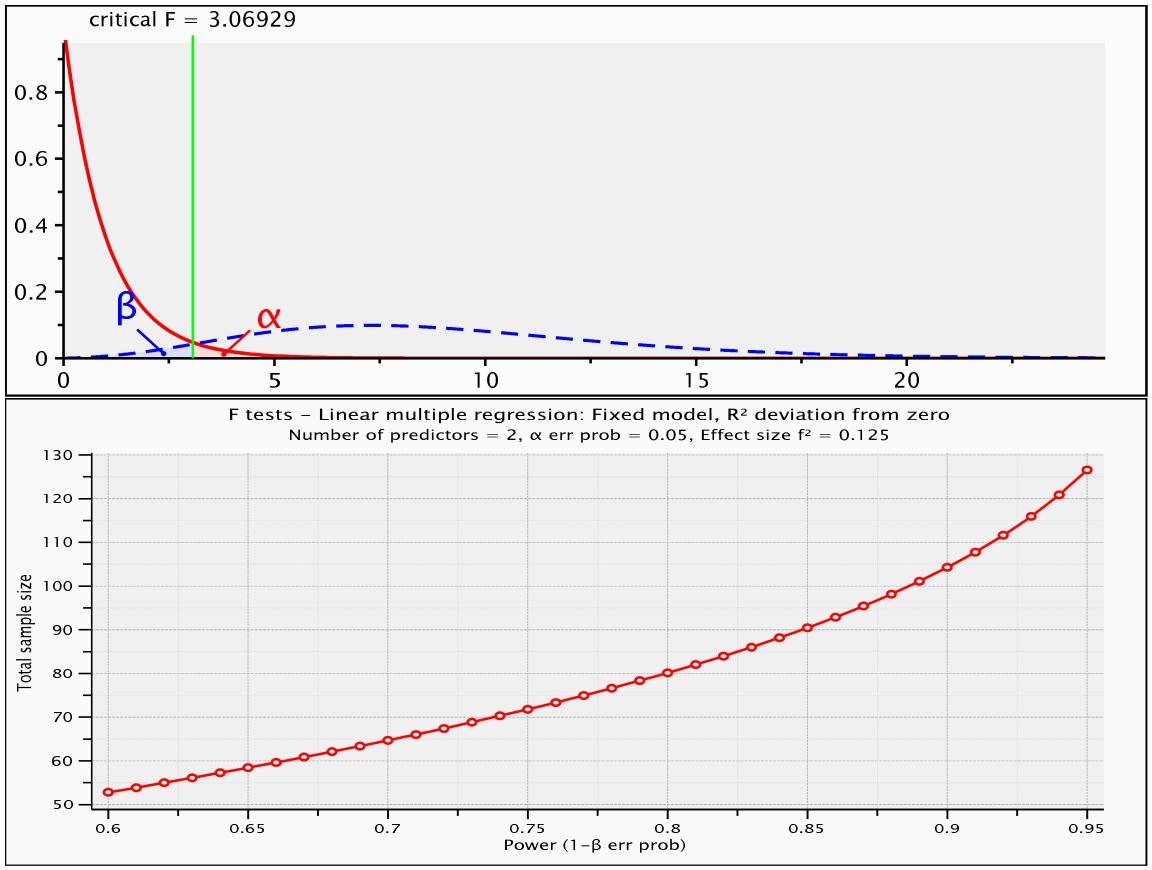
Appendix C: G*Power Calculations

F tests - Linear multiple regression: Fixed model, R^2 deviation from zero
Analysis: A priori: Compute required sample size
Input:

Effect size f^2	=	0.125
α err prob	=	0.05
Power (1-β err prob)	=	0.95
Number of predictors	=	2

Output:

Noncentrality parameter λ	=	15.8750000
Critical F	=	3.0692864
Numerator df	=	2
Denominator df	=	124
Total sample size	=	127
Actual power	=	0.9506401



Appendix D: Permission from ISPE

Gmail by Google

Francisco Gutierrez <francisco.gutierrez@waldenu.edu>

Permission Request for Directory

Debra Sher <dsher@ispe.org> Mon, Jun 8, 2015 at 2:24 PM
To: Francisco Gutierrez <francisco.gutierrez@waldenu.edu>

Dear Francisco,

My apologies for not realizing this sooner, but since you are a student member, you already have access to the Member Directory. Just log into the website (your login ID is 236530), hover your cursor over the "ISPE Membership" tab at the top, and in the drop-down menu, you'll see "ISPE Member Directory."

I wish I could just pull a list for you, but we're not able to send out email addresses—however, you can gather emails from the Member Directory. I hope that helps!

Regards, Debra

Appendix E: Pilot study demographics

Table E1

Age Group of Participants

Answer Options	Response Percent	Response Count
20-30	0.0%	0
31-40	0.0%	0
41-50	28.6%	2
51-60	42.9%	3
60+	14.3%	1
Prefer not to answer	14.3%	1
Note: answered question: 7		7
skipped question: 2		2

Table E2

Management Decision-Makers

Answer Options	Response Percent	Response Count
Manager	0.0%	0
Director	57.1%	4
Vice President	28.6%	2
Executive	14.3%	1
President	0.0%	0
CEO	0.0%	0

Note: answered question: 7
skipped question: 2

Table E3

Operational Function

Answer Options	Response Percent	Response Count
Manufacturing	14.3%	1
Quality	57.1%	4
Logistics	0.0%	0
Engineering	0.0%	0
Other (please specify)	28.6%	2

Note: answered question: 7
skipped question: 2

Table E4

Academic Background

Answer Options	Response Percent	Response Count
High School	0.0%	0
Bachelors	42.9%	3
Masters	14.3%	1
MBA	0.0%	0
Ph.D.	42.9%	3
Other (please specify)	0.0%	0

Note: answered question: 7
skipped question: 2

Appendix F: Main study demographics

Table F1

Age Group of Participants

Answer Options	Response Percent	Response Count
20-30	0.0%	0
31-40	0.0%	0
41-50	31.8%	7
51-60	50.0%	11
60+	13.6%	3
Prefer not to answer	4.61%	1

Note: answered question: 22
skipped question: 0

Table F2

Management Decision-Makers

Answer Options	Response Percent	Response Count
Manager	27.2%	6
Director	59.1%	13
Vice President	9.1%	2
Executive	4.6%	1
President	0.0%	0
CEO	0.0%	0

Note: answered question: 22
skipped question: 0

Table F3

Operational Function

Answer Options	Response Percent	Response Count
Manufacturing	22.7%	5
Quality	22.7%	5
Logistics	0.0%	0
Engineering	40.9%	9
Other (please specify)	13.7%	3

Note: answered question: 22
skipped question: 0

Table F4

Academic Background

Answer Options	Response Percent	Response Count
High School	4.6%	1
Bachelors	27.3%	6
Masters	40.9%	9
MBA	10.2%	4
Ph.D.	9.0%	2
Other (please specify)	0.0%	0

Note: answered question: 22
skipped question: 0