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Leadership Strategies for Addressing U.S. Pharmaceutical Drug Shortages and Supply Chain Disruptions

Adrian Grant Scioli
Walden University

Walden University

College of Management and Technology

This is to certify that the doctoral study by

Adrian Grant Scioli

has been found to be complete and satisfactory in all respects,
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Review Committee

Dr. Charlotte Carlstrom, Committee Chairperson, Doctor of Business Administration Faculty

Dr. David Moody, Committee Member, Doctor of Business Administration Faculty

Dr. Charles Needham, University Reviewer, Doctor of Business Administration Faculty

Chief Academic Officer
Eric Riedel, Ph.D.

Walden University
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Abstract

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MBA, Norwich University, 2011

BS, Gwynedd-Mercy University, 2010

Doctoral Study Submitted in Partial Fulfillment

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Abstract

Health care providers in the United States expend more than $400 million in unnecessary direct costs annually managing the effects of widespread drug shortages. Based on the theory of complexity and complex adaptive systems, the purpose of this exploratory multiple case study was to identify the strategies that health care pharmaceutical procurement leaders from the Eastern region of the United States use to address widespread drug shortages. Data were collected from 5 semistructured interviews with pharmaceutical procurement leaders, recorded field notes, and a review of public documents from company websites. Data analysis included deductive and open coding techniques. Emergent themes included: (a) proactive planning for supply chain and distribution channel disruptions, (b) creating strategic processes for alternative procurement methods, and (c) relying on proven sources of actionable information. Findings may influence business practices for health care procurement leaders by contributing new knowledge to develop strategies to address disruptions and drug shortages. Health care policy makers may use the findings to assess key strategies in delivering pharmaceutical products from manufacturers to end users.

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Dedication

I give thanks and praise to the Lord my God, who without his grace and mercy, I would not have been able to begin my journey. I dedicate my research to my family, friends, colleagues, and professors. Each person encouraged me to exceed my expectations and deliver exceptional results. I am truly thankful I was pushed out of my personal comfort zone to experience deeper levels of academic rigor.

To my family, especially Melody, thank you for your support and understanding. You held me accountable for every aspect of this journey and encouraged me to continue even during the roughest circumstances. You held the light to guide me through the calm and the storms. I love you for being there beside me.

To my friends, colleagues, and professors, I humbly acknowledge your dedication to listen to me as I struggled to articulate how this educational journey was changing my perceptions and changing me. You supported me with your counsel and sometimes silence as I grasped for a deeper understanding of my research topic. In the end, you helped me to persevere and triumph. I am forever grateful to all of you.

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I also wish to acknowledge the faculty of Walden University for giving me an opportunity to excel. The faculty, whom I interacted with, provided me with helpful hints on polishing my study. I also wanted to acknowledge their willingness to understand many of the complexities of my study and be willing to defer their judgment to me in areas of my expertise.

Finally, I wish to acknowledge my friend and colleague, Dr. Kenneth D. Gossett, a mentor and peer who has encouraged me in many academic, professional, and personal aspects. Working with Dr. Gossett on my research has been highly rewarding and enlightening. Dr. Gossett has challenged my intellectual capacity well beyond my expectations. I am more conscious of my gifts than before. Dr. Gossett is a valuable asset to the Walden University faculty and the doctoral process. I am forever in your debt.

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Section 1: Foundation of the Study

Health systems rely on consistent supplies of pharmaceuticals to support acute and subacute patient care. Increasing disruptions within the supply chain and distribution channel place patients and health systems at risk for maintaining continuity of care (Sharma et al., 2013). Disruptions also cause lengthened patient treatment plans and increased health care spending (Hunnisett-Dritz, 2012; McLaughlin & Skoglund, 2015). Sharma et al. (2013) explained that globalization of modern treatment protocols places additional burdens on supply chains and distribution channels to maintain adequate supplies of critical medications.

Ventola (2011) stated hospitals, clinics, and outpatient treatment centers in North America, as early as 2001, began experiencing widespread shortages of mainstay pharmaceuticals. Fox et al. (2009) commented that the frequencies of pharmaceutical shortage events continued to grow without reliable preventive strategies. In a pharmacology update, Mullins and Cook (2011) argued that doctors and clinicians continued to treat patients with substitute and alternate drugs that were less effective than branded medications and often had profound side effects. The extremely high cost associated with managing and mitigating supply chain disruptions remain through a period of health care reform (United States Department of Commerce, 2013).

In 2013, complications found in some U.S. pharmaceutical supply chain disruptions were dependent on increases to the global market demand from emerging nations' desires for westernized medicine (Sharma et al., 2013). Disruptions in the supply chain and drug distribution channel influence the demand curve for modernized

pharmaceutical products (Sharma et al., 2013). Basheer (2012) observed the process of product innovation and market exclusivity are vital components to a robust pharmaceutical economy; however, health care expenditures continue to become a greater portion of the U.S. gross domestic product (United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, 2016).

Fox et al. (2009) suggested scholars, legislators, and leaders of industry cannot provide comprehensive solutions to the issue of drug shortages and manufacturer interruptions. Fox et al. noted much of the focus of this problem was ex post facto strategies implemented to help health care providers mitigate the effects of drug supply disruptions. The adaptive nature of the complex and chaotic system known as pharmaceutical supply and distribution requires systematic approaches to understanding the dynamics of the issues (Abdulsalam, Gopalakrishnan, Maltz, & Schneller, 2015; Shah, 2004).

Rosoff et al. (2012) and Born (2012) reported successful efforts to create a comprehensive universal protocol with strategic objectives to detect and minimize drug supply disruptions eluded hospital pharmaceutical procurement leaders. Rosoff et al. commented reductionist behaviors by many uninformed pharmaceutical stakeholders impede the likelihood of creating a viable solution because of the misunderstanding of the complex and chaotic behaviors in the system. I conducted an explorative multiple case study of how senior health care procurement leaders in the Eastern region of the United States describe impediments to the detection and mitigation of drug supply chain disruptions. This multiple case study was an opportunity to explore organizational and

independent strategies used in response to reported shortages as well as strategic planning used to minimize adverse effects in treatment protocols. Findings and conclusions from this the study may provide new knowledge and new information to support the development of additional leadership strategies, which may strengthen global responses to drug supply chain and distribution channel disruptions. The focus of this study was to explore the leadership strategies implemented to reduce the frequencies of disruptions to the pharmaceutical supply chain and distribution channel within the health system.

Background of the Problem

Since 2005, the compounded annual growth rate (CAGR) of drug shortages in the United States exceeded 23% (American Society of Health-Systems Pharmacists [ASHP], 2014). The CAGR for national health care expenditures since 1960 was 8.86 % (Centers for Disease Control and Prevention, 2015). Quilty et al. (2011) indicated a pharmaceutical manufacturer experienced challenges maintaining product at adequate levels of inventory in the supply chain because of increased disruptions. Fox et al. (2009) indicated disruptive conditions led to substantial resource shifting of clinical staff attempting to obtain medications using other suboptimal strategies. Kaakeh et al. (2011) found similar responses from a survey of pharmacy directors. Heydari, Najar, and Bakhshi (2015) concluded intensive care nurses should receive specialized training to curtail supply chain disruptions and other training the practical management of the hospital's scarce resources. Drugs in short supply adversely affect disease states like cancer, infectious disease, and surgical procedures because of shortages of anesthesia medications (United States Government Accountability Office, 2014).

According to ASHP (2014), pharmaceutical drug shortages involve 220 individual pharmaceutical products. One of the greatest ongoing health risks from supply chain disruptions is the availability of generic sterile injectable drugs for cancer treatment (Woodcock & Wosinka, 2013). In 2014, chemotherapy drug types made up more than 80% of the total reported shortages (ASHP, 2014; United States Food and Drug Administration [FDA], 2015). Chabner (2011) argued the unreliability of pharmaceutical supply access creates complex sets of issues such as rising drug costs, grey market utilization, and increasing related care for patients taking less effective alternative medication.

Problem Statement

The number of drug shortages reported to the Center for Drug Evaluation and Research (CDER) quadrupled from 61 shortages in 2005 to 282 shortages in 2012 (FDA, 2014). Between 2005 and 2011, the CAGR of newly reported drug shortages exceeded 23% (ASHP, 2016). U.S. health care providers expend more than $400 million in unnecessary direct costs annually managing the effects of widespread drug shortages (Fox, Sweet, & Jensen, 2014; Hoffman et al., 2012; Kaakeh et al., 2011). The general business problem was some health care pharmaceutical leaders address operational challenges resulting from pharmaceutical supply chain disruptions in a suboptimal manner. The specific business problem was some health care pharmaceutical procurement leaders have limited strategies to address disruptions in the drug supply chain and distribution channel.

Purpose Statement

The purpose of this qualitative multiple case study was to explore the strategies that health care pharmaceutical procurement leaders use to address disruptions in the drug supply chain and distribution channel. The participants in the semistructured interviews included five leaders from pharmaceutical procurement departments in health care systems who have successfully addressed the research problem. The companies included three health care organizations from the Eastern region of the United States. The participants shared their strategies of mitigating supply chain and distribution channel disruptions. The hospital pharmaceutical leaders also shared company documents and internal policies containing relevant data that supported the triangulation of data sources (see Denzin, 2012). The findings of the study may contribute to social change by improving health care leadership's understanding of the internal strategy limitations resulting from drug supply chain disruptions. Findings may also assist health care procurement leaders in understanding the perceived quality problems related to treatment delivery influenced by drug supply chain disruptions. In addition, the findings may increase health care leaders' awareness of system challenges with pharmaceutical supply channel disruptions and drug shortages in the health care system.

Nature of the Study

A qualitative multiple case study (see Yin, 2014) was the most appropriate means of achieving a unique understanding of the meaning, motivation, and perceptions of health care procurement leaders facing drug supply chain disruptions. Pepe (2015) used a case study design to explore the decision-making by manufacturing personnel through

end users in a collaborative supply chain system. An investigator can use a qualitative case study to develop a deeper understanding of the rationale of health care procurement leaders to address disruptions in the drug supply chain. Case study inquiry is suitable for addressing research questions that require a meticulous understanding of processes in social or organizational constructs (Moll, 2012). Following the suggestions of Bernard (2013), I considered alternative research methods before choosing a qualitative approach. I concluded a quantitative or mixed methods approach was unsuitable for my study because the use of quantitative methodology impedes an investigator's ability to probe the underlying study participants' decision-making processes (see Alojairia & Safayenib, 2012; Bernard, 2013; Knight & Cross, 2012). A mixed methods approach was a potentially promising research design; however, limited resources, participant availability, and time constraints render mixed methodology an impractical choice for this study (see Sadan, 2014).

Using the suggestions of Bernard (2013), I considered the following major qualitative research designs: phenomenology, ethnography, case study, and grounded theory. I chose an exploratory multiple case study design. Yin (2014) argued that a case study design enables the researcher to answer *how* and *why* questions. Patton (2015) observed case study research questions also answer *what* questions. A case study approach is an effective way to explore a real-life phenomenon in a natural setting (see Cronin, 2014). Based on the guidance of Moustakas (1994), I decided a phenomenological study was not applicable because the focus of the study was not on the lived experiences regarding a particular event or to find out the unique or common

experiences that individuals may have experienced. A grounded theory design would not be appropriate because the research purpose was not to develop a new theory (see Bernard, 2013, Denzin & Lincoln, 2011). Denzin and Lincoln (2011) suggested an ethnographic study is not suitable when the investigator does not intend to focus on any group culture through direct observations. The case study design was appropriate to explore the phenomenon of supply chain and distribution channel disruptions.

Research Questions

The overarching question for this study was the following: What strategies do health systems pharmaceutical procurement leaders use to address drug supply chain and distribution channel disruptions?

Interview Questions

1. What types of strategies do you use to manage supply disruptions in the pharmaceutical supply chain and distribution channel?
2. What are the most important factors you consider when implementing strategies to reduce or eliminate supply chain disruptions?
3. What strategies have been the least effective in reducing or eliminating supply chain and/or distribution channel disruptions?
4. What specific supply chain management strategies do you use to address disruptions in the supply chain or distribution channel?
5. How have your organization's supply chain management strategies changed or evolved since you assumed the leadership role?
6. What barriers prohibit supply chain management strategies from becoming

successful?

7. What other information would you like to discuss, which we have not already addressed?

Conceptual Framework

The objective of this study was to explore strategies that senior procurement leaders practice to reduce or eliminate disruptions in the pharmaceutical supply chain and distribution channel. An investigator can use a single conceptual framework as a guide (see Ravitch & Riggan, 2016) to assist in the exploration of the strategies practiced by senior procurement leaders to mitigate disruptions in the supply chain and distribution channel. Modern complexity theory and complex adaptive systems evolved through the research by Kauffman (1995) in complexity sciences at the Santa Fe Institute (1986-1997). Kauffman conceptualized the idea that complexity theory has an enormous scope of business application because all real-world systems are complex. Complexity theory, a multidisciplinary science (Di Toni & Comello, 2013), served as a viable lens to develop a deep understanding of the strategies used by senior procurement leaders to alleviate supply chain and distribution channel disruptions. Complex adaptive systems (CAS) theory was a scientifically appropriate conceptual framework to use in this study (see Di Toni & Comello, 2013).

Complex Adaptive Systems

Investigators use complexity theory to analyze complex systems by developing an understanding of the structure and behaviors of a system. The premise of complexity theory was the understanding of a hidden order or a mathematical structure in the

behavior of systems. Geer-Frazier (2014) found complexity leadership generates innovation, learning, and adaptation of an organization and a system. A central concept in complexity theory was the notion of emergence (Drack, 2009). Emergence supports the rejection of reductionism in science because the natural world has been organized in a hierarchical fashion from the simplest (subatomic) to the most complex systems (ecosystem) (Iosim, 2016). Mazzocchi (2012) identified hierarchical levels that contain emergent principles not found in lower levels of the system; therefore, an investigator would have difficulty explaining the functional behaviors of the system by utilizing only the basic information obtained at the lowest levels of the system. Another central concept of emergence is the notion of feedback. The discovery of positive and negative feedback loops in financial investments, which drive the system forward and away from equilibrium challenges the conventional notion of systems theory identified in previous research (Arsenault, Clayton, & Peng, 2013). Conversely, Kuziemsky (2016) stated complex adaptive systems (CAS) were diversely open-ended systems that interact nonlinearly with each other and their environments demonstrating capabilities of learning and evolving through experiential exposure. This perception was especially true of negative feedback systems, which are found in health, human services, and educational programs (Gossett, 1989).

Definition of Terms

The following terms were defined below:

Drug shortage: Drug shortage is a situation in which the total supply of all clinically interchangeable versions of a regulated drug by the FDA is inadequate to meet

the current or projected demand at the patient level (CDER, 2014).

Electronic health record: An electronic health record (EHR) is a longitudinal electronic record of a patient's historical health information generated by one or more encounters in any care delivery setting. EHRs commonly contain a patient's, diagnoses, medications, medication reactions, treatment plans, immunization history, allergies, radiology images, and laboratory and test results (Health Information Technology, 2015).

ePrescribing: ePrescribing is the transmission via electronic media of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefits manager, or health plan, either directly or through an intermediary, including an e-prescribing network between the point of care and the dispenser (United States Department of Health and Human Services: Office of the National Coordinator for Health Information Technology, 2012).

Feedback loop: A feedback loop is a closed sequential circular path exhibiting cause and effect through information and causal stimulation and produces a specific behavior because of its structure and activity (Strauss & Borenstein, 2015).

Grey markets or gray markets: Grey or gray markets refer to an unintended parallel marketplace in which products are bought and sold without authorization or knowledge of the original manufacturer (McBride et al., 2013).

Meaningful use: Meaningful use is a three-stage process referred to in the Patient Protection and Affordable Care Act (PPACA) that promotes the ideals of efficient and comprehensive exchanges of electronic health information related to patient encounters. Enhancing electronic health records allows health care provider to qualify for incentives

from the government, which continues the value stream in future exchanges (Centers for Medicare and Medicaid Services, 2014).

Reverse payment or pay for delay: Reverse payment or pay for delay is a highly criticized common practice of a pharmaceutical patent holder that pay potential competitors of generic drugs to delay introduction of less costly product; thereby, securing an extended period of market exclusivity (Jones, Carrier, Silver, & Kantarjian, 2016).

Secondary use: Secondary use is an enhancement to health care data and individual patient encounters for expanding knowledge about diseases and appropriate treatments and strengthening the understanding of the effectiveness and efficiency of health care systems (National Institute of Health, 2012).

Assumptions, Limitations, and Delimitations

Some types of scholarly inquiry address public views of reality through the analysis of values, practices, rituals, assumptions, and perceptions found in paradigms (Denzin & Lincoln, 2011). The scholarly researcher accepts that some methods of the analysis are critically limiting in nature such as the reasoning process, human incompetence, or lack of crucial resources, which present a potential for research deficiency. Scientific exploration must address shortcomings in an optimal way and research studies must exist within the designated boundaries of the researcher's assumptions, limitations, and delimitations (Denzin & Lincoln, 2011).

Assumptions

An assumption is an intangible perceived truth that cannot be proven but assumed

(Merriam, 2014). The first assumption was participants, who held senior level positions with their employers, would provide complete and truthful answers to interview questions. The purpose of the data collection process is to solicit meaningful, clear, and truthful responses while maintaining professional integrity (Lichtman, 2014). To achieve the desired responses, qualitative researchers rely on the research principle of participant confidentiality, which eliminates the possibility of identity exposure when answering sensitive questions (Yin, 2014).

I assumed participants had the health care organization's best interest in mind when answering the interview questions. Qualitative researchers should employ active listening skills and not deviate from questions except to clarify participants' perceptions through open-ended questioning (Rubin & Rubin, 2012). A final assumption was the participants had experience in pharmacy leadership and were capable of articulating their experiences regarding the research problem. Qualitative researchers should identify emerging themes and patterns from the data in an unbiased manner (Lichtman, 2014; Yin, 2014).

Limitations

A limitation is a condition or restriction preventing the state of completeness (Kirkwood & Price, 2013). The primary limitation was a general lack of academic research material available in qualified peer-reviewed journals. Personnel from government departments and industry organizations report the bulk of direct empirical data with a similar but differing method of peer-reviewed scholarly publishing. Inferences drawn in the study may not apply to other industries or other geographical

areas. Qualitative researchers attempt to reconcile the differing degrees of knowledge transferability based on possible research design deficiencies (Marshall & Rossman, 2016). The current study contained no longitudinal component; therefore, the findings reflected a brief point in time regarding the participants' perceptions (see Rubin & Rubin, 2012).

Delimitations

Delimitation are self-imposed limitations or restrictions (Bernard, 2013). The delimitations of the study included senior leaders perceptions of pharmaceutical procurement and administration strategies for medium to large health systems. Ensuring sample sufficiency and data saturation is necessary in choosing a purposeful interview sample size (Rubin & Rubin, 2012). I intended to interview two to three individuals at each of the three sites to achieve data saturation (see Rubin & Rubin, 2012).The sample objective was six to nine participants. According to Rubin and Rubin (2012), saturation of the data is evident, comprehensive, and focused when further exploration of perceptions of the participants support commonly held understandings between the participants.

Significance of the Study

Contribution to Business Practice

The findings from the study may contribute to the body of knowledge related to pharmaceutical supply chain and distribution channel disruptions. Leaders may use the information to fill gaps in their business practice to mitigate specific areas of disruptions. Understanding strategies used by health care leaders may provide valuable insight into

both effective and ineffective methods to reduce or eliminate pharmaceutical supply chain and distribution channel disruptions. Health care executives may also use the findings from this study to evaluate the need for future strategies and to make informed decisions.

Findings from this study may contribute to the development and implementation of organizational or industry protocols needed to strengthen the responses to notifications or conditions of drug supply chain and distribution channel disruptions. Senior procurement leaders may develop integrated best practices through a deepened understanding of the influences of pharmaceutical delivery. Refinement of best practice models may help health care providers address excess costs and leverage new strategies to eliminate non-value added costs.

Implications for Social Change

This study was a deductive exploration of the strategies used to mitigate drug supply chain and distribution channel disruptions in the U.S. health care environment. Drug supply chain and distribution channel disruptions represent one of the most challenging problems confronting health care providers. Health care procurement leaders must attempt to reduce costs related to treatment while delivering better value for the health care dollar (Schweitzer, 2013). Drug supply chain and distribution channel disruptions affect the cost control process because the medical practitioner reassigns clinical staff to search for other means of procuring drugs in short supply or to research substitute medications when faced with delays (Schweitzer, 2013).

Study findings may lead to social change by educating senior health care leaders

about growing challenges encountered in health care, related to the resolution of drug shortages through repurposing administrative and clinical resources. The pending challenges brought about by the PPACA may push patients, providers, and payers to demand more efficient productive and distributive organizational practices within the drug distribution channel. The study findings may contribute new knowledge to health care organizations attempting to adopt new methods and strategies of addressing drug supply chain and distribution channel disruptions. Health care policy makers may reconsider key processes in distributing pharmaceutical products from manufacturers to end users based on the finding of the study.

A Review of the Professional and Academic Literature

The multiple case study design enabled me to explore qualitative perceptions of senior leaders to the discover best practices and new knowledge related to management of drug shortages in the United States. I completed a review of the professional and the academic literature to assess the need for this study, which included professional, academic, governmental, and industrial journals, books, dissertations, and authoritative reports. The content of the review includes the most recent trends facing the industry and stakeholders.

Academic Sources Utilized to Conduct the Review

The online Walden University library was the primary source for the literature review. Business and management databases, as well as health sciences databases, provided integrated information because of the dual focus of the study. Query of business's and management databases included Business Source Complete/Premier,

ABI/Inform Complete, Emerald Management Journals, Sage Premier, LexisNexis Academic, and the National Bureau of Economic Research identify the business aspects of the research study. Interrogation of Health Sciences databases included MEDLINE, PubMed, and Science Direct identify health care aspects of the research study. I excluded articles from newspapers, magazines, and trade publications because of the potential perception of bias.

The total number of references was 278. Of these, 250 (90%) have publishing dates between 2012 and 2017. In the review of professional literature, the total references equal 159. In this section, 136 references (86%) have publishing dates between 2012 and 2016. Of the 278 total references, 272 (98%) were either (a) a peer-reviewed journal, (b) an academic resource book, (c) a doctoral dissertation, or (d) an authoritative source.

Key Words, Phrases, and Terminologies

I used the following keywords, phrases, and terminologies when searching the reference databases for the literature review: *drug shortage, manufacturer delay, pharmaceutical scarcity, pharmaceutical supply chain, drug distribution channel, grey market, drug substitution, therapy interruption, alternate therapy, stock out, pay-for-delay, clinical trial delay, patent expiration, compounding pharmacy, vendor-managed inventory,*and *reverse payments.*

Diversity of Literature Sources

The regulated nature of pharmaceutical manufacturing and product distribution created a need to review literature from various clinical professions, governmental agencies, industrial organizations, and private firms assessing the pharmaceutical supply

chain and distribution channel. The FDA regulates the quality of pharmaceutical products by protecting the rights of patients who are subject to clinical trials of new medications. The FDA's responsibilities include monitoring pharmaceutical promotional material. Some of the selections in literature review included information released by government agencies deemed authoritative.

The research topic incorporates regulations from numerous government bodies; therefore, the separation from the academic discourse and the discourse of the regulatory body was difficult to characterize. Industry and private organizations offer comprehensive reporting to identify high-level market conditions and assessment of future revenue opportunities necessary for stakeholder competition. Literature about drug shortages from these groups appears to be subjective in nature because of the potential economic benefits gained by the users. Some for-profit companies like IMS Health and the health care Distribution Management Association provided widely accepted meaningful market analysis (Generic Pharmaceutical Association, 2012), which was considered authoritative but lacked certain rigors of academic interrogation. I used these types of informational reports to validate the content in the peer-reviewed literature, which may help to assess and validity of the literature review.

Significant Legislation Affecting Pharmaceuticals

Five pieces of intertwined legislation affecting the pharmaceutical industry created complex sets of regulatory boundaries and legal compliance challenges. First, the Bayh-Dole Act of 1980 remediated previous government regulations related to patent, trademark, and intellectual property statutes for universities and institutions receiving

federal funding for research and development. Second, the Hatch-Waxman Act of 1984 simplified the process of generic introduction as a means to make affordable medications accessible to more Americans (Hemphill & Sampat, 2012). The Act allowed generic manufacturers to take advantage of faster and more cost efficient methods of introducing low-cost drugs into the marketplace than in previous years. Some scholars considered this Act as placing a bounty worth millions of dollars on a drug innovator's product patent (Hemphill & Sampat, 2012).

Third, the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) created Part D benefits for Medicare recipients. Part D benefits helped Medicare beneficiaries acquire prescription medication at a discount. The MMA also pinned price increases for drugs used in intravenous (IV) therapy to 6% of average sale price. Fourth, the 2011 Executive Order 13588-Reducing Prescription Drug Shortages required pharmaceutical manufacturers to provide the FDA with a 6-month notification for any potential drug shortages or delays (Executive Order No. 13588 3 C.F.R. 281, 2011). Additionally, Executive Order 13588 prohibited the stockpiling and price gouging in the supply chain and distribution channel (Executive Order No. 13588 3 C.F.R. 281, 2011; USGAO, 2014). Finally, in 2012, the FDA passed the United States Food and Drug Administration Safety and Innovation Act (Pub. L. 112-114) (FDASIA, 2012), which allowed the FDA to collect user fees for drugs and medical devices from the medical industry (USGAO, 2014). These funds streamlined the FDA's processes for drug and medical device approvals to create an efficient and expeditious process for generic application approvals (United States Food and Drug Administration, 2014).

Constraints on Traditional Economic Theories

Recent federal legislation designed to increase consumer access to affordable health care outcomes and to reduce the costs associated with health care delivery constrain fundamental economic theories. Health care economics do not operate in perfectly competitive markets (Phelps, 2012). Health care economics do not consist of low entrance and exit barriers, homogeneity of product, a full understanding of product quality; a single entity does not influence market pricing. In contrast, the health care economies consist of imperfect market conditions and complexities of feedback loops reflecting the value of resource consumption impair the ability to examine allocative efficiencies throughout the supply chain and distribution channels (IMS Health, 2012). Excess capacity and excess demand characteristics in pharmaceutical supply chains and distribution channels are economically inconsistent with those in traditional theories of price elasticity because of filters placed within feedback loop structures of drug supply and demand (Crawford, 2010). Pharmaceutical health care markets exhibit conditions of supply inelasticity, partly because the lifesaving, products are available to consumers who might pay any price to obtain them (Crawford, 2010).

Themes in Literature Review

Six themes were prevalent in the current body of academic literature, (a) supply and demand, (b) regulatory and public health policy, (c) capacity and sustainability of the pharmaceutical supply chain, (d) business decisions, (e) complexity of pharmaceutical delivery systems, and (f) adverse effects on patient outcomes. I provide a comprehensive discussion focused on complexity sciences and their applicable disciplines. The majority

of the current literature include information relate to ex post facto behaviors, which follow drug shortage events. A smaller portion of the current literature focuses on ex ante organizational processes to address the leadership responses to the research problem. Gaps in the academic literature exist in the ex ante contribution. The exploration of complexity theory, as applied to this research problem, may yield definitive results because other management researchers have yet to completely grasp the capabilities of complexity sciences (see Pollack, Adler, & Sankaran, 2014).

Complexities Sciences

Complex adaptive systems (CAS). Complex adaptive systems are intricate, self-organized, complex, chaotic systems, composed of independent agents (Higgins, 2013; Iosim, 2016; Neely, 2015; Sturmberg, O'Halloran, & Martin, 2012a; Tsasis, Evans, & Owen, 2012). A range of variables interacting with each other and emerging from agent adaptations (norms) to form a system may influence system behaviors (Higgins, 2013; Sturmberg et al., 2012a; Tsasis et al., 2012). Strumberg, O'Halloran, and Martin, (2012b) argued health care delivery systems follow the CAS construct. Strumberg et al. (2012b) observed (a) no existence of a central control point or referring authority driving system design, (b) varieties of stakeholder influences creating complexity, and (c) system agents developing structural mechanisms that deviate from system norms to serve the interests of individual agents. Competitive systems must operate between order and disorder to optimize performance and adapt to the critical queues in the competitive industries in which they operate.

Tsasis et al. (2012) used a qualitative research design to explore participants'

experience in health systems integration to assess the utility of a CAS framework in integrated care. Tsasis et al. concluded that barriers to system change toward integrated care resulted from a lack of understanding of (a) interplay among diverse organizational components, (b) contextual factors that moderate a system's capacity to integrate, and (c) organizational resistance to adapt or learn from emerging experiences. Kuziemsky (2016) argued for using the CAS approach to support management decision-making in health care because traditionally prescribed methods were used for stable and predictable systems. Gilson, Elloker, Olckers, and Lehmann (2014) suggested sense making, the process individuals use to understand their environment, which shapes their understanding of how organizational environments work and the interplay among system components to reform health care. Gilson et al suggested that during organizational change, individuals attempt to understand their local experiences by engaging colleagues to generate shared interpretations of change initiatives, which may or may not be aligned with organizational intentions.

Complexity theory (CoT). Complexity theory is a toolset of theoretical and conceptual methods used by researchers in the development of nonlinear abstract structures (Cudworth & Hobden, 2013; Psychogios & Garev, 2012). Complexity is a decentralized configuration of multiple objects lacking a nucleus and a defined command structure, but having characteristics of an evolving or learning entity (Jianbo, Feiyan, Jianfang, Jing, & Yinhe, 2013). In contrast, Cudworth and Hobden (2013) suggested complexity theory lacked common threads and tools to solve complex social problems. During the 20th-century complexity theory had roots in three interdisciplinary fields: (a)

cybernetics, (b) systems dynamics, and (c) general systems theory (theoretical biology). Early cyberneticians included mathematicians Pitts, Weiner, and von Neumann, engineers Bigelow and Shannon, and neurobiologists McCulloch, Rosenbluth, and Lorente de No (Byrne & Callaghan, 2014).

From 2000 to 2010, researchers focused on complexity theory for new applications and new areas of research (Zuchowski, 2012). Serdarasan (2013) stated the degree of interdependencies of system relationships, and the volume of system components characterized the sense of increased complexity and randomness. Baykasoglu (2016) concluded system complexity for retail supply chain increased with the use of a central forecasting tool. Serdarasan used findings in the context of complexity to develop leadership best practices for supply chain management. The U.S. pharmaceutical supply chain consists of multiple autonomous entities, governmental regulations, objectives, stakeholders, and processes. When considered as a whole, pharmaceutical supply and distribution entities comprise a complex system of interdependent relationships (Janvier-James, 2012; Kaakeh et al., 2011; Mullins & Cook, 2011; Shah, 2004).

A central concept in complexity theory is the notion of emergence (Baykasoglu, 2016; Drack, 2009). When researchers reject reductionism, they may identify emergent behaviors in the system they are exploring. Reductionism theorists have sought to explain behaviors and relationships at the smaller unit level, which contrasted with the arguments of Baykasoglu (2016) and Drack (2009). Shah (2004) suggested pharmaceutical supply chains and distribution channels contain many complex processes, formulas, coordination

issues, and development challenges. Morçöl (2012) stated complexity theorists use conceptual tools and methodological tools to simplify because of the human simplifying mind.

Feedback and feedback loops. Another central concept in complexity theory is the notion of feedback. Information in a complex system is a tool to understand the degree of integration in relationships. Self-organizing components in a complex system are (a) dynamic, (b) nonlinear, (c) co-evolving, and (d) interconnected with other system components. Intricate biological systems comprise varying levels of feedback within hierarchical levels (Jørgensen, Nielsen, & Fath, 2016; Nielsen, 2016). Systems have dynamic information driven feedback loops that transforms the system to achieve its goal and to achieve equilibrium to allow the system to maintain its functions (Adomavicius, Curley, & Gupta, 2013).

Several scientific tenets comprise feedback loops. Feedback loops contain adaptive characteristics of complex systems. Without feedback loops that are both direct (+) and inverse (-), complex adaptive systems cannot change or evolve and become obsolete. Co-evolution governs that self-preservation relies on the constant communicative interaction between all interdependent entities (Akgun, Keskin, & Byrne, 2014). The discovery of positive feedback loops in financial investments that drive the system forward, and away from equilibrium (Arsenault et al., 2013) challenges the forms of systems thinking identified in previous research. Additionally, Li, Yang, Sun, Ji, and Feng (2010) discussed a precise notion of complex adaptive systems network (CASN), which was similar to the explanation from Kuziemsky (2016) but also included the notion

of adaptation as a choice of survivability. Understanding the makeup of feedback loops within the supply chain and distribution channel was paramount to the exploration of the strategies associated with the research question.

The nature of feedback loops evokes the notion of circular or increased complexity in the chains of causation (Mella, 2015). Feedback loops exhibit distinct patterns of organizational closure forming and creating harmony. These patterns also show autonomy and the means to activate a change to extend self-preserving characteristics (Beer, 2014). Feedback loops are patterned organizational behaviors with an abstract pattern of self-adaptive, self-organizational, and self-emergent behavior. New patterns of organizational behavior emerge when the system presents conditions acceptable for modification (Beer, 2014). Feedback loops are information conduits operating on dynamic change and acting on system difference or system dissimilarity.

Feedback loops contain an originator adapting through responses to its behavior (Akgun et al., 2014). Meanings of the feedback message come to the researcher in the answers to the message. Self-adaptation changes reflect in the replies made to the originator's message. Message noise or conflicting intentions may render the response invalid or impaired. Feedback loops achieve a purpose or satisfy values. Values and purposes may appear implicit or tacit. In satisfying a value or achieving a purpose, the feedback loop may increase (+) or decrease (-) the previous action, change to a different, but corresponding behavior, change to a different type of behavior or change the reference point of the outcome. Mella (2015) suggested systematic maximization without consideration in other areas of the system results in extreme behaviors affecting system

dynamics. Mella suggested looking for both consistency and variance in causal chain exploration.

Several distinct characteristics exist in feedback loops. Feedback loops may encroach on physical boundaries because information conduits are free from either internal or external physical limitations. Feedback loops have cycle times and delays that may not appear efficiently measurable. Cycle time, queue time, or delay was the length of time for all parts of the feedback loop to interact and process the message by completing its journey around the loop. Cycle, queue, or delay may occur in milliseconds or longer depending on the complexity and the distance from the originator. Longer cycle times may skew the message and may decrease the visibility of systematic relationships. Decentralization in pharmaceutical supply chains may appear subject to lengthy feedback delays because of the sheer expanse of the loop's path.

Feedback loops have two basic types. The first basic type was a positive or direct feedback loop. The positive feedback loop (+) has three main physiognomies: self-amplification, self-reinforcement, and acceleration in system design. Positive feedback loops have direct relationships to other process variables. Financial process models, personal nutrition models, and social economics use feedback models to understand system characteristics (Higgins, 2013)

The second type of feedback loop (-) is the negative or inverse feedback loop. Characteristics of negative feedback loops are stabilization, balance, equalization, and convergence. Negative feedback loops are self-sustaining and self-regulating. Negative feedback loops have inverse relationships with other process variables. As they go up, the

other variables will go down; as they go down, the other variables will go up. In comparison, positive feedback loops thrust the system to operational limits and boundaries through exponential growth or inconsistent behavior while negative feedback loops push the system to dynamic equilibrium and convergence through comparisons of the current state to the desired state.

Feedback loops have thresholds and boundaries. Reinforcing and balancing feedback loops demonstrate aspects of limitations and thresholds (Morecroft, 2015). Reinforcing feedback loops may move the system toward and eventually over a threshold. Balancing feedback loops maintain the system within bounds and close to midpoints. Escalating feedback loops depend on the rate of system change. Steep inclines or declines in the rate of change obstruct proper balancing feedback response times (Morecroft, 2015).

Feedback loops may include controls or varying degrees of tolerance to support self-adaptability (Macías-Escrivá, Haber, del Toro, & Hernandez, 2013). In the past, control engineering focused on feedback modeling in dynamic systems to increase the knowledge of the science (Macías-Escrivá et al., 2013). Proximity to system thresholds inhibits balancing feedback response times. Increasing tolerances may reduce the tuning ability of the controls.

Feedback loops operate on multiple levels. The human body operates many feedback loops, which maintains homeostasis (a desired metabolic state) (Gianaros & Wager, 2015). In mechanical sciences, this state is known as equilibrium. Multiple feedback loops in complex adaptive systems may be required to maintain homeostasis or

equilibrium.

False positive and false negative feedback loops regularly exist in natural sciences (Yamaguchi et al., 2012) and overwhelmingly in health care. Impaired data collection techniques caused false indicators in complex systems (Yamaguchi et al., 2012). The potential for false positive and false negative indicator readings in supply chains may cause material disaggregation of systems knowledge leading to a gap in system understandings further impairing decision-making (Guertler & Spinler, 2015). Identifying the correct methodology and the scheduling of feedback loop systems measurement may contribute to the elimination or reduction of false indicators.

Feedback loops support the ongoing operational cycle of complex adaptive systems such as pharmaceutical supply chains. The complex and chaotic behaviors in feedback loops are natural occurrences that may contribute to the difficulties of increasing system knowledge or other metrics tied to effectiveness or efficiency. Systems may fragment into infinite numbers of levels determining causal compatibility or relevance to the governing objective of a particular process (Jerbrant, 2013). Critical system knowledge was essential for proper alignment of operational strategies related to disruptions in drug supply chains and distribution channels.

General systems theory (GST). Scientists such as von Bertalanffy (1934), who introduced GST in 1934, and Emerson, Luhmann, Rapoport, and Churchman defined, shaped, and supported the notion of GST in the research process. General systems theory was the brainchild of Ludwig von Bertalanffy, who collaborated with Gerard, Rapoport, and Boulding while visiting Stanford University creating the Society for General Systems

Research (SGSR) in 1956. Poincare founded modern forms of systems dynamics in 1880 originally discovered by Sir Isaac Newton. System dynamics has new aspects, such as chaos theory, catastrophe theory, and fractal geometry with the strong influences of the computer revolution. In a supporting fashion with CAS theory, general systems theory, complexity theory, and chaos theory (ChT) may support the understanding of paradigms of the disruptions in the pharmaceutical supply chain and the drug distribution channel. Mishra, Kumara, and Garg (2013) studied the manufacturing, procurement, and distributions processes of supply chain management using general systems theory. As the supply channel system grows, so would the need for growth in the supporting systems (Mishra et al., 2013). The basis for advancing operational process efficiency is operating with enterprise governance best practices using a general systems theory approach or systems thinking (Medvedeva, 2012; Stephens, 2013; White & Fortune, 2012). Sweeney, Grant, and Mangan (2015) limited their research analysis to supply chain management in Ireland because of the emerging complexities of the current market along with increased globalization of product sourcing.

A system is a group of elements arranged in a particular design Mangal (2013). Boulding (1956), a contemporary of von Bertalanffy, described GST as theoretical modeling of levels existing between abstract principles of mathematics and distinctly specialized disciplines. Systems theories use a methodological approach to understanding the functions and behaviors of system objects. Bode and Wagner (2015) discussed the existence of positive direct relationships between supply chain disruptions and the complexity found in vertical, horizontal, and spatial systems. Baykasoglu (2016) and

Drack (2009) argued the impossibility to know every part and every relationship in a system. Conversely, Baykasoglu and Drack suggested the possibility of researching system laws above individual system parts. Pharmaceutical supply chains exhibit most of the same challenges as indicated by Drack. U.S. pharmaceutical supply chains and distribution channels may demonstrate characteristics of highly structured and or highly functional systems.

General systems thinking. The focus of general systems thinking is on the behaviors of whole systems. The concept of system thinking originated from a complex computer simulation model for handling management problems (Marshall & Farahbakhsh, 2013). Researchers using systems thinking constructs examined relationships between different parts of a system, thereby reducing the effect of complexity on the interpretation of the findings (Marshall & Farahbakhsh, 2013). Wallis (2013) suggested the use of systems thinking and complexity theory supported the creation of enriched public policies. General systems thinking help researchers understand the whole system was greater than the sum of all parts (Logan, 2015).

Chaos theory (ChT). Early modern physicists were unable to solve the nonlinear solutions to differential equations (De Brasi & Laracy, 2013). Dynamical time delayed systems may exhibit multiple opulent or nonperiodic behaviors including the possibility of high-dimensional chaotic behavior (Soriano, Flunkert, & Fisher, 2013). Deterministic chaotic systems, evolved into radically different states when exposed to minute variances from the original state (Franzke, Osprey, Davini, & Watkins, 2015). In the 1960s, Edward Lorenz studied intricate mathematical equations related to varying weather

conditions and resurrected the importance of chaos theory for a newer generation of meteorological researchers (Krishnamurthy, 2015). In a contrasting approach, researchers would not use ChT theory for a qualitative study because any system that continually operates on the fringes of chaos cannot appear productive and a system continually operates on the fringes of order lacks the capacity to adapt to environmental changes and ceases to exist (Spencer & Carlan, 2008). Croson, Donohue, Katok, and Sterman (2014) concluded managers and leaders have difficulty controlling systems that include complex, volatile behaviors with feedback and information delays; therefore, the researchers suggested developing enhanced training tools.

Complex systems have conceptual structures similar to a spider's web (Di Toni & Comello, 2013); the slightest disturbance to a remote area of the web resonates throughout the complex system and potentially manifests itself in areas unrelated to the original point of origin. Gubin and Santos (2012) identified chaotic systems by the divergences of trajectories where the original state of each system was comparable. The pharmaceutical supply chain and the distribution channel exhibits many of the same structural characteristics of a spider's web. The similarities are because of the multiple groundings found in the regulatory, legal, ethical aspects and the interrelated associations of the entities in the system. Burns, Bradley, Weiner, and Shortell (2012) identified micro-systems (individual patient care), mesosystems (population delivery care models) and macrosystems (industry and governmental regulation) existing in the health care delivery system. The various systems identified by Burns et al. demonstrate a defined model of system integration and interconnectedness between the health care provider and

clinical operational processes.

General systems theory methodology supports the interrogation of models with complex entities created from the interactions of constituents by conceptualizing the variables of constructs. Use of general systems theory permits the researcher to focus on the dynamics of defining specific functionality and supports the discovery of internal and external relationships and abstract properties. General systems theory advances the investigator's potential to explore normative and critical perceptions concurrently. Systems sciences contain a vast collection of tools to study real lived perceptions and develop cognitive maps, which help investigators understand the perceptions, articulations, conceptions, and explanations of complex entities.

Complexity is a framework of emerging scientific approaches containing theoretical and conceptual tools (Byrne & Callaghan, 2014). Complexity theory methodology assesses how incremental changes precipitate behavioral changes to a complex system Complexity theory emphasized the relational thinking of organizational and network processes. Complexity theory may introduce new perspectives on how to approach open systems using the notion of emergence and non-linearity, which may find use in the assessment of international system concepts (Rouse & Seban, 2014).

Chaos theory clarifies the complexity of perceived randomness or chaotic behaviors (Soriano, Flunkert, & Fisher, 2013). Understanding the foundations of chaos theory promotes the development of mathematical tools to help in the development of solutions to complex business problems such as complex supply chains (Mason, 2013). Chaotic operating environments in business normalize as supply chains and distribution

networks become multinational and multicultural. Chaos theory may contain the understanding of the fluctuations and unpredictable nature of supply and demand for critical use commodities.

For the purpose of addressing my research question, I used CAS theory to describe health systems. Health systems interventions are complex in nature, comprised of many interacting components, and require organizational agility in decision-making (flexible leadership) to meet changing and sometimes chaotic market dynamics (Paina & Peters, 2012). Additionally, CAS theory helps researchers identify and describe the behaviors and outcomes of interactions between the agents and environments of defined systems (Nan, Zmud, & Yetgin, 2014).

Supply and Demand

Blome, Schoenherr, and Rexhausen (2013) identified *supply chain agility* as a key tenet of operational excellence. Blome et al. suggested multiple supply chains in multiple countries may cause extensive logistical disruptions because of the lack of integration of the health care supply chain. In the health care continuum, supply and demand involve the orchestration of different entities gathering products and therapies for medically needy consumers with predisposed requirements. The abundance or lack of feedback information was a determinant of the degree of integration and interdependence of the system (Faucher, 2013).

Becker et al. (2013) indicated minute disturbances in the supply chain for the few companies (sole source) manufacture sterile injectables for oncology may cause extensive periods of drug shortages. Fragmentation of feedback information, because of the diverse

locations of manufacturing facilities, may impair the ability to collect and analyze data on a consistent basis. Kaakeh et al. (2011) point to multiple Internet sites containing fragmented data where study participants only rate 2% of the sites as having very good content. Information gaps and data fragmentation within the management reporting applications in the distribution channel result from different uncertainties in supply and demand and diverse system complexities (Chaudhuri, 2015; Cherici et al., 2011; Fox et al., 2009). Drug shortage administration from the aspect of information gathering may cause diligent efforts to maintain customary standards of care for all patients (Becker et al., 2013).

The economic theory of supply and demand contains the concept of elasticity or inelasticity of price; however, Becker et al. (2013) argued profits for generic sterile injectables, used in the majority of oncology treatment regimens, are subject to increase price limits by reimbursement regulations in the MMA. This legislation influenced the profit margin for mainstay drugs used successfully in clinical practice for decades thus oncology drugs may demonstrate limited pricing responses to elasticity or inelasticity conditions (Chabner, 2011; Havrilesky, Garfield, Barnett, & Cohn, 2012; Woodcock & Wosinka, 2012).

The manufacturing of pharmaceutical drugs by the manufacturer first requires the appropriation of raw materials, then the process of turning raw materials into the active pharmaceutical ingredient (API). Steinbrook (2009) argued certain types of drug supplies are unreliable especially when patient demand steadily increased. Even though high levels of demand exist for lifesaving and life-sustaining drugs, the supply chain faces

several challenges.

Information from analyzing retail distribution channels may contain insights of how vendor managed inventory (VMI) contract agreements may reduce costs and improve performance (Guimaraes, Crespo de Carvalho, & Maia, 2013). Guimaraes et al. (2013) identified particular partnership relations among participants within the supply chain may create information sharing, which was more efficient than traditional inventory models. A multi-site general hospital was the focus of this single case study.

A central finding to Guimaraes et al. (2013) quantitative single case study was the notion of VMI, recommending the manufacturer instead of the supplier control the volumes of product within the distribution channel. Guimaraes et al. concluded VMI scenarios reduce total channel costs to a greater degree than when health care workers manage the volume of product within their supply warehouses. This condition reduces direct effects of uncertainty among channel partners and seeks to eliminate excessive costs.

Loss of equity in capital markets. According to Kumar, Liu, and Scutella (2015) increases in the direct and the indirect cost was not the only economic disruptions faced by pharmaceutical manufacturers and distributors in India. Kumar et al. (2015) concluded equity loss related to the performance of the manufacturer's stock demonstrated no relation to the location of the disruption or responsible party. This study reflected the loss of equity in long-run stock performance may manifest itself in future cash flows as well as capital structure (Kumar et al., 2015). Perceptions of changes in economic risk affect future demands for increased investment returns.

Kumar et al. (2015) calculated underperformance of stocks for Indian organizations experiencing disruptions with the larger portion of the performance challenge occurring before the announcement of the disruption in manufacturing. In the 10-day period, before disclosure and following the disclosure, Indian companies lose 2.88 percent of shareholder wealth (Kumar et al., 2015). The findings from the study conducted by Kumar et al. may demonstrate financial disincentives, which may dissuade early supply deficiency disclosure as suggested in other academic discussions (Fox et al., 2009; Johnson, 2011; Kaakeh et al., 2011; Krisl, Fortier, & Taber, 2013).

Difficulties managing risks associated with potential supply disruptions magnify with the effects of global sourcing, increased supply chain stakeholders, and increasing product lead times (Chopra & Sodhi, 2014; Quilty et al., 2011; Schweitzer, 2013). Global sourcing increased stakeholders and increased lead times may increase complexities in feedback loops (Shah, 2004) and diminish the reasonableness of disruption management (Kumar et al., 2015). Kumar et al. concluded supply chain disruptions in developing countries may have a greater negative influence on stock and equity than in the U.S.

Information fragmentation. Information sharing fragmentation was a primary concern of one study conducted in 2011 (Kaakeh et al., 2011). Kaakeh et al. discussed the existence of multiple drug shortage websites, which only 2% of their surveyed population deemed as having actionable content. The lack of websites with cohesive content may contribute to additional resource planning necessary to compile and interpret data from multiple locations to manage disruptions. Kaakeh et al. reported survey respondents in their study reported they were unaware of varying disruptions in the supply chain until

they attempted to purchase the product from a wholesaler because of limited information found on websites. One of the complications studied by Becker et al. (2013) was multiple definitions of the term drug shortage. Differing definitions with various scopes unnecessarily look to add to the complexity and confusion of the problem (Becker et al., 2013; Le et al., 2011; Ventola, 2011). Ventola also concluded the broadly used term medically necessary also differed among groups and agencies.

Although external information dissemination was critical to health systems, Kaakeh et al. (2011) argued pharmacists must also provide support to internal information systems resulting from drug shortages. Kehl et al. (2015) concluded physicians in integrated health systems were less likely to experience drug shortages. Extra resource applications from the pharmacists focused on educating internal clinicians on alternate or substitute drugs, updating formularies with new drug information, modifying treatment policies, and communicating with supply chain and distribution channel partners about shortages. Efforts to mitigate drug shortages caused pharmacists to forego other responsibilities. The lack of consistent information sharing including the definition of the term *drug shortage* caused Kaakeh et al. to conclude senior clinical staff may not effectively manage drug shortages. The findings in the study indicate FDA regulators should require drug manufacturers to provide advanced notification of at least six months before product shortages or manufacturing interruptions.

Fragmentation of the pharmaceutical supply chain and distribution channel exists because of complexities in the historical design. Revisions are extremely difficult to implement for total system changes or improvements (Rees, 2011). Mikihisa (2015)

suggested the existence of stability and product quality in supply chains because of production leveling. Production leveling was an operational smoothing process of production demand planning (Bandyopadhyay, 2016). This manufacturing concept creates economies of repetition. Economies of repetition build on the premise manufacturers face uncertain demand yet must assemble multiple products to meet production expectations. Bandyopadhyay (2016) suggested a leveled production process reduces the detrimental effects of fragmentation through operational enhancements in the balancing of supply and demand.

Sandhil and Gupta (2013) reported hypothetical improvements in supply chain management through the implementation of an Enterprise Resource Planning (ERP) tool. Sandhil and Gupta indicated the intended goal of using an ERP system was to identify a single real-time truth from multiple data sources and complex interfaces between suppliers and customers. Design deficiencies in fragmented supply chain management systems do not track product flows properly from manufacturer to distributor and then from the distributor to the end user. Implementing an ERP system was a valid approach to reconciling and analyzing data from the supply chain because of the focuses on delivering actionable information in different forms. Melnyk, Narasimhan, and DeCampos (2014) called for future comparative studies to understand the context and characteristics of distinct supply chains.

Sandhil and Gupta (2013) posited the primary goal of supply chain management was to reduce inventory. Sandhil and Gupta's conclusion does not support the data in their report. Schaltegger and Burritt (2014) suggested two competing strategies for supply

chain management: risk and opportunity. The risk strategy relates to the methodology of supply chain leaders to eliminate adverse effects while opportunity relates to the methodology to increase the positive effects of supply chain management (Schaltegger & Burritt, 2014). Supply chain management effectually optimizes inventory levels and product turnover through constant analysis of the monitoring points within the supply chain.

In special circumstances such as natural disasters or terrorist attacks, health care providers require utilization of some unique but not commonly used pharmaceutical products. Limiting the specialized inventories used by disaster responders during humanitarian relief efforts may put public health at greater risk than maintaining lean inventory supply levels. Tukamuhabwa, Stevenson, Busby, and Zorzini (2015) concluded supply chain management research in cross-functional knowledge sharing strategies, cross-organizational collaboration, and improved combined technological approaches strengthen the foundation of future supply chain management strategies for disaster relief responses.

System complexities in a growing globalized supply chain. Cherici et al. (2011) postulated instabilities reside in the supply chain because of systems complexities. In this commercial analysis, Cherici et al. suggested globalization of the pharmaceutical supply chain lead to increased product recall, a reduction of API quality because of the lack of foreign regulatory inspections, and a decrease of product profit margins. Each case of instability may cause delays, increase costs, or amplify life-threatening medical errors.

Part of the manufacturing process for medication requires an abundance of

foreign-sourced raw material (Cherici et al., 2011; DeOlivera, Theilken, & McCarthy, 2011; Johnson, 2011; Quilty et al. 2011; Ventola, 2011). Cherici et al. (2011) suggested 80% of raw materials are foreign sourced. Johnson (2011) also submitted raw materials for the production of existing low margin API's be at risk of diversion for the manufacturing of more profitable next generation products. Cherici et al. (2011) indicated 42% of pharmaceutical product recalls for sterile injectable drugs related directly to the quality of the manufacturing process. Cherici et al. (2011) theorized additional costs from the product recall will burden the manufacturer and may divert profits from addressing the manufacturing deficiency or investing in modern equipment and personnel training. Cherici et al. (2011) suggested adopting a formal purchasing policy and maintaining clear channels of communication may help to manage drug shortages. Pharmaceutical product recalls present additional processing challenges because of less than optimal reverse distribution channels (DeOlivera et al., 2011).

DeOlivera, Theilken, and McCathy (2011) and Woodcock and Wosinka (2013) reasoned a growing question of sustainability existed in the pharmaceutical supply chain. DeOlivera et al. (2011) concluded the increase in the duration of drug shortages supports the notion of decreased sustainability within the supply chain. The introduction of lean manufacturing and lean supply processes had detrimental effects on the viability of many mainstay drugs (DeOlivera et al., 2011; Fox et al., 2009, Le et al., 2011). In 2011, multiple drugs existed within the same therapeutic class on extended shortage, increasing manufacturing complexity for newer therapies, and increasing shortages in areas such as pediatric oncology or anesthesiology (DeOlivera et al., 2011; Le et al., 2011). Even the

slightest disturbance may exacerbate fragile lean supplies (Fox et al., 2009; Ventola, 2011).

One of the most affected drug classes was oncology, which includes sterile injectable medication (Balkhi et al., 2013; Sharma et al., 2013). DeOlivera et al. (2011) concluded the proliferation of drug shortages related to this class continues to present a clinical challenge to oncologists and patients. Proportionately, with other medications experiencing shortages, sterile injectables increased 37% in 5 years (DeOlivera et al., 2011). Complexities in the manufacturing process of these types of drugs may have a causal relationship to shortage conditions within the drug class (Balkhi et al., 2013).

Industry consolidations and solely sourced pharmaceuticals. Industry consolidations influence the economic health of the industry (Dorsey et al., 2009; Fox et al., 2009; Schweitzer, 2013). In this quantitative study, Dorsey et al. (2009) analyzed the economic costs related to the drug substitution for a drug used to treat Parkinson's disease. When the production of Apotex consolidated to one manufacturer, the supply of the medication experienced shortages and delays (Dorsey et al., 2009). The societal costs associated with this shortage, lasting four months, totaled $75,000.00 (Dorsey et al., 2009).

Consolidation through mergers and acquisitions are a method used in industry to diversify the organization's drug portfolio and to spread economic risk among greater portions of the organization (Dorsey et al., 2009; Fox et al., 2009; Schweitzer, 2013). Dorsey et al. (2009) viewed these types of consolidations as potentially anti-competitive because of the internal economic conflicts between branded and generic drugs, which

may hinder the production of lower cost products. Iacocca, Sawhill, and Zhao (2015) concluded pharmaceutical manufacturers are reluctant to lower prices during brand to generic conversions because of conditions of brand loyalty and price insensitivity. Consumers have a growing preference for newer drugs in the market (Iacocca et al., 2015). Dorsey et al. concluded single sourced drugs may be at risk for increased inspection levels for all facets of the production process. This condition could require the manufacturer to expend additional costs towards the inspection process.

Early warning sentinel systems for supply chain disruptions. Born (2012) stated the accumulation of allocative and productive inefficiencies in the U.S. drug supply chain and distribution channel required congressional leaders to devise a collective response plan among all stakeholders. The collective response would reduce the negative qualitative and quantitative effects of drug supply disruptions (Born, 2012). In the pharmaceutical industry report, Fox et al. (2009) offered several observations. Staff members of effective health care organizations are primarily required to participate in strategic planning including management of drug supply chain disruptions as part of business contingency planning. Drug shortages may occur without adequate advanced warning even with the introduction of new technology in the supply and distribution network (Jagsi et al., 2014). Another observation from Fox et al. was rural hospitals may appear at greater risk because of the lack of borrowing power from neighboring hospitals or pharmacies. Fox et al. argued drug shortages may cause unnecessary situations of large-scale stockpiling or hoarding as a reaction to new shortage notifications, while Gupta and Huang (2013) stated that wholesalers should stockpile hard to acquire

products. Fox et al. associated this type of behavior to the lack of information because of system complexities, fragmentation, and uncertainty created by inadequacies within feedback loops.

Fox et al. (2009) recommended the development of an early-warning sentinel system designed to notify health care providers when a potential supply interruption exists. Hunnisett-Dritz (2012) found clinical use documentation in treatment protocols of most drug classes, which identify acceptable forms of drug rationing or substitution. Advanced warning programs may reduce the possibility of patient prioritization, drug rationing, and changes in therapy regimens, each having an ethical consideration as part of the decision process (Chabner, 2011; Fox et al., 2009; Johnson, 2011; Krisl et al., 2013; Quilty et al., 2011; Ventola, 2011). Fox et al. warned of legal implications resulting from improper care, which may harm the provider's reputation and cause additional expenses to defend possible legal proceedings. In an opinion article, Born (2012) identified a 2011 bill introduced in the United States Senate, the Preserving Access to Life-Saving Medications Act (S. 296), which added civil penalties to manufacturers who failed to notify the FDA adequately of instances, which may lead to supply interruption or shutdown.

In a quantitative study reviewing future pharmaceutical expenditures, Hoffman et al. (2012) revealed 78% of all retail prescriptions in 2010 were generic equivalents to branded medications. The direction of consumer markets leans towards less expensive generic drugs, with lower profit margins than the original formulation, and away from brand name drugs. Hoffman et al. and Schweitzer (2013) declared utilization of generic

drugs continues to grow in outpatient settings, but the growth of generic utilization was flat in hospital settings.

Hoffman et al. (2012) surmised health care systems in the United States would expend an additional $216 million in annual labor costs related managing drug shortages. Kaakeh et al. (2011) and Ventolla (2011) arrived at a similar amount of expense in their studies as Hoffman et al. When the less expensive drug was in short supply, additional health system profits are lost to the procurement of more expensive alternate medications (Hoffman et al., 2012; Kaakeh et al., 2011, Le et al., 2011; McBride et al., 2013; Ventola, 2011). Hoffman et al. illustrated this problem by discussing the difference in the market price for levoleucovorin, the alternate drug, which was 60 times higher than the generic sterile injectable drug leucovorin. Leucovorin was a mainstay oncology drug used to treat colon and rectal cancer for several decades (Van Cutsem et al., 2012).

To moderate overall growth, Hoffman et al. (2012) concluded reductions in drug expenditures attributed to the conversion of brand name drugs to generic equivalents help to subdue costs. Likewise, biosimilars, the generic approved version of a biologic agent, have the potential of contributing to cost savings. Hoffman et al. discovered 39% of clinical practitioners were unfamiliar with the concept of biosimilar use, and 21% would require additional information before making any decision to prescribe the product.

In a 2011 quantitative study, Le et al. (2011) argued children, elderly, and individuals with rare diseases face the greatest challenges resulting from drug shortages or supply interruptions. This issue exists partially because as of June 1, 2011, Le et al. calculated the average duration of a drug shortage reported to ASHP was 511.1 days. Le

et al. (2012) and Krisl et al. (2013) postulated shortages affect almost every therapeutic class of drugs. Severely challenged individuals may prove physically or mentally unable to endure the length of the average shortage without the introduction of other costly medical interventions (Krisl et al., 2013).

Additional risks to productive efficiencies lay in the absence of multiple active ingredient manufacturers for drugs in short supply (Le et al., 2011). Manufacturing capacity has an effect on supply chain efficiencies (McBride et al., 2013). Le et al. (2011) observed almost 50% of all drug shortages reported to ASHP, relate to products made by fewer than four manufacturers. Le et al. also calculated 76.5% of all drug shortages are sterile injectables creating a substantial negative impact on oncology treatment protocols.

Resulting from the procurement of alternate or substitute drugs, Krisl et al. (2013), Le et al. (2011), and McBride et al. (2013) theorized the providers incur additional costs because of additional (a) tracking methodologies, (b) training of clinical personnel, and (d) monitoring of the affected patients. Frequently, this changeover must take place rapidly because of the lack of notification from the manufacturer. The unplanned therapy disruption has adverse effects on treatment outcomes (Le et al., 2011).

Krisl, Fortier, and Taber (2013) studied drug shortages from the perspective of organ transplants. Krisl et al. discussed complexities of the changes made to prove treatment regimens when cornerstone transplant drugs are in short supply or completely discontinued. Clinicians may face difficult decisions to ration particular drugs when supply was limited or delayed. Challenges to transplant patients may continue because of adverse effects of alternate or substituted drug treatment (Krisl et al., 2013). Krisl et al.

(2013) theorized other drugs may fall into supply deficiencies because of the switch away from the original product placing an undue burden on the supply of the alternate product. Hawley, Mazer-Amirshahi, Zocchi, Fox, and Pines (2016) concluded medications for use in hospital emergency departments (ED) face severe challenges because of the steep increase in the occurrence of ED shortages since 2008.

Situational awareness in supply chain conditions. Awareness of supply chain conditions was the first step in the contingency planning process for transplant clinicians (Krisl et al., 2013). The next steps involved comprehensive assessments of the therapeutic and operational process in understanding durations, severity, and the affected population. The findings in the analysis helped the researcher understand what types of products would be in demand during a shortage (Krisl et al., 2013). Krisl et al. (2013) supported increased communications from every entity as a tool to manage drug shortages efficiently.

Schweitzer (2013) had a different perspective on how to resolve drug shortages. Instead of resolutions from industry, Schweitzer proposed to have the FDA implement two possible solutions. Schweitzer contended profit margin pressures from industry manufacturers have led to the globalization of production environments where manufacturing of multiple products or components were at a single site. Nagurney, Yu, Masoumi, and Nagurney (2012) indicated financial pressures and reduced profit margin pushed some manufacturers to cease production entirely. Schweitzer maintained lean inventory levels were insufficient to sustain long durations of shortages or disruptions. A tradeoff of economic risk exists between the financial advantages of lean inventories and

the potential financial costs of remediating drug supply disruptions. Each manufacturer evaluates and chooses their level of risk knowing the costs and their flexibility during changes of direction.

Regulators at the FDA should first develop ways to improve their inspection process before conditions warrant taking the deficient production facility offline (Schweitzer, 2013). The outcome of the inspection should not reflect passing or failing but rather one of four grading levels designed to identify the quality aspects of the production process and the upkeep of the facility (Gupta & Huang, 2013; Schweitzer, 2013). Schweitzer (2013) also explained consumers are sensitive to quality issues and may be more apt to pay for products with greater effectiveness and reduced risk. Gupta and Huang (2013) recognized that industry lacks quality indicators for consumer evaluation, which may support the notion of improving the profit margin for better quality products.

Sharma et al. (2013) discussed the global perspective of drug supply chains and distribution channels. New emerging markets, such as Brazil, India, China, Mexico, and Russia, experienced the benefits of greater health care access including access to mainstay drugs. Sharma et al. estimated the CAGR for global pharmaceuticals was 5% between 2011 and 2017. Emerging markets will increase spending another 16% of health expenditures by 2015 (Sharma et al., 2013).

From a pharmaceutical consumption perspective, Sharma et al. (2013) calculated spending on brand name products would decrease 23% in the global market because of patent expiration. The markets would experience the same percent of the increase in

generic formula spending respectively (Sharma et al., 2013). This global shifting circumstance may exert additional capacity pressure on generic manufacturers. Sharma et al. suggested India's pharmaceutical manufacturing industry be a consideration for large manufacturers as a means to produce low-cost products. Given the shrinking U.S. wage gap with countries such as China, Mexico, and India, the pharmaceutical industry should require other stable economic incentives to place large volumes of production requirements in locations with a growing labor force.

Fragile complexities exist in the supply of raw materials used for the treatment of enzyme-deficiency disorders and radioactive isotopes used in cardiac and bone scans. Steinbrook (2009) as an example suggested a virus hindered the growth of ovarian cells in Chinese hamsters used to develop biological medications. Clinical managers at the production plant were able to use part of their safety stock and help with information on dose conservation during the cleaning and sterilization process of the facility. In the second example, two nuclear reactors unexpectedly shut down causing a shortage of Technetium-99M, a radioactive isotope used in radiopharmaceuticals (Steinbrook, 2009). Each of the reactors showed signs of aging because of neglected long-term maintenance requiring immediate attention.

Steinbrook (2009) identified fragility in the supply chain for radiopharmaceuticals, calling into question the effects of global political pressures to reduce excess amounts of highly enriched uranium, which may fall into the hands of terrorists. Steinbrook (2009) proposed shifting production to low-grade uranium to make some of the radiopharmaceutical products because low-grade uranium was not suited to

use in the production of a weapon of mass destruction. Steinbrook realized comprehensive contingency plans have a higher possibility of success rather than improvising when faced with a clinical crisis.

Quilty et al. (2011) offered examples of supply opacity by explaining that new supply shortages and disruptions occurred because of natural disasters across the globe. Hospitals in Australia had two weeks of advanced notice to prepare for a penicillin shortage. Quilty et al. suggested nations reliant on pharmaceutical imports are more vulnerable to the system fragility, which may threaten the state of public health.

Quilty et al. (2011) observed how a large Australian hospital prepared to assess the effects of a local disaster on drug stocks. Quilty et al. postulated no specific guidelines existed to help plan for disaster contingencies in the hospital. Furthermore, Quilty et al. called into question the importance of constructing pharmacies to withstand basic types of disasters. This position on business contingency resonated throughout Ventola's (2011) study. Quilty et al. also hypothesized the importance of requiring local manufacturers to build excess capacity; thus, creating safety stocks of critical medications, which supports sustainability in light of potential disasters. Quilty et al. suggested planning for natural disasters should include intelligent supply thresholds of essential disaster medications to assist in extensive recovery efforts.

Ventola (2011) argued supply and demand could exceed expectations as feedback response interpretation fails to modify the conditions of the system. Ventola identified the presence of this situation by discussing the problems in the supply chain caused by a change in a therapeutic guideline for pediatric influenza vaccines. Ventola pointed to the

Centers for Disease Control's failure to provide advance warning to the manufacturers before expanding the age requirements for this therapy.

FDA regulators may expand agency capabilities to assist manufacturers and health systems with issues related to drug shortages (Ventola, 2011). Drug wholesalers with constrictive supply chain models such as product exclusivity agreements with manufacturers may create shortages without implied intent (Ventola, 2011). Wholesalers provide higher quality communications about drug shortage notifications and or updates on the status when placed in strategic positions. Based on survey data Ventola (2011) wholesalers ranked last as an information resource for drug shortages. Ventola also observed an increased supply risk in geographic areas serviced by only one wholesaler.

Spencer and Carlan (2008) discussed the effects of complexity theory found within the automobile industry. Spencer and Carlan hypothesized positive feedback loops disrupt employee safety in manufacturing environments. In this study, parallel situations exist similar to those in pharmaceutical manufacturing. Positive feedback loops in the automobile manufacturing industry disturb the control environment as they do in the pharmaceutical environment. The coincidental similarities discussed by Spencer and Carlan are concerning because comparable levels of manufacturing complexities exist between automobiles and pharmaceuticals. In both industries, comparable regulatory oversight exists.

Positive feedback loops, described in Spencer and Carlan's (2008) study, have irremediable and indeterminable outcomes, which magnify risks for system and process functions leading to manufacturing interruption or complete collapse. Negative feedback

loops such as those found in ISO 9000 or ISO TS 14000 series can mitigate the effects of positive feedback loops and restore system equilibrium. The interactions between positive and negative feedback loops help to develop new organizational processes thus moving strategic objectives, such as quality or zero defect manufacturing closer to realization.

Stevenson and Busby (2015) focused on the prominence of counterfeit and adulterated drugs, which may enter the global supply chain or distribution channel and cause further disruptions. Bollampally and Dzever (2015) argued for the further research and potential global use of radio frequency identifiers (RFID) to reduce counterfeit and adulterated drugs in the supply chain. In developed countries, minimal counterfeiting exists because of the overlapping regulatory and security measures in place within the supply chain, distribution channel and at the end user (Blackstone, Fuhr, & Pociask, 2014).

Greater percentages of tainted products exist in emerging markets than established markets, which seem to indicate the absence of a structured quality assessment process in newer economies (Bollampally & Dzever, 2015; Woo, Wolfgang, & Batista, 2008). Woo et al., (2008) reported since the introduction of Internet-based pharmacies, the FDA investigators published online a list of foreign-based pharmacies, which have instances of selling counterfeit medications.

Woodcock and Wosinka (2013) theorized the root cause of drug shortages was because of the absence of incentives and rewards for production quality. Lack of quality perceptions from the buyer and end user was because of limited visibility in the market,

which includes stability of the supply chain and distribution channel (Gupta & Huang, 2013; Woodcock & Wosinka, 2013). The focus of Woodcock and Wosinka's (2013) discussion was the notion of supply interruptions becoming channel shortages. Lean inventories, single sourced manufacturing, aging equipment, and facilities contribute to supply interruption risk (Woodcock & Wosinka, 2013). Shah (2004) suggested the supply chain was a value channel where innovations in organizational development reverberate through the flow of products. The supply chain and distribution channel are also a source of usable information and a source of valuation.

Regulatory and Public Health Policy

The FDA was responsible for a large portion of the regulations associated with pharmaceutical manufacturing and product development. Pharmaceutical policy was a sub-category of health policy with responsibility for framing the drug development process. Pharmaceutical policy manages the factors of use and delivery and qualifies the components of drug formularies. These elements help shape the pharmaceutical industry landscape. Chabner (2011) opined as pharmaceutical spending outpaced medical spending, the United States began passing laws to curb the growth of drug expenditures.

The United States Food and Drug Administration. Before 1980, regulators at the FDA acted paternally in a protectionist approach to drug approvals and manufacturing inspections (Richert, 2016). The FDA regulators would frequently exert their influence on manufacturers because of perceptions of patients requiring protection from unsafe products devoid of clinical benefits (Richert, 2016). Several executive administrations leading up to the AIDS movement in the early 1980s supported this behavior.

The AIDS movement of the 1980s pushed FDA's senior leadership to reconsider changing its direction because of patient activism. Richert (2016) suggested the FDA transitioned away from protecting patients from quality issues to helping patients gain access experimental drugs by allowing them to weigh the treatment risks independent of clinical trial participation. Butterfield, Cash, Pham, and Advocacy Committee for the Pediatric Pharmacy Advocacy Group (2015) suggested the FDA include special management processes for pediatric drugs in their mitigation strategies.

Dorsey et al. (2009) concluded single source generic products may have potential risks with the lack of available substitutes. Considering drug shortages in generics, patients who switched back to the more expensive branded drug were less likely to return to the original generic version (Dorsey et al., 2009). McLaughlin and Skoglund (2015) suggested drug shortages are especially apparent in the outpatient home infusion areas of health care delivery often lacking viable alternates or substitutes. This circumstance prolongs higher than expected drug spending and contrasts with the economic goals of branded to generic pharmaceutical conversions.

Ventola (2011) discussed the need to increase the methods and cadence of FDA communications. The FDA may receive as much as a 6-month notification from a manufacturer alerting the agency of potential manufacturing problems (Ventola, 2011). Increasing the lead-time of notifications may help other manufacturers to increase the capacity of their production lines and potentially avert a severe shortage situation. Ventola also concluded wholesale manufacturers and other specialty distributors must act in the best interest of the market by alerting their customers in the early stages of

shortages or delays.

Crediting the diligence of the FDA, Woo et al. (2008) declared the U.S. pharmaceutical supply chain as one of the safest and most secure pipelines in existence. Globalization now brings additional complexities and challenges to maintain security from counterfeit or adulterated products entering the supply chain and distribution channel (Link et al., 2012; Woo et al., 2008). Woo et al. posited globalization also increased the complexity with not only the number of new products but also the organizations working in the industry. Officials at the FDA have also posted on-line lists of Internet pharmacies, which distribute counterfeit drugs from a foreign-based pharmacy (Woo et al., 2008)

Roberts (2014) concluded information security was an important component of the security of the drug supply channel. Woo et al. (2008) recommended the FDA use a combination of safety and security concerns when marshaling resources to apply to drug shortages. Combating problems of data inconsistencies, fragmentation of systems and regulatory bodies, and the problem with import circumvention, Woo et al. concluded electronic pedigrees affixed to pharmaceutical containers represent the most effective means of reducing or eliminating counterfeits or adulteration. Woo et al. did not discuss the costs of global implementation, which may prohibit practical application of a vital element of supply chain safety.

Y2K: The infancy of the FDA's response to drug shortages. Kweder and Dill (2012) discussed in their empirical study the genesis of drug shortage monitoring. Established by officials at the FDA in 1999, the Drug Shortage Program's (DSP) mission

was monitoring the drug supply chain and distribution channel for interruptions caused by the passing of the century into a new millennium. Although nothing extraordinary came about from the Y2K phenomena, smaller pharmacies inquired with the FDA about obtaining assistance. Officials at the FDA responded by revising the feedback process between the distributors and the providers (Kweder & Dill, 2012).

Reported shortages and delays of medications increased, and the durations became longer and more frequent, which caused regulators at the FDA to focus more on the quality issues of the production process (Kweder & Dill, 2012). The DSP began tracking drug shortages in 2005. Initially, the DSP report contained 61 known shortages, which 51 were sterile injectables for use with oncology patients (Kweder & Dill, 2012). In this study, Kweder and Dill (2012) argued a significant amount of authority evade the FDA. The FDA regulators cannot make a manufacturer produce a product or increase production levels of the product, decide how and where to distribute, and until recently could not require advanced notification of a pending shortage, delay or discontinuance of any product (Kweder & Dill, 2012).

New improvements for FDA's business process. Officials at the FDA are recommending their regulators take on the role of a first responder when notified of pending shortages. Chabner (2011) discussed new efforts by the FDA to step up the frequency of inspections of new and refurbished facilities. Regulators at the FDA will try to expedite approvals for non-domestic sources of products. Pfizer and Sanofi are among growing number of drug companies offering generics overseas, which are comparable to those found in the United States (Chabner, 2011). Chabner postulated the drug

manufacturers should encourage FDA officials to examine these sources of pharmaceutical supply and open new market sources to stem the rising incidents of shortages and delays.

Woodcock (2012) commented on the leadership position of the FDA related to developing the manufacturing quality of domestic manufacturing facilities. Woodcock offered commentary to suggest other manufacturing sectors utilized various quality and defect management systems like ISO series and Lean Six-Sigma to attain higher standards Woodcock commented these types of programs would strengthen domestic manufacturer's ability to resolve the intractable problems of shortages and delays.

All types of U.S. pharmaceutical manufacturers, large and small, producing branded and generic products, prescribed, or over-the-counter have been the subject of supply disruptions (Woodcock, 2012). Improving the mission of the FDA by (a) implementing more educational programs for manufacturers, (b) conducting more investigations before manufacturing quality becomes a disqualifying characteristic, and (c) promoting the elevation of manufacturing sciences among global manufacturing aligns industry goals with the compliance goals of the FDA (Woodcock, 2012).

Pharmaceutical patent regulations in drug development process. A central feature of drug development was the reward of a patent and market exclusivity. Granting of patents from the United States Patent and Trademark Office happen after FDA regulators issue approval. Patents have a 20-year lifespan. During the patent period the recipient of the patent can recoup costs associated with the research and development of future medications; however, in countries like Japan and Europe, government regulations

may place constraints on the price of the newly patented drug (Daemmrich, 2013). Patents enable drug manufacturer to recoup costs associated with the development of the drug along with the costs of other drugs, which failed the clinical trial process (Basheer, 2012).

Market exclusivity rights granted by regulators at the FDA may run concurrently with the patent. Exclusivity was a method of creating market economic parity between generic and new product innovation competition for 180 days and 7 years depending on the type. Basheer (2012) argued pharmaceutical manufacturers require longer patent exclusivity because of the large capital expenditures; however, research findings suggested manufacturers may take advantage of weak areas in FDA legislation to protect investments in research and development.

In his findings, Kesselheim (2011) concluded pharmaceutical development increased through government research projects following the Bayh-Dole Act of 1980. Concerns about intellectual property protection may raise the investment costs of biomedical research and slow the investigative process (Kesselheim, 2011). Additionally, the passing of the Hatch-Waxman Act in 1984 ignited the tremendous expansion of the generic market (Hemphill & Sampat, 2012), which drove down the costs associated with drug treatment regimens.

Kesselheim (2011) evaluated the effects of the Orphan Drug Act and concluded the act had limited success while finding support for his conclusion in the results from similar European legislation. Orphan drugs are more likely to hold a substantial profit margin and less likely influenced by generic competition than brand name drugs

(Kesselheim, 2011). In an earlier study, Kesselheim observed a potential for the manufacturer to manipulate the deployment of orphan drugs to earn incentives citing the original 1989 release of epoetin alpha (Epogen, Amgen). Initially, the drug released as an orphan drug for anemia, but in later clinical indications doctors used the medication in cancer and cardiovascular treatment. Kesselheim summarized market exclusivity alone did not influence product innovation because of other confounding issues. The best scenario for the industry and public health was linking incentives to tangible treatment outcomes (Kesselheim, 2011).

Kesselheim (2011) conducted an empirical review of major pieces of legislation. From a legislative perspective, drug development was a uniquely complex process, which requires substantial capital investments and was highly resource intensive. The patent and market exclusivity rewards help to offset the losses from the failed clinical trials of other pharmaceutical projects. Fleischhacker, Ninh, and Zhao (2015) claimed the clinical trials supply chain requires more research exploration to support consistent outcomes. Kesselheim proposed stretching the product patent to 25 to 30 years for highly therapeutic drugs may have limited economic effect because of the highly discounted net present value (NPV) of the calculation in later years. Instead, Kesselheim promoted the notion incentives aligned with development outcomes would produce a better response from manufacturers.

In an earlier empirical study, Kesselheim (2011) speculated patent extension should spur drug development and innovation in research. Spreading out financial returns may reduce the initial price of the drug, thereby increasing levels of therapy compliance

(Kesselheim, 2011). Kesselheim postulated some of the approved drugs related to the Prescription Drug User Fee Act (PDUFA) of 1992 wind up on recall possibly because of rushed approvals. Kesselheim argued misuse of incentives often influence cost savings to patients and the government.

Kesselheim, Polinski, Fulchino, Isaman, and Gagne (2015) discussed potential effects on approval pathways, which the Generic Drug User Fee Act (GDUFA) had on the FDA's ability to increase processing of new generic applications. The expected total fees, $299 million per year for 5 years, would help agency officials at the FDA acquire resources and technologies needed for long-term administration of the program (Sisodia, 2013). Sisodia (2013) calculated the program would cost an average of 10 cents per prescription. The fees will assist smaller first-time entrants with the ability to receive expedited reviews and reductions in the time to commercialize their product (Krisl et al., 2013).

The FDA will undergo momentous but warranted changes between 2013 and 2017, which will (a) enhance organizational efficiency, (b) build backlog and application metrics, (c) promote good manufacturing processes from site inspections, and (d) explore new industry guidelines. The proposed enhancements provide layers of safety (Krisl et al., 2013; Sisodia, 2013). Officials at the GDUFA may attempt to create parity between foreign and domestic good manufacturing processes (GMP) inspections and to identify those manufacturers who do and do not receive regular GMP inspections. Sisodia (2013) concluded the GDUFA helps new entrants and increases the quality and access to lower-cost generic medications, which may support the mitigation of drug shortages.

Schweitzer (2013) discussed another possible change to FDA regulations suggesting regulators at the FDA implement a grading system rather than a pass-fail system for manufacturer inspections, which may influence consumers and producers to strive for higher quality rankings. Higher quality rankings indicate a competitive advantage for producers. Consumers have shown sensitivity to ranking or grading schemes in other areas (Schweitzer, 2013). Schweitzer further concluded consumers may pay for quality and may have stronger brand loyalty to manufacturers, who consistently rank higher on the quality scale.

The FDA regulations contain a pass-fail system, similar to the previous system of the food service industry. Regulators in cities around the United States moved away from this grading system in favor of letter grade quality indicators (Schweitzer, 2013). Restaurant owners may appear concerned with slipping grades than whether they were going to pass or fail a health department inspection. This mindset may translate to pharmaceutical manufacturers and provide an extra incentive to maintain higher levels of quality in their manufacturing process.

Reverse payments or pay for delay: Unintended consequences. The growing process of reverse payments concerned Kesselheim (2011). Reverse payments mean generic manufacturers accept payments from brand-name manufacturers to delay the release of the generic equivalent (Hemphill & Sampat, 2012; Kesselheim, 2011). Reverse payments or the pejorative pay for delay tactics effectively increase the market life of branded drugs (Hemphill & Sampat, 2012). When the patent for terazosin (Hytrin, Abbott Laboratories) expired, and the generic manufacturer was about to enter the 180-day

exclusivity period, Abbott Labs paid the generic challenger to delay the launch of the generic drug (Frank & Hartman, 2015). The results of pay for delay settlements caused economic damage by artificially extending inflated drug costs to patients and both private and government insurers (Hemphill & Sampat, 2012). This transaction was a perceived consequence of the Hatch-Waxman Act, which should expeditiously facilitate the abundance of affordable drugs into the supply chain (Frank & Hartman, 2015; Hemphill & Sampat, 2012). Chabner (2011) proposed to improve the Hatch-Waxman Act by requiring the generic applicant to include a declaration of the production levels and methods of production redundancies to meet the market demands, prior to filing, for patent invalidation.

Frank and Hartman (2015) observed both branded, and generic manufacturers support the legal standing of pay for delay settlements by promoting therapeutic and generic competition. In contrast, consumers perceive pay for delay settlements are anti-competitive in nature because they eliminate a low-cost provider from entering the market. Hemphill and Sampat (2012) posited some of the court decisions favor settlement over protracted litigation. Furthermore, Frank and Hartman observed generic competition was the only method of fighting the influences of branded market economies. In patent law, the litigation settlements favor the innovator over the consumer. This conflict seems to increase delays in cost savings, which creates treatment compliance issues not found in treatments with low-cost medications (Kesselheim, 2011).

Persuaded by the settlement offer of a pharmaceutical company, generic companies holding an Abbreviated New Drug Application forego manufacturing the

bioequivalent drug because the proposed settlement outweighs the profit potential of the generic launch (Kesselheim, 2011). Kesselheim further argued a 30-month generic launch delay awarded to the manufacturer for protesting the invalidation of its patent adds continuing challenges to the accesses of lower cost drugs. Kesselheim suggested looking at the cause of weak or invalid patents as the best solution to the issue. Currently, Congress was now considering making changes to patent laws relieving pressures on judges to choose between strengthening public health policy and eliminating unnecessary legal actions (Kesselheim, 2011).

Drug importation and compounding pharmacies for critical national shortages. Hunnisett-Dritz (2012) conducted a case study to describe the process of importing the drug from outside the United States using the Personal Importation Policy (PIP) of the FDA. Cytarabine, an antineoplastic agent, used to treat several types of leukemia, was in short supply, in the United States, in 2011, but not in short supply globally (Hunnisett-Dritz, 2012). A large acute care hospital, which treated approximately 2,000 new cancer patients per year, decided to locate and to procure Cytarabine from a reputable European supplier because of lingering shortages of oncology drugs (Hunnisett-Dritz, 2012).

The hospital's pharmacy team utilized the PIP guidelines to import a one-time small supply of the drug from the European supplier at an elevated per unit cost (Hunnisett-Dritz, 2012). Hunnisett-Dritz highlighted the decision process and the components of the risk-benefit assessment; however, no information was available to assess the costs associated with the procurement process including the repurposing of staff, both hospital and supplier, to complete the transaction. Hunnisett-Dritz (2012)

attempted to demonstrate the thought process of senior procurement leaders faced with difficult challenges and limited resources.

Barlas (2011) opined Hospira, the manufacturer of propofol 1%, an important drug used in operating room sedation, was subject to recall of the product because of particles found in the vials. Officials at the FDA could not identify sufficient stock in the domestic supply chain; therefore, APP's Fresenius Propoven 1% was temporarily imported. This importation was outside of the PIP constraints. Barlas (2011) suggested the imported drug had special dispensing preparations, which created a new set of procedures and risks. All health care providers may consider the positive aspects of a global governing agency because of the globalization of the supply chain (Johnson, 2011; Kweder & Dill, 2012). Regulators at the FDA, as a last resort, will relax importation rules to supplement the distribution channel artificially until the United States approved manufacturer was capable of resuming production (Kweder & Dill, 2012; McBride et al., 2012).

Outterson (2012) discussed the health benefits of having compounding pharmacies available to support critical drug shortages; however, Outterson argued for greater regulatory involvement by the FDA in light of the outbreak of fungal meningitis at the New England Compounding Center in 2012. These businesses operated an undefined grey area of health care supply (Outterson, 2012). FDA officials attempted to regulate the larger industrial-scale compounding sites with limited success. Outterson argued several factors of concern exist when evaluating products from a compounding pharmacy like sub-potency, super-potency, contamination, overmedication, and medical

replacement.

Outterson (2012) explained the solution may require full disclosure to physicians and patients regarding the origin of the product, increased incentives for whistle-blowers and modifications of reimbursement standards for these types of operations. Outterson's explanation focused on ex-post facto conditions. More workable solutions may focus on ex-ante standard compounding processes across the various state and local laws and establish uniform criteria for industrial-sized compounding operations, which service high patient volumes. These conditions ease support to local markets when supply disruptions exist for pharmaceutical prescribers.

Medicare Prescription Drug, Improvement, and Modernization Act.

Hornbrook et al. (2014) discussed substantial reimbursement changes by the federal government under the MMA affecting how government sponsored health insurance reimburses drug treatment administration on non-acute settings. Link, Hagerty, and Kantargian (2012) argued the reduction of reimbursement would redefine treatment methodologies of oncologists and the clinical settings for patients. Woodcock and Wosinka (2013) claimed prior to the enactment of MMA, price competition for sterile injectable drugs were already present in industry. Medicare and Medicaid beneficiaries purchase the most oncology drugs of any other payer class (Hornbrook et al., 2014). Hornbrook et al. (2014) reported one of the steepest reductions in reimbursement was a long-term cornerstone drug, Taxol (paclitaxel). Reimbursement for Taxol declined 81% from $138.28 to $25.84 beginning January 2005 (Havrilesky et al., 2012; Hornbrook et al., 2014). Link et al. (2012) suggested setting reimbursement floor limits for price

reduction would bolster the production of already lower cost generic oncology products. Creating a floor limit would provide a greater profit margin for pharmaceutical manufacturers without greatly increasing pharmaceutical spending (Link, Hagerty, & Kantarjian, 2012). Kinney (2013) reported physician reimbursement was the focus of several pieces of legislation; however, the emphasis was on controlling fraud and abuse and not creating fair compensation.

One of the health care cost benefits of having oncologists administer these types of drugs was treatment infusion occurred in the physician's office, helping to reduce the higher cost treatment in acute care centers (Malin, Weeks, Potosky, Hornbrook, & Keating, 2013). Further research may determine the long-term financial influence of MMA (Hornbrook et al., 2014; Malin et al., 2013). Havrilesky, Garfield, Barnett, and Cohn (2012) confirmed this position. The regulations in the MMA do not address the root causality of this situation by placing the economic burden on oncologists rather than requiring pharmaceutical companies to disclose the cost structures of their products.

Chabner (2011) offered an argument suggesting multiple interrelated problems are the source of drug shortages and delays. Companies record a very small profit margin on the ledgers when they sell manufactured generic products on older equipment in less efficient settings (Link et al., 2012; Woodcock & Wosinka, 2013). This condition emphasized the need for legislators to understand the ramifications of reducing reimbursement (Link et al., 2012; Woodcock & Wosinka, 2013). The risk of shortage or interruption increases when exposed to leaner inventories and demands on raw materials shared with medications, which are more profitable (Chabner, 2011; Link et al., 2012).

Historical inspection records show a portion of the quality issues causing supply disruptions related to product contamination caused by older equipment in the manufacturer's facility. Although a pharmaceutical product was still in high demand, some manufacturers, because of reduced reimbursement, hazarded their manufacturing process to maintain even small profit margins (Woodcock & Wosinka, 2013).

Colla, Morden, Skinner, Hoverman, and Meara (2012) conducted a study to investigate changes in chemotherapy treatment at the end of life, leading up to and after the implementation of the MMA. Colla et al., (2012) concluded decreased utilization of chemotherapy existed for patients after the full implementation of the MMA legislation. Colla et al. (2012) concluded while chemotherapy treatment declined 20% in physicians' offices, no such decline existed in hospital outpatient treatment centers. Antithetical outcomes existed for end of life cancer patients receiving treatment regimens in a physician's office or outpatient clinic. Colla et al. (2012) suggested the reason may appear because of the lack of financial benefit to the oncologist prescribing chemotherapy in a hospital setting. Although more individuals have access to treatment, the intent of the act failed to control costs and harmed manufacturer's ability to maintain production of the less profitable products.

Capacity and Sustainability of the Supply Chain and Distribution Channel

Woo et al. (2008) in a public policy article suggested the American pharmaceutical supply chain boasts one of the most impressive high standards of quality and security among other global pharmaceutical delivery systems. Spending in the U.S. pharmaceutical market by the year, 2016 will reach over $363.3 billion (IMS Health, Inc.,

2012). The large aging population in the United States requires the drug supply chain and distribution channel to demonstrate characteristics of capacity and sustainability. The characteristics of capacity and sustainability may help the shift in process by health care providers to utilize pharmaceutical treatment regimens to meet evolving needs. Emerging nations not yet assimilated to westernized medical practices have unknown medical demands; thus, unknown supply demands exist on differing production timetables.

This segment of the literature review includes: (a) the structural aspects of the pharmaceutical supply chain, (b) compounding pharmacies, and (c) the risks of grey markets. The complex and chaotic cadence of the pharmaceutical lifecycle challenges the notion of sustainability. As more disease states receive treatment with new drug regimens, the supply chain expands, just as distribution channel expansion occurs with new consumers.

Globalization of the pharmaceutical supply chain. In 2015, officials in 17 emerging market countries will spend more than $308 billion on medications (Sharma et al., 2013). According to Woo et al. (2008), China and India made up approximately 40% of all foreign FDA registered manufacturing sites in 2008.The entire pharmaceutical economy expects to grow at a rate of 5% CAGR (IMS Health, Inc., 2012). Maintaining high standards of quality and security are prominent objectives of all parties of the supply chain. Jaberidoost et al. (2015) concluded political unrest and war in countries like Iran have nearly eliminated the pharmaceutical supply chain. Sharma et al. (2013) suggested because of a large amount of brand to generic conversions; pharmaceutical organizations would build manufacturing facilities as a cost savings measure in emerging economies.

Sharma et al. (2013) posited some of the drug classes like oncology and antibiotics have a higher growth rate in countries such as India, China, Russia, Brazil, and Japan. This economic incentive may become a new marketing roadmap for manufacturers. One of the most serious concerns for pharmaceutical supply chain analysts was the information limitations to predict forward demand because of the lack of data collection to support feedback models Sharma et al. (2013). Newly developed products to treat new disease states require the economic benefits of adding manufacturing capacity to the supply chain equation.

Gray and Manasse (2012) discussed the paradox of product expansion without capacity expansion. New pharmaceutical products for new disease states exist in the supply chain without the benefit of adding new manufacturing capacity. Without surplus capacity, minor disruptions can have catastrophic effects on the supply chain (Gray & Manasse, 2012). Without adequate data collection, a way of predicting demand or capacity may not exist; therefore, procurement leaders may consider *what if* strategies to assist with managing supply chain and distribution channel disruptions.

Reports of worldwide shortages of mainstay drugs in fragile markets became normative (Goozner, 2012; Gray & Manasse, 2012). Again, the fragmentation of the information feedback loops was evident in this discussion. Neither discussion identified a common fundamental protocol in alerting markets of possible shortages or delays. The amount of employee time or resources health care procurement leaders may save if they received immediate access to the notifications was missing from the discussion in either discourse.

Goozner (2012) opined even though pharmaceutical regulators in the United States reached out to other markets for assistance in importing drugs in short supply, those nations also had similar supply disruption issues. The economic slowdown of 2008 and 2009 coupled with the instability of the European financial markets caused investors to withdraw investments from pharmaceutical stocks. In turn, a decrease in investor capital may have created novel economic challenges for the manufacturers to upgrade or maintain equipment and facilities during the downturn of the economy.

Quilty et al. (2012) described the evolving global supply chain as a Pandora's Box of vulnerabilities because of simple demographic differences. Disruptions from natural disasters such as fire, floods, and earthquakes may harm system equilibrium causing supply disruptions. Quilty et al. suggested the senior leadership staff members of The World Health Organization should include regulatory language associated with disaster recovery in its version of good manufacturing quality guidelines. Quilty et al. explained as the supply chain reaches the remote area, the risk of disruption increases exponentially.

Schweitzer (2013) discussed the industry's transition of complex supply chains for raw materials and finished pharmaceutical products from industrialized nations to emerging nations with lagging technology because of reduced profit margins. Schweitzer concluded the FDA found difficulty inspecting the offshore facilities rendering FDA supervision of foreign facilities ineffective. In one particular example, a manufacturing facility in China went without inspection because the FDA did not have a Mandarin-speaking inspector. Noteworthy to this incident was the large heparin recall from this

facility in 2008 (Schweitzer, 2013).

Both Cherici et al. (2011) and Johnson (2011) discussed the risks of raw material shortages occurring in distant locations outside of the U.S. manufacturer's purview. Raw materials are the source of all drugs and hold the key to the production. Ventola (2011) posited a single raw material distributor could supply multiple manufacturers. Ventola further theorized an interruption of raw materials would affect all manufacturers. These interruptions could come from issues other than natural causes such as political unrest, wars, terrorism, and trade disagreements (Ventola, 2011).

Woo et al. (2008) concluded the growing global base of pharmaceutical manufacturing created a risk for counterfeit or adulterated drugs. The global markets add complexity to a fragmented and siloed system, lacking complete visibility (Woo et al., 2008). In this study, Woo et al. suggested the use of product DNA or the placement of RFID systems on the packaging to curb product tampering.

Advantages of a growing global pharmaceutical production environment in emerging countries are the potential to solicit higher numbers of populations to provide human tissue, blood, stem cells, and other raw materials to make drugs and new biotech therapies (Farrugia & Cassar, 2013; Salter, Zao, & Datta, 2014). Emerging nations may also have new raw materials to use in pharmaceutical development from previously unknown plants, animals, or natural features. The literature review did not include discussion related to new raw materials, but this point of view was important to include in the literature review discourse to understand the influences and detractors of sustainability.

Lean manufacturing and lean inventory practices. Jahanbakhsh and Akafpour (2013) examined trade-offs between financial reward and risk in a lean production environment. Much of the pharmaceutical supply chain and distribution channel design engineers embraced lean thinking because of the financial rewards attributed to cost reduction. Lean production contains foundations of agility and flexibility gained by reducing or eliminating non-value added activities and concentrating on value added activities. Jahanbakhsh and Akafpour discussed the transition from a traditional *push* system to a more efficient *pull* system provides better workforce utilization and cost control than traditional methods. Pull systems enable the customer to pull the product through the supply chains with better quality and lower cost than traditional methods. Feedback models in the pull system alert upstream process areas of the need to satisfy a pending demand. Mehralian, Zarenezhad, and Ghatari (2015) suggested business environments rich with uncertainty and unpredictability deal with the changes by developing organizational agility or process fitness.

From a financial perspective, lean production reduces overall costs because the production schedules align with demand drivers thus eliminating waste in idle processes. This process was also a vital component of Just-in-Time (JIT) delivery. One of the challenges with this methodology was for the manufacturer to be thoroughly entrenched in the culture, both internally and externally because unpredictable demand challenges can disrupt a production system out of alignment with customers and suppliers. Alizadeh (2012) interjected the idea of exponential smoothing in lean production where the organization builds better processes from routines and fixed sequences, thus driving out

process defects.

Just as lean production reduced costs for manufacturers, lean inventories reduced the costs of inventory holding and the cost of obsolescence (Fox et al., 2009). Lean inventories in health systems, distributors, and large mail order pharmacies help health care professionals maximize the organization's cash flow. Investors and other stakeholders recognize this practice as sound business management. Manufacturers are commonly managing the inventory levels of the distributors to ensure the supply level was appropriate for the demand. Fox et al. debated if inventory levels in rural hospitals should reflect the risks of delivery problems because of the distance from the distributor and the lack of other health care providers to borrow critical products. The remote location of some health systems was a risk because the health system personnel may not be capable of maximizing inventory cost savings as hospitals in urban settings.

Grey market distributors. Hospitals and wholesale distributors average one month of supply while health systems average about 2 weeks (DeOlivera et al., 2011). Woodward (2012) reported opportunistic distributors appear attractive to remote locations and hoard or stockpile drugs in short supply and then sell them to needy providers at significantly higher prices than before the shortage. Grey market distributors operate strictly for profiteering purposes (Chaudhry, 2014; Qureshi et al., 2012). Some products acquired on the grey market sold for as much as 600% of the regular wholesale distribution cost. Ahmadi, Iravani, and Mamani (2015) determined the extent of grey market distribution has increased with the growth of efficient global logistics networks.

Woodward (2012) suggested grey market distributors, although legal, represent a

medical risk because of lacking process standardization. Industry questions their ability to obtain problematic drugs and sell them to hospitals with a limited and often contradicting chain of custody documentation. Hospitals have little alternative, but to trust the distributor and dispense the medication especially in time-sensitive acute care situations. Woodward (2012) argued the government has not done enough to control medical price gouging. The current political response was ineffective against this growing area of pharmaceutical distribution.

Business Decisions

Multiple drivers contributed to business strategy development. The swift global economic downturn in 2008 and 2009 caused executives of companies in the pharmaceutical market to pay closer attention to sales and profits rather than research and development. Pharmaceutical manufacturers were less likely to upgrade manufacturing equipment and facilities because investors withdrew massive amounts of money from the stock market. Barlas (2013) discussed the decision by the manufacturer not to upgrade equipment or facilities may be one of the reasons for drug supply disruptions

One of the objectives of operating a large publically traded pharmaceutical company was to take a portion of the profit and reinvest the profit into the organization's infrastructure to maintain its capital assets, like buildings and equipment. Another objective was to take a portion of the profit and return the profit to investors in the form of stock dividends. Both objectives may make the stock appear as an attractive investment. When companies face threats to their profit margin, the executives from the company may abandon one or both of the objectives above. Since the investor was an

essential source of funding, the choice was likely to reduce capital maintenance until financial conditions change and permit the resumption of manufacturing the product.

Barlas (2013) opined severe price competition influenced the capabilities of generic manufacturers to maintain equipment and facilities. The notion of paying for quality resonates through the health care industry. Barlas indicated pharmacy leaders see government-mandated pricing control as a contributing factor to drug shortages. Barlas opined the industry may need subsidies from the government to help generic producers deliver products similar to government crop subsidies paid to farmers. Barlas suggested a national reserve stockpile administered by the Centers for Disease Control; however, no cost-benefit analysis was available for drawing these conclusions.

The value and reimbursement imbalances in the system confound the perception of sustainable cash flows. Kumar, Liu, and Scutella (2015) reasoned when pharmaceutical manufacturers in India discover specific potential supply disruptions for a drug, investors, and stakeholders of the firm may conclude a possible risk of equity loss exists. Market uncertainty may lead to unstable financial performance. From a system's perspective, the disruptions within the supply chain may influence the financial health of other stakeholders related to this industry.

Crawford (2010) expressed pharmaceutical manufacturers employ highly paid lobbyists to argue for maintaining industry status quo when lawmakers attempt to introduce pricing regulations to lower the overall cost of care. One of the pricing regulations needing regulatory intervention was the issue of price discrimination, which suggests the individual price of the product in various markets be subject to inconsistent

pricing (Crawford, 2010). Circumstances of this type would mean the manufacturer could manipulate profits as needed. Health care regulations with minimal government intervention seemed to insulate manufacturers from most of the financial pressures during the last economic downturn. Crawford reported the drug makers maintained profit increases and confirmed positive earnings guidance throughout the economic slowdown between 2006 and 2009.

Government intervention was not entirely bad for business (Crawford, 2010). In his analysis, Crawford explored pricing controls on monopoly producers of goods and or services. Crawford decided regulating prices may increase the quantity in the supply chain by reducing the risk of disruptions. The objective of Crawford's study was to assess manufacturers of branded drugs having a healthy profit margin and not necessarily analyzing the effects on generic product profits.

The business perspective of reverse payments. Academic literature related to reverse payments or the pejorative pay-for-delay scenarios identified opposing viewpoints. Hemphill Kraus (2012) posited senior leadership in the pharmaceutical industry rely heavily on patent protection for products and for steady profits. Others claim the patent protection supports product exclusivity and the capability to attract investors strengthening the equity flow to companies interested in the research and development (Drake, Starr, & McGuire, 2015). At stake are substantial long-term revenue rewards and the balance between innovation and competition. Drake et al. (2015) concluded stock prices for the patent holder fell 6% when the settlement notification included a reverse payment.

Hemphill Kraus (2012) posited the pay-for-delay scenario was disruptive to the spirit of the Hatch-Waxman Act by providing an imbalance between the innovator and the competition. In two instances, the FTC pursued litigation to invalidate pay-for-delay settlements because they seemingly violated anti-trust legislation (Hemphill Kraus, 2012). Manufacturer's profits for branded pharmaceuticals decrease once the generic producer has gained access to the marketplace. The loser in this profitability fight was the consumer (Hemphill Kraus, 2012; Kesselheim, 2011).

Hemphill Kraus (2012) described different methods, which branded, and generic manufacturers sidestepped the United States Circuit Court's antitrust intervention. Generic manufacturers will often include an unrelated product license, which functionally overstates the settlement price to the branded firm. In other instances, Hemphill Kraus identified branded drug firms would just supply the product to the generic firm at a discounted price, which then placed their generic label on the product and sold the new. Hemphill Kraus concluded because of the evolving settlement product at favorable prices structures in pay-for-delay settlements; the courts will have difficulty identifying and condemning these actions.

Complexity of the Pharmaceutical Delivery System

Narayana, Pati, and Prem (2014) suggested the existence of academic reservations within supply, capacity, and demand functions related to systems complexities in the pharmaceutical delivery system. Narayana et al. indicated limited academic research in pharmaceutical supply chain management contributes to the complexity within the supply chain and distribution channel. Research conducted by investigators in academia into new

product development, upstream processes, and increased business integration show small frequencies of interest (Narayana et al., 2014).

Woo et al. (2008) discussed how the globalization of supply chains increased the degree of complexity because of additional lines of transportation, new distributors and repackagers, warehouses, expediters, brokers, and import or export agents. Woo et al. observed complexities in the system and fragmentation of regulators support the possibility to introduce counterfeit products because information gathering takes place only at the point of entry and not sequentially throughout the distribution process. Woo et al. argued in a public policy article the FDA cannot and should not police the entire supply chain; the industry must rely on systematic capabilities of advanced technological solutions to reduce or eliminate threats of drug supply disruptions. Janvier-James (2012) concluded the development and growth of supply chains involve intensive management planning of functions and roles by personnel to become efficient.

Janvier-James (2012) used the findings of the study to identify potential solutions to the resource fragmentation in the supply chain. Woo et al. (2008) recommended using an executive order, which formed the Interagency Working Group on Import Safety to manage the safety concerns of imported products in the United States. Utilizing the process of working cooperatively, employees of government agencies and private sector manufacturers will solve problems at the source rather than mitigating them after product importation (Woo et al., 2008). Members of the Interagency Working Group on Import Safety's focus was on ex-ante solutions but disbanded without public explanation.

Spencer and Carlan (2008) discussed the complexities of the automobile industry

in the same context of the pharmaceutical supply chain. Spencer and Carlan postulated the automobile production environment operates far from equilibrium because of deficient equipment maintenance, and facility cleanliness, which leads to the issue of worker safety and health. Likewise, with pharmaceutical production, positive feedback loops push the system into imbalance possibly for the same reasons with similar consequences.

From a complexity theory perspective, Spencer and Carlan (2008) theorized the automobile production process as operating between order and chaos highlighting the natural progression of emergent behaviors. Similarly, the pharmaceutical supply chain faces areas of order and areas of chaotic behavior as the realization of globalized medical care integrates into domestic practices. Gimenez, van der Vaart, and van Donk (2012) found adverse effects on supply chain costs with the increase of structured communications to obtain system integration. The global health care landscape will yield additional similarities over time.

The emergence of pharmacoeconomics and biogenetic drugs add further complexity to the manufacturing process (Shah, 2004).Users of the pharmacoeconomics discipline assess the total costs and outcomes of treatment and biogenetic drugs target individual patient treatment regimens based on DNA mapping (Shah, 2004). Terror attacks with biologic agents and pandemic instances such as H1N1 influenza, Ebola, Zika, or Avian Flu (H1N5) necessitating new capacity needs requiring the addition of supportive products to the supply chain and distribution channel (Shah, 2004). New types of demands related to pandemics and bioterrorism may mandate manufacturers revise the

production process to become agile and flexible when delivering new drug therapies, which may eventually drive the system into further imbalance.

In a process simulation and case study, Li, Yang, Sun, Yi, and Feng (2010) discussed CASN evolve because of influences from demand, market conditions, and regulatory measures. Li et al. cautioned industry firms to become more diligent about refusing inappropriate regulation because new regulations could quell adaptive and emergent behaviors necessary for the health of the supply network. Maintaining vibrant long-term relationships are vital to the performance of the stakeholders in the supply network.

Li et al. (2010) identified costs and quality as the most important elements of the evolutionary process. From a managerial control standpoint, Li et al., observed CASN has an ability to adapt and emerge through self-organization. Li et al. suggested standardizing the manufacturing process into central locations to produce finished products where cost controls and quality maintenance procedures can have a maximum effect on operational controls. Contrasting theories appear to exist between Li et al., and others regarding globalization. Li et al. prefer the comfort of boundaries and rules, which are more concrete than other studies.

Fox and Tyler (2013) observed the difficulty encountered by buyers making value-based decisions when the information was unavailable in an understandable and consumable format. Fox and Tyler supported the study by Woodcock and Wosinka (2013) and stated the conclusions of the study were rational. When discussing fragmentation, Fox and Tyler reported the FDA Orange book, FDA Medwatch Reports,

and FDA Form 483 (inspection reports) in conjunction with manufacturer appraisals provide a more comprehensive assessment of the degree of quality manufacturing processes. Fox and Tyler also reported the buyers were unable to make reasonable procurement choices without a proper manufacturer disclosure.

Adverse Effects on Patient Outcomes

Aside from the social aspect of drug shortages having a physical effect on patients, economic burdens increase on health care providers whom must pursue sudden alternative processes to care for the serious conditions (Institute of Safe Medication Practices [ISMP], 2010). ISMP was the nation's leading authority on medication safety and acts as a centralized reporting location for medication errors in the United States. In 2010, members of ISMP surveyed health care practitioners (*N=1800)* to understand the perceptions related to drug shortage treatment options. Members of ISMP reported 630 (35%) of the 1800 surveys reported a *near miss* incident, which could have injured a patient further, directly tied to a drug shortage.

In the survey, members of ISMP (2010) reported approximately 68% of the respondents were pharmacists. In the responses, nearly 80% reported severe financial impact related to the management of drug supply disruptions. The survey conducted by the members of ISMP also identified nearly 70% of respondents used significant resources administering or preparing alternative medications for patients. More than half of the respondents surveyed identified internal hoarding of drugs in short supply at their medical facility. These situations may be responsible for the 55% of the reported anger from physicians toward pharmacists and nurses identified in the survey.

The members of the ISMP (2012) survey team conducted a follow-up survey of 100 practitioners to understand if the harmful effects of drug shortages continued. The introduction of substitute or alternate medications into the treatment regimen forced patients and caregivers into unfamiliar situations. Drug supply disruptions do not allow patients or their caregivers ample time to familiarize themselves with the dosing, administration, and new side effects of the new drug. Respondents to the ISMP 2012 survey reported alternative medications accounted for derisory care in 35% of the cases. Practitioners in the follow-up survey reported medication errors related to strength and form of administration in greater than 25% of the responses. The survey contained many horrific adverse patient outcomes including multiple deaths because of errors in administering alternative or substitute medications.

Mullins and Cook (2011) suggested in a pharmacy update article the causes of drug supply disruptions are numerous, and the effects on patient care are immeasurable. In their update article, Mullins and Cook suggested some drugs have alternates; some have substitutes, and some drugs have neither causing patients to endure long durations without the proper drug therapy. Mullins and Cook observed acute patient admissions to the hospital increased because disease states progress when the patient does not receive adequate drug therapy. For instance, Mullins and Cook observed patients receiving medication therapy for spinal cord injuries were unable to receive treatment with a high dose of methylprednisolone immediately following the injury because of shortages. These patients may face extended neurological recovery and increased lingering medical needs.

Physicians and clinical practitioners select new alternative drugs with subtle differences in side effects, efficacy, duration of treatment, and interaction with other drugs, which potentially could also be alternate or substituted (Mullins & Cook, 2011). Each gradation of a new treatment procedure increases the risk of errors in judgment or practice. Iterations of new processes require the introduction of new cost structures into the budget allocation, further pressuring the cost curve.

Mullins and Cook (2011) reported in a pharmacy update article increased costs affect three areas of health care treatment. Patients face higher deductibles when taking branded drugs instead of generics. Insurance companies pay for the costs of branded drugs or alternate therapies resulting from changes in patient treatment. Hospital leaders lose profit when using more costly drugs in procedures and when locked into a fixed price reimbursement from the insurer. Hospital leaders and physicians lose revenue when they have to cancel or delay procedures because of the inability to secure one or more of the drugs used in the procedure.

The different faces of drug supply disruptions. For children with Hodgkin's Lymphoma, the best curative treatment regimen involves a drug, mechlorethamine or nitrogen mustard, which has over 50 years of clinical use. Metzger, Billett, and Link (2012) opined pediatric Hodgkin's Lymphoma was an extremely treatable form of cancer. The alternative drug in the treatment regimen was cyclophosphamide. Metzger et al. (2013) suggested treating children with the alternate product would significantly reduce the effectiveness of the therapy. The alternate drug had a greater occurrence of debilitating side effects.

The health issues created by drug supply disruptions retrograde the treatment of this condition by several decades (Metzger et al., 2013). Once thought to be highly treatable, Hodgkins Lymphoma was just a manageable waiting game. Until the supply of this product returns to acceptable levels, hospitals and doctors must rely on alternate or substitute chemotherapeutics resulting in serious inferior patient outcomes (Metzger et al., 2013). Metzger et al. recommended increasing clinical evaluation of alternate or substitute products before including them in new treatment regimens.

Griffith, Pentoney, and Scheetz (2012) reported that antimicrobial agents are second to oncological drugs in total drug shortages. Griffith et al. posit the growth of antimicrobial shortages changed treatment paradigms from a more measured informative approach to one of a calamitous process. In their longitudinal empirical study, Griffith et al. discussed 87% of the reported shortages were generic. Of the reported cases, greater than 60% related to quality manufacturing issues. Griffith et al., also observed the shortages did not resolve expeditiously nor was any advanced warning given by the manufacturer.

Griffith et al. (2012) stated the key to drug shortage management was proper stewardship by institutional pharmacists. These individuals would act as a centralized communications link between the external reporting sites, FDA, and ASHP, alerting the institution of emerging supply information. The pharmacists may marshal additional resources and stakeholders for formulating business contingency strategies (Griffith et al., 2012). Paina and Peters (2012) suggested using the theoretical tools of complex adaptive systems to optimize outcomes during the scaling up of new health care processes as a

means to achieve efficiency.

Goldsack et al. (2014) utilized an online survey of pharmacy directors (*N=1334)* to identify the challenges of delivering treatment therapy to oncology patients and to identify the effects of these conditions on organizational cost drivers. Respondents to this survey communicated 64% had run out of at least one oncology drug from their formulary. One-quarter of the responses identified one or more safety events related to substitute or alternate oncology medications, where the reaction was moderate to very high. A fair percentage of the responses felt a reasonable risk of patient mortality exists because of drug supply chain and distribution channel disruptions.

Management of drug shortages has multiple implications in addition to complexity (Nagurney, Yu, Masoumi, & Nagurney, 2012). Institutional clinical managers prioritized patients to receive treatment based on clinical standing (Goldsack et al., 2014). Greater than one-fifth of the survey participants reported receiving referred patient or referring patients to other institutions to continue treatment because the medication was unavailable and no alternate or substitute drug exists. Saedia, Kundakcioglu, and Henry, (2016) recommended using a complex algorithm to manage inventory supply; however, the algorithm assumes at least two substitute medications exist in the supply chain. Based on the findings in the previous research of Goldsack et al. (2014), Saedia et al.'s (2016) assumption was invalid because of the limitations to the population of the algorithm. Continuity of care was another challenging dimension of drug shortages because the provider commits resources to either accept new patients or transfer patients to other providers to complete treatment. One of the challenges to maintaining treatment regimens

was to locate a provider who participates in the patient's insurance program.

The Goldsack et al. (2014) survey included inquiries related to facility costs associated with drug supply disruptions. More than two-thirds of the respondents acknowledged a moderate to severe increase in facility costs in the areas of extra resource allocations, paying higher prices for alternate, or substitute drugs and procuring drugs in a secondary or grey market. Goldsack et al. concluded none of the legislation recently adopted such as PDUFA, GDUFA, and FDASIA has had a measurable effect on influencing drug supply disruptions for sterile injectables for oncology drugs.

Rosoff et al. (2012) offered a structured decision matrix based on four ethical benchmarks. Adhering to the guiding principles of accountability for reasonableness, Rosoff et al. identified the benchmarks as (a) transparency, (b) relevance, (c) appeals, and (d) enforcement. A committee of various hospital staff oversaw the development of the policy. A unique feature of this policy was the presence of a compounding pharmacy, which may help the hospital staff to mitigate critical needs.

Propofol, a sterile injectable used in anesthesia introduction and management, was in short supply at an academic hospital (Roberts et al., 2012). Propofal's primary use was in surgical sessions preparing the patient for sedation. Without a consistent supply of this drug, clinical staff must re-evaluate new surgical sessions to determine if alternate or substitute drugs are available and if a patient can tolerate the treatment (King & Ogg, 2012). Shortage of this drug means delayed recovery and rehabilitation from the patient's underlying illness or injury further complicating the continuity and cost of care.

Propofol was one of the growing drugs in the neuromuscular blocking agents list

added to the increasing list of drug shortages. Anesthesiologists rely on propofol because propofol was a proven product with little or no side effects (Roberts et al., 2012). This product had a stable demand, where historically the manufacturer had little or no excess capacity.

Medical practitioners may ignore the label instructions of single-use propofol vials by multiple entries as a means of extending the administration of the leftover product, which should alarm the FDA. This unethical practice led to the outbreak of Hepatitis C causing the testing of another 40,000 individuals for other serious conditions. King and Ogg (2012) stressed the need for medical clinicians to act responsibly by adhering to safe medication practices even in the event of drug supply disruptions.

Drug supply disruptions effect on affordable care. Implementation of the PPACA supported the formation of integrated health care delivery structures, which share the costs and profits of patient care (O'Donnell & Vogenburg, 2013). Affordable Care Organizations (ACO's) and other groups of providers assume the total responsibility of care for covered individuals in return for a lump sum payment from an insurer. The ACO was accountable for improving patient outcomes while accepting the financial and legal risk of the patient population. O'Donnell and Vogenburg (2013) reported on the legal aspects of drug shortages, medical errors, and related cost overruns.

Hospitals and health systems under this type of operating framework were at risk because Medicare can sanction penalties for inadequate care that result in additional treatment or readmission, which providers are unable to bill (Bharel et al., 2013; O'Donnell & Vogenburg, 2013). O'Donnell and Vogenburg debated which conditions of

drug supply disruptions put providers at the greatest legal risk. This situation calls for the evaluation of *failure to supply* language in procurement contracts as a novel means to reduce potential legal liability in risk-bearing clinical providers. Data does not exist to support the considerations of how these new types of organizations will administer care in situations of drug supply disruptions (O'Donnell & Vogenburg, 2013).

Teagarden and Epstein (2013) identified a new form of integrated provider structure, the Pharmacy Benefit Manager (PBM). This type of organization operates on the premise of supplying mail order prescriptions across all 50 states and earns its revenue through management of cost-saving formularies. These companies represent a significant portion of the consumable pharmaceutical product and requiring daily high volume shipments to keep pace with outbound orders.

Teagarden and Epstein (2013) recommend PBM's consider a conservative approach to reacting to drug supply disruptions by resisting hoarding or have methods of validating patient demands through a pre-authorization program. Teagarden and Epstein reported when PBMs become more capacious the data generated by filling prescriptions may have an extended use by predicting forward demand or predicting changes in demand. This type of secondary use may support new methodologies to alert or monitor the drug supply chain and distribution channel for inconsistent behaviors.

Transition and Summary

A comprehensive review of the literature associated with drug supply disruptions affirmed the confounding problem interconnects with multiple areas of causality. Clinical professionals, academia, and government leadership have drawn inferences individually

and jointly as to the potential solutions to this problem. The legislators in the federal government through many different agencies enacted regulations and statues to create equal and cost-efficient access to pharmaceutical health care treatment (Fox et al., 2009). Mature and emerging industrial economies influenced the evolution of pharmaceutical development and delivery. The laws of supply and demand do not translate well in this business sector because of the high degrees of price inelasticity coupled with the high levels of government regulation and intervention. health care expenditures related to pharmaceutical spending increase despite efforts to slow its growth in part because of the ineffective protocols to address drug supply disruptions (Schweitzer, 2013). The statement of the problem and study purpose was consistent with how health care procurement leaders perceive the obstacles and challenges with detecting and mitigating drug supply disruptions. An investigator can use general systems theory and complex adaptive systems network analysis to identify interactions in dynamic systems, which create impairments in the feedback loops within drug supply chain and distribution channels.

In Section 2, I describe the structure and manner of the execution of the study. Section 3 includes an overview of this study and presentation of findings from the analysis of collected interview data. Section 3 also includes discussion of professional applications of the research to health systems organizational practice and the presentation of recommendations, reflections, and conclusions resulting from the conduct of this study.

Section 2: The Project

Section 2 contains the following subsections: (a) the purpose of the study, (b) a discussion of the researcher's role, (c) a description of participant strategies for the conduct of the study, (d) descriptive information on the research method and design, (e) amplification of the participant population, and (f) explanation of the ethical research process. Additionally, this section contains specific information on the data collection technique, instrumentation, and data analysis. Furthermore, this section contains a description of reliability and validity.

Purpose Statement

The purpose of this qualitative multiple case study was to explore the strategies that health systems pharmaceutical procurement leaders use to address disruptions in the drug supply chain and distribution channel. The participants in the semistructured interviews include five leaders from pharmaceutical procurement departments in health systems who had successfully addressed the research problem. The companies included three health care organizations from the Eastern region of the United States. The participants shared their strategies of mitigating supply chain and distribution channel disruptions. The hospital pharmaceutical leaders also shared additional company documents and internal policies containing relevant data that supported the notion of triangulation (see Denzin, 2012). The findings of the research may contribute to social change by addressing important issues. The first concern was improving health care leadership's understanding of the internal strategy limitations resulting from drug supply chain disruptions. The second matter was assisting health care procurement leaders to

understand the perceived quality problems related to treatment delivery influenced by drug supply chain disruptions. The final benefit was increased health care leaders awareness of systemic challenges with the pharmaceutical supply channel disruptions and shortages in the health care system.

Role of the Researcher

In qualitative research, Denzin and Lincoln (2011) stated the researchers are responsible for the design, collection, and interpretation of data. Palmer, Fam, Smith, and Kilham (2014) added the researcher must also ensure the mitigation of ethical concerns and the privacy of the study's participants. Although research design, data collection, and data analysis are important considerations for the qualitative researcher, the role of the researcher as an interpreter of meaning is also a foundational consideration in guiding their actions (Denzin & Lincoln, 2011). As the translator of meaning, the researcher is inseparable from the phenomenon and context they are exploring in identifying the strategies to address the problem of drug supply disruptions.

In this qualitative case study, my role as the researcher was to explore the strategies of health systems pharmaceutical procurement leaders practice to eliminate or reduce supply chain and distribution channel disruptions. Based on the suggestions from Jacob and Fergerson (2012), I followed an interview protocol, which was useful when a researcher seeks to understand the experiences and perspectives of individuals participating in a study. Qualitative researchers utilize open-ended interview questions to further explore responses as an adjunct to obtaining deeper understandings of participant responses and substantive direction of new understandings. I collected and interpreted

data in a reliable method to mitigate bias (see Kemparaj & Chavan, 2013; & Smit, 2012). I bracketed my prior knowledge and experiences concerning leadership procurement strategies, participants' potential reactions, personal emotions, or opinions of individuals participating in research interviews. No previous relationships existed with the participants. Areas of potential bias for the study included the following concerns: (a) uncertainty of resource allocations, (b) fluidity of the pharmaceutical supply chain and distribution channel, (c) historical practices to contemporary events, and (d) strategies utilized but not widely recognized in the industry.

Bailey (2014) defined qualitative research as an inductive approach used to gain a deeper understanding of a person or group's experience about a shared experience or phenomena. Maxwell (2013) suggested identifying and managing personal biases prior to beginning an interview to ensure the integrity of the data collection and analysis process. Following Maxwell's (2013) recommendations, I was mindful of personal biases and focused on my responsibilities and duties throughout the data analysis process, prior to beginning the review of documents and participant interviews. I reviewed the Belmont Report's *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (United States Department of Health and Human Services: Office for Human Research Protections, 1979) and completed the National Institutes of Health (NIH) Office of Extramural Research Protecting Human Research Participants certification (Certification No.:883410) as documented in Appendix E. Three basic ethical principles guided the research, in accordance with the findings of the Belmont Report. These principles were respect for individuals, beneficence, and justice.

I have 20 years of managerial experience with multiple supply chains, global distribution channels, and clinical drug therapies. Unbiased interviewing techniques were used to support the conduct of all interviews. The case study protocol (Appendix D) guided the conduct of all interviews. Denzin and Lincoln (2011) concluded effective qualitative researchers strive to present interview questions in a neutral manner, record the interview, and take notes throughout every interview. Participants had the opportunity to respond to each interview question and to offer additional insights and perspectives on the problem of inconsistent drug supplies.

Participants

The eligibility criteria for the five health care procurement leaders to participate in the study were the following: (a) employed in a leadership position with a pharmaceutical health system, (b) administration and development of pharmaceutical supply chain and distribution channel strategies, (c) responsible for the administration, provision, delivery, and regulation of pharmaceutical supplies, and (d) demonstrated implementation of successful strategies to address supply chain and distribution channel disruptions (see Appendix B). I sent emails to the current executive leadership teams of three health care organizations in the Eastern region of the United States, which operate pharmaceutical procurement departments to explain an overview of my study and to find out if they would be willing to allow their pharmaceutical procurement leaders to participate in the study. I encouraged the members of the executive leadership teams to contact me so I could discuss the purpose of my study in detail. If any member of the executive leadership team contacted me, I would discuss the overview with them and provide basic

information about my problem, purpose, research question, and interview protocol, which I intended to follow. I would explain to the members of the executive leadership team the prospective study participants may include chief procurement officers (CPO), chief operations officers (COO), senior vice presidents, vice presidents, directors, and associate directors who could represent a knowledgeable and experienced group, which may assist me in addressing my research question. Additionally, I would explain to the members of the executive leadership team's need to sign a formal letter of cooperation (Appendix G) with myself as the researcher giving me permission to conduct research as a graduate student at Walden University.

If members of the executive leadership team had an interest in supporting the study, I would ask for the contact information of the person who was in various leadership positions of their pharmaceutical health system's supply chain. Prospective interview participants would then be sent an invitation letter (Appendix A) and a consent form Study participants would acquire a full understanding of their rights through the informed consent notification prior to signing the consent form. Participants were able to contact me by phone or by email if they had any questions. All participants would have the opportunity to decide whether to participate in the study on a voluntary basis based on the contents of the letter and information provided in the consent form. The participants were initially advised they had the ability to withdraw at any time while the interview process was taking place. If a participant changed their mind or chose not to participate in the study, they were free to withdraw. Although voluntary participation may decrease the response rate for a study, the likelihood of honest responses may increase because

individuals who willfully submit responses feel decreased pressure to fabricate responses (Marshall et al., 2013). The names of the health systems and individual participants remained confidential.

After signing the consent form, I arranged to meet the participants at an agreed time and location. The individual participants agreed to participate in open-ended semistructured interviews conducted in face-to-face interviews to share their strategies. If the study participants desired, after the interviews, the procurement leaders had an opportunity to share additional company documents such as news releases, standard operating procedures, policies, and best practices for the purposes of triangulation (see Lichtman, 2014).

I gained access to participants by petitioning members of the current executive leadership team of three health care organizations having pharmaceutical procurement departments in the Eastern region of the United States requesting support of the study and access to their most knowledgeable employees. After several formal discussions and a thorough review of the proposal for conducting research, I obtained a letter of cooperation (Appendix G) authorizing the data collection and interview process and member checking. Working with the company's human resources department, I also gained access to the names of potential participants who fit the eligibility criteria for this study. By following these procedures, I used purposive sampling to obtain a sample of knowledgeable and experienced leaders currently employed by health systems. The sample obtained using a reliable process was appropriate for understanding the strategies that pharmacy procurement leaders successfully use to administer the pharmaceutical

supply chain and distribution channel strategies in addressing drug shortages. Establishing a working relationship with business leaders also required a formal request, in advance, describing the nature of the study and the possible benefits and discomforts associated with participating.

Study participants in the sample pool were expert pharmaceutical supply leaders in pharmaceutical procurement procedures for health systems. Each study participant received an informed consent form to review and sign. I developed effective working relationships with the participants by encouraging participants to share information from their perspectives. Marshall and Rossman (2016) encouraged qualitative researchers to frame initial and follow-up questions in an open-ended manner and listen attentively in a relaxed manner to the participants' responses.

Measures taken to ensure ethical protection of participants included, but were not limited to, (a) use of informed consent forms, (b) confidentiality agreements, (c) approval of the proposed study from the Walden University institutional review board (IRB), and (d) an increased sensitivity to physical and emotional stress exhibited by the participant. Potentially qualified participants received e-mail letters that included descriptions of the intent and study objectives. The e-mail notifications included sufficient information for participants to determine their willingness to participate in the study. Appendix A includes the template for the cover letter to recruit study participants.

If the study participants desired, after the interviews, the procurement leaders shared additional company documents and policies for the purposes of triangulation. Based on the concepts of Denzin (2012), the hospital pharmaceutical leaders also shared

additional company documents and internal policies containing relevant data, which supported the conception of triangulation. To support the recruitment of additional individuals to the study, the initial study participants were able to recommend the inclusion of additional persons in the study (Gyarmathy, Johnston, Caplinskiene, Caplinskas, & Latkin, 2014) based on their specialized knowledge and expertise of pharmacy supply chains and distribution channels. I also developed effective working relationships with participants by encouraging participants to share information from their perspectives. Using the guidance of Patton (2015), I was mindful to remain neutral and convey to study participants their attitude, experiences, insights and knowledge had importance in the study, thus building rapport. Marshall and Rossman (2016) encouraged qualitative researchers to frame initial and follow-up questions in an open-ended manner and listen attentively to the participants responses.

Research Method and Research Design

Research Method

The guiding framework for the exploration of the study research question was a qualitative research method (see Denzin & Lincoln, 2011; Vanio, 2013). Researchers using the qualitative research method's design allowed the conduct of a qualitative assessment and helped develop a deeper understanding of the rationale of health care providers faced with reapportioning members of their workforce to address the problem of drug supply disruptions. Bernard (2013) argued for careful consideration of other alternative research methods before deciding on a study design. Bernard (2013) and Knight and Cross (2012) determined quantitative or mixed method studies were not

appropriate applications for some studies based on the inability to probe underlying study participant relationships and decision-making processes. Sadan (2014) suggested mixed methods approach was a potentially promising research design; however, my limited resources, participant availability, and critical time constraints rendered mixed methodology an impractical choice.

Research Design

Case study research was the optimal design for this study because well-defined research questions compliment the statement of the problem, the purpose of the research, and the nature of the research study. A purpose of case study research was to contribute to enhance and strengthen theory rather than oversimplification of a population (Sharma & Kamalanabhan, 2012; Webb, Bunch, & Wallace, 2015). Yin (2014) argued case study research designs allow the researcher to preserve the universal and evocative characteristics of real-lived events. Stake (1995) emphasized researchers conducting case studies need to represent the multiple realities described by study participants and interpret data collected from document reviews, observations, and interviews to construct descriptions of phenomena.

Other qualitative research designs do not support the rich case exploration and thick descriptions desired for the study. The use of a phenomenological design by an investigator would have permitted data collection from the conduct of interviews (Moustakas, 1994) but would not allow for the gathering of information from publicly available documents and artifacts. Ethnographic study designs would have been appropriate for the examination of the beliefs and behaviors of culture-sharing groups

(Marshall & Rossman, 2016), which was an inappropriate focus for the study of strategies used by health systems pharmaceutical procurement leaders to address drug supplies disruptions. Grounded theory study design, as described by Omar, Davis-Sramek, Fugate, and Mentzer (2012), did not support the study objectives of in-depth case exploration and analysis because grounded theory researchers are reliant on the creation or identification of one or more underlying theories, which does not support the study objective of in-depth multiple case study and analysis.

In the research study, I concentrated on concerns associated with drug supply disruptions. Zyngier and Burstein (2012) suggested case study research contributes explicit descriptions of the governing issues related to the research topic. Sillanpää, (2015) recommended using qualitative case studies for exploring and understanding modern phenomena within the field of supply chain management. Goffin, Raja, Marek-Szwejczewski, and Martinez (2012) used a repertory grid technique (RGT) during interviews in their case study to help the participants articulate complexities of supply chain management.

Using the concepts of Yin (2014), I selected a qualitative case study as the most appropriate means of achieving a unique understanding of the meaning and motivations of the experiences and perceptions of health care providers faced with the problem of supply chain disruptions. Investigators may use a case study research design to explore those situations, where the evaluation of the intervention or strategies identifies no clear or single set of outcomes (Yin, 2014).

Population and Sampling

The sample population for the study consisted of individuals in hospital pharmaceutical procurement leadership positions in three health systems settings along the Eastern region of the United States with responsibility for the administration, provision, and procurement of drugs and drug supplies. The objective of the study was the collection of data from documents and participants possessing knowledge of drug procurement channels and knowledge of drug shortage remediation. Accordingly, I utilized purposeful sampling to recruit participants with appropriate knowledge and experience to participate in this study. Purposeful sampling was a nonprobability sampling technique useful for a particular group because of their characteristics (Cassidy, 2013). In a qualitative study, Jondle, Ardichvili, and Mitchell (2014) utilized purposeful sampling to explore how business executives characterize ethical business cultures.

I also utilized snowball sampling as an apparatus for recognizing and recruiting further study participants. A researcher can use snowball sampling to support the identification of new participants within difficult to recruit or elite populations (Bernard, 2013; Holloway et al., 2015). Use of the snowball sampling method allows a researcher to ask current participants to identify and recommend additional participants (Bernard, 2013; Holloway et al., 2015). Kim (2015) employed snowball sampling during business research to recruit participants for a qualitative case study of the significance of biotechnology clusters in San Diego. Kim expressed value in snowball sampling for influencing rich and meaningful stories from the participants.

No correlation existed between sample size and data saturation (see Marshall,

Cardon, Poddar, & Fontenot, 2013). I defined an appropriate sample size for the study of the problem of inconsistent drug supplies by considering the number of potential qualified participant sites. Potential participant selection included analysis of the number of hospitals, and the number of knowledgeable persons involved with pharmaceutical supply chains and or distribution channels in the Eastern region of the U.S., and the targeted number of participants from each site. Rubin and Rubin (2012) suggested the number of sites selected for a qualitative study remains dependent on the nature of the study, research questions, and the number of factors, which may influence the studied phenomenon. Hospital pharmaceutical procurement leaders with responsibility for the administration, provision, and procurement of drugs and drug supplies contributed perspectives on the organizational strategies addressing the problem of inconsistent drug supplies. Based on the three site types included in the study and an assumption of two to three interviews per site type, I determined a minimum pool size of 3 to 6 participants was an appropriate beginning for my study.

O'Reilly and Parker (2013) observed sample population adequacy for a qualitative study was a function of the topic of study, participant availability, and sufficiency of sample size for permitting the examination of the research study questions. Rubin and Rubin (2012) asserted the inclusion of a large number of interviewed participants was not necessary to achieve balance and thoroughness during the conduct of a qualitative study. Nilsson et al. (2016) and Patton (2015) recommended qualitative researchers should define sample size from considerations of the purpose of the study and the assessment of the diverse opinions and perspectives offered by the study participants.

Rubin and Rubin (2012) suggested a minimum of two to three interviews per subsample area was sufficient to ensure the achievement of a suitable depth and diversity of perspectives to achieve saturation on a topic. Lichtman (2014) suggested saturation was an iterative process of case sample selection and simultaneous data collection until no new information was generated from the data collection. Saturation was a determinant of sample size (Walker, 2012). I expected to achieve saturation and a rich diversity of perspectives at the completion of 3 to 6 interviews because of the narrowed scope of the research study to people in hospital pharmaceutical procurement leadership positions through a multiple case study approach. Lichtman suggested smaller sample sizes in qualitative research help the researcher to obtain depth in the material. Bernard (2013) suggested researchers utilize small sample sizes by using purposeful sampling to identify and recruit study participants.

Ethical Research

Several principles guide the ethical conduct of a researcher when working with human subjects. The principle of informed consent requires the researcher to disclose both the risks and benefits of participation to potential study participants. The principle of voluntariness requires participants in a research project must be completely voluntary because a person's choices should be based on free will and not related to coercion or duress in any way (Edlund, Hartnett, Heider, Perez, & Lusk, 2014; Hardicre, 2014). The final principle required that study participants should not encounter any risks to their safety or well-being and to be protected from harm (Walden University, 2015). In concordance with these principles, I sought and received approval from the Walden

University IRB for permission to conduct the study.

Based on Walden University IRB requirements for ethical research, study participants should not encounter any risks to their safety or well-being and should not require protection (Walden University, 2015). During the exploration of sensitive topics in the interview, participants may experience the minor risk of discomfort such as fatigue, stress, or become upset (Seidman, 2013). If difficulties related to participant stress exist during the collection of the data, the participant or research may stop or suspend the interview process. No participants needed to stop or suspend the interview process.

Members of the Walden University IRB ensure compliance with federal regulations and Walden University's ethical standards. Prior to receipt of IRB approval of the submitted research proposal, no data collection took place. Before beginning data collection, I successfully completed and passed the National Institutes of Health (NIH) web-based training course pertaining to the protection of human subjects.

Prior to the conduct of interviews, I provided all participants with information about the study objectives and intent and provided each participant with an informed consent form (Appendix C) to review and sign. Potential participants did not receive incentives in exchange for participation. All participants had the opportunity to decide if they wished to participate in the study based on information provided in the consent form.

I also ensured the confidentiality and subsequent privacy of all study participants and their affiliated institutions through the de-identification of participants during the data analysis process (Conway, 2014). Participants were not asked to share any

information they perceived may compromise their professional status. Participants did not have to respond to specific interview questions if they felt uncomfortable responding. All document references were in the text of the research, appended in the appendices, and identified in the table of contents.

I will store all data collected during the data gathering and analysis process in a safe, secure location for a period of 5 years to protect the rights of participants. Participants will receive direction on the method to withdraw from the study process at any time without any negative consequences. All electronic copies of all collected data and files are kept on a password-protected computer in a locked container maintained in my home office. All hard copies of data, notes, recordings, and analytical materials are kept in a secure fashion. Walden University issued IRB number 08-12-16-0327496 for this study.

Data Collection

Instruments

Xu and Storr (2012) suggested that in qualitative research the researcher was the data collection instrument. Based on the discussion of Camfield and Palmer-Jones (2013), in a qualitative research study method, I was the data collection instrument. I collected study data from a review of public documents, news releases, website information, and the conduct of face-to-face semistructured interviews with individuals in hospital pharmaceutical procurement leadership positions in three health care settings in the Eastern region of the United States. The participants were responsible for the administration, provision, and procurement of drugs and drug supplies. Marshall and

Rossman (2016) indicated the use of multiple sources of data support study construct credibility through triangulation. Yin (2014) stated case study researchers could use triangulation by collecting information from multiple sources of data to corroborate the same phenomenon and to ensure overall study quality. Denzin (2012) suggested methodological triangulation as the use of several different data sources to support the comprehensive examination of identified phenomena. Methodological triangulation provides confirmation of similarities found in different data collection sources (Bekhet & Zauszniewski, 2012; Drouin, Stewart, & Van Gorder, 2015; Houghton, Casey, Shaw, & Murphy, 2013). Data sources are not the methods used to gather information but are the observational units used for the collection of information.

Researchers developing a case study protocol ensure the dependability of the study by outlining procedures to follow during the conduct of research (Yin, 2014). Use of this protocol ensures data collection, analysis, and reporting efforts remain focused on the study line of inquiry (Marshall & Rossman, 2016; Yin, 2014). The case study protocol included seven steps to be followed (a) an overview; (b) descriptions of the purpose and intended use; (c) descriptions of data collection procedures; (d) an outline of the case study report content; (e) a list of interview questions; (f) a summary of the data analysis techniques and tools; and (g) a description of the study dependability, credibility, and transferability methods (Yin, 2014). Appendix D included the case study protocol.

Qualitative researchers may also enhance the dependability of case studies by creating and utilizing case study databases (Yin, 2014). The development of a case study database by the researcher supports the process to study, which strategies health systems

pharmaceutical procurement leaders need to address the problem of inconsistent drug supplies. The database will include (a) notes from the document reviews and the interviews; (b) copies of documents, audio files from interviews, and transcripts; (c) tables of codes and patterns; and (d) initial (draft) narratives written during the analysis.

Data Collection Technique

Qualitative interviewing reconstructs complex situations and events from multiple perspectives, which help the investigator to create mental representations of the problem (Rubin & Rubin, 2012). Rubin and Rubin also suggested qualitative interviews help the investigator explore matters, which are complex, chaotic, and contradictory. One of the drawbacks of qualitative interviewing was the difficulty to use the results to estimate or generalize the characteristics of the findings to other groups.

I collected study data from the review of documents and information obtained from qualitative interviews. Yin (2014) proposed researchers conduct case studies using letters, memoranda, e-mail communications, written reports, administrative documents, and newspaper articles as forms of study documentation. Singh (2014) reviewed archives, reports, policies, and other organizational documents to understand non-profit organizations. Boblin, Ireland, Kirkpatrick, and Robertson (2013) gathered data by reviewing an organization's strategic documents, artifacts, and observations of the environment. Boblin et al. gathered project proposals, operational policies, internal communications, and data from audits to understand the process of implementing new best practice guidelines.

Information gathered from a review of publicly available documentation

supported the exploration of how health systems leaders addressed problems of inconsistent drug supplies. Study participants had the opportunity to provide copies of administrative documents, public reports, and or memoranda they reason may provide beneficial information for the assessment of individual perspectives regarding the problem of inconsistent drug supplies. I did not require study participants to provide documents to support their opinions and perceptions and stressed the provision of such information was voluntary. I did not conduct a pilot study because there was no need to validate a new data-gathering instrument with reliability and validity data. Helpful in conducting data triangulation were resources referenced by study participants once the IRB had approved the study for data collection and independent exploration for informational resources relevant to the study research question.

All participants were able to request face-to-face interviews in private conference rooms convenient to their location. When participants selected their interview locations, they were less likely to experience inconvenience and were able to effectively participate in the interviews. During the conduct of each interview, I monitored and assessed the participant's emotional and physical responses to each question to ensure lines of communication did not create any undue discomfort for the participants.

An investigator conducting semistructured interviews supports the exploration and description of how health systems pharmaceutical procurement leaders need to address inconsistent drug supplies problems efficaciously. Rubin and Rubin (2012) proposed to conduct semistructured interviews allowing investigators to focus the discussion on topics specifically related to study research questions. Schatz (2012)

employed nesting of semistructured interviews within surveys to explore deeper micro perspectives of a gender context study. Lynch, Bruhn, and Henriksen (2013) used semistructured interviews in determining how educators should prepare when counseling lesbian, gay, bisexual, or transgendered clients.

Participants were able to request a telephone or Internet-based interview as a follow-up discussion from the initial interview for member checking. Irvine, Drew, and Sainsbury (2013) noted telephone interviews provide a less effective means of building rapport with participants and may result in less information or elaboration in response to interview questions. Bryman and Bell (2015) supported researchers in using the telephone to conduct interviews as long as they followed a specific qualitative protocol. Mikecz (2012) discovered telephone interviews were equally effective as face-to-face interviews; however, Mikecz argued the researcher must confirm knowledgeability of the participants for a successful interview. During any phone interviews, participants would have the opportunity to respond to each interview question and any follow-up questions in as much detail as they desired.

I electronically recorded each interview using standard technology applications. Before starting individual interviews, all participants provided expressed written permission for recording the interview session. A password-protected laptop was used to store electronic copies of all interview audio files for the creation of successive transcripts for interview analysis.

Before commencing data analysis, I sent the transcribed interviews to the participants to verify the accuracy of the data through transcript review and a validation

process of member checking as suggested by Maxwell (2013). Member checking was a rigorous review process of the qualitative participant responses to interview questions, which provide the researcher with confirmation of the understanding and meaning of the responses to the interview questions (Marshall & Rossman, 2016). Participants examined the documents from their recent interviews to determine if the researcher captured their responses to the interview questions accurately and completely (Houghton et al. 2013; Koelsch, 2013; Morse 2015; Sinkovics & Alfoldi, 2012).

Data Organization Techniques

I created and maintained electronic data logs on a password-protected computer. Entries in the log for every data element included information on (a) the data type, (b) data identifier, (c) date of collection, (d) place of collection, and (e) corresponding research notes identifier. I recorded notes during the review of collected documents and interviews. Formalized note taking during the conduct of case study research was an essential practice for ensuring researchers captures the core messages from the discussion during interviews and immediately following the collection of data in the field (Yin, 2012).

I have stored all research materials (organizational documents, electronically recorded interviews, electronic transcripts, coded data files, and analytical reports) in a password-protected laptop computer. Encrypted electronic files, a backup archival system for secondary copies of study materials, are subsequently stored in a secured location. The data collection and analysis process included the deidentification of study participants. Data and analysis files will include references to participant identification

numbers only. I also plan to store all collected data and analytical results for 5 years. Destruction of all data copies (both electronic and hard copy) will take place after 5 years from the publication of the manuscript.

Data Analysis Technique

I developed interview questions to facilitate the exploration of the primary research question guiding the conduct of the qualitative case study: What strategies do health systems pharmaceutical procurement leaders use to address drug supply chain and distribution channel disruptions? Structuring of open-ended interview questions will encourage study participants to share and describe their perspectives (Irvine, Drew, & Sainsbury, 2013; Wilson, 2012) and experiences regarding the problems of drug shortages and inconsistent drug supplies.

I have aligned the collection and analysis of study data with the complex adaptive systems conceptual framework on completion of the interviews with the study participants. Study participants will share insights and perspectives on operational strategies pharmaceutical procurement leaders utilize addressing disruptions in drug supply chains and or distribution channels. Augmented data gathered from analyzing organizational documents and artifacts using methodological triangulation (Lichtman, 2014; Maxwell, 2013; Patton, 2015) may support further assessment of how individual, institutional, and societal factors affect the strategic response to disruptions in the drug supply chain.

I have assessed the operational strategies of health systems procurement leaders in planning or response to drug supply disruptions affecting the health care system. My

intent was to utilize feedback loop modeling concepts from complex adaptive systems related to general systems theory (GST) to understand paradigms in the pharmaceutical supply chains and the distribution channel.

Boulding (2013), a contemporary of von Bertalanffy, described GST as theoretical modeling of levels existing between abstract principles of mathematics and distinctly specialized disciplines. Corning (2014) considered the influence of synergies among empirical system objects on the overall biological complexity of living systems. Researchers using systems theory utilize a methodological approach to understanding the functions and behaviors of system objects. Systems consist of dynamic information driven feedback loops, which transforms the system to achieve its goal or purpose. I have endeavored to capture and identify systems objects related to the operational strategies employed by the health systems.

A researcher can use GST to focus on the behaviors of whole systems. Researchers understand the whole system was greater than the sum of all parts (Anaafo, 2013). Drack (2009) argued the impossibility to know every part and know every relationship in a system; however, possibilities exist to research effects of the system above the individual parts of the system. Pharmaceutical supply chains and distribution channels exhibit many of the same challenges specified by Drack. The supply and distribution elements may demonstrate emergent characteristics of highly structured and highly functional systems. Shah (2004) suggested pharmaceutical supply chains and distribution channels contain many complex processes, formulas, coordination issues, and development challenges.

Using GST approach, I have conducted document reviews and interviews for collecting data to characterize the various factors, which influence and impede leadership strategies related to drug supply disruptions. Coding was useful as the primary data analysis technique for the exploratory qualitative multiple case study. Qualitative researchers use coding methodologies for categorizing and describing collected data. Bernard (2013) has suggested coding methodologies should include both deductive coding and inductive (open) coding.

The researcher can use both deductive and open coding to support the comprehensive analysis of data collected for a qualitative case study. I have employed deductive coding to develop codes for the analysis of document reviews and interview data. Deductive coding was useful in the study of management perspectives, which identify emerging themes believed important in the service creation process (Russell-Bennett, Härtel, & Worthington, 2013). In addition, Fourie and Theron's (2012) data analysis technique employed deductive coding to develop coded categories on the coping resiliency of young women with a specific health issue. Creating unique deductive codes from analyzing the responses to the interview questions enables the identification of key words and themes, which relate to the conceptual framework selected for this study.

Open coding involves the identification of themes and conceptual thoughts, which emerge from a review of collected qualitative data (Bernard, 2013; Rubin & Rubin, 2012). Russell-Bennett, Härtel, and Worthington (2013) employed open coding to isolate conceptions and themes, which emerged from managers' responses to interview questions. Open coding was useful to isolate new themes and theoretical concepts during

the review of data collected using formal business plans, policies, project plans, and internal communications (Fourie & Theron, 2012). I used open coding throughout the review of the study documents and interview data to examine concepts and themes, which were supplemental to the deductive codes used during the analysis process. Stake (1995) suggested the use of open coding supports the application of theoretical triangulation: the exploration of alternative explanations for an observed social phenomenon.

Categorization of deductive and open codes by research subquestions and conceptual framework facilitates the identification of themes related to the study research question and conceptual framework. Creation of additional subcategories of codes enables the evaluation of the nature of participant responses and document content. I created code subcategories to categorize responses of the participant group and to capture miscellaneous comments, which may emerge during the document analysis process.

Yin (2014) concluded the reasonableness to utilize software technology to analyze coded case study transcripts. I used data from document reviews and interviews during the study to interface with ATLAS.ti, a software tool for qualitative research. Researchers using ATLAS.ti software find support in the management, taxonomy, and analysis of data. Researchers using ATLAS.ti find support in the performance of (a) keywords-in-context (KWIC) analysis, (b) constant comparison analysis, and (c) classical content analysis. Application of ATLAS.ti to perform KWIC analysis permitted me to ensure analysis of collected study data would appear robust via data analysis triangulation (Sanders & Woodward, 2014).

Saiki and Kloyes (2014) and Sanders and Woodward (2014) conducted KWIC analysis to explore the use of keywords in context and to identify underlying connections within document wording or language used by participants. Moreover, the researcher can use a KWIC analysis with ATLAS.ti to support the identification of open codes within the collected study data. Constant comparison analysis involves the identification of underlying themes within collected data by the way of the deductive and inductive coding of passages of text (Sanders & Woodward, 2014). I utilized ATLAS.ti to perform constant comparison analysis of collected documents and interview transcripts and to identify and document emerging themes.

A researcher can use software applications (e.g., Atlas.ti) to support qualitative and mixed methods research designs when utilized to support data coding and thematic identification in the creation of a cluster analysis (Ware, 2012). Ware suggested these types of applications encourage the discovery of triangulated data. I utilized ATLAS.ti to perform classical content analysis of the collected study data to determine the accumulated total count for each code isolated during analysis. Information regarding code counts support the determination of the relevant importance of deductive and inductive codes and identification of prominent underlying themes within the data. The use of ATLAS.ti to conduct co-occurrence analysis facilitated exploration of relationships or thematic links between codes.

To assess *code saliency*, I compiled and developed information about the frequency of codes across all study source materials (documents and interview transcripts) to determine which codes to preserve during final thematic analysis. Bernard

(2013) noted the frequency of a code within a data set indicates the saliency (importance) of the code. Collingridge (2013) suggested methods of turning qualitative data into quantitative values to the extent mathematical formulas could determine statistical significances in code frequencies. Collingridge concluded appropriate use of permutation testing may identify *p* values and analyze code.

Reliability and Validity

Reliability

Richie, Lewis, Nicholls, and Ormston (2014) posited qualitative researchers answer the reliability question when other researchers replicate their research findings. Making certain the results of the study are consistent with the data collected was one of the key tenets of consideration during the study design phase, and qualitative studies include mechanisms for ensuring dependability (Lichtman, 2014). Dependability ensures the integrity of the data and findings in the study (Marshall & Rossman, 2016). Qualitative researchers demonstrate the consistency of their research efforts through the focus on dependability instead of reliability (Marshall & Rossman, 2016; Morse, 2015). Study databases and study protocols are useful to researchers in demonstrating case study dependability (Yin, 2014).

Yin (2014) advocated documenting the research process to strengthen reliability and dependability. To ensure the dependability and reliability of the research findings, I recorded and utilized a precise case study protocol. The study protocol (Appendix D) included: (a) research study summary, (b) a statement of the protocol purpose and use, (c) data collection process flow chart, (d) an outline of the case study report content, (e)

interview questions, (f) a brief description of the data analysis techniques and instruments, and (g) a dependability assessment and study credibility. Lynch, Bruhn, and Henriksen (2013) utilized a case study protocol to document their research questions, research methodologies, and guidelines for data collection and analysis during a study of counselor educators.

I also created and maintained a case study database for the study of how health systems pharmaceutical procurement leaders have addressed the problem of inconsistent drug supplies. The database will contain: (a) document review and interview notes, (b) copies of documents, interview audio files, and transcripts; (c) tables of codes and thematic elements, and (d) initial (draft) narratives written during the analysis of collected data and summarization of study findings. Use of the case study database enhances the study dependability and reliability by providing other investigators with insight into the data products and analytical methods used to derive study findings and conclusions.

Validity

Research quality was dependent on the qualitative researcher's focus on key means of study validity. Contrastingly, quantitative researchers ensure the integrity of their research through the execution of procedures, which ensures study credibility (Bell & Waters, 2014; Marshall & Rossman, 2016). I utilized the following processes, which demonstrated study credibility: (a) methodological triangulation, (b) the assessment of contending explanations, (c) bias identification of the researcher, and (d) member checking as outlined by Lichtman (2014).

To enhance credibility, Boutin (2012) in an open communication piece recommended utilizing a clear and comprehensive evaluation process to increase credibility and relevancy during the conduct of case studies. To achieve study credibility and enhance quality elements of a case study, Yin (2014) discussed the utilization of document reviews, interviews, and direct observations in businesses case studies. I collected data from the review of available documents, artifacts, observations, and information from semistructured interviews. Yin (2013) suggested methodological triangulation increases the notion of validity of case study research.

Marshall and Rossman (2016) recommended establishing the credibility of the study by using: (a) the assessment of rival explanations, (b) researcher bias identification, (c) member checking, and (d) method triangulation. Strategies to establish validity in case study research included the use of multiple sources of evidence, which maintains a link between evidence and member checking methodologies (Houghton et al., 2013; Lub, 2015). Utilization of member checking methods by the researcher enhances the credibility of this study. Gathering data from other sources such as company documents was useful to triangulate findings and enhance the study quality. Gathering study data across multiple sites in the Eastern region of the United States will ensure appropriate spatial variability in the study of observational units and will support the comprehensive examination of leadership perspectives regarding drug supply disruptions.

Zitomer and Goodwin (2014) stated internal validity was a parallel of credibility in the lens of postpositivist qualitative research. Credibility was a primary concern for explanatory case studies only (Yin, 2014). I conducted an exploratory multiple case study

of pharmaceutical procurement leadership strategies used to address disruptions in the drug supply chain and the distribution channel. Accordingly, methods described by Yin (2014) as suitable for establishing credibility for explanatory case studies (e.g., pattern matching and explanation building) were not strictly applicable to my study; however, one method suggested by Yin (2014) for achieving credibility was the assessment of contending explanations. Moreover, Yin advocated the use of researcher bias identification methods and member checking during the data collection and data analysis phases of the research study enhances study credibility. Contending explanations for phenomena do not undermine case study designs or procedures but pose challenges to the interpretation of study findings and formulation of study conclusions (Yin, 2012). Researchers may face challenges to credibility and transferability of the findings conducting online research, because of the potential of inadequate substantive data in online communities, which may lead to inaccuracies in data interpretation (Richie, Lewis, & Nichols, 2014). Conversely, Synnot, Summers, and Taylor (2014) found in their study online interviewing and data collection was generally comparable to in-person interviews because of the technological advances in internet communications.

I explored alternative conceptual frameworks during the data analysis process and examined the suitability of systems theory as a framework for study findings. A single conceptual framework, the complex adaptive systems network (Akgun et al., 2014) supported the collection and analysis of study related data. The premise of systems theory was interactions and interrelationships among components of a system governing the properties and behaviors of the system (Sturmberg, Martin, & Katerndahl, 2014).

As a second strategy, I utilized researcher bias identification to ensure credibility and validity of this case study. Yin (2012) cautioned researchers' theories, personal views, or presumptions may influence the methodology and conduct of the intended studies. Engaging in self-reflection, having an internal discussion with one's self, before conducting case study interviews, helps identify and articulate attitudes about the research topic, which may influence the collection and analysis of data (Peredaryenko & Krauss, 2013). Corrupted data collection and analytical processes may be the result of researchers who did not recognize or manage the data capture, data translation, or data analysis process (Hurst et al., 2015).

Yin (2012) posited researchers' personal values, individual theories, or prejudices may influence their intended study construct. I conducted a personal assessment of biases, prior to the initiation of data collection, for the study of drug supply disruptions. An assessment matrix will include each identified bias with an accompanying narrative description. Review and assessment of the bias identification matrix throughout the data collection, analytical process, and during the preparation of study completion enable effective strategies to manage or mitigate personal biases.

I used a third technique called *member checking* for establishing the credibility in a qualitative case study. Member checking was a process for assuring the validity of the researcher's summaries. Qualitative researchers provide study participants with selected data elements, draft findings, and conclusions then ask the study participants to comment on the degree of accuracy of the materials provided (Marshall & Rossman, 2016). During the 2011 study of the social dynamics of a community associated with college football,

faculty colleagues, athletic experts, and participants in focus groups shared study findings and participant perceptions (Reilly, 2013). Burda, van den Akker, van der Horst, Lemmens, and Knottnerus (2016) involved participants in assessing and providing commentary on the credibility of the findings as a method of member checking.

I also provided study participants with a copy of initial study findings and conclusions and offer an opportunity to review and provide commentary. Comments from participants will enhance the accuracy and credibility of study data collection and analysis efforts. Study participants received a summary of the study's findings, recommendations, and conclusions after receipt and notification of the final study approval. The participant's summary may include findings, recommendations, and conclusions detailed in this study and less than three pages in length to ensure study participants receive a brief document they can reference efficiently.

Case study researchers enhance the transferability of case studies by providing a deep analysis of the reasons for the selection of case study populations and describing the unique details of case study contexts (Alex da, Näslund, & Jasmand, 2012; Reybold, Lammert, & Stribling, 2013). Qualitative research emphasizes transferability of the methods used in the study instead of the external validity of study findings (Marshall & Rossman, 2016; Yilmaz, 2013). Holloway et al. (2015) demonstrated transferability of their study findings by providing thorough definitions, demographics, and geographical boundaries of the study participants

I documented in the study a detailed description of the sample population and geographic boundaries for the study. The inclusion of rich descriptions of the study

population and the context for the collected data and study findings would enable a reader to judge the transferability of study findings and supporting conclusions. Specific to this study, readers received the information necessary to assess the transferability of findings, conclusions, and to the characteristics of drug supply disruptions.

Confirmability was the extent to which the findings of a study reflect the participants' responses as opposed to the researcher's imagination or preconceived biases (Cuthbert & Moules, 2014; Elo et al., 2014; Polit & Beck, 2013). To create transparency and confirmability in this study, I provided documentation of all the steps in the data collection and analysis process. Saturation occurs when no new findings or information emerges during the interview and research process (Roy et al., 2015). I continued to interview members of the sample using member checking until I was satisfied that I had fully captured the complexity and variation of the phenomenon under study and had reached data saturation. In qualitative research, a small sample size was generally appropriate to achieve saturation (Marshall et al., 2013). In this study, the population under consideration consisted of 5 pharmaceutical leaders who were knowledgeable about drug shortages. I continued the interview process until no new information emerged from the participants.

Transition and Summary

Section 2 includes an outline of the intent of the research study, the research design, the population sample, and the analytical methodologies used for the study of drug supply disruptions in the United States. The conduct of a qualitative case study enables exploration of how health care procurement leaders in the Eastern region of the

United States perceive strategy limitations in the mitigation and detection of drug supply disruptions. I gathered data from the review of documents and the conduct of semistructured interviews to build a deep understanding and extensive knowledge of leadership strategies. New information obtained supported advances in new operational protocols, which may detect, control, and potentially eliminate drug supply disruptions. Section 3 will include an overview of the study and presentation of findings from the analysis of collected data from study participants. Section 3 includes applications of the research to professional practice and the presentation of recommendations, reflections, and conclusions resulting from the conduct of the study.

Section 3: Application to Professional Practice and Implications for Change

A description of the general and specific business problems appears in Section 1. The purpose of this exploratory multiple case study was the exploration of the central research question: What strategies do pharmaceutical procurement leaders of health systems use to address drug supply chain and distribution channel disruptions. Section 1 contained a description of the conceptual framework used in this study and the review of the professional literature. A description of my role as a researcher, the study's population, participants, and ethical research requirements were in Section 2. Section 2 contains an explanation of the research approach, data collection tools, and data analysis process.

In Section 3, I discuss an overview of the findings and the relevance of the findings to professional practice in contemporary business settings. This section includes my discussion of how researchers and senior leaders in health care systems may use the findings and my recommendations to effect changes in social structures. Section 3 also includes a discussion on topics for further research. Conclusions in Section 3 contain final reflections on completing the research study.

Overview of Study

The purpose of this qualitative multiple case study was to explore the strategies that health care pharmaceutical procurement leaders use to address disruptions in the drug supply chain and distribution channel. The qualitative approach allowed me to develop a deeper understanding of the participants' perceptions regarding pharmaceutical supply disruptions. The objective of the study was to develop a comprehensive understanding of

the strategies used to address pharmaceutical supply disruptions. The participants, senior leaders in health systems, in this research study answered the specific research question: What strategies do pharmaceutical procurement leaders of health systems use to address drug supply chain and distribution channel disruptions? The analysis of the transcripts of the interviews resulted in the identification of 59 codes and 557 meaningful quotes that supported the identification of emerging themes and confirm the underlying conceptual framework. I used the process of text analytics (Gururajan et al., 2016) to weight and categorize clusters of text to develop hidden insights and assign weighted values to the participant's responses. I also used the query tool in Atlas ti to identify and or confirm the saliency of text clusters and code categorization.

Three key themes emerged from my analysis of the aggregation of the codes that summarized the strategies pharmaceutical procurement leaders used to address pharmaceutical supply chain disruptions (Table 1). The three themes were (a) pharmaceutical procurement leaders proactively plan for supply chain and distribution channel disruptions, (b) pharmaceutical procurement leaders create strategic processes for alternative procurement methods, and (c) pharmaceutical procurement leaders rely on proven sources of actionable information. The three themes support the conceptual framework of Kauffman (1995) and aligned with the research topic of pharmaceutical supply chain and distribution channel disruptions. Alignment of the emerging themes was also found in current peer-reviewed published research. I offer study findings in the ensuing section.

Table 1

Code Clusters Relating to the Three Emerging Themes of the Research Study

Participant	Proactive planing	Creating alternate processes	Developing reliable sources of actionable information
P1	38	84	6
P2	60	123	24
P3	21	56	9
P4	27	37	13
P5	33	55	19
Total	179	355	71

Presentation of the Findings

The overarching research question was as follows: What strategies do pharmaceutical procurement leaders of health systems use to address drug supply chain and distribution channel disruptions? I developed specific interview questions to explore the strategies used to address pharmaceutical supply chain and distribution channel disruptions. I used interview transcripts, field notes, and publically available documents to triangulate the data (see Fusch & Ness, 2015). The interview questions supported my exploration of strategies used by senior leaders to mitigate a critical social problem with broad-range effects.

Emergent Theme 1: Pharmaceutical Procurement Leaders Proactively Plan for Disruptions

The first key theme of the study identifies the complex planning process used by pharmaceutical procurement leaders for ensuring adequate pharmaceutical inventory for scheduled admissions, outpatient treatment therapies, and commonly used pharmaceutical consumables. The strategy of closely monitoring available inventory to compare with the usage requirements for acute care, outpatient care, and trauma care was repeatedly

emphasized by participants and recorded in my field notes. Another highly emphasized strategy of the study participants was the ongoing contract negotiations for increased access to products through group purchasing organizations (GPO) or wholesale distributors. Additionally, codes related to reporting to stakeholders and assessing trends of alternative sources showed significant frequencies in the participants' responses. Table 2 depicts the response frequencies for highly emphasized strategies in Emerging Theme 1.

Table 2

Strategies Relating to the Emerging Theme One of Proactive Planning for Disruptions

Participant	Conduct regular analysis of on-hand inventory and usage trends	Negotiate increased access to drugs through GPO and distributor	Reporting to stakeholders and regulators	Assess trends with alternate source providers
P1	30	17	15	6
P2	67	50	29	19
P3	50	38	15	18
P4	99	49	45	6
P5	59	30	32	4
Total	305	184	136	53

Participants expressed feelings that proactively analyzing on-hand supply and comparing it to usage trends helped identify potential risks of disruptions before they influenced patient treatment schedules. Specifically, participants expressed a strong desire to connect to external data sources containing advanced warning information to support potential changes in their procurement practices. Jagsi et al.(2014) concluded relying solely on advanced warning may not be an adequate measure to stop supply disruptions, which Participants 2 and 5 supported in their responses. Both Participant 2 and 5 felt the information in advanced warnings was often incomplete. Missing critical

information about the duration of the disruption perplexes health care leaders. Participant 5 felt that "the earlier the health system receives the notification of a shortage, the more likely a comprehensive game plan is implemented."

Adomavicius et al. (2013) suggested complex systems drive dynamic information through networks of feedback loops in complex systems. IMS Health, Inc. (2012) concluded complexities in systems may impair an individual's ability to analyze allocative efficiencies and feedback in the supply chain and distribution channel. Participant 2 felt that even though they received advanced notifications from their GPO's and wholesalers, the information cannot be completely relied on to make informed decisions. Participants 3 and 4 have received conflicting information from one source of notification and entirely different information from the actual manufacturer. Participant 3 said they spent time validating the disruption with the manufacturer because they did not trust the grey market sources on the original notification.

Participants felt the decrease of supply chain capacity caused by lean inventories may increase the risk of supply disruption. Mehralian et al. (2015) support the participant's perceptions because of the demand uncertainty in the supply chain. The uncertainty of demand and the uncertainty of supply caused participants to negotiate with their GPOs and wholesalers for expanded access to pharmaceutical supplies. Participant 2 explained some drugs or manufacturers are exclusive with one wholesaler. Participant 2 added, "there is difficulty in some circumstances trying to procure an exclusive product from a non-contracted wholesaler." Participant 3 indicated when the wholesaler is unable to provide a specific drug, because of disruption, and the health system has to go outside

of the contract provisions and procure the drug from an alternate supplier, the health system receives the difference through reimbursement between the contract price and the acquisition price from the alternate supplier.

All participants reported increased levels of communications to physicians, pharmaceutical buyers, and wholesalers related to supply chain disruptions. Participant 1 felt that keeping the physicians who were prescribing medications aware of the details about a disruption would decrease the level of interdepartmental animosity. Participants 1 and 2 felt their departments were unjustly subject to unprofessional behavior by some physicians affected by supply chain disruptions. Participant 1 stated

> I think the strategies can be successful if you are creative and if the people involved have a willingness. If you have a doctor who doesn't care or doesn't want to hear that we can't get Lasix and he or she just keeps pounding the table, then your strategies aren't going to work.

Systems that operate on the fringes of chaos disrupt strategic managerial control (Croson et al., 2014). Conversely, participant 4 believed much of the anxiety or animosity dissipates when all stakeholders are involved in the mitigation of the disruptions.

Participants 1, 2, 3, and 4 believed assessing the trends of alternate source providers added new dimensions and insights into supply chain disruptions. Specifically, Participant 3 revealed grey markets are "a sore spot because they do seem to always have the products that are on backorder." Participant 3 stated

> The hard to find companies may find out that something is not going to be produced in mass or the end of the year. You always wind up with backorders, so

> they go ahead and buy all this stuff, and then they try to turn around and sell it to us at increased cost. So, they create a lot of the problems.

Parallel to the response of Participant 3, Participant 1 thought "I think that there are certainly people who will take advantage of the system." Emergent behaviors analyzed in the context of a grey market provide alternate sources of feedback to the pharmaceutical procurement leaders to use in the planning of their strategic process.

Emergent Theme 2: Pharmaceutical Procurement Leaders Create Strategic Processes for Alternative Methods

The second emergent theme was the essential process of creating alternative methods. Participants discussed the necessity to utilize alternative methods of supply delivery. The participants demonstrated a high degree of consensus when relating their experiences of alternatives in drug choice, treatment regimen, and wholesaler access.

Participant 1 felt occasionally increased difficulty explaining the use of an alternate drug to a prescribing physician. Participant 1 stated "trying to convince physicians that Drug X might be as good as Drug Y because the reason they chose Drug X in the beginning because they think that it is the best." Participant 5 felt more confident using the health systems' electronic health records to identify near-term shortages. Participant 5 indicated alternates and substitutes were available but potentially not as optimal as the prescribed drug. All participants reported patient safety as the greatest concern when switching to an alternate or substitute drug.

Participants felt switching drug treatment plans had distinct safety concerns, but the affected patients were mostly long-term outpatient cases. Participant 3 indicated the

physician is counseled to reduce the dose or decrease the use of a specific drug until the supply chain has regained capacity. Participant 4 supported Participant 3's process but warned "it can add extra hoops to the process. Generally, though you are limited in the number of treatment plans you can put the patient on." Changing the system design, however minute, may create other more amplified problems not directly related to the changes (Krishnamurthy, 2015). Janvier-James (2012) supported a dynamic method and thought process to change supply chain structures and workflow.

Participants introduced two novel strategies in their responses. The first strategy was trading or borrowing from neighbor hospitals. The second strategy involved the limited use of compounding pharmacies to manufacture small amounts of drugs subject to supply chain disruptions. Outterson (2012) supported the structured use of compounding pharmacies to add redundancy and a safe alternative for health systems to acquire drugs in short supply. Trading and bartering are an emergent behavior, which was not present in the review of the current professional literature. Table 3 identifies the strategy coding disbursement among the participants for Emergent Theme 2.

Table 3

Strategies Relating to the Emerging Theme of Creating Strategic Processes for Alternative Procurement Methods

Participant	Alternative drug	Alternative wholesaler	Trade or barter	Alternative therapy	Compounding pharmacy
P1	105	31	27	30	27
P2	80	46	22	18	33
P3	34	46	19	16	13
P4	127	46	33	32	19
P5	78	27	18	19	11
Totals	424	196	119	115	103

Emergent Theme 3: Pharmaceutical Procurement Leaders Develop Reliable Sources of Actionable Information

Feedback is a critical component of any complex adaptive system involving production (Spencer & Carlan, 2008). Feedback within the pharmaceutical supply chain and distribution channel is a vital source of analytics used by pharmaceutical procurement leaders to make informed decisions. Emergent Theme 3 is bound to the identification and use of reliable sources of actionable information or feedback.

All participants felt analyzing feedback in the system supported the creation of departmental strategies used to eliminate or reduce the risk of supply chain disruptions. Participant 5 stated

> we utilize intelligence that we get from our group purchasing organization, wholesaler, some news articles, and list services, basically monitoring the buzz of pharmacy and what even some sales representatives we get intelligence from. Then, once we identify there is a shortage, we bring it to a weekly meeting that we have, a drug shortage meeting. For us, the key is first to identify that there is going to be an issue.

Participant 2 supported the strategy of participant 5 by stating

> I have a new buyer at one of our other hospitals, and we've told her don't close your screen to the wholesaler. You gotta keep looking and you gotta watch when the numbers decline, you gotta get in there and order something so that you get something.

All participants reported feedback comes from internal and external sources across multiple systems and through multiple filters. Pharmaceutical procurement leaders assess the sources of feedback and make a determination on the degree of legitimacy associated with the source. Participants 1, 2, and 5 hold weekly roundtable meetings to discuss current and potential supply chain disruptions with internal stakeholders.

Pharmaceutical procurement leaders have to train their staff on the process of discerning information in the system. Participant 4 described "So you have to go a step further than just listening to what the wholesaler is telling you. They code things *back ordered* even if they are waiting for shipment to come in to them." Yamaguchi et al., (2012) classifies this circumstance as a false negative or false indicator, which may impair strategic decisions. Participant 3 supported the strategy of Participant 4 through additional qualification of the feedback source and the on-going training of departmental staff.

Participants felt using actionable information from reliable sources supported the deeper development and strengthening of relationships with internal and external stakeholders. Strong relationships with stakeholders reinforced the strategic information analysis process. Participant 3 reported, "So if we are going to bring in a different product, we want to make sure we educate people about it." Participants reported an increased sense of purposeful communication even to the extent of excessive communication resulting in decreased anxiety levels among clinical staff. Participant 5 stated,

> When you are stuck like that you might be borrowing it from one of our own hospitals, maybe an outside hospital, maybe you could get an emergency delivery from a wholesaler, we go through a myriad, or you come up with a substitution you know and then communicate the plan to the physician real-time.

Participant 2 and 3 reported their departments communicate to physicians and other clinical staff on a regular basis of all known or potential disruptions affecting the patient population of the health system. All participants felt the levels of interdepartmental animosity diminished as the relationships between the pharmacy staff and clinical staff removed much of the systems chaotic or complex behaviors and replaced them with reliable sources of information.

Participants reported varying degrees of repurposing staff to accommodate the increased influence of supply chain disruptions. Although new tools were available to health systems from manufacturers and wholesalers, the participants offered no consensus on the use of new inventory checking or inventory management tools. Participant 5 reported the most significant advances in the repurposing of staff,

> We put in a specific policy and probably the most effective thing we did is we utilize the residents. We have 2 pharmacy residents we use to lead this once a week drug shortage call where we pull together a myriad of people and basically come up with a game plan for each individual drug shortage.

Participants 1, 2, 3, and 4 felt training the individuals who buy pharmaceutical products for the health systems were ideal candidates to use new tools and training on methods of analyzing the supply chain. All participants distinguish the need for additional resources

to analyze supply chain information; however, cost control is a key factor in the decision process to add new roles to the pharmacy department.

Emergent Theme 3 reflects the principles of emergent behaviors and self-organization in complex adaptive systems (Reimana, Rollenhagen, Pietikäinen, & Heikkiläc J., 2015). New patterns of networks among dissimilar agents suggest changes in the normative behaviors in the work groups within the health system. The new patterns may lead to increased success rates of reducing or mitigating pharmaceutical supply chain disruptions. Table 4 identifies the strategies coded to Emergent Theme 3.

Table 4

Codes Relating to the Emerging Theme of Develop Reliable Sources of Actionable Information

Participant	Development and equiping departmental staff	Strenghten relationships with internal and external stakeholders	Deploy department resources in unconventional roles
P1	27	28	4
P2	56	17	29
P3	16	20	5
P4	44	30	41
P5	25	18	28
Total	168	113	107

Pharmaceutical procurement leaders have a difficult challenge creating strategies that may eliminate or reduce supply chain disruptions. Nonlinear complex adaptive systems confound the leader's ability draw conclusions about the dynamic supply chain environment (Croson et al., 2014). Kulkarni (2017) suggests using models to thoroughly analyze and explain stochastic behaviors over time in such objects like supply chains. I offer a feedback model to explicate the causal relationships between the external drivers to the complex adaptive system, implementation of strategies from the pharmaceutical procurement leaders, and the relationship to reducing or eliminating supply chain

disruptions (see Figure 1). A feedback model identifies a visually simplistic method of depicting relationships between elements occurring within a system (Higgins, 2013; Kulkarni, 2017). Variables and associations among system elements in the feedback model identify the relationship between choices and results (see Figure 1). Interactions among system components create causal loops, which demonstrate foundational problems exclusive of whole system complexities (Mella, 2015; Strauss & Borenstein, 2015).

Direct relationships (+) represent changes from X to Y in the same direction. If X increases then Y increases; if X decreases then Y decreases. Inverse relationships (-) represent changes from X to Y in the opposite direction. If X increases then Y decreases; if X decreases then Y increases. The feedback model first presents external variables, which may affect any system regardless of complexity or simplicity. As the external variables increase so shall the demands for access to the health care continuum. Additionally, the increase or decrease of access demands increase or decrease the demand for health care products and services because of the positive causal relationship in the feedback loop (see Figure 1).

Increases in demands for health care products and services increase the demands on the US pharmaceutical supply chain and distribution channel for related products. The increased consumer demands shall also increase the improvement or degradation of the supply chain efficiencies; thereby, affecting the degree of risk for frequencies in the supply chain or distribution channel disruption. When the demands of the US pharmaceutical supply chain and distribution channel flow through the management strategies introduced in this study, the feedback loop split into one positive and one

negative relationship (see Figure 1). The applications of management strategies from this study have a direct relationship to improvements in pharmaceutical supply chain efficiencies and an inverse relationship over the degradation of supply chain efficiencies. Strategies identified in the three emergent themes affect both sides of the research problem (see Figure 1). Strengthening and standardizing the supply chain efficiencies through management strategies found in this research study may also support growth rates of pharmaceutical products and services at the same rates of demand growth driven by increased access by individual consumers to the health care continuum. The findings strongly suggest the identification and implementation of best practices within the organizational process lens of systems thinking (Medvedeva, 2012; Stephens, 2013; White & Fortune, 2012).

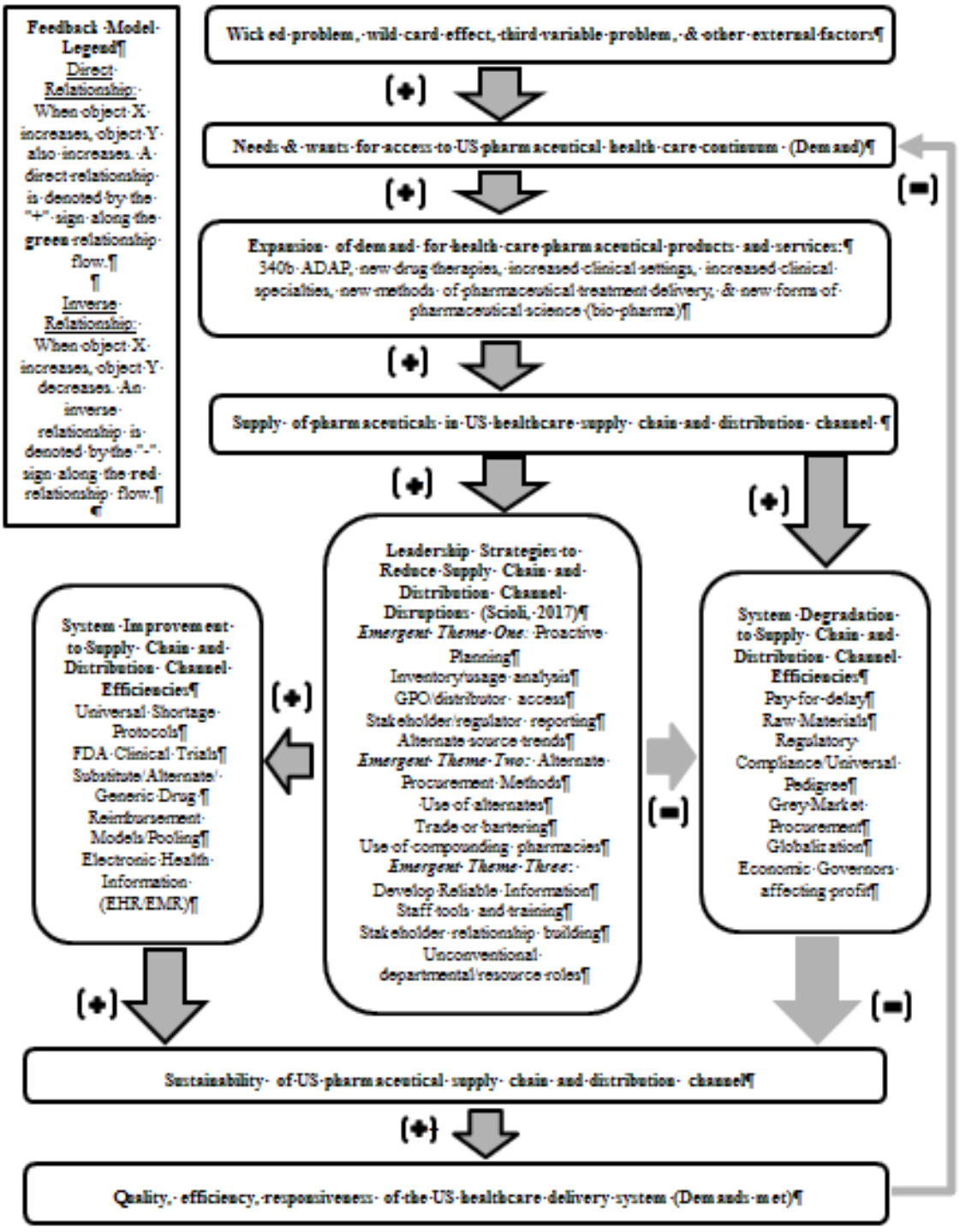

Figure 1: Feedback Loops in a complex adaptive system network associated with U.S. drug shortages. Model developed in consultation with K. D. Gossett (2017).

Applications to Professional Practice

The pharmaceutical supply chain and distribution channel have sustained long-term vulnerability to disruptions causing health care providers to endure the effects of a chaotic, complex system while attempting to maintain proven treatment protocols (Chen et al., 2016). After conducting an exhaustive search of scholarly literature and other academic publications, no direct alignment between the present study and previous academic studies was identified. The findings from this study provide an important exploration of the strategies used by pharmaceutical procurement leaders who create policies associated with pharmaceutical procurement and distribution. The findings illustrated the perceptions of pharmaceutical procurement leaders in health systems in the eastern region of the United States.

Creating a series of comprehensive strategies in the health system address pharmaceutical supply levels augment the sustainability of the pharmaceutical supply chain for long-term viability. Findings from the study indicate strategic decisions from the pharmaceutical procurement leaders are focused on (a), proactive methods of planning for patient needs, (b) open access to safe alternate procurement methods, and (c) acquiring rich sources of actionable information. Strategic planning is required for drug supply chain disruptions with the same level of acuity as weather and mass casualty related events (Fox et al., 2009). The results also suggest pharmaceutical leaders are focusing strategies on ex-ante processes to acquire rich forms of feedback from internal and external sources.

Pharmaceutical procurement leaders prioritize needs and allocate resources to meet those needs. Findings from this study amplify two central characteristics of a complex adaptive system. The first amplified characteristic is emergence through self-organization (Baykasoglu, 2016; Drack, 2009). The second amplified characteristic is leaders within a CAS operate in the grey area between predictable and unpredictable or on the edge of chaotic behaviors (Gimenez et al., 2012). Strategies from the procurement leaders focused intensely on using emergent behaviors to develop new strategic methodologies, which may reduce unpredictability or uncertainty in the supply chain and distribution channel.

The practical application of the findings from this study exists in the overall strengthening of technical capacities of the supply chain and distribution channel, which may increase system awareness and reduce chaotic behaviors. Strengthening supply chain and distribution channel technologies build analytical and trending capabilities required to predict future states of supply and demand. Specifically, pharmaceutical procurement leaders must develop reliable methods to predict supply levels in anticipation of demand trends. Utilization of predictive supply chain management strategies, through connecting to enhanced new feedback mechanisms in the CAS, may influence the degree and duration of the severity of the disruption. Findings from this study are consistent with Becker et al. (2013), Blome et al. (2013), Chaudhuri (2015), Cherici et al. (2011), Fox et al.(2009), Faucher (2013), and Kaakeh et al. (2011) because of similar characteristics of systems and feedback mechanisms identified in the academic literature.

Drug shortages of some magnitude may continue in the future. Senior pharmaceutical procurement leaders creating or improving strategies aligning with the main themes of this study will reduce or eliminate the risk of critical disruptions. Pharmaceutical procurement leaders must create more process-oriented strategies to enhance knowledge exchange versus supply chain element exchange (Narayana et al., 2014). Kauffman's body of work (1986 – 1998) on complexity at the Santé Fe Institute conceptualized greater areas of application than previous investigators. Concepts and themes found in this study support notions of complex adaptive systems from Arsenault et al. (2013), Di Toni and Comello (2013), Drack (2009), Geer-Frazier (2014), Gossett (1989), Iosim (2016), Kuziemsky (2016), and Mazzocchi (2012).

Senior procurement leaders desiring to implement improvements to their strategies will appreciate the results of this study. Investigators from previous studies concluded the need for similar strategic goals, which may eliminate or reduce pharmaceutical supply chain and distribution channel disruptions. Investigators from previous studies desired the need for proactive analysis (Chabner, 2011; Fox et al., 2009; Griffith, et al., 2012; Jagsi et al., 2014; Johnson, 2011; Krisl et al., 2013; Quilty et al., 2011; & Ventola, 2011). Investigators from previous studies encouraged developing or strengthening strategies for alternate procurement methods (Dorsey et al., 2009; Goldsack et al., 2014; Hoffman et al., 2012; ISMP, 2010; Kaakeh et al., 2011; Krisl et al., 2013; Le et al., 2011; McBride et al., 2013; McLaughlin & Skoglund, 2015; Metzger et al., 2013; Mullins & Cook, 2011; & Ventola, 2011). Finally, investigators from previous studies inferred the need to acquire and maintain reliable sources of actionable information,

which may be used in strategic planning scenarios (Janvier-James, 2012; Kaakeh et al., 2011; Marshall & Farahbakhsh, 2013; Mullins & Cook, 2011; Shah, 2004; & Wallis, 2013).

Implications for Social Change

The implications for positive social change include effective leadership strategies to mitigate pharmaceutical supply disruptions. Health care systems with low incidents of supply chain disruptions recognize competitive advantages above health systems, which may struggle to maintain continuity of care for drug therapies (ISMP, 2010). Senior procurement leaders may achieve lower costs through the reduction of disruptive or chaotic behavior in a complex supply and demand system using strategies identified in this study. Elimination of systematic inefficiencies, caused by an absence of actionable information, through the development of refined networks of feedback analysis and predictive supply chain modeling may strengthen basic foundational procurement processes. The development and refinement of the strategies presented in this study may stimulate increased information exchange and relationship building among stakeholders and health systems employees.

My desire is to envision the influence of the study findings on senior procurement leaders who may formulate new strategies addressing supply chain and distribution channel disruptions. My hope is the study findings compel senior procurement leaders and stakeholders to participate in dialogs leading to the exploration and revalidation of system configurations, strategies, and pharmaceutical procurement processes. Ultimately, my aspiration for this study it to change the trajectory of the health care cost curve. The

measure of success to the degree of positive social change brought about through the findings of this research study correlates to the quality of new informed decisions and strategies in the health system.

Recommendations for Action

The findings from this study prompted the development of recommendations for senior pharmaceutical procurement leaders to create supply chain and distribution channel strategies, which eliminate or mitigate disruptions. A programmatic process to analyze internal and external trends in pharmaceutical supply and demand utilizing distributor, supplier, and industry feedback models is a necessary recommendation to plan proactively for potential disruptions. Strategic processes allowing additional methods of procurement through alternate (a) distributors, (b) drug substitutes, (c) trade and barter relationships, and (d) compounding pharmacies, is a crucial recommendation for health systems to sustain disruptions. Additionally, feedback consistency must improve to support repeatable informed and actionable decisions; therefore, a needed recommendation is to build skill sets and tools to extract reliable feedback from sources utilizing staff and stakeholders.

The findings from this study are relevant to senior pharmaceutical procurement leaders. Utilizing the recommendations, senior procurement leaders responsible for creating supply chain strategies could introduce modifications to their procurement process. As an agent for positive social change, I am dedicated to ensuring the dissemination of the study findings at local, regional, national, and international

conferences and academic or trade publications. I will be available to senior leaders and managers seeking clarification or deeper understanding of the findings.

Recommendations for Further Study

My study may provide the first academic opportunity to analyze disruptions in pharmaceutical supply chains and distribution channels in United States health systems through the lens of complex adaptive systems. Avoidable costs to health care spending exceed $400 million resulting from supply and distribution disruptions (Fox, Sweet, & Jensen, 2014; Hoffman et al., 2012; Kaakeh et al., 2011). Recommendations for further research include a mixed methods approach to quantifying post implementation outcome of new strategies. Metrics from further studies may include measurements of duration and severity of disruptions. Additional metrics may focus on cost per disruption event and lost revenue from disruptions. A limitation of this study was the geographic area. Increasing geographic areas of the participant pool may identify additional qualitative viewpoints or opinions relating to supply and distribution disruptions.

Another opportunity for further research exists in the exploration of strategies at pharmaceutical manufacturers. Limited information exists on the strategies of pharmaceutical manufacturers to procure raw materials, which is another critical supply chain in health care, without disruption. A comparison of strategies between manufacturers and health systems may highlight conflicting processes that confound the entire system.

Reflections

My objective for conducting this study was to build my academic and professional competencies as a researcher exploring the qualitative nature of pharmaceutical supply chain and distribution channel disruptions. Engaging study participants in an open and probing manner enabled me to explore senior procurement leaders' strategies for mitigating or eliminating pharmaceutical supply disruptions. I remained mindful of personal biases throughout my conduct of the study. I retained a focus on capturing and representing the opinions and perspectives of participants in an unbiased manner. Sun Tzu wrote, "The line between disorder and order lies logistics." Peter Drucker said, "What gets measured gets improved." Both quotes contain deep concepts applicable to this study, and both authors share a strong presence in modern business management.

Prior to commencing data collection, I identified areas of potential personal bias. Specifically, how my professional experience in pharmaceutical distribution may influence the data analysis process of participants' responses towards leadership strategies. All participants of this study acknowledged that supply chain and distribution channel disruptions exist in health care with varying degrees. Participants were quick to add that the system is too complex and too chaotic to suggest eradication of disruptions is plausible in the current state. Conduct of the data gathering and data analysis created a new awareness in me. Participants stated a willingness to adopt strategies to reduce and or eliminate disruptions if the strategies were cost effective. One profound note I uncovered in this study, the participant response contained a great number of words and

phrases related to uncertainty or unpredictability. This statistic caught me off guard but challenged by this discovery; I will continue to research complex and chaotic systems.

Summary and Study Conclusions

This study concluded an exhaustive journey to provide a comprehensive exploration of how senior pharmaceutical procurement leaders set strategies to mitigate supply chain and distribution channel disruptions. Senior leaders and stakeholders in the health care delivery system must consider including themes from this study, which are (a) proactive planning, (b) alternate procurement methods, and (c) reliable and actionable information. The completion of this research came at an important time for this nation. Access to affordable universal health care is a primary concern to congressional leaders and American citizens alike. I offered comprehensive recommendations and a call for action based on the findings of this study.

Pharmaceutical products are a critical element in today's health care continuum. The more drugs you take, the longer you may live. The longer that you live, the more drugs you may take. The costs of pharmaceutical products have the ability to bend the health care cost curve, only when sufficient profit margins are sustainable across all drug classes. A sustainable pharmaceutical supply chain and distribution channel is a key element to the entire health care system and should be subject to additional research studies and findings from academic scholars pursuing an understanding of the complex adaptive system called health care.

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Appendix A: Invitation to Participate

Date
Dear _____:
My name was Adrian G. Scioli, and I am a Doctor of Business Administration (DBA) candidate at Walden University. I am conducting a doctoral study project to explore the research question of what strategies do health systems pharmaceutical procurement leaders need to address inconsistent drug supplies Based on your experiences as a health systems pharmaceutical procurement leader; I would like to interview you to gather information about your perceptions and beliefs about drug supply disruptions. The interview may require 45-90 minutes of your time and will be scheduled at your convenience within [INSERT TIME PERIOD FOR INTERVIEW PROCESS FOLLOWING COMPLETION OF IRB PROCESS]. I will conduct this in person interview at a location most convenient for you. I am also inviting you to share with me any e-mail messages, administrative documents, reports, and/or memoranda, which you think may provide additional information regarding your participation in mitigating drug supply disruptions. However, I note the provision of any documents on your part was voluntary. If you do not wish to provide documents, I am still asking you participate in the study as a participant.
Your participation in my study will be instrumental in ensuring I gather data from health systems pharmaceutical procurement leaders in the Easter region of the United States. If you decide to participate in my study, I will send you an informed consent form via e-mail for your review and signature. This informed consent form provides background information on the study and outlines your rights during the interview process. Please contact me if you have any questions or require additional information. My telephone number was 215-234-0466 or 215-285-0861. I kindly request an email response to this letter indicating your agreement to participate or your declination by _____.
My e-mail address was adrian.scioli@waldenu.edu. I thank you in advance for your consideration and your support of my doctoral study.

Sincerely,
Adrian Scioli

Appendix B: Case Study Participants' Eligibility Requirements

- Greater than 3 years in leadership position
- Employed within Eastern US health system
- Responsible for the administration and development of pharmaceutical supply chain and distribution strategies
- Responsible for administration, provision, delivery, and regulation of pharmaceutical supplies
- Successful implementation of operational strategies relating to pharmaceutical supply chain and distribution channel disruptions

Appendix C: Informed Consent

CONSENT FORM

You are invited to take part in a research study of how health systems pharmaceutical procurement leaders in the Eastern region of the United States describe limitations for the detection and mitigation of drug supply disruptions. The researcher was inviting health care leaders with experience administering, providing, and procuring pharmaceutical products in the Eastern region of the United States to participate in the study. This form was part of a process called "informed consent" to allow you to understand this study before deciding whether to take part.

This study was being conducted by Adrian G. Scioli, a Doctor of Business Administration (DBA) candidate at Walden University. The researcher was conducting this study in his capacity as a doctoral candidate at Walden University. The study has no relationship to the researcher's professional activities and affiliations.

Background Information:
The purpose of this study was to examine and explore how health care procurement leaders in the Eastern region of the United States describe the necessary strategies for managing the effects of drug supply chain and distribution channel disruptions.
Procedures:
If you agree to be in this study, you will be asked to:

- Participate in a single interview requiring no more than 45-60 minutes of your time
- Agree to have the interview audiotaped for later transcription and analysis by the researcher
- Provide copies of documents, (e-mail messages, administrative documents, policies, procedures, reports, and/or memoranda) which provide additional information and perspectives on strategies utilized to eliminate or reduce the effects of drug supply disruptions.
- Review a copy of initial study findings and conclusions provided to you by the researcher and to provide the researcher with feedback on the accuracy of the findings and conclusions

The provision of documents to the researcher was encouraged and voluntary. You are not obligated to do so. If you are not comfortable providing documents to the researcher, you are still requested to participate in a single interview described above.

Questions for the interview are as follows:

- Interview Questions
    - What types of strategies do you use to manage the pharmaceutical supply chain and distribution channel?

- What are the most important factors you use when implementing strategies to reduce or eliminate supply chain disruptions?
- What strategies have been the least effective in reducing or eliminating supply chain and or distribution channel disruptions?
- What specific supply chain management strategies do you use to address disruptions in the supply chain or distribution channel?
- How have your organization's supply chain management strategies changed or evolved?
- In your experience, what barriers prohibit supply chain management strategies from becoming successful?
- What other information would you like to discuss, which we have not already addressed?

The researcher will provide you with a copy of the transcript of your interview. You will have the opportunity to review and concur with the transcript contents prior to the researcher proceeding with the analysis of the transcript contents. At the completion of the study, the researcher will provide you with a brief document, (no more than two pages in length) which summarizes findings, recommendations, and conclusions from the study.

Voluntary Nature of the Study:
This study was voluntary. You will not be provided with any thank you gifts, compensation or reimbursement (for travel costs, etc.) in exchange for your participation in this study. Your decision regarding whether or not to participate in the interview and provide documents will be respected, and you will not be treated differently by the researcher should you elect not to participate. If you decide to participate in the study now, you can still change your mind during or after the study. You may end your participation in the study at any time.

Risks and Benefits of Being in the Study:
Being in this type of study involves some risk of minor discomforts, which can be encountered in daily life, such as fatigue, stress, or becoming upset should sensitive topics arise for discussion. The risk of such discomforts occurring is, however, considered to be low. Additionally, the researcher will endeavor to ensure the potential for personal discomfort was kept to a minimum during the conduct of the interview. Being in this study would not pose a risk to your safety or well-being.

Participation in the study will provide you with the opportunity to share your knowledge, thoughts, and experiences with the pharmaceutical supply chain and limitations in the detection and mitigation of drug supply disruptions. This study could contribute to greater understanding of how administrative and leadership responses are formulated in response to the problem (drug supply disruptions) of national significance. Conduct of this study may support the development of leadership models supportive of effective drug supply disruption mitigation strategies.

Privacy and Limits to Confidentiality:
The information you provide will be kept confidential. However, should you reveal evidence of criminal activity or abuse during the conduct of the interview, the researcher was obligated to report such evidence to relevant law enforcement authorities. The researcher will not use your personal information for any purposes outside of this research project. In addition, the researcher will not include your name, organizational affiliation, or any other information, which could identify you in study reports. Electronic data will be kept secure by participant deidentification and archival on a password-protected laptop computer and a private cloud data storage account accessible only to the researcher. The researcher will store any hard copies of data (e.g., printed interview transcripts used for notation and analysis) in a lockable container. The researcher will keep data for a period of at least 5 years as required by Walden University.

Contacts and Questions:
You may ask the researcher any questions you have at this time. Should you have questions following the conduct of the interview, you may contact the researcher via phone or e-mail. If you want to talk privately about your rights as a participant, you can contact the Walden University Research Participant Advocate via phone at 1-800-925-3368, extension 1210 within the USA or 001-612-312-1210 from outside the USA. You may also contact the Walden University Research Participant Advocate via e-mail at irb@waldenu.edu. Walden University's approval number for this study was _____ and it expires on _____.

The researcher will give you a copy of this form to keep.

Statement of Consent:

I have read the above information, and I feel I understand the study well enough to make a decision about my involvement. By signing below, I understand, and I agree to the terms described above.

Printed Name of Participant

_____

Date of Consent

_____

Participant's Written or Electronic* Signature

_____

Researcher's Written or Electronic* Signature

_____

* Electronic signatures are regulated by the Uniform Electronic Transactions Act. Legally, an "electronic signature" can be a person's typed name, their email address, or any other identifying marker. An electronic signature was just as valid as a written signature as long as both parties have agreed to conduct the transaction electronically.

Appendix D: Case Study Protocol

A. Case Study Introduction

1. Research Question

a. What strategies do health systems pharmaceutical procurement leaders need to address inconsistent drug supplies?

2. Conceptual Framework

a. Complexity Theory

B. Protocol Purpose and Intended Use

1. The protocol serves as the primary guidance in the conduct of study data collection, data analysis, and interpretation research efforts

2. The protocol used ensures reliability of case study methodology, research findings, and research conclusions

C. Data Collection Procedures

1. Data to be collected from the review of documents voluntarily provided by participants and the conduct of semistructured interviews with health system procurement leaders from a purposeful sample.

2. The researcher will recruit participants from the development of a purposeful sample of potential participants.

3. Identification and finalization of specific study sites and site-specific contact persons occur after the invitation to participate letters are sent, and responses are received from participants

4. Expected preparation activities to take place prior to site visits to conduct interviews

a. Preparation of informed consent forms for each participant

b. Prepare interview question guide for each participant

5. Data collection tools

a. Digital audio recordings

b. Researcher field notes

c. Case study database

D. Outline of Case Study Report Contents

1. Overview of study

2. Presentation of the findings

3. Applications to professional practice

4. Implications for social change

5. Recommendations for action

6. Recommendations for further study

7. Reflections

8. Summary

9. Study conclusions

E. Case Study Interview Questions

Interview Questions

1. What types of strategies do you use to manage supply disruptions in the pharmaceutical supply chain and distribution channel?

2. What are the most important factors you consider when implementing strategies to reduce or eliminate supply chain disruptions?
3. What strategies have been the least effective in reducing or eliminating supply chain and or distribution channel disruptions?
4. What specific supply chain management strategies do you use to address disruptions in the supply chain or distribution channel?
5. How have your organization's supply chain management strategies changed or evolved since you assumed the leadership role?
6. What barriers prohibit supply chain management strategies from becoming successful?
7. What other information would you like to discuss, which we have not already addressed?

F. Data Analysis Techniques and Tools

1. Coding
2. Analysis tools
    a. ATLAS.ti.7
    b. Microsoft Excel

G. Study Reliability and Validity Methods

1. Reliability methods
    a. Use of case study protocol
    b. Creation of case study database
2. Validity methods

a. Construct validity

i. Multiple data sources

b. Internal validity

ii. Research bias identification

b. External validity

i. Rich description of study sample population and context

Appendix E: National Institutes of Health (NIH) Office of Extramural Research

Protecting Human Research Participants Certification

Certificate of Completion

The National Institutes of Health (NIH) Office of Extramural Research certifies that **Adrian Scioli** successfully completed the NIH Web-based training course “Protecting Human Research Participants”.

Date of completion: 03/06/2012

Certification Number: 883410

Appendix F: Case Study Interview Protocol Checklist

Pre-Interview	
Interview date:	Interview time:
Interview location:	Interview duration estimate:
Participant pseudonym:	Participant code:

Interview documentation and materials	
Receipt of Informed Consent (Yes or No):	Eligibility criteria met (Yes or No):
Receipt of Permission to Record and Transcribe (Yes or No):	Test Primary and back-up recording device (Yes or No):

Conduct of interview	
Introductions (Yes or No):	Overview of research topic (Yes or No):
Discuss purpose	Questions from participant (Yes or No):
Discuss risk	Questions from participant (Yes or No):
Discuss confidentiality	Questions from participant (Yes or No):
Discuss right to withdraw	Questions from participant (Yes or No):
Discuss benefits	Questions from participant (Yes or No):
Discuss data security	Questions from participant (Yes or No):

Interview	
My observations and actions: a. Body language b. Non-verbal cues c. Paraphrasing d. Probing questions e. Follow-on questions	a) What types of strategies do you use to manage supply disruptions in the pharmaceutical supply chain and distribution channel?
	b) What are the most important factors you consider when implementing strategies to reduce or eliminate supply chain disruptions?
	c) What strategies have been the least effective in reducing or eliminating supply chain and or distribution channel disruptions?
	d) What specific supply chain management strategies do you use to address disruptions in the supply chain or distribution channel?
	e) How have your organization's supply chain management strategies changed or evolved since you assumed the leadership role?

	f) What barriers prohibit supply chain management strategies from becoming successful?
	g) What other information would you like to discuss, which we have not already addressed?

Post-interview follow-up	
Thank participant for contribution	Actual interview duration:
Discuss next steps:	Questions from participant (Yes or No):
a. Completion of transcript b. Concept of member checking c. Set up a date for member checking follow-up d. Notification of findings e. Duration of data security	Questions from participant (Yes or No):

Member checking follow-up	
Follow-up date:	Provide copy of synthesis for each question
Introduce member checking process	Questions from participant (Yes or No):
My observations and actions: • Additional probing questions • Affirm synthesis for each question • Ask for further interpretation or additional information • Ask what was missed in the initial interview	a) Synthesis of 1st question b) Synthesis of 2nd question c) Synthesis of 3rd question d) Synthesis of 4th question e) Synthesis of 5th question f) Synthesis of 6th question g) Synthesis of 7th question

Appendix G: Organizational Letter of Cooperation

Letter of Cooperation for Doctoral Research Study

<Contact Information>

Date: <Date of Correspondence>

Dear Adrian G. Scioli,

Based on my review of your research proposal, I give permission for you to conduct the study entitled Leadership Strategies for Addressing U.S. Pharmaceutical Drug Shortages and Supply Chain Disruptions. As part of this study, I authorize you to solicit eligible participants for participation, conduct data collection through interviews and member checking activities. Individuals' participation will be voluntary and at their discretion. We understand that our organization's responsibilities include: The time for eligible participants to participate in the study. We reserve the right to withdraw from the study at any time for any reason if our circumstances change.

I confirm that I am authorized to approve said research activities in this setting and the plan complies with the organization's policies.

I understand data collected from the above activities will remain entirely confidential and may not be provided to anyone outside of the student's supervising faculty/staff without permission from the Walden University's Institutional Review Board.

Sincerely,

_____

(Printed name and title)

Walden University policy on electronic signatures: An electronic signature was just as valid as a written signature as long as both parties have agreed to conduct the transaction electronically. Electronic signatures are regulated by the Uniform Electronic Transactions Act. Electronic signatures are only valid when the signer was either (a) the sender of the email or (b) copied on the email containing the signed document. Legally an "electronic signature" can be the person's typed name, their email address, or any other identifying marker. Walden University's staff verify any electronic signatures not originating from a password-protected source (i.e., an email address officially on file with Walden University)