2015

Medical Academia Conflict of Interest Policy and Potential Impact on Research Funding

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Abstract

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MPA, Troy University, 1993

BA, Ripon College, 1990

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Public Policy and Administration

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Abstract

The partnership between medical academia and the pharmaceutical industry has been scrutinized for issues associated with research bias. As a result of this scrutiny, the Institute of Medicine (IOM) issued policy recommendations in 2009 directing academia to adopt comprehensive conflict of interest (COI) policies. During the same time, a slowdown of funded research into academia occurred, and it is not clear whether the IOM recommendations contributed to this problem. The purpose of this case study was to determine the extent to which compliance with the IOM policy resulted in a reduction in funded research. The Advocacy Coalition Framework (ACF) was the theoretical lens used for study. COI policy statements (n = 15) were analyzed from American Association of Medical Colleges member schools that engage in medical research. In addition, in-depth interviews were conducted with 4 medical academic researchers. Data were inductively coded and organized around key themes. Key findings indicated that medical academia is compliant with IOM recommendations and COI policies did not appear to have a direct effect on research placement by industry. Interestingly, a possible explanation for reductions in industry funding relate to inefficient institutional review board processes. Additionally, the ACF construct was validated via an observed complex and slowly evolving COI policy process. The positive social change implications of this study include recommendations to academia to continue to monitor and report on COI and explore efficiency improvements related to IRB oversight in order to support important pharmaceutical research that ultimately improves the health and wellbeing of people.

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Dedication

I would like to dedicate this work to my children, Alexandra, Katherine, Elizabeth, and Matthew, for being a source of inspiration and having made me reflect on how important education is and the implications for making the world a better place, and to my wife Maria: Your support and helping push me along has allowed me to accomplish this work.

Acknowledgments

I would like to acknowledge several people for their assistance with this project. I would like to thank Darlene Wesenberg Rzezotarski for being my APA style and grammar editor. Also, I would like to thank Dr. Kirk Yancy Williams for being an effective chair for my dissertation and for all of his advice along the way. He helped inspire me to create a timely and significant body of work with this study. Finally, I would like to thank Dr. LaToya Johnson and Dr. Anne Fetter for all their hard work and their individual instruction.

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Chapter 1: Introduction to the Study

During the 20th century, significant research and collaborative projects ranging from molecule discovery and development, Phase 1 through 4 clinical trials, and investigator initiated research typified the working partnership between medical academic institutions and the pharmaceutical industry (Brody, 2011a; Furman & MacGarvie, 2009; Maahs, 2012). Pharmaceutical industry backed research comprised of approximately one-third of all research support at United States based medical academic centers ranging from $27.1 to $38.4 billion annually (Dorsey et al., 2010) and has involved tens of thousands of patients on an annual basis (Maahs, 2012).

This relationship between academia and industry has come under close scrutiny during the last 20 years due to public concerns over undue influence, research bias, and conflicts of interest (Brody 2010; Insel, 2010; Maahs, 2012; Mansi et al., 2012; Roseman et al., 2011; Wynia & Boren, 2009). Calls have been made by both the government and the medical community for policy reform and the establishment of restrictive interaction and COI policies (Breenan et al., 2006; Maahs, 2012; Rothman & Chimonas, 2008; Steinbrook, 2009) has further shifted this relationship from collaborative (open) to noncollaborative (restrictive) in nature. Consequently, the medical academic community has seen a slowdown in the quantity of research funding placed by the pharmaceutical industry during the last 10 years (Dorsey et al., 2010; Maahs, 2012).

Dorsey et al. (2010) found that when adjusted for inflation, the annual growth rate of pharmaceutical research placement to the medical academic centers decreased

statistically significantly from 8% during 1994 to 2003 to 6% for 2003 to 2007 ($p < .05$). It is important to note that these funding levels occurred before the global recession from 2007 to 2009. Dorsey et al. (2010) also reported that the number of new Food and Drug Administration (FDA) medication approvals annually from 1998 to 2002 ($\bar{x} = 21$) and 2003 to 2008 ($\bar{x} = 20$) was flat, and pharmaceutical industry backed research comprised approximately one-third of all research support at United States based medical academic centers ranging from $27.1 to $38.4 billion annually.

The extent to which noncollaborative interaction and COI policies has been related to these decreased funding levels is unknown, is a problem, and, therefore, requires further investigation (Maahs, 2012) and provides a scholarly justification for this scientifically based qualitative research. The potential social implication of decreased medical research as a result of a more noncollaborative environment between academic medical institutions and the pharmaceutical industry is profound. The unintended consequence of such policies could result in a slowdown of new medicine development and disease management and/or prevention. From a social justice perspective, this could imply an unexpected delay in the development of life-saving medications and a dramatic impact on world health.

In Chapter 1, I provide an overview of the research problem and methodology, the conceptual framework employed, and a discussion of the existing and growing strained relationship between the pharmaceutical industry and the medical academic community during the last 6 years. In Chapter 1, I also introduce the corresponding development of

restrictive interaction policies adopted by academia and the slowdown of research placement by the pharmaceutical industry into academic medical institutions.

Background

The medical profession and the pharmaceutical industry enjoyed an open and unrestricted working relationship during the 20th century (Brody, 2011a; Furman & MacGarvie, 2009). This relationship ranged from research conducted involving molecule discovery and development to all four phases of FDA monitored research. These four phases of FDA research are described as follows;

- Phase 1: New medication treatment on low census of humans to determine overall safety, dosage range, and side effects.
- Phase 2: New medication treatment to larger census of humans to determine effectiveness and further determination on safety.
- Phase 3: New medication treatment on even larger census of humans to reaffirm effectiveness, collect further safety data, track side effects, and compare it placebo or other commonly used treatments. A double blind placebo study is common in Phase 3 research projects.
- Phase 4: Research done on human patients after a medication has been approved (post marketing trials) to gather information on medication effect on various populations and side effects with regard to long term use.

During the 20th century, significant new medication development was fostered through collaborative partnerships between the medical academic community and

pharmaceutical companies involving all four phases of FDA monitored research (Maahs, 2012). Furman and MacGarvie (2009) examined the rapid development of new medications and the corresponding statistically significant positively correlated growth ($n = 102$, $r = 0.21$, $p < .05$) of the pharmaceutical industry and found that firms that engaged with universities had higher rates of new medication development and laboratory growth than those that did not engage partnerships with academia. This collaboration typically took the form of pharmaceutical industry funded medication research trials conducted independently by the medical academic community. Funded research varied from very open study designs and control by the research university to very tightly controlled where an academic institution was provided exact parameters of the research to be completed to include complete study design, methodology, and data analysis.

During the last 2 decades, these research partnerships, as well as the entire framework of interactions between the medical academic community and the pharmaceutical industry, have come under intense criticism and scrutiny. One of the central issues concerning this debate is the issue of influence and bias (Maahs, 2012). Angell (2008) contented that prior to the 1980s, more free-form pharmaceutical research grants to academic centers gave the principal investigators (PIs) primary control over the research process, whereas now this control has shifted, typically involving the sponsoring companies providing an entire template covering all aspects of the research directing the academic research process and sometimes even suggesting the outcome (dependent

variables). This involved elements including setting the research questions, the research methodology, the study purpose and design, sample size and the population to which the findings would be generalizable, selection of testing instruments, reporting of side effects, and statistical analysis. The control of this process created concerns that the pharmaceutical industry was attempting to create research with the intended outcome preprescribed by the funding entity. The defense of this process can also be explained that when doing large medication studies across multiple sites and institutions, the research design, methodology, and analysis must be mirrored across all locations or the entire study would be invalid due to replicability issues.

Currently, limited scientifically based and scholarly research exists to report the nature of the interaction between the pharmaceutical industry and medical professionals within the academic community. A random survey of 3,080 medical academic researchers, where 17% were identified as PIs (and fellow and hospital staff medical providers were excluded), found that 53% of the respondents had some form of interaction or relationship with the pharmaceutical industry (Zinner, Bolcic-Jankovic, Clarridge, Blumenthal, & Campbell, 2009). Campbell et al. (2007) conducted a 2006 survey of department chairs at 125 medical schools and 15 large teaching hospitals and reported a slightly higher level of interaction with close to 60% of academic medical department chairs reporting some form of paid industry contact or relationship including being on a consultancy or advisory board, being a part of a compensated speaker bureau, being a board of director member, or being a company officer.

These questionable financial relationships between medical professionals and the pharmaceutical industry have called into question the entire concept of COI (Campbell et al., 2007; Maahs, 2012; Zinner et al., 2009). The prevailing thought process of those inherent in such relationships is that this potentially creates ethical dilemmas for medical professionals relative to patient care and safety and their respective pharmaceutical industry involvement (Brody, 2011a; Maahs, 2012). Numerous calls for reform and regulation on this topic have become more prevalent during the last decade. From 2001 to 2008, at least 16 prominent reports (Steinbrook, 2009) have called for reform and policy development with respect to interaction and COI medical academia and industry.

Brennan et al. (2006) created a turning point with regard to the entire topic of interaction and COI at the medical professional level. This particular article (Brennan et al., 2006) was the result of a task force appointed by the American Board of Internal Medicine Foundation (ABIMF) and the Institute on Medicine as a Profession (IOMAP) in 2004, and the authors found that existing policy and guidelines on industry interaction was minimal and not well defined. Recommendations by this task force (the ABIMF and IOMAP) in 2006 called for widespread reforms in medical academia including restricting pharmaceutical industry representatives' access to physicians, restrictions on medication samples, prohibiting involvement in pharmaceutical speaker bureaus, and developing institutional level COI policies (Brennan et al., 2006; Maahs, 2012).

By 2008, at least 25 public and private medical academic institutions including Yale University, University of Massachusetts, Boston University, University of

Pittsburgh, University of Pennsylvania, University of Chicago, University of Michigan, University of Wisconsin, and the entire University of California medical school system voluntarily adopted comprehensive COI policies (Rothman & Chimonas, 2008). A February 2009 report issued by the AAMC called on all major research universities to adopt comprehensive COI policies within 2 years. The policy recommendations from the AAMC were consistent with the Breenan et al. (2006) policy recommendations and further sought to ban all pharmaceutical representatives from academic campuses as well as prohibit any industry provided food as it would be considered a "gift" and fall under the zero-dollar gifting giving provision.

Following the 2009 policy recommendations by the AAMC, the NIH, National Research Council (NRC), National Academy of Sciences (NAS), and the IOM all weighed in on COI across the entire spectrum of medicine. In April 2009, with partial funding provided by the NIH, the IOM with an endorsement from the NRC and the NAS issued its nationwide report on COI in medical research education and practice (Lo & Field, 2009). The IOM defined COI as a set of circumstances that created a risk that professional judgment or actions might be unduly influenced by a secondary financial interest (Lo & Field, 2009). The IOM called for all public and private institutions engaged in medical research and education to adopt policies across an entire range of interaction, medical samples, continuing medical education activities, speaker bureau involvement, and consulting contracts that pertain to medical providers and industry (Lo & Field, 2009).

Problem Statement

During the 20th century, productive and collaborative working relationships existed between United States based medical academic institutions and the pharmaceutical industry. These collaborative relationships have been credited for significant medical advancements as a result of collaborative research projects (Brody, 2011a; Furman & MacGarvie, 2009; Maahs, 2012). Concerns about undue influence and integrity of academic research led to calls for policy reform at the public and private medical institutional level (AAMC, 2009; Breenan et al., 2006; Lo & Field, 2009). The working relationships between these entities have become more noncollaborative in nature as the policy recommendations set forth in the 2009 IOM report were adopted at the individual institution level (Gozalez-Campoy, 2009; Huddle, 2010). It is not known, however, exactly how compliant all medical academic institutions have been with enacting COI policies and how similar their policies are to the 2009 IOM's recommendations.

The slowdown of funding collaborative research projects by the pharmaceutical industry to medical academic centers in the United States from 2003 to 2007 (Dorsey et al., 2010) came during a time typified by industry-academia scrutiny and the call for restrictive interaction and COI policies (Maahs, 2012; Steinbrook, 2009). It has also been reported that from 2003 to 2008, the number of new FDA approved medications has been relatively flat (Steinbrook, 2009), raising concerns relative to research effectiveness and efficiency. This creates a gap in the current literature and is a problem because it may be

an unintended consequence of adopting noncollaborative policies between academia and industry and potentially has already stifled medical advancement.

Purpose of Study

In a qualitative manner, I intended to study 10 academic medical institutions and the extent to which these academic medical institutions have adopted interaction and COI policies governing their healthcare professionals' interface with the pharmaceutical industry from 2007 through 2014 and in line with the 2009 IOM recommendations. The timeline that was studied is important to understand within the context of the COI policies that were nonexistent or not well defined prior to a call for action by Breenan et al. (2006) and the corresponding evolution and compliance of these policies post 2009 IOM recommendations through 2014. Additionally, this qualitative study was designed to determine the nature of the relationships between pharmaceutical firms and medical academic institutions when a financial arrangement exists. The qualitative study was intended to more fully understand the rationale and decision making process of medical academic institutions (and the pharmaceutical funding implications) when developing interaction and COI policies, whether mandated or not. Finally, implications for social change were examined with regard to patient safety and medicine development in light of the revisions to policies.

The purpose of this qualitative research study was to genuinely understand the evolution and current relationship that exists between medical academic institutions and the pharmaceutical industry. It should be noted that the purpose of this research was not

intended to show that noncollaborative medical academic institutions were negatively impacted by research placement and that collaborative institutions were positively impacted by research placement. The purpose of this research was also not intended to call for a reversal of COI policy and drive an argument for the return in the way in which these entities interacted in the late 1990s through early 2000s.

Research Questions

Qualitative Research Question 1: Since the release of the IOM Policy Report (Lo & Field, 2009), to what extent have interaction and COI policies been fully complied with by United States based medical academic institutions, what were the rationale(s) and decision making considerations involved in developing such policies, and how would these institutions classify the current nature of their relationship with pharmaceutical companies as opposed to pre 2009?

Qualitative Research Question 2: What are some of the effects that new COI policies have had on pharmaceutical industry research funding for United States based medical academic institutions since the implementation of the IOM Report (Lo & Field, 2009)?

Conceptual Framework

As qualitative researchers develop their methods of inquiry, they bring their own sets of beliefs and assumptions, as well as their worldviews, about the environment around them. These paradigms or worldviews as discussed by Creswell (2007) helped to shape the processes and practices that researchers undertake. I have been in the

pharmaceutical industry since 2003 and currently am employed by Pfizer as a hospital sales representative. I have observed first-hand the implementation of the new 2009 IOM recommendations on COI policies and the corresponding changes in the working relationships between academia and industry. It is through this lens that I am able to bring the insights from my professional experience to this qualitative research study. I have an ethical responsibility to be objective and control my own personal bias on the topic. I mention this throughout the study and my attempts to be bias free. I have made the proper financial disclosures in Appendix A of this dissertation.

The conceptual framework ACF was initially developed by Sabatier and Jenkins-Smith during the late 1980s to the early 1990s to understand coalition behavior and structure, the influence of science and information technology on policy development, and the role of contentious policy subsystems on policy change and behavior (Birkland, 2001; Sabatier & Jenkins-Smith, 1988). Sabatier and Jenkins-Smith (1988) presented that ACF is based on five premises: (a) technology and science based information plays a central role in the policy process, (b) a minimum of 10 years is needed to fully understand policy change, (c) vested parties are expanded beyond traditional players to include multiple parties (all levels of government, media, consultants, and scientists), (d) enacted policies and programs are a reflection of beliefs, and (e) the policy subsystem itself can be measured by policy topic, geographic scope, and stakeholders. Within these premises, Sabatier and Jenkins-Smith submitted that decision making, whether by the individual or institution, was based on a heuristic decision making platform as opposed to

more rational one. This conceptual framework has been applied worldwide across a wide array of policy topics including medical education and drug policy (University Colorado – Denver, 2013). Particular to policy development itself, one can observe multiple parties exercising their own opinions based on their own individual experiences, and the end result is policy that while intended to protect patient safety may actually stifle medical advancement.

The two qualitative research questions investigated dealt with interaction and COI policy development by the medical academic community and the nature of its relationship with research funding placement by the pharmaceutical industry in these same medical institutions (Maahs, 2012). Concepts around the ACF were used to develop the lens that informed and guided the research process; that is, the beliefs and actions of several subsystems were observed during research question development and study design. Combined with the contentious nature of the overall topic, it can be argued that using ACF as the conceptual framework was a good fit for this dissertation because multiple stakeholders across many levels of government, the medical community (institutional and individual), the pharmaceutical industry, and the media have all been involved in the discussion and evolution of COI policy development.

Nature of the Study

The initial research design was qualitative in nature, included an open-ended online survey, and incorporated an interview element of 10 nationally representative institutions that voluntarily agreed to be a part of the interview phase of the research (*n* =

10). The research approach was to arrive at 10 institutions total that fully participated in both the survey and the interview portion of the study. An internet records review of COI policy was employed to verify and answer portions of the research questions. An invitation to participate in research with an open-ended online survey and voluntary follow-up interview was sent to the medical directors of the 75 medical academic institutions affiliated with the AAMC that conduct medical research to solicit information about interaction and COI policy and research funding received by the pharmaceutical industry from 2007 through 2014. My intention was to capture information about the evolution of institutional policy development pre- and post-2009 IOM recommendations on COI, institutional research funding trends from the pharmaceutical industry, and the rationale and decision making process relative to institutional COI policy development. Being qualitative in nature, data collected were examined and analyzed across a wide array of circumstances and categories. This included and was not limited to how similar an institution's actual COI policy was to the 2009 IOM recommendations, based on the responses given (Lo & Field, 2009), public versus private institution policy development, research funding trends at individual institution level and association of similarity to 2009 IOM recommendations, similarity of institution motivation, concern, and decision making process relative to policy development and enactment.

Operational Definitions

Certified medical education (CME): The medical industry term pertaining to continuing education credits earned by healthcare professionals required to maintain an

active medical license (Shi & Singh, 2008). Determined by individual state, physicians are required to complete between 12 to 50 hours of CME on an annual basis (Advanced Health Care Media, 2013).

Collaborative institution: Term developed by medical researchers to identify an academic institution that allows open access and interaction between its healthcare professionals and the pharmaceutical industry. This includes allowing staff to engage in compensated activities to include researcher, advisory board member, or speaker bureau member. Healthcare providers are typically compensated via grant and/or consultant contract and are usually required to disclose such financial arrangements with their respective academic institution. Additionally, these financial arrangements are to be reported by the pharmaceutical industry as required by Physician Payment Sunshine Act (PPSA) of 2010 (American Medical News, 2013) by 2014.

Collaborative research: Common medical industry term describing joint research funded by the pharmaceutical industry and conducted by medical academic institutions; concept describing a process by which both parties (industry and academic) engage in research from a shared common goal of advancing human science (Hughes, 2008; Kitsis, 2011).

Conflict of interest (COI): Common medical industry term describing when a healthcare provider's or medical researcher's motives are and/or an appearance of the same are placed in a situation where the moral decision making process with regard to patient care and safety could be compromised by personal gain, association with the

pharmaceutical industry, or being influenced by marketing and promotion practices (AAMC, 2009; Brennan et al., 2006; Lo & Field, 2009). Application of COI primarily defined by individual institution in the form of its' own respective COI policy.

Contract medical organization (CMO): Scientific medical industry term pertaining to a private organization that exists to perform medical research on an independent third-party and contracted basis for the pharmaceutical industry, with no vested interest implied in the findings (Abodor, 2010).

Disclosure: Common medical industry term pertaining to the reporting of financial arrangements between healthcare professionals and the pharmaceutical industry including practices as compensated researcher, speaker bureau, or advisory board member (Rothman & Chimonas, 2008). Typically covered under institutional COI policies, physicians who engage in such activities are required to report these financial arrangements with their respective institutions. Under the provisions of the PPSA of 2010 (American Medical News, 2013), pharmaceutical companies will be required to report such arrangements via a publicly available searchable database beginning in 2014.

Healthcare professional: Common medical industry term referring to an individual who is licensed to prescribe medications and includes medical doctors, nurse practitioners, and physician assistants (Baker & Baker, 2011).

Interaction policy: Common medical industry term referring to policies developed by medical academic institutions to govern their respective healthcare professionals contact and association with the pharmaceutical industry (Brennan et al., 2006).

Medical academic institution: Common medical industry term referring to an organization that performs functions involved with medical research and/or education as well as patient treatment and care (Baker & Baker, 2011).

Noncollaborative institution: Term developed by me to identify a medical academic institution that restricts access to and interactions between its healthcare professionals and the pharmaceutical industry. This includes prohibiting such compensated activities as independent researcher, advisory board member, or speaker bureau member (Maahs, 2012).

Research bias: Common academic and medical industry term describing a process where the individual researcher's decision making with regard to research questions, methodology, design, sampling, conduct, analysis, interpretation, and presentation may be affected intentionally or unintentionally by preference or COI (Creswell, 2007; Sismondo, 2007) or the appearance of COI.

Transparency: Common medical industry term referring to the practice of healthcare professionals and medical academic institutions reporting payments from industry; pharmaceutical industry publicly disclosing its compensation, commercial support, and research support to healthcare professionals, medical academic institutions, and healthcare professional associations (Brody, 2005, 2006).

Undue influence: Common language that will be used in this study describing the potential effect of the pharmaceutical industry employing various interaction, marketing,

and promotional practices that might influence physician research or prescription behavior to the benefit of the pharmaceutical industry (Sismondo, 2007).

Assumptions

1. Institutions that comprised the sample (n = 10) and replied to the qualitative open-ended survey and participated in the interview were representative of the 75 medical schools in the United States engaged in medical research. That is, whether an institution has enacted collaborative or noncollaborative policies, a representative distribution of these types of institutions replied and therefore were representative of medical academic institutions as a whole. A desired sample size of at least 20 institutions for the survey and 10 institutions that would have completed the survey and volunteered for the interview portion of the study would have been preferred.
2. Survey and interview responses were consistent with institutional attitudes and beliefs. Surveys and interviews were addressed to the medical director of the 75 institutions initially selected for this qualitative study. Every attempt was made to interview an administrator with decision making authority with regard to COI policy from 10 institutions. While responses were being prepared by individuals within an institution, the answers provided were assumed to be representative of the institution itself.

3. The survey was written in an objective manner and therefore was not "leading" the respondent to answer in a manner inconsistent with his or her own institution's beliefs.

Scope and Delimitations

1. The scope of this qualitative study included the 75 publicly and privately funded medical academic centers in the United States that were currently members of the AAMC and conducted medical research at a teaching institution. The AAMC included 141 accredited member schools from the United States and Canada (AAMC, 2011) with not all institutions engaged in medical research.
2. The definition of a collaborative or noncollaborative institution evolved through the data collection and analysis phase. The assignment of an institution as collaborative or noncollaborative was not preassigned but coded emergently. Analysis of COI policies and the interview portion of the research study research provided patterns, themes, and associations eventually defined as collaborative or noncollaborative in relative terms. That is, my analysis of the data helped to determine if an institution was more or less collaborative in nature as opposed to an absolute assignment.
3. Research funding placement was limited only to research grants awarded at the institutional level by the pharmaceutical industry from 2007 to 2014.

Study Limitations

This qualitative study had several design and methodological weaknesses. The first concern was whether or not noncollaborative policies on interaction and COI at the institution level had a relationship to research funding placement. That is, medical academic centers that could have made a deliberate decision to no longer be involved in pharmaceutical funded research and restrictive policies enacted after the fact were reflected only as a by-product of that decision (Maahs, 2012). The interview portion of the research study included questions asking institutions to identify issues like this. Another limitation involved long term research grants that may have come to an end or were just initiated during the years examined in this study. For example, a 5 year study may have come to an end that was not intended to be renewed at the same time a restrictive policy was put in place. Without knowing this, one could make the assumption that research funding was reduced due to restrictive policies where in fact it was merely a timing issue of research coming to an end (Maahs, 2012). Again, this was accounted for by asking open-ended and follow-up questions to solicit this type of information from study participants through member checking.

The first portion of this study using survey based information gathering could have be problematic if a low response rate had occurred. Ten institutions were the proposed sample size for completion of the survey and subsequent interview phase of the research. The quality and relevance of this study was dependent upon having enough data to be coded and to analyze emergent patterns or themes from the institutions responding

through the use of emergent coding and saturated data. One way to address a potential low survey response issue was to collect information already available publicly and cross check it through the online surveys. Many public medical academic centers are upfront in their reporting of interaction and COI policies. For instance, the University of Wisconsin Health website has a link that directly provides its policy on interactions with industry concerns (UW Health, 2012). Whether the information required for this qualitative study was compiled via open-ended survey and/or semistructured interview and/or already publicly disclosed information, the data were available to adequately answer the research questions. However, the quantity and quality of information to be gathered presented numerous challenges, and, as a result, the study was modified to elicit additional meaningful data via recorded interviews and online policy reviews. I discuss this further in Chapter 4.

Significance

The significance of this qualitative study potentially applies at many different levels. The study was conducted during a time when the United States economy was struggling and the placement of pharmaceutical research was gravitating away from the university level to contract research organizations abroad (Maahs, 2012). Many of the medical advancements that have occurred in the last 40 years have been made possible through a mechanism of open collaboration between the private sector and the university setting. The inherent value of this research calls for a fair, balanced, and transparent approach to this working relationship moving forward. While an industry-academia

relationship with no parameters or guidelines in place would potentially create COI issues, overly restrictive policies can also stifle medical advancements that would otherwise only come about because of collaboration. The implication for overall change would be for a call for interaction policies that foster collaboration yet are open and transparent enough to reasonably address COI concerns (Maahs, 2012).

From a social change perspective, medical advancement and patient safety concerns could be more adequately addressed through collaborative partnerships as opposed to noncollaborative ones. It can be argued that more positive and symbiotic relationships between the pharmaceutical industry and the medical academic community might allow this. This more collaborative platform entertains the possibility of getting new medicines to the world in a faster and more efficient manner through the mechanism of reputable United States based and FDA desirable research produced at medical academic centers.

Summary

The working relationship between the pharmaceutical industry and medical academic institutions was reported to be more restrictive and less collaborative in the last 5 to 10 years. Concerns about research bias, undue influence, and COI have facilitated a call for reform with regard to this relationship between academia and industry. Policy development by medical academic institutions attempted to account for these issues through the enactment of interaction and COI policies. While generally observed that policies have been adopted at the institutional level, it is unknown to what extent such

policies would be consistent with 2009 guidelines from the IOM concerning COI. Additionally, it was unknown, from a monitoring, enforcement, and disclosure standpoint, if such policies are effective. It has been observed that research funding to medical institutions by the pharmaceutical industry has slowed during the last 10 years (Dorsey et al., 2010; Maahs, 2012). Further, the nature of the relationship between pharmaceutical funding at medical institutions and their stated interaction and COI policies is unknown. Thus, this qualitative and exploratory study attempted to address these issues. In Chapter 2, I provide a review of the pertinent literature with regard to the evolution of interaction and COI policies adopted by medical academic institutions. I present a qualitative research design, methodology, data collection and analysis instruments used for this study in Chapter 3. In Chapter 4, I provide the results from a qualitative and data rich analysis of actual current COI policies from (n = 15) AAMC institutions and interviews from (n = 4) administrators from those respective school. I present recommendations to industry and academia about embracing a more efficient research and collaboration platform for the purpose of developing new medicines for the benefit of humankind in Chapter 5.

Chapter 2: Literature Review

Introduction

Literature research was completed using a number of different of sources and search strategies. A very macro-oriented approach was started using Google and Google Scholar and then funneled down using more specific and scientific databases including Medline, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and Science Citation Index Expanded. Google and Google Scholar were used employing general search terms *medical school* or *medical institution,* along with *pharmaceutical industry* or *pharmaceutical company* as the root for all inquiries. Additional search words and phrases, including *research funding placement, conflict of interest, interaction with industry, research bias, conflict of interest policy, collaboration,* and *contract medical organizations* were all used in various combinations with root phrases. Research references from Google produced usable news articles with regard to historical and recent developments concerning the general topic. Google Scholar provided scholarly and professional research content from a peer-reviewed journal article perspective ranging from *Journal of the American Medical Association, British Medical Journal,* and *New England Journal of Medicine* to the *American Journal of Bioethics, Journal of Business Chemistry,* and the *Journal of Business Ethics.* The total number of usable and useful peer-reviewed journal references cited in this dissertation was approximately 30 articles. The next search strategy employed resources available through the Walden University Library via various online search databases. The database search engines included

Medline, CINAHL, and Science Citation Index Expanded. Search inquiries used the root term *pharmaceutical industry,* with additional search terms *conflict of interest, interaction, collaboration, bias,* or *contract research.* This search strategy had a duplicative effect of about 70% of the Google searches and produced around 20 additional citable references. This particular search strategy produced peer reviewed journal articles consistent with Google search, and additional cited references came from the *Journal of Law Medicine & Ethics, Nature Reviews: Drug Discovery, Clinical Pharmacology & Therapies, Mayo Clinic Proceedings,* and *Pain Medicine.*

The final search strategy used Academic Search Complete and ProQuest Central databases using the same search strategy detailed above. Using the same generic search terms produced a high rate of duplication of previous articles found. Approximately five peer-reviewed articles were selected using this final search strategy.

The overall search strategy employed a number of different search engines to capture both breadth and depth of the overall topic area. The timeframe employed for Google searches went as far back as 1995 in an attempt to capture an adequate historical perspective of the research topic. Fewer than 8% of the articles cited in this dissertation are before 2007. All other literature searches (92%) used a publication date of 2008 and newer as a search limiter to elicit current research in the field of study.

Pharmaceutical companies have historically faced central challenges of time and expense to bring new medications to market (Festel, Sticker, & Boutellier, 2010). During the 20th Century, a productive working relationship existed between medical academic

institutions and the pharmaceutical industry (Maahs, 2012). This working partnership was credited for significant medical advancements because of collaborative research projects (Brody, 2011a; Furman & MacGarvie, 2009). This relationship became strained at the beginning of the 21st Century as concerns about the pharmaceutical industry exercising undue influence, potential research bias, and concerns over patient safety were reported (Angell, 2008; Lexchin, Bero, Djubegovic, & Clark, 2003; Sismondo, 2007; Yank, Rennie, & Bero, 2007). The overall integrity of medication safety in the United States was questioned when Merck withdrew the multibillion dollar pain reliever Rofecoxib from the market in September, 2004 when serious and/or fatal cardiovascular risks and complications surfaced (Psaty & Charo, 2007).

Brennan et al. (2006) published seminal work, which called for wide sweeping changes and policy development in the way in which healthcare professionals interacted with the pharmaceutical industry. Concerns about COI, including patient safety, lack of transparency, and the potential for undue influence exercised by the pharmaceutical industry over healthcare professionals were identified as some of the reasons calling for such a change. This resulted in a dramatic shift in the way in which medical academia and the pharmaceutical industry interacted when a growing number of institutions adopted restrictive COI and interaction policies (Rothman & Chimonas, 2008).

The IOM issued wide sweeping policy recommendations with regard to conflict across the entire medical field in 2009 (Lo & Field, 2009). Three major policy reforms were called for at both the institutional and the governmental level to include medical

academic centers establishing comprehensive COI policies, a publicly available national register for all medical industry concerns to report all financial arrangements with physicians, and finally, for the Department of Health and Human Services (DHHS) to employ evidence based measures to determine the effectiveness of the COI policy and unintended consequences from such a policy. Medical academic institutions were directly called upon to incorporate 10 major elements into COI policies ranging from institutional COI development to policy governing physician interaction and financial involvement with the pharmaceutical industry.

Congress reacted to the 2009 IOM Report and passed the PPSA of 2010 that required medical industry concerns to report on a publicly available database all payments to physicians and institutions in the United States. The DHHS started to make this information available beginning 2014 (American Medical News, 2013). The NIH followed with rule changes in 2011 concerning medical institutions that receive federal research and mandated institutional COI policy, reporting requirements, and lowering the financial reporting levels of researchers involved with industry.

Faced with increased costs for developing new medications (Festel et al*.,* 2010), and a more restrictive operating environment, pharmaceutical companies significantly slowed the rate of growth of medical research grants provided to academic institutions (Dorsey et al*.*, 2010). A reduction in the number of medical academic physicians involved in industry-sponsored research was reported as well (Zinner et al*.*, 2009).

It is recognized that scientific advancements require collaboration (but not coercion) between all parties involved (McKinnon, 2009). The development of restrictive interaction and COI policies by the medical academic community created a contentious environment within which industry and academia operate. This is a problem because the unintended consequence of this operating environment may have led to stifling advancements in medicine as a result of reduced research funding, institution mistrust between parties, and a misalignment of collaborative effort.

In Chapter 2, I discuss the overall topic and the central issues studied in this dissertation. I present a brief history of interactions between the pharmaceutical industry and the medical academic community from the last 10 years and included topics about undue influence, research bias, COI, and policy reform. Additionally, I report topics that included research funding reductions, the practice of "out sourced" (even out of the country) research, and the future of collaboration. Finally, I provide a brief discussion of ACF as the conceptual framework employed for this study.

Published Authors' Potential Bias and Effect on Entire Body of Literature

The overall issue of the pharmaceutical industry and its interactions with healthcare professionals and institutions could be considered a political hot topic and one where researchers, editors, and peer-reviewed journals may have introduced their own personal or organizational biases into the topic with regard to research design and approach, commentary, and article selection. An in-depth disclosure review of all authors referenced in this dissertation was not performed. However, a number of key authors

were identified as Brody (2005, 2006, 2009, 2010, 2011a, 2011b, 2012), Sismondo (2007) and Stossel (2007, 2008). An author search in Science Citation Index Expanded was conducted to determine how widely these authors were published from 2005 to 2013. A search of five of the 10 largest United States based pharmaceutical industry websites that disclosed payments to healthcare professionals found no payments disclosed for any of these major authors (Allergan, 2013; CNN Money, 2013; Johnson & Johnson, 2013; Lilly, 2013; Merck, 2013; Pfizer, 2013).

Brody (2005, 2006, 2009, 2010, 2011a, 2011b, 2012) was the most highly published author on this topic in the research domains of life sciences and biomedicine, physical sciences, and social sciences. Brody was also most prominently affiliated with the University of Texas Medical – Galveston, Michigan University, and had no disclosures of financial affiliation with the pharmaceutical industry. Brody's work was highly critical of the pharmaceutical industry and the potential effect of undue influence and research bias. Brody did, however, take the position that collaboration between these two entities was very essential to advancing healthcare science. Stossel (2007, 2008) was the next most highly published in the research domains of life sciences and biomedicine, physical sciences, and social sciences. Brody was most prominently affiliated with Harvard University and his work would be considered propharmaceutical in nature. Brody's major position was that interactions between these two entities did not immediately translate into a COI and that these interactions were important for scientific development.

Sismondo (2007) was also cited in the research domains of life sciences and biomedicine, social sciences, and technology, and was affiliated with Queens University-Canada and had no reported ties to the pharmaceutical industry. Sismondo's work was the most critical of the pharmaceutical industry and its interactions with academia. He was the most vocal on the topic of the pharmaceutical industry exercising undue influence on the entire research process when involved with medical academic institutions. It should be noted that being Canadian, Sismondo may have had a systemic and institutional bias against the pharmaceutical industry being based in a socialist medical delivery system that has been credited with very few new medication developments.

Potential Bias: Researcher

As provided in Appendix A, I disclose that I have a financial interest with Pfizer. Care with regard to objectivity and working from a bias free approach was taken during the literature review process. An analysis of references cited in this dissertation is considered a mixture of proindustry, neutral, and antiindustry, peer-reviewed journal articles.

Conceptual Framework

The ACF was initially developed by Sabatier and Jenkins-Smith during the late 1980s to early 1990s to understand coalition behavior and structure, the influence of science and information technology on policy development, and the role of contentious policy subsystems on policy change and behavior (Birkland, 2001; Sabatier, 1999; Sabatier & Jenkins, 1988). This theoretical framework has been applied worldwide across

a wide array of policy topics to include education and drug policy (University of Colorado – Denver, 2013).

The articles presented in the literature review are a combination of qualitative, quantitative, case study, and editorial commentaries in peer-reviewed medical and scientific journals. Rarely, if any, of these articles referenced a conceptual or theoretical framework as the basis for the work presented. For example, Sismondo (2007) sought to determine if positive research results for a medication study could be linked to the funding sponsor. He answered the research question by conducting a qualitative meta-analysis review of 19 previous studies examining this topic. The approach was significant in that it synthesized a large array of research and answered the question at hand but provided no theoretical or conceptual basis for doing the research itself. This was extremely common across all research reviewed. It could be argued that this was a systematic flaw of all research on this topic.

The two central qualitative research questions addressed in this dissertation deal with COI policy development by the medical academic community and potential effect on research funding placement by the pharmaceutical industry (Maahs, 2012). Concepts around ACF were used to develop the lens upon which the literature review was conducted. That is, the views and actions of several subsystems were evaluated when the literature review was conducted. The contentious nature of the overall topic as well as the strained relationships between these entities was recognized as being consistent with the

tenets of ACF. That said, I employed concepts of ACF that facilitated an informed approach to the literature review and was useful in the research design for this study.

Review of Literature

History of Collaboration

A long history of collaboration between the pharmaceutical industry and United States based medical academic institutions was recognized for tremendous advancements in science and medicine. Furman and MacGarvie (2009) reported a symbiotic and progressive relationship between these entities in that academic science contributed greatly to the transformation of emerging apothecary type pharmaceutical firms to research-intensive institutions and the support that industry played in the establishment of enduring scientific programs at the university level. Furman and MacGarvie concluded that the development of industrial based research platforms and the evolution of the higher education were two crucial elements regarding technological advancement in the United States. Furman and MacGarvie further reported that pharmaceutical companies that actively collaborated with academia had higher rates of patenting new medications and industrial laboratory expansion.

Potential Research Bias Reported

Concerns with regard to research quality and bias and the extent to which the pharmaceutical industry had exercised a growing control over the research process at academic centers has been reported over the last 20 years (Angell, 2008; Lexchin et al., 2003; Sismondo, 2007; Yank et al., 2007). A number of studies were completed

examining favorable study results tied back to the funding sponsor. Lexchin et al. (2003) examined 30 studies in a case-control analysis comparing industry-sponsored research versus other sources of funding research conducted from 1966 to 2002 and found that medical research supported by the pharmaceutical industry was more likely to have outcomes favorable to the sponsoring of entities' medications as compared to results supported by another funding source (*OR* = 4.05; 95% *CI* = 2.98 to 5.51). Sismondo (2007) conducted a qualitative review of 19 previous analyses of research trials and found 17 of the analyses (89%) showed positive study results favoring the industry trial sponsor (Maahs, 2012). Moreover, Yank et al. (2007) evaluated 124 published meta-analyses of antihypertensive drugs and found that 40% of studies had financial ties to a pharmaceutical company; while financial affiliation was not necessarily associated with favorable results, funding sponsor was the only characteristic significantly linked to favorable conclusions.

Researchers reported a number of postulations to explain the tendency of favorable study results tied back to funding sponsorship. Lexchin et al. (2003) offered four different possibilities to explain funding sponsorship linked to favorable results. First, pharmaceutical companies potentially picked comparator medications that were inferior to the medication being researched. Lexchin et al. found, however, that researchers could not accurately predict results of trials in advance. Second, positive results were tied to low quality study design and implementation. Lexchin et al.'s data suggested, however, that industry-backed research was of comparable quality to

nonindustry funded research. Third, study design with regard to how study medications were used relative to comparator medications could predict outcome. Lexchin et al. commented on the potential practice of a comparator medication being studied at a less effective dose (lower potency) than the study medication. In this case, the less effective dose medication (comparator medication) would then to be closer to placebo with regard to efficacy and the medication at the higher dose (study medication) could then statistically separate from both placebo and the comparator medication. Lexchin et al. discussed that their data did not adequately capture this potential explanation. Finally, Lexchin et al. reported that publication bias (the desire for research to be published) could be another factor in favorable study results. Additionally, Lexchin et al. commented on the questionable tactic by pharmaceutical companies to suppress nonstatistically significant research findings which would have a potentially profound effect on FDA medication approvals. Lexchin et al., however, did not take on the issue of undue influence or COI being credited for positive study results.

Sismondo (2007) suggested the nature of funding itself created a systematic bias that could not be corrected alone by scientific methodological design considerations. Sismondo further reported a tendency toward actively publishing positive study results, and discussed practices relative to ghost writing of clinical research trials. Sismondo did, however, glance at the overall topic of COI and undue influence and recommended additional consideration with regard to transparency and disclosure, rigorous study reporting standards, and clinical trial registries.

One argument concerning a tendency toward favorable research results has been linked not just to research dollars placed with medical academic institutions, but the practice of the pharmaceutical industry having access to and interactions with medical professionals. Campbell et al. (2007) and Zinner et al. (2009) conducted mailed surveys to faculty and staff at both public and private academic medical centers, and between 50 to nearly 60 % of medical professionals had some form of interaction with the pharmaceutical industry (Maahs, 2012). These interactions varied greatly from casual contact and meeting with pharmaceutical representatives, to serving on a pharmaceutical company's Board of Directors.

Undue Influence and Conflict of Interest Issues Reported

The pharmaceutical industry historically spent a significant amount of money promoting its medications directly or indirectly to healthcare professionals. A study by Wazana (2000) set in context many of the practices the pharmaceutical industry employed and its effectiveness to influence prescribing behavior and product advocacy. Wazana reported that pharmaceutical companies spent upwards of $11 billion per year in marketing efforts, with around $5 billion used by sales representatives that called on physicians. Wazana estimated that total marketing efforts ranged from $8,000 to $13,000 yearly per physician. Dana and Lowenstein (2008) also examined the practice of gift giving by the pharmaceutical industry from a social science perspective and the effect on relationships between industry and healthcare provider.

Wazana (2000) conducted a meta data analysis and synthesis of 29 peer reviewed studies about physician interactions and involvement with the pharmaceutical industry and corresponding attitudes about the pharmaceutical industry, disease state knowledge, and prescribing behavior of physicians. Wazana found that interactions between healthcare professionals and pharmaceutical industry representatives were generally endorsed, began during medical school, and upon entering practice continued at an average frequency of four visits per month total from a pharmaceutical representative (total industry). The types of interactions and financial support included product presentations, medication samples, promotional giveaways, free gifts, free meals, sponsored Continuing Medical Education (CME) seminars, travel, food and lodging for CME events, compensated speaker bureau positions, research funding, and compensated advisory board engagements. The overall results from this study (Wazana, 2000) showed a statistically significant positive association between physician interaction with the pharmaceutical industry and change in prescription behavior favorable to the pharmaceutical industry (brand name vs. generic) as well as a physician endorsement for favorable hospitable or health plan formulary placement for branded medications. Wazana concluded that the extent of industry and physician interactions was widespread and needed to be further addressed by new policy and education. This report further opened up the entire topic of undue influence and potential COIs between healthcare professionals and the pharmaceutical industry for the next decade.

Sierles et al. (2005) reported that interactions between the pharmaceutical industry and medical school students were very common and quite extensive. Sierles et al.'s survey of 1,143 third-year medical students from eight public and private schools found that on average these students attended one industry sponsored lunch or received one gift on a weekly basis. Sierles et al. also reported that the majority of students were not aware of any policies at their respective schools that addressed or restricted such activities. The overall conclusion of Sierles et al. was medical school students were at risk for undue influence by the pharmaceutical industry, and further research should be conducted to ensure physician decision-making is based purely on best outcomes for patients.

Insel (2010) provided further editorial comment about the issue of conflicts of interest and erosion in public trust in the psychiatry field when it was reported that several leading academic psychiatrists failed to report financial ties to the pharmaceutical industry. Insel additionally noted that undisclosed financial relationships were not singular to the field of psychiatry and was commonplace across a wide array of medical specialties. Insel, however, did argue that collaboration still needed to exist between industry and academia, and policy development needed to address financial disclosure and transparency.

Patient Safety and Challenges at the Food and Drug Administration

Kuehn (2008) asserted that the underfunding of the FDA from the 1990s through 2000s left the agency incapable of meeting growing demands relative to medication

safety and public health. Additional critics contended that the FDA oversight of the pharmaceutical industry as a whole as well as the process for evaluating new medications and monitoring the safety of medications already on the market was lax and presented significant patient safety risks (Mitka, 2006; Wood, 2006). A prime example of this potential disconnect was the events surrounding the removal of the multi-billion dollar pain medication Rofecoxib. Marketed by Merck, Rofecoxib was withdrawn from the market in late 2004 when pre marketing and post marketing serious and/or fatal cardiovascular side effects were found to be linked to the medication (Psaty, Meslin, & Breckenridge, 2012). The highly publicized manner in which a pharmaceutical company would allow a potentially fatal medication to stay on the market and the inability of the FDA to quickly catch this type of event eroded public trust in safety monitoring for prescription medications. Kuehn (2009) further criticized the FDA for little effort in monitoring conflicts of interest relative to clinical trial researchers when it was reported that of the 118 applications approved by the FDA in 2007, more than 41% did not have sufficient financial disclosures. Additionally, Kuehn reported that in 20% of the instances where a potential or perceived COI was revealed, no corrective action was taken by either sponsoring entity or the FDA. Congress took action in part and passed the FDA Amendments Act of 2007 which provided the FDA new resources and the authority to require post marketing studies as well as implement active medication surveillance safety system to capture spontaneous adverse events (Psaty, Meslin, & Breckenridge, 2013). This legislation was consistent with a 2007 IOM report that charged the FDA with taking

a life-cycle approach to medication monitoring and safety as opposed to focusing efforts on medication safety prior to approval. Through September, 2011, the FDA had ordered 675 post market studies of which 87% were on schedule (Psaty, Meslin, & Breckenridge, 2012).

The underfunding of the FDA was partially acted on when Congress passed the US Food and Drug Administration Safety and Innovation Act in October, 2012 (Steinbrook & Sharfstein, 2012). This essentially, renewed a major funding source for the FDA by allowing the FDA to continue collect fees from industry with prescription drug user fees being renewed since 1992 and medical device user fees from 2012. The increased sources and amount of funding across industry was planned to allow the FDA to hire more scientists with the intent on better monitoring and reduced prescription and medical device application review times. For instance, the filing fee in 2012 for a new drug application with clinical data review increased to $ 1.8 million (Wapner, 2012). Overall approval times from the FDA were still problematic in that the time for priority review has decreased from an average of 2 years to 1.1 years while a backlog of over 2,500 over applications for drug approvals still remains (Steinbrook & Sharfstein, 2012).

A review of the literature showed that Congress, DHHS, and the IOM did not directly charge the FDA with taking on the topic of COI. Congress essentially passed legislation to strengthen the FDA's ability to deliver on its public health mandate relative to medication approval, safety, and monitoring and left the larger issue of COI to the DHHS which is discussed later in this chapter.

Reform: Call for Conflict of Interest Policy Development

In January 2006, Brennan et al. published the seminal work that led to a series of policy developments at the university level with regard to COI and interactions with the pharmaceutical industry. Brennan et al. defined that COIs occurred when a physician's motives were, or they were placed in a situation where the moral decision making process with regard to patient care and safety could have been compromised by personal gain, association with the pharmaceutical industry, or being influenced by marketing and promotion practices. They directly called on medical academic centers to lead the way in wide sweeping reform in the way in which the entire healthcare industry interacted with the pharmaceutical industry. Brennan et al.'s rationale was that academia needed to provide leadership for medicine in the United States, had a responsibility to train medical students and staff on issues of COI, and had the capacity to quickly enact new policies. They directly recommended the following: eliminate all gifts, free meals, medication samples, direct or indirect sponsorship of all CME activities, participation in speaker bureaus, authorships associated with ghostwriting practices, reimbursement for travel to CME activities, and barring hospital or medical group formulary committee member from any financial relationship with the pharmaceutical industry. They did recognize, however, that new medication development depended on input from academia and consulting and research support from industry should not be strictly prohibited. They further recommended that these types of interactions should be highly regulated and fully transparent. Cosgrove and Bursztajn (2009) further elaborated on transparency and

disclosure recommendations and reported that most COI polices did not address general funding provided to an academic department for research or medical department for continuing education. Cosgrove and Bursztajn recommended that full disclosure of these indirect sources of funds be required.

A task force appointed by ABIMF and the Institute on Medicine as a Profession (IOMAP) in 2004 published its policy recommendations about COI in 2006 and the Association of American Medical Colleges (AAMC) followed with its recommendations in 2008 (Rothman & Chimonas, 2008). Both sets of recommendations were consistent with reforms called for by Brennan et al. (2006), but the AAMC recommendation sought to ban pharmaceutical representatives from medical academic centers and considered any provided food by the pharmaceutical industry as a "gift" and thereby prohibiting it under the zero dollar limit for gift-giving. Additional authors published various studies and commentaries consistently supporting this reform movement (Angell, 2008; Miller, 2009; Robertson, Rose, & Kesselheim 2012; Rodwin, 2011; 2012; Rothman et al., 2009; Steinbrook, 2009).

The most prolific author with regard to COI policies was Brody with seven articles published in medical journals in the last 10 years (2005; 2006; 2009; 2010; 2011a; 2011b; 2012). Brody's work was generally supportive of the policy reform recommendations made by Brennan et al. (2006), but was critical of the thought process that mere association with industry is a COI. Brody's research actively moved the issue forward and focused the argument on balancing the moral, ethical, and integrity concerns

of the healthcare profession with the need for collaboration and transparency in the pursuit of medical advancement and treatment. Brody's views remained conceptual and philosophical, as he never fully articulated his stance on a point-by-point basis with regard to policy development called for by the AAMC or IOM. The effect of this call for reform was quite profound in the number of institutions that quickly adopted COI policies. Rothman and Chimonas (2008) reported that more than 25 public and private medical institutions had adopted COI policies representing the entire United States to include University of Massachusetts –Worcester, University of Pennsylvania, University of Wisconsin, Pittsburgh University, Yale University, University of Michigan, University of Chicago, and all of the University of California system. Other healthcare delivery systems had also adopted such policies, including Henry Ford Health Systems (Michigan), Kaiser Permanente (California), and the Veterans Administration health system.

Institute of Medicine 2009 Report on Conflict of Interest

The IOM appointed the Committee on COI in Medical Research, Education, and Practice in 2007, and published its policy recommendations in 2009 (Lo & Field, 2009). This report was funded in part by the NIH and was endorsed by the NAS and the NRC. The IOM recommended that all medical institutions, including patient advocacy groups, academic medical institutions, professional societies, and medical journals, all establish COI policies. The IOM called for full transparency about individual and institutional financial disclosure of ties to industry. The IOM acknowledged the extensive nature of

commercial ties to medical education and recommended that teaching hospitals and academic medical institutions enact the following measures with regard to COI (Lo & Field, 2009)

1. Board level involvement at the individual institution level to develop comprehensive COI policy.
2. Researchers should not be involved in research in human subjects if they have a financial interest in the outcome unless researcher expertise is vital to the safe conduct of the research itself.
3. Ban faculty from receiving any gifts from industry.
4. Prohibit faculty from involvement in industry speaker bureaus.
5. Prohibit faculty from claiming authorship for ghost-written articles.
6. Prohibit the provision of free meals from industry.
7. Prohibit faculty from entering into consulting arrangements not recognized for expert services at fair market value.
8. Restrict pharmaceutical sales representative access to medical academic centers.
9. Restrict medication samples to only economically challenged patients.
10. Separate CME activities from industry influence.

At a broader health policy level, the IOM called for three major changes. First, the IOM called on the DHHS to develop an evidenced based research platform to determine further COI policies to include an examination of the impact of said policies on both

desired outcomes and unintended consequences. Additionally, the IOM sought a standardized method for all facets of medicine to disclose financial relationships with industry. Finally, the IOM called on Congress to require the creation of a national reporting platform to disclose all pharmaceutical, medical devices, biotechnology firm's payments to physicians, patient advocacy and disease groups, health care institutions, researchers, and professional societies (Lo & Field, 2009).

Reform Post 2009 Institute of Medicine Report

Congress reacted to the 2009 IOM's recommendation and passed the PPSA in 2010 (American Medical News, 2013). The provisions of this act were generally consistent with the IOM 2009 recommendations and required all medical device, pharmaceutical, and biotechnology companies to report all payments to physicians and institutions. The implementation of the PPSA was somewhat delayed with all firms being required to make these disclosures to the DHHS beginning in the second half of 2013. The DHHS disclosure website will be available in 2014 (American Medical News, 2013). Many of the largest pharmaceutical companies started making these disclosures available via their respective websites beginning 2009 through 2011.

The NIH as an agency of the DHHS is largest source of funding for medical research in the world (2011). From 2003 to 2008, nearly one-third all research funding placed in United States based medical academic centers came from the NIH (Dorsey et al., 2010). In August 2011, the NIH made a number of rule changes to the previous COI policy rules issued in 1995 (2011). Researchers were then required to disclose to their

respective institutions all significant financial interests related to their organization with the annual monetary threshold being reduced from $10,000 to $5,000. It also required by the NIH that institutions provide reporting on COI to include policy, management, and institutional training to researchers (NIH, 2011). It is interesting to note that while the NIH made some rule changes, it did not establish a standard of COI policy for institutions to adhere to as was called for by the IOM. This left the primary burden of actual COI policy development, enactment, and enforcement to the actual medical academic centers themselves.

When examining the provisions of the PPSA of 2010 and the 2011 NIH rule changes regarding COI combined, institutions should have an easier time managing and enforcing potential COI issues beginning in 2014. When the DHHS website starts making publicly available all payments physicians receive from the medical industry, an institution will not have to trust that a faculty member made the appropriate financial disclosures regarding financial arrangements with industry. As a part of institutional COI enforcement, academia will now be able to look up an individual faculty member to determine if they, in fact, have made the proper financial disclosures. This also created an interesting format for the NIH to audit COI issues at the individual and institution level if it sees fit.

Adherence to the actual recommendations set forth by the IOM was challenged by Poses (2012) who reported that an accurate accounting of how well institutions had adopted such polices and the corresponding disclosure requirement by physicians having

a financial arrangement with industry had been overstated and lax. This combined with the reporting of financial relationships by industry to the DHHS made for a potentially contentious situation for institutions that discover that faculty members have been under-reporting or not reporting financial ties to industry.

The American Medical Association (AMA) representing, approximately 213,000 healthcare providers in the United States, has not updated its COI guidelines with regard to institutions since 2007 (AMA, 2007). The AMA contented that organized medical staffs were self-governing entities and the COI policy development was an individual institutional responsibility. The AMA provided a very general definition of what COI was (consistent with the commonly accepted definition) and provided proposed disclosure forms that institutions could require their respective healthcare providers to use to report financial arrangements with industry. It is interesting that the AMA has not acted on this topic, has not implemented any of the 2009 IOM recommendations, and has let the 2009 IOM recommendations stand without its own institutional guideline update to its members.

The IOM released further updated and more specific guidelines on COI in early 2011 (IOM, 2013). Within the topic of medical organizations creating clinical practice guidelines, the IOM recommended that any healthcare professional being considered for inclusion to a development guideline group should be required to make full disclosure on any potential COI. Furthermore, if a healthcare professional was selected to a development group, he or she should fully divest himself or herself (to include family

members) from any financial interest with industry that could constitute or have the appearance of a COI.

Counter Point: Conflict of Interest Reform Challenged

The call for all encompassing policy reform from 2006 through the 2009 IOM's Report on COI was not widely accepted across the entire medical community and was challenged by numerous authors (Beran, 2009; Brody 2010; Flier, 2009; Gonzalez-Campoy, 2009; Stossel, 2007; 2008). The common theme argued by these authors was that the mere association or contact with the pharmaceutical industry and healthcare professionals did not necessarily equal a conflict of interest, and no evidence has yet or had then been provided showing an adverse effect on patient care. Additionally, they commented on tremendous advancements in medicine development credited to the collaboration between industry and academia.

One recommendation by the Association of American Medical Colleges (AAMC) to ban the practice of pharmaceutical representatives conducting sales presentations was directly challenged by Huddle (2010), who offered that the mere exchange of information would not create a patient decision-making error by the physician was therefore not an unethical exchange and was therefore a flawed argument to consider. Huddle reasoned that physicians had the capacity to make informed decisions and to compartmentalize interactions with industry in an appropriate manner. Huddle further observed that to propose such policy discredited the profession, was not scientifically based, and discounted the value of information pharmaceutical representatives actually possessed.

A number of medical professional associations countered with their own statements concerning COI and interaction with the pharmaceutical industry. The American College of Cardiology, American College of Emergency Physicians, American College of Radiology, American College of Rheumatology, American Gastroenterological Association, and the American Society of Plastic Surgeons issued a joint statement that medical professional societies had an ethical and positive relationship with industry (2009). While these organizations may not represent private or public institutions per se, they do represent the individual doctors that practice within those institutions but have an affiliation with a medical society that represents their particular medical specialty. For instance, when the medical community looks for treatment guidelines for rheumatoid arthritis, they do not consult the AAMC; the American College of Rheumatology provides this expertise. These professional medical societies added that without external support from industry, they would be unable to provide the same level of education and patient care advancements moving forward. Additionally, these societies reported that restrictive interaction and COI policies would stifle scientific advancement and offered that policy development needed to address issues of product bias and could be accomplished through collaborative and transparent policies.

The American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) issued their own statement affirming the value they placed on the interaction between physicians and the pharmaceutical industry (2009). The AACE and ACE reported such interactions had been consistent with ethical

standards and had been responsive to patient needs. Additionally, the AACE and ACE contented that no inherent COI existed, and both the AACE and ACE had formulated policies with regards to collaborative interactions with industry.

A group of physicians formed the Association of Clinical Researchers and Educators (ACRE) in direct response to the COI reform movement (Bloomgarden, 2009). This association directly challenged the notion that interaction, association, or affiliation between healthcare professionals and industry was inherently an issue of COI. They countered that managing this issue from the basis of perception was short sighted and would have the unintended consequences and outcomes. Finally, they offered that limiting the free flow of support to academic medical institutions, professional societies, and health advocacy organizations threatened to delay medical advancement, innovation, and education.

Self-Regulation in the Face of Conflict of Interest and Disclosure

The pharmaceutical industry has reacted numerous times to public and governmental pressure and self-regulated many of its marketing and promotional practices during the last 20 years. The Pharmaceutical Research and Manufacturers of America (PhRMA; 2003) was formed in 1958 initially to represent America's pharmaceutical research companies and seek essential alignment between public policy and medical research to address patient needs. PhRMA voluntarily adopted promotional guidelines in 1991 after congressional hearings raised concern over marketing practices that were considered expensive and eroded public trust (Katz, Caplan, & Merz, 2010).

The practice of "gift" giving was reduced to items under $100 and had to have relevance to a medical practice, which included "branded" pens, notepads, and staplers. The "lavish gift giving" practices that included golf outings, tickets to sporting events, and expensive meals was eliminated.

The PhRMA Board adopted its revised *Code on Interactions with Health Care Professionals* in 2008, which further refined its members conduct with regard to marketing, communications, and interactions with health care providers. All noneducational items such as pens and notepads were prohibited. "Gifts," such as items or entertainment considered to be for personal benefit were reaffirmed as being unacceptable. Pharmaceutical representatives were allowed to provide occasional meals, provided they were modest and only offered in an office or hospital setting. The exception to this was the recognized promotional and educational practice of conducting a "dinner program," where a formal educational presentation could be presented in conjunction with a meal at an off-site restaurant, hotel, or conference center.

The next wave of self-regulation occurred when individual pharmaceutical companies started disclosing payments to health care providers under the pressure of the medical community and the passage of the PPSA of 2010 (American Medical News, 2013). The American Medical News reported that all pharmaceutical and medical device manufacturers would have to publicly disclose, via searchable database, all gifts and payments made to healthcare professionals by September, 2014. Eli Lilly and GlaxoSmithKline started reporting health care professional payments in 2009 with Pfizer,

Johnson & Johnson, and Merck following suit in 2010. Novartis and AstraZeneca started reporting payments in 2011. These companies represented four of the five largest pharmaceutical companies in the United States, and five of the 10 largest worldwide pharmaceutical companies, in terms of total sales (CNN & Money, 2013; Contract Pharma, 2013).

Food and Drug Administration New Medication Approvals Stagnant

Dorsey et al. (2010) reported that from 1994 to 2003 research funding for new medication development nearly doubled (adjusted for inflation) while the number of new medication approvals from the FDA remained stagnant. Dorsey et al. also observed that from 2003 to 2007 research investment started to stall and FDA new medication approvals continued to be flat. Data provided by the FDA (2013) in Table 1 reports the number of priority and standard new molecular entities (NMEs) and biologic license approvals (BLAs) and medication review times from 1997 to 2008.

Table 1

FDA Medication Approvals and Review Times

Calendar year	Total medication approvals	FDA review time priority (months)	FDA review time standard (months)
1997	33	10.0	18.9
1998	34	8.4	15.9
1999	37	6.9	14.2
2000	37	6.5	14.1
2001	31	6.2	14.4
2002	27	7.7	14.0
2003	25	7.8	14.3
2004	25	7.7	14.7
2005	24	7.7	14.8
2006	23	7.7	14.1
2007	23	6.1	14.2
2008	24	6.0	14.0

The above information was only available from the FDA (2013) through 2008. It is interesting to observe that from 2003 to 2008 the number of medications approved did not vary by more than two and the median FDA review time whether priority or standard application was relatively stable beginning in 2000. Raw data from the FDA (2013) from NMEs and BLAs continued to show a relative flat number of approvals. Table 2 reports this information as well as a 5 year running average of combined NME and BLA approvals from the FDA.

Table 2

FDA Medication Approvals With 5-Year Running Average

Calendar year	NME approvals	BLA approvals	Total approvals: 5 year running average
2002	17	0	
2003	21	0	
2004	31	5	
2005	18	2	
2006	18	4	23.2
2007	16	2	23.4
2008	17	3	23.2
2009	20	6	21.2
2010	21	0	21.4
2011	24	6	23.0
2012	32	5	26.8

One could argue that increased application fees paid by the pharmaceutical industry would lead to a decreased number of NME or BLA applications submitted to the FDA. Application fees charged by the FDA increased to $ 1.8 million that require a clinical review (Wapner, 2012). This would be considered not a significant barrier to medication development; however, as it has been reported by numerous authors that total new medication research and development costs through the approval process are around now around $800 million (Festel et al., 2010).

Research Funding Placement to Academia

The literature, with regard to pharmaceutical funding at the academic university level, was not widely reported. Two studies from the late 2000s attempted to answer this general question. Research by Zinner et al. (2009) sought to measure interactions and

relationships between academic scientists and the pharmaceutical industry. They surveyed 3,080 medical academic professionals in 2007 and found that 53% of them had some form of industry contact or financial relationship. Zinner et al. also reported that academic professionals that had industry support (sponsored funding) had higher levels of productivity (published research) than those that did not. Zinner et al. (2009) also compared survey results with similar surveys they conducted in 1985 and 1995 and found in 1985 23% of academic scientists were involved as principal investigators on research projects, compared to 21% in 1995, and 17% in 2007. While this did not assess research dollars awarded to university research institutions, it adequately reported a shrinking trend in the percentage of faculty members involved in industry sponsored research trials.

Dorsey et al. (2010) sought to directly measure the funding of United States based medical research at academic institutions by the pharmaceutical industry from 2003 to 2008. They examined publicly available data to quantify funding from federal, state, and local governments, as well as private and pharmaceutical industry sources during the timeframe from 1994 to 2008. They found when comparing periods of 1994 to 2003, and 2003 to 2008, the compounded annual growth rate (adjusted for inflation) dropped statistically significantly from 8% to 6% respectively. They also noted that the number of new medication approvals did not increase from 2003 to 2008.

The combined research efforts of both Dorsey et al. (2010) and Zinner et al. (2009) showed a decrease in the prevalence of industry sponsored research with academic scientists and the overall slowdown of actual research funding placement on a dollarized

basis. Both sets of research reported generalized observations about cost concerns relative to new medication development and slowdown of new drug approvals. Zinner et al. (2009) added, however, that the slowdown was also potentially due to restrictive policy development and use of contract medication organizations in emerging market countries.

Contract Medical Organizations

As the growth of United States based pharmaceutical research began to slow during the late 2000s, the practice of outsourcing to this function to contract medical organizations in emerging market countries was reported (Abodor, 2010; Drabu, Gupta, & Bhadauria, 2010; Festel et al., 2010; Zinner et al., 2009). Pharmaceutical giants, such as Pfizer, Astra Zeneca, Eli Lily, and Novartis continued to shift research placement abroad. The economic impact of this in India alone was quite dramatic at approximately $70 million in 2003, with estimates upwards of $200 million by 2007, and projections up to $1.5 billion by 2010 (Maiti & Raghavendra, 2007).

Several observed reasons contributed to the practice of employing contract medical organizations. Masri, Ramierez, Popsescu, and Reggie (2007) cited cost containment by industry, and the ability to be more nimble in a quickly changing healthcare environment. Additional researchers offered increased costs domestically, a slowing of new medications being approved by the FDA, and a more highly regulated operating environment (Abodor, 2010; Festel et al., 2010). Zinner et al. (2009) reported the possibility that newly adopted university policies restricting academic-industry

relationships might have contributed additionally to the practice of using contract medical organizations.

The same issues about research bias and integrity were raised by researchers concerned about the relationship between the pharmaceutical industry and academic universities (Sismondo, 2007: Yank et al., 2007) which was also reported with regard to the practice of using contract medical organizations (Adobor, 2012; Zinner et al., 2009). Festel et al. (2010) offered additional concerns with regard to overall research quality and the potential loss of internal expertise. Whether placed domestically in the United States with academic universities, or awarded internationally to contract medical organizations, the pharmaceutical industry continued to be criticized in how it conducted its research trials.

Transparency, Conflict of Interest, and Collaboration

McKinnon (2009) presented a compelling perspective with regard to the future of public and private partnerships. He submitted that six key tenets have proved to be effective in arriving at mutually productive public-private partnerships. A couple of those tenets had the most application to the COI debate. First, that "doing good" and "making money" were not separate concepts, but actually complementary. Additionally, collaboration and honest dialogue about outcomes and agendas by both parties needed to occur. Finally, both parties needed to agree to the larger shared objective. The practical application of these tenets would support collaborative and transparent partnerships between industry and academia to advance medical care in a responsible manner. Kitsis

(2011) supported this concept, and called for a more collaborative approach to the entire concept of COI. She stated that academia needed to establish reasonable steps to prevent conflicts of interest, and the pharmaceutical industry needed to be held accountable, but should be involved in the process and development policy.

Changes in science and technology have facilitated a new era of collaboration between the pharmaceutical industry and medical academic institutions (Hughes, 2008). Vallance, Williams, and Dollery (2010) best defined this when they noted that the expertise at medical academic centers, and large research based pharmaceutical companies is very different, and this partnership was necessary to facilitate new medicine. From a quality perspective, impactful research has trended toward much greater control over carefully conducted studies with smaller groups of patients using expertly trained academic investigators. The authors noted, this was in contradiction to the contract research organization model, where investigators followed a set protocol at an agreed price. Vallance et al. (2010) believed that a cultural shift by both academia and industry was required to make the collaborative model work. Concerns about COI needed to be managed through disclosures and transparency; academia needed push aside its prejudices about industry, and industry had to develop trust through openness and allow more open publication of clinical trials.

Gap in the Literature

The literature review process did not answer some interesting questions with regard to the overall topic of conflicts of interest, interactions between industry and

academia, and research funding at medical academic centers. The 2009 IOM Report on COI (Lo & Field, 2009) directly called on medical academic centers to adopt comprehensive COI policies. The number and extent to which United States based medical academic centers have actually adopted comprehensive interaction and COI policies consistent with the IOM recommendations is unknown and warrants further investigation. Additionally, the IOM (Lo & Field, 2009) charged the DHHS with the task of evaluating the effectiveness of institutional COI policy to include unintended consequences of these policies. It is unknown if the development of these policies has potentially had an effect on pharmaceutical company research placement at medical academic institutions and potential fallout of a research platform that is not as efficient or effective at developing new medicines. The research design in this qualitative study attempts to answer these basic questions and is presented in Chapter 3.

Summary

The nature of the relationship between medical academic institutions and the pharmaceutical industry has changed from an environment that was once classified as open, unrestricted, and unregulated. This relationship would now be typified as restricted, regulated, and contentious. The exact extent to which this once positive working relationship between these entities has become more restrictive and less collaborative in the last 5 to 10 years is unknown as concerns about research bias; undue influence, patient safety, and COI have facilitated numerous calls for reform. Policy development by medical academic institutions has attempted to account for these issues through the

enactment of interaction and COI policies. While generally observed that policies have been adopted at the institutional level, it is unknown to what extent such policies would be consistent with 2009 guidelines from the IOM concerning COI. Additionally, it is unknown, from a monitoring, enforcement, and disclosure standpoint, if such policies are effective. It is has been observed that research funding to medical institutions by the pharmaceutical industry has slowed during the last 10 years (Dorsey et al., 2010; Maahs, 2012). My intention with this qualitative research was to more fully understand this dynamic and the way in which this relationship has changed and the potential implications on research funding. In Chapter 3, I provide an overview of the research completed to include research questions, study design and methodology as well as ethical issues, role of the researcher, and various study considerations.

Chapter 3: Research Method

Introduction

In this qualitative study, I investigated the extent to which academic medical institutions adopted interaction and COI policies consistent with the 2009 IOM policy recommendations (Lo & Field, 2009) concerning healthcare professionals' relationships with the pharmaceutical industry from 2007 (prepolicy recommendations) through 2014 (postpolicy recommendations). Additionally, the study was designed to determine the nature of the relationships between pharmaceutical firms and medical academic institutions when a financial arrangement existed. I designed this qualitative study to more fully understand the rationale and decision making process of medical academic institutions (and the pharmaceutical funding implications) when developing interaction and COI policies, whether mandated or not. Finally, I discuss implications for social change with regard to patient safety and medicine development in light of the revisions to academia/pharmaceutical COI policies.

In Chapter 3, I present the qualitative research method and design that was employed to address the two research questions. I also discuss information concerning the role of the researcher, issues of trustworthiness, and ethical procedures. An in-depth examination of exact methodology is presented to include sample selection process, instrumentation, data collection, storage and data analysis is presented as well.

Research Design and Rationale

Research Questions

Qualitative Research Question 1: Since the release of the IOM Policy Report (Lo & Field, 2009), to what extent have interaction and COI policies been fully complied with by United States based medical academic institutions, what were the rationale(s) and decision making considerations involved in developing such policies, and how would these institutions classify the current nature of their relationship with pharmaceutical companies as opposed to pre 2009?

Qualitative Research Question 2: What are some of the effects that new COI policies have had on pharmaceutical industry research funding for United States based medical academic institutions since the implementation of the IOM Report (Lo & Field, 2009)?

Research Methodology

Creswell (2009) detailed many reasons to justify the qualitative research method. Most simply, a problem needs to be explored and a complex and detailed understanding of the issue is required. In the literature review from this qualitative study I reported a slowdown of research funding by the pharmaceutical industry at the medical academic institution level. One possible relationship is the development of noncollaborative interaction policies developed after the 2009 IOM Report was issued (Lo & Field, 2009).

Case Study Approach

In qualitative studies, many research approaches are available to the investigator. A commonly employed method is the case study approach as presented by Creswell (2007). This approach fits when a researcher is investigating multiple bounded systems over time and an in-depth data collection is required from multiple sources (triangulation), which also increases reliability and validity. In this qualitative case study, I sought to examine multiple United States based medical academic institutions and the evolution of interaction and COI policies from 2007 (pre 2009 IOM recommendations) through 2014 and the potential corresponding effect on research funding placement. The overall goal was to study 10 medical academic institutions in an in-depth manner (including both an open-ended survey and semistructured interview).

Conceptual Framework

The conceptual framework chosen for this study was the ACF. Initially developed by Sabatier and Jenkins-Smith during the late 1980s to early 1990s, they sought to understand coalition behavior and structure, the influence of science and information technology on policy development, and the role of contentious policy subsystems on policy change and behavior (Birkland, 2001; Sabatier & Jenkins, 1988). This conceptual framework provided the lens that guided my research on many levels. Relative to study design and methodology, I considered the contentious nature of the relationship between the pharmaceutical industry and medical academic institutions.

Role of the Researcher

As the primary investigator in this study, I was integral to many facets of the research that included being an active participant in the research itself. Investigators need to be mindful of their own personal biases when conducting research (Creswell, 2007). In Appendix A I provide full disclosure of employment in the pharmaceutical industry. With that in mind, I was prudent when establishing the working definition of collaborative or noncollaborative institutions. Additionally, when I reviewed interaction and COI policies provided by medical academic institutions, I worked from an objective point-of-view. To facilitate this, I disclosed the criteria by which the collaborative or noncollaborative institution assignment was derived. The goal is that upon review by someone in academia, the assignment criteria employed would be considered both reasonable and objective.

I do not have any immediate relatives employed by either medical academic institutions or the pharmaceutical industry. Therefore, no other potential financial COI exists other than my own. I have not had any direct contact with any of the 75 medical schools initially selected as potential participants in this qualitative case study in the capacity of my professional career. As discussed throughout this dissertation, I was sensitive to my own potential bias and corresponding potential COI. This is, of course, a study about COI and without being fully transparent it would be hypocritical.

Methodology

Participant Selection Logic

The nature of the research problem drives the participant selection for this study. That is, United States medical academic institutions were the study population for this research. Seventy-five medical institutions identified as members of the AAMC (2013) that teach and conduct medical research (Center for Measuring University Performance, 2013) were selected for initial inclusion as possible participants in this study. Potential study participants were contacted via an email research letter requesting their voluntary participation in the initial online survey with a further invitation for their participation in the interview phase of the research. Miles and Huberman (1994) reported that in qualitative research, sample size is not necessarily prespecified and usually evolves once research actually begins. Due to the complex nature of the data analysis that was performed, a participation size of 10 institutions was desired. Ideally, a mix of approximately half public and private (nonprofit) would have allowed for another differentiator of analysis.

Instrumentation

The main data collection tool being employed was an initial brief online survey followed by an open-ended semi structured interview if the participant volunteered. The data gathered from these tools included both finite and attitudinal data. The finite portion of the survey asked for annual pharmaceutical research funding received and copies of interaction and COI policies from 2007 (pre 2009 IOM recommendations) through 2014

and research funding data from the pharmaceutical industry from 2007 through 2014. The rationale for using data from this timeframe was to establish levels of research funding prior to the 2009 IOM Report (Lo & Field, 2009) and after this major policy recommendation (through 2014). The interview portion of data collection was the attitudinal component and sought more information to fully understand the rationale and decision making processes of institutions in light of the 2009 IOM Report (Lo & Field, 2009) and to clarify if research placement was affected by other elements than just the adoption of collaborative versus noncollaborative interaction polices. Additionally, interaction and COI policies were examined that have an implied attitudinal component contained within them.

Researcher Developed Instrument: Survey and Interview

Basis

The open-ended survey portion of this research was intended to collect finite data as well as establish if an institution was willing to participate in the interview portion of the research. In qualitative research, the interview data collection method is common when combined with the case study approach (Creswell, 2007). Through this study, I intended to more fully understand a wide array of issues concerning COI policy development, and the interview method of data collection allowed for an in-depth insight to this phenomenon. All aspects of the research questions are addressed in the collection of survey information as well as the interview portion of the study.

Content Validity

Maxwell (2005) presented that with regard to content validity, research needs to allow for competing factors and discrepant data. Maxwell further explained this in the context that research conducted should not be an exercise in the investigator's own self-fulfilling prophecy. With regard to this study, I was sensitive and aware that I did not intentionally design the study to show what I wanted it to show. That is, I had a hypothesis that noncollaborative interaction policies had a negative effect on research funding placement, but I remained as open-minded and unbiased as possible and let the data drive the research. Without accounting for this in some fashion, my qualitative case study would not have content validity. This was discussed in both the limitations and delimitations sections in Chapter 1.

The semi structured interview questions were developed to specifically address issues of content validity. For example, one institution may have adopted a noncollaborative interaction policy while at the same time it elected to disengage in any research with the pharmaceutical industry. Without developing a survey question to account for this scenario, one might otherwise observe that research funding placement went down as a result of an interaction policy. This would be a false assumption. Additionally, I ensured that the interview questions were as open ended as possible and were not leading an interviewee to provide answers that would be skewed in the direction of what my initial instinct was that a possible explanation of decreased research placement was a result of changes in policy post 2009 IOM Report (Lo & Field, 2009).

Finally, with regard to issues of reliability, I had to assume that interviewees were answering the interview questions consistently with the beliefs and decision making process employed when COI policies were developed and were reflective of the institution itself. With this in mind, the desired interviewee subject was the medical director from the respective institution or an administrator with decision making authority that was involved in COI issues.

Sufficiency of Data

The data collected were of sufficient depth to answer the two qualitative research questions. Collecting data on research placement and examining interaction and COI policies were fairly fixed pieces of data and were not unreasonable to produce sufficient data and themes within the context of the research questions. It should be noted, however, that within the parameters of Research Question 2, interview questions were developed to account for compounding variables that if otherwise not addressed created problems of content validity.

Procedures for Recruitment, Participation, and Data Collection

Recruitment and Participation

A research request cover letter and Walden University IRB informed consent forms with a link to the online survey was sent via email to the medical director of the 75 members of the AAMC that were actively engaged in medical research (Center for Measuring University Performance, 2013) and are provided in Appendices B and C. The main criteria for selection into the interview portion of the study was to be quality of

initial survey responses provided, institution size, and willingness to participate in the interview portion of the study. For example, a small institution with complete survey answer input was chosen over a large institution with only partial survey answers provided. The intention was to have over 10 medical academic institutions respond to the initial survey and have 10 of them voluntarily complete the interview phase of the research. The total initial amount of time allocated for both portions of the data collection process was initially limited to 90 days once Walden University IRB approval (02-24-14-0168299) to proceed with research was granted.

Data Collection

Data were electronically collected from the online survey and included information on research funding provided from the pharmaceutical industry to individual medical academic centers and individual institution interaction and COI policies from 2007 to 2013. Additionally, data were collected about the nature of the research placed and any circumstances that would explain large or small fluctuations of research placement during the time studied. Information about the rationale and decision making process employed by these institutions when interaction and COI policies were adopted was collected as well. Data to answer both research questions were derived from the review of online COI policies and the interview, which was audio recorded, transcribed, and reviewed by each interviewee for accuracy (member checking).

Data Analysis Plan

Coding Plan: General

Miles and Huberman (1994) described emergent coding as an effective way for qualitative researchers to deal with significant amounts of information that need to be collected, organized, and retrieved later. Discussed below, coding was important to answering the two research questions as it was the primary means by which I was measuring and assigning data particular values. For example, medical academic institutions were ultimately assigned a code as "collaborative" or "noncollaborative" in their dealing with the pharmaceutical industry. This was not predefined by me and emerged over the course of the study.

Data Analysis and Coding: Research Question 1

Interaction and COI policies received from medical academic centers were analyzed to determine how compliant an academic institution's policies were to the 2009 IOM Report (Lo & Field, 2009) as well as if that institution was considered collaborative or noncollaborative in its dealings with the pharmaceutical industry. The scoring categories were consistent with the policy recommendations made by the 2009 IOM Report on COI (Lo & Field, 2009). Accordingly, these COI policies were evaluated against the following parameters:

1. Board-level involvement at the individual institution level to develop comprehensive COI policy.

2. Researchers should not be involved in research in human subjects if they have a financial interest in the outcome unless researcher expertise is vital to the safe conduct of the research itself.
3. Ban faculty from receiving any gifts from industry.
4. Prohibit faculty from involvement in industry speaker bureaus.
5. Prohibit faculty from claiming authorship for ghost-written articles.
6. Prohibit the practice of free meals from industry.
7. Prohibit faculty from entering into consulting arrangements not recognized for expert services at fair market value.
8. Restrict pharmaceutical sales representative access to medical academic centers.
9. Restrict medication samples to only economically challenged patients.
10. Separate CME activities from industry influence.

Coding was accomplished manually by assigning (scoring) a possible spectrum score of zero points (did not comply) to 10 points (completely complied) on each of the above parameters. Information was also gathered and coded with regard to institutional rationale and decision making processes, stated or implied relationships with industry, financial interest reporting, and enforcement issues. Inductive coding and theme development was used to look for similarity and associations across many topics. These were included but not limited to;

- Similarity by individual institution to 2009 IOM Policy Report.

- Similarity by all institutions to 2009 IOM Policy Report.
- Percent similarity among institutions to each other within/without each parameter to 2009 IOM Policy Report.
- Dissimilarity on above information to 2009 IOM Policy Report.
- Emergent trends from data collection, coding, and theme development.

It is important to note that I did not predetermine the classification of collaborative or noncollaborative. That is, institutions that had a lower policy similarity score to the 2009 IOM Report (Lo & Field, 2009) would be considered more collaborative than institutions that had a higher policy similarity score. In the spirit of the qualitative research, an institution being classified as collaborative versus noncollaborative emerged through the research process, data collection, and data analysis. Analyses were done looking for data patterns to include private versus public medical academic centers to ascertain if the type of institution was a differentiator with regard to similarity to the 2009 IOM Report (Lo & Field, 2009). Additionally, similarity of policy development across all study participants was examined. Finally, multiple queries looked for patterns and associations within different policy categories. An example of this could be that upon observation and analysis, academic centers that allowed pharmaceutical representative access on their campuses had a tendency toward allowing patient education materials, but not medication samples. Finally, multiple runs of association were done to examine the rationale and decision making process concerning COI policy development. These are just some of the ways in which the

research data were analyzed and additional ways in which to analyze the initial data collected emerged during this process as well.

Understanding the rationale and decision making process by conducting an analysis of interaction and COI policies presented numerous challenges. This process required not only figuring what was said within the body of a policy being examined, but also deducing the larger meaning what a policy inferred with regard to institutional rationale, motivation, self-interest, and bias. It was for this reason that the value of using the interview method and to be able to ask open-ended and more comprehensive questions was important for the depth and value of the information collected. Institutional interview information and data from COI policies was coded and analyzed to look for similarities, associations, and dissimilarities accordingly.

It was interesting to note that through this emergent process, the results took shape in some different and unpredictable combinations. For instance, the possibility existed that all institutions complied with every facet of the 2009 IOM Policy Report (Lo & Field, 2009). Another possibility existed that almost all institutions complied with a majority of policy recommendations and added more stringent COI policies. Finally, the possibility existed that institutions would fall into two divergent categories of extremely collaborative or extremely noncollaborative. Until the data were collected and analyzed, one would not know or could not accurately predict the results of what was being studied.

Data Analysis and Coding: Research Question 2

Analysis for this research question examined to what extent collaborative or noncollaborative COI polices adopted by medical academic institutions had on research funding placement by the pharmaceutical industry. Institutions were assigned the definition of noncollaborative or collaborative in nature. A more complicated analysis involved looking at institutions that evolved from being collaborative to noncollaborative over the time period studied or vice versa. Again, through the data analysis I looked for patterns of policy evolvement and a potential effect on research placement.

As the researcher, I remained objective and once again, made sure that my own personal biases did not taint the process of deducing institutional motivation. For example, when a examining a COI policy, one justification could be to control undue influence and another could be concern about patient safety. These justifications would have been coded and compared against each school interviewed. Again, this was an emergent process and what was identified as having/not having a potential effect on research funding was identifiable. That is, the data may have showed no similarity or dissimilarity on any parameter, theme, or association to research funding placement received by medical academic institutions.

Discrepant and Outlying Cases

The inclusion and discussion of discrepant cases was important with regard to both validity and controlling for bias (Maxwell, 2005). With this mind, discrepant cases were discussed and rationale for inclusion or de-selection in data analysis was provided.

Typically data distribution in any study has a tendency to clump or regress to a midpoint. It was possible that a particular case that was farthest from the norm could have actually shown the highest correlation to the research questions being investigated. For example, an institution that developed the most noncollaborative interaction policies compared to other institutions might have had the most dramatic decrease in research funding.

Issues of Trustworthiness

Credibility

Researchers suggest that in order for a study to have credibility the actual findings need to make sense to both the reader and people involved in the field of study (Miles & Huberman, 1994). A process similar to triangulation was employed to accomplish this. The responses from the interview were compared to the actual COI policies within an institution. If the survey responses led one to believe the institution was very open and collaborative in nature and the actual COI policy is very restrictive and noncollaborative in nature, then the responses from the interviewee needed to be more closely scrutinized.

Transferability

The concept of transferability was important with regard to the potential application across a broader sphere than the research itself (Miles & Huberman, 1994). The study's findings were limited to medical academic institutions in the United States engaged in medical research. With regard to transferability, the research might have application to other countries that have medical academic universities. This would have

to be applied with a cautious eye as other countries have different medical delivery systems (private versus socialized) and regulatory environment.

Dependability

Miles and Huberman (1994) discuss dependability in terms of whether the research process was stable, consistent over time, and the research questions are clearly stated. Additionally, they contend that the investigators role and status within the context of the study needs to be disclosed fully. The research questions were straightforward and my role as the researcher already has already been discussed in terms of defining the operational research terms and what I examined with regard to interaction and COI policies. At such point that the data emerged from both the survey and interview portion of the study, a determination of an institution being considered collaborative or noncollaborative was assigned and objectivity was exercised during this process.

Confirmability

Confirmability was an important concept with regard to the researcher being reasonably neutral and free from unacknowledged researcher bias (Miles & Huberman, 1994). Additionally, a study needs to be replicable from the standpoint that another researcher could come in and repeat the study using the same methodology. This study met these two criteria for a number of reasons. Full disclosure for a potential COI is documented in Appendix A. A discussion of methods employed to remain as bias-free as possible were also provided throughout the dissertation. From the replicability standpoint,

the research design and methodology were provided throughout this chapter and in the appendices. Finally, study data were retained and available for review upon request.

Ethical Procedures

Much of the information about interaction and COI policies was already a matter of public record and provided by medical academic institutions. What is not readily available, however, was an exact accounting of how many research dollars were placed at medical academic centers. Public universities, however, are required to disclose this information if requested under provisions of the Freedom of Information Act (United States Department of Justice, 2013). One could argue that private institutions based on the quantity of NIH awarded research grants and operational reimbursement through Medicare (federal) and Medicaid (state) would also have to disclose the same information. With that in mind, ethical issues surrounding data disclosure and reporting for this portion of the study were really not an issue. My intent in this research, however, was not to report research funding levels at the individual institution level and therefore was not disclosed.

Ethical considerations were addressed with regard to survey and interview information. Both the survey and interview were intended to elicit information about the rationale and decision making with regard to the enactment of interaction and COI policies. All information collected was de-identified and will remain confidential. The intent of this was to solicit honest input that might otherwise be stifled if not left confidential. After the initial completion of the study, all hard-copy (printed) data and

electronic data were saved electronically via password protect computer hardware thumb drive. All hard-copy (printed) confidential information will then be destroyed. After five years, all confidential information stored via hard drive will be deleted.

Another ethical issue that required comment is my own bias as a result of a potential COI because I am employed in the pharmaceutical industry. Discussed numerous times during this dissertation proposal, I fully disclosed my financial interest in the pharmaceutical industry. From an ethical perspective, it is important to discuss that from the outset, my interest in the research topic was not to "prove a point" but rather to more fully understand the entire topic and move the body of literature forward as it pertains to the interface between academia and industry.

Summary

In this qualitative case study my purpose was intended to examine the extent and similarity to which a sample of the 75 United States based medical academic universities enacted COI policies and degree of compliance with the 2009 IOM's (Lo & Field, 2009) recommendations and the potential implications of research funding placement by the pharmaceutical industry. An initial letter of invitation and online survey was sent out to these academic institutions requesting information about institutional COI development and research placement by the pharmaceutical industry. A voluntary follow-up interview of 10 academic centers was proposed to more fully understand this phenomenon. Actual COI policies, research funding data, and interview information were coded and analyzed to look for emergent patterns, themes and associations. I discuss the results of this

research in Chapter 4 and the recommendations and implications are presented in Chapter 5.

Chapter 4: Results

Introduction

In Chapter 4, I investigate the extent to which medical academic institutions' adopted interaction and COI policies are consistent with the 2009 IOM Policy Report (Lo & Field, 2009) concerning healthcare professionals' relationships with the pharmaceutical industry. I also examine the potential effect that COI policy development had on research funding placement by the pharmaceutical industry into medical academia. The initial research plan was altered as numerous challenges with securing 10 institutional representative interviews were encountered. I evaluated 15 medical academic centers respective COI policies in relationship to the 10 major policy recommendations issued in the 2009 IOM Policy Report (Lo & Field, 2009). An administrator from four of those institutions was interviewed to discuss general COI issues, relationships with the pharmaceutical industry, and research funding by industry post 2009 IOM policy recommendations.

Setting

The participants ($n = 4$) in the interview portion of this qualitative research were all currently employed and in good active standing with the institutions they represented at the time of the interview. Follow-up with these individuals to review interview transcripts and clarify minor information items verified this situation as all participants were readily available and not under duress during or after the interview process.

Participants were interviewed in their respective office space via teleconference and at a time that was convenient for them to complete the interview without time constraints.

Demographics

Demographic information with regards to this study is interesting in that the research questions pertain to AAMC institutions that conduct medical research in the United States. Of the 75 schools invited to participate, 42 were publicly funded and 33 were nonprofit private institutions. Administrators from four different institutions that elected to participate in the interview portion of the study represented three public and one private institution and had been with their respective institution for the last 6 to 9 years and had all been involved with COI issues since at least 2009. These administrators' functions with their institutions included one dean of medical school and executive vice president for medical affairs, one associate dean for regulatory affairs, and two directors, COI office/program. Five different administrators replied with initial interest in being involved with the interview but were lost during the follow-up and scheduling process. Ten institutions declined to participate in the study, and the remaining 56 institutions did not reply to multiple queries via email, voicemail, or phone call.

The total number medical academic institutions that had their current COI and interactions with industry policies reviewed totaled 15 with nine being public and six being private (nonprofit). This purposed selection process was intended to closely mirror the mix of public and private institutions and included drawing schools from across the

entire United States so as to prevent potential regional (geographic) tendencies. Of the 11 institutions that had their COI policies reviewed without a corresponding interview, six had previously declined to be involved in the research and five were from the no reply category.

Data Collection

Challenges With Data Collection

An invitation to participate in research was emailed to the medical director (dean) of the medical school of the 75 identified AAMC institutions on three different occasions consistent with the IRB application. This solicitation resulted in no survey responses, with one institutional participant being interviewed, eight institutions declining to participate, and the remaining 66 institutions not responding to the three research invitations. The research plan was altered to study publicly available COI policies via the internet and a new invitation to participate in research was emailed to a director of research and/or director of COI office and yielded one interview and two institutions declining to participate. Two interviews were scheduled as a result of telephone calls placed to the director of research and/or director of COI offices. The challenge with securing interviews was extremely time consuming, and it was decided to use an $n = 4$ as opposed to the initially planned $n = 10$. It was centrally frustrating that through all three processes employed to solicit interviews (study participants), a nonresponse from potential research candidates was most common. Many reasons could explain why such a low response rate occurred, but one potential explanation is that I was forthright in my

identification of working in the pharmaceutical industry and a bias for noncontact (nonengagement) with industry may have been present. On three separate occasions, I was told that my research invitation would be forwarded to a schools legal counsel and they would get back in touch with me if they were interested. Multiple times, phone messages were left without return phone calls or I was asked to email or reemail an invitation to participate in research and no follow-on response from a potential interviewee occurred.

Overall Data Collection Plan Altered

Based on the challenges with securing interested parties to participate in research, an alternative data collection plan was instituted. The initial data collection plan would have involved an $n = 10$ for both the institutional review of current COI policies and the corresponding interview of an administrator. This was altered to increase the number of institutions COI policies to be reviewed to be increased to an $n = 15$ and the number of institutions with an interviewed representative being decreased to an $n = 4$. The rationale behind this was to be able to compare and contrast the COI policies of interviewed institutions against noninterviewed institutions. That is, if COI policy was generally consistent between interviewed and noninterviewed institutions, a reasonable parallel could be drawn. While this may be somewhat of a stretch with regard to credibility and transferability, the intention was to in some fashion be able to examine $n = 4$ (interviewed and policy review) to $n = 11$ (policy review only) and still be able to have the study potentially apply to the 75 AAMC schools that conduct medical research. This situation

helps explain and potentially justifies why a qualitative design for this research was warranted. Essentially, an emergent process with regard to qualitatively based research warranted increasing the *n* from the COI policy data sources in an attempt to accommodate for the decrease in the *n* of institutional interviews performed. Other than the central challenge of finding study participants, there were no unusual circumstances that occurred during the data collection process.

Interview Data Collection

The individual participants were all interviewed using the interview questions provided in Appendix D. Each interview was started with me introducing myself and explaining my purpose for the research and the disclosure that I work for Pfizer Pharmaceuticals. I spent a couple of minutes reviewing my interest in the topic itself and that I was not trying to purpose my research as a means to call for COI policy reversals. The duration of these interviews ranged from 47 minutes to 1 hour, 7 minutes and was recorded using a digital recording device. A transcribed typed interview transcript was provided to each participant for review. Interviewees were allowed to clarify and/or change their answers accordingly for accuracy and context purposes. Any revisions were minor in nature and still allowed for genuine and nonguarded answers. My introduction to the topic and the interviewees' ability to review transcripts post interview yielded honest and insightful answers.

COI Policy Data Collection

To answer the central research question about the extent to which United States based medical institution have adopted COI policies consistent with the IOM Policy Report (Lo & Field, 2009), a review of current COI policies was initiated. When starting the review of these policies, it was determined that the IOM policy recommendations were usually housed in two separate policies. The first policy was usually titled a COI, Financial COI, or COI in Medical Research policy and the second was an Interaction with Industry or Vendor Relations policy. A third type of policy entitled COI in CME was also present at some schools. The range of the number of institutional policies and/or policy links (online policy subset) that governed institutional COI issues was one to 16 with an average of 6.7 policies/links per school.

The four institutions that had a representative interviewed provided or had available on-line their current policies and their respective COI Policies ranged from a current version date of 2012 to 2014 with an average late 2012 date and the Vendor Policies ranging from 2009 to 2013 with an average 2011 date. Eleven institutions purposely selected had their policies accessed via the Internet with their COI Policies ranging from 2010 to 2014 with an average 2012 date and the Vendor Policies ranging from 2009 to 2014 with an average 2012 date. It is important to note that all of these policies were put in place since the release of the 2009 IOM Policy report and would seem to indicate that interaction and COI policies at the medical academic center level

are actively monitored and updated. This is in contrast to findings of previous authors that prior to 2009, COI policies were nonexistent, lax, or not enforced (Maahs, 2012).

The process to collect elements from these policies and capture them in relation to the 2009 IOM Policy Report involved building a grid with the institution recorded on the y-axis and the policy recommendation displayed on the x-axis (Appendix H). This allowed me to visualize and summarize all 15 institutions across 10 policy recommendations. This is discussed in further detail in the data analysis section.

Data Analysis

COI Policy Analysis – Coding and Themes

The review of institutional COI policies in relation to the 2009 IOM Report was not as simple as a yes or no proposition by specific policy recommendation. For instance, the 2009 IOM Report specifically called on institutions to ban all free meals provided by industry. Of the 15 institutions' policies reviewed, only four institutions specifically prohibited all free meals, and one allowed free meals with a $5.00 per person limit. The remaining 10 institutions prohibited free meals, but with four different types of exceptions allowed. From this, a data analysis approach using a spectrum was employed with each policy recommendation being assigned 10 points and an emergent process of coding (scoring) each individual institution's own policies against each recommendation. That said, the only preset codes with regard to per-policy analysis was that if a policy completely conformed with the policy, it was assigned 10 points and a policy that did not confirm was assigned 0 points. An emergent coding process was then employed to

capture range of conformity in between these opposite ends and was coded (scored) between 2 to 9 points. Each institution's adherence (coded and scored) to the IOM Policy Report by all 10 recommendations was then added together to arrive at a possible spectrum score of 0 to 100 points. It is important to note that this process was emergent, was qualitatively based, and was not intended to absolutely score "percent compliance" to IOM Policy Report. This was done to arrive at some form of measurement to examine overall compliance to the IOM's policy recommendations by institution and compare and contrast each different IOM policy recommendation to each school's policy as well. Institutions studied were placed on the y-axis and each IOM Policy recommendation was placed on the x-axis. The summary institution versus policy recommendation and corresponding coding (scoring) is detailed in Appendix H. The coding (scoring) process by comparing institutional policy to IOM Policy Report is provided as follows:

1. Board-level involvement at the individual institution level to develop comprehensive COI policy. Category scored yes =10 points, across all institutions. Depth of individual institution policies as well as adherence to IOM Policy Report recommendations 2 through 10 demonstrated broad policy coverage and development of comprehensive COI policy by all 15 institutions studied.
2. Researchers should not be involved in research on human subjects if they have a financial interest in the outcome unless researcher expertise is vital to the safe conduct of the research itself. Category scored yes-managed = 6 points,

across all institutions. No single institution completely adhered to this policy. This recommendation became very highly regulated through COI committees, review processes, management plans, Office of Research Integrity involvement, and IRB involvement. Participant 103 articulated this by stating, "We completely disagree with IOM as pertains to research. Industry contacts the experts and that is how research gets placed". Participant 103 elaborated further by explaining that having a PI that has a consulting agreement with industry creates greater transparency because it is disclosed, managed, and monitored by the institution. In application, this policy recommendation was more practically replaced by the NIH in 2011 when rules governing COI in research was issued (NIH, 2011). This is discussed further in the results section.

3. Ban faculty from receiving any gifts from industry. Category scored yes = 10 points; yes –medical textbooks allowed = 8 points; no -- $5.00 per meal and $75.00 per company per year limit = 2 points. While allowing a medical textbook may appear as a major loophole within this policy domain, the actuality of its occurrence is very uncommon as industry has highly gravitated away from this practice.
4. Prohibit faculty from involvement in industry speaker bureaus. Category scored yes = 10 points; no--non promotional speaking only = 5 points; no--discouraged but not prohibited = 6 points; no = 0 points. The practice of

nonpromotional speaking (nonproduct) on a general disease state is highly unused by industry. The real effect of allowing this was very minimal and was discussed by Participants 101, 102, and 103. The practice of discouraging the practice of industry speaker bureaus but not prohibiting entirely them was consistent with the policy and interview of Participant 105 and their institutions' policy. Essentially, due to the heightened awareness due to COI issues the largest majority of faculty no longer participated in speaker bureaus.

5. Prohibit faculty from claiming authorship for ghost-written articles. Category scored yes = 10 points across all institutions. This category was very fairly simple to code (score) as all institutions had straightforward language dealing with this policy recommendation. An example provided by Institution 101 policy stated, "(School) prohibits faculty, trainees, and students from allowing their professional presentations of any kind, oral or written, to be ghostwritten (i.e., written by someone who is not an author) by any party, industry or otherwise."
6. Prohibit the provision of free meals from industry. Category scored yes = 10 points; yes--CME events allowed though = 8 points; yes--off site only if sponsored by industry = 8 points; yes-on site or off site only if sponsored by industry = 7 points; yes--holiday snacks allowed = 8 points; no--$5.00 per meal with $75.00 per company per year limit = 2 points. This category was the most problematic to code (score) as the provision to allow free meals in

conjunction with CME events might appear to ignore this policy recommendation. CME events usually occur during "Grand Rounds" where a faculty member provides a presentation in a lecture hall during lunch or an off-site CME event where industry sponsorships for the event are common to defray the cost of the CME event for the individual attendee. In either case, these types of activities when they do occur are highly regulated by both academia and industry. For instance, it is common in the pharmaceutical industry for companies to allow representatives to attend CME events, but representatives are not allowed to wear name tags, engage in promotional information, or provide food. For off-site CME programs, industry is allowed display space, but it is required to be in a separate room from the CME activity itself. Institutions that allowed a provision for on-site or off-site meals further created potential confusion on this topic as it could refer to CME events and/or non CME promotional events. As these institutions were not interviewed, it could not be determined what the actual policy meant. The reality is that with regard to the provision of free meals, the common practice of industry representatives bringing food for product discussions and in-services has been largely eliminated. Coupling this policy with the recommendation of restricting representative access to medical academic centers (see recommendation eight) confirms that this previous practice has primarily ended.

7. Prohibit faculty from entering into consulting arrangements not recognized for expert services at fair market value. Category scored yes=10 points; no=0 points. This policy recommendation was expressed by Participant 102 by stating, “We developed policy on consulting with the bio-medical industry that allows for consulting provided there are specific deliverables that they have to provide”. Policy language around this topic discussed reporting, monitoring, enforcement, and compliance NIH reporting rules (NIH, 2011).
8. Restrict pharmaceutical sales representative access to medical academic centers. Category scored yes=10 points; no-managed=6 points. This category typically included language about representatives only being allowed access to an institution if they had a prior scheduled appointment and representatives having to sign-in at a specific location. This mechanism created a highly restrictive environment at some institutions because the cultural norm was for faculty and staff to not schedule appointments and email communication from a pharmaceutical representative could be “firewalled” by IT as spam and not be delivered. Participant 105 addressed this issue by stating, “We don’t have pharmaceutical representatives coming in and meeting with our faculty to talk about the latest pain medication. It just isn’t going to happen”.
9. Restrict medication samples to only economically challenged patients. Category scored yes=10 points; yes-no samples allowed at all=10 points; unknown=2 points; no=0 points. This category was interesting as a majority

of institutions actually banned samples completely. This once common practice as a means for representatives to talk to physicians and staff while providing medication samples and those samples being used for a patient medication start has become almost nonexistent in the medical academic hospital setting. It could be observed, however, that the elimination of samples almost had equally to do with hospital accreditation requirements dealing with sample secured storage, documentation, dispensing, and inventory requirements.

10. Separate CME activities from industry influence. Category scored yes=10 points; no-managed=6 points, unknown=2 points; no=0 points. This policy category fell to a highly managed environment with many CME activities being reported, documented, managed, and approved through a COI Office. For instance, Participant 103 elaborated on this topic by talking about a request they received to attend a CME event and after a full review of the activity agenda it was determined that the majority of the time (trip) was not being spent on continuing education and the request to attend the event was not allowed.

Several different data manipulations were done to look for patterns, themes, and discrepant cases. The coding grid provided in Appendix H was used and examined all 15 institutions in summary, interviewed versus noninterviewed institutions, publicly versus privately funded academic centers, and least number of COI policies to most number of

COI policies reported/available to review. Patterns by these demographic categories were observed as well as patterns within each policy recommendation as well. This is presented fully in the results section.

COI Interview Analysis – Coding and Theme Development

The four participants interviewed provided their input as it pertains to their respective institutions COI policy development, management, and adherence. The open-ended nature of the questions provided the interviewees a forum to share their insights that were most topical to them. No two interviews took on the same shape or content, however, some very interesting themes, associations, and disassociations became apparent when coding the interviews for themes accordingly. Some of the questions presented more direct theme alignment while other questions elicited thought and opinion that produced various themes throughout the interview. For instance, the interview question with regard to the positive and negative aspects of working with industry elicited responses fairly close to topic while the question with regard to opinion about the IOM Policy recommendations being justified and why yielded responses that went in a number of different directions.

The process to analyze these interviews followed a grounded and narrative analysis approach (Hesse-Biber, 2010). Each interview was examined by preset topics (themes) based on the interview questions. All interviews were coded within these topics to allow for themes, patterns, similarities, and discrepancies between/among interview participants to emerge. I typically read interview transcripts four or five times to look for further

context and clarity in addition to codes from each topic were then also cross referenced. This process could be best described as spiraling up and down the data as well as across it. This was intentionally done in the classic "by hand" approach as opposed to using computer software. To properly analyze the interview transcripts, an innate knowledge of the research topic was required and the contextual meaning of what the interviewee's was communicating required deductive methodology. The preset topics for analyzing and coding are provided below:

1. Function with institution prior to 2009 IOM Policy Report and current function with institution.
2. Familiarity with 2009 IOM Policy Report, justification, and institutional policy changes made.
3. Institution's current policy and how it addresses concerns from the 2009 IOM Policy report.
4. Describe current relationship with pharmaceutical industry.
5. Positive aspects of working with the pharmaceutical industry.
6. Negative aspects of working with the pharmaceutical industry.
7. Medical research funding sources from and how much of it is from the pharmaceutical industry.
8. Changes in COI policy and impact on pharmaceutical funding placement.
9. Other changes within institution and impact on pharmaceutical funding placement.

10. State or federal legislation that has impacted COI policy.

11. COI Policy enforcement.

A coding to themes tree is provided in Appendix I. Some participants provided information that directly applied to each preset theme while some interviewees did not. This approach, while somewhat cumbersome, made sense from the standpoint that many times what an interviewee "said" had to be translated to" in-context meaning".

The second approach to coding emerged in that themes produced from the preset coding process, produced additional approaches to examine the data. This, in addition to "open reading" of the interview transcripts produced additional themes to analyze. This process could be best described as contextual data sifting. For instance, Participant 102 articulated several times during the interview about how the culture of medical schools has changed dramatically in its' interactions with industry as a result of COI policies. Within the nuances of the interview, this participant indirectly refers to this theme as a result of faculty and institution change in behavior not only from policy development, but from individual and institutional sensitivity and awareness as well. Additionally, Participant 105 did not mention "cultural change" directly in their interview, but did talk about it in reference to a previous practice of the pharmaceutical industry providing stethoscopes with a medication name on it by stating, "They didn't want the swag anymore (referring to medical students). They bought their own because they didn't want to be tainted." This comment speaks to a profound cultural change at medical academic centers in that what was once a common and accepted practice is now shunned. That said,

both participants articulated a very direct change in behavior by their physicians and staff relative to accepted/not accepted behavior. The emergent codes to themes approach tree is detailed in Appendix I. A full discussion of this is provided in the results section and the emergent codes to themes are provided below:

1. Negative Perception of Pharmaceutical Industry.
2. Positive Perception of Pharmaceutical Industry.
3. Role of Academia in Pharmaceutical Research.
4. Speaker Bureaus.
5. Institution and Individual Cultural Shift with Regard to Industry Contact.
6. Better Research.
7. Collaboration.
8. NIH Reporting Rules and Impact on Research Funding.
9. Institutional Challenges with IRB Efficiency.

Evidence of Trustworthiness

Credibility

As I discussed in Chapter 3, credibility can be a challenge with ensuring the actual results are logical to the reader and those in the field of study (Miles & Huberman, 1994). I accounted for this by comparing the interview responses by institution to the actual institution policies of that representative institution. Each interview was read in comparison to each institution's policies looking for consistency and discrepancies. For instance, many interviewees reported that their institution banned faculty from

participating in industry sponsored speaker bureaus. In every case, this was consistent to the corresponding policy reviewed. Additionally, while many institutions went with a more conservative approach to medication samples than the IOM Policy Report (Lo & Field, 2009) by completely banning samples, it is logical as a course of action when thinking about both potential COI policies as well as the compounding issue of hospital-based reporting requirements with regard to sample storage, inventory, and dispensing information.

Transferability

With regard to transferability, I altered the research data collection plan in a good faith effort to have the results from this study have a broader application beyond the four institutions that were interviewed and policies evaluated. As discussed earlier, the means to purposely select eleven additional schools to have their policies reviewed without a respective interview and then have those schools policies compared to the four schools with interviews was used as a bridge. It was interesting to observe that from a policy perspective, all 15 schools with or without regard to being interviewed, were very similar in the their policies adopted post 2009 IOM Policy report. It can be argued that because only four institutions are represented from interviews, this particular research is challenged with regard transferability to all 75 AAMC institutions that conduct medical research.

Dependability

The research process was consistent during the time of this study in that the interview process from candidate to candidate was not altered. This consistency was demonstrated in the relatively similar amount of time it took for each interview and the overall lack of interview corrections or clarifications requested by the interviewee. The interviewees demonstrated dependability as a source of information with regard to time in position at their respective institution and their knowledge of COI issues as demonstrated by their ability to talk about the topic in depth and with relative ease. When the general research topic was introduced to interviewees, it was easily understood and topical to their functional area at their institution. The research question in relation to individual institution policy development versus the 2009 IOM Policy Report recommendations made data analysis straightforward. The research question with regard to exact research funding levels was more nuanced in that most schools did not have an exact research funding number to report by the pharmaceutical industry. This will be discussed further in the Results section.

Confirmability

Based on the methodology and my upfront disclosure of working in the pharmaceutical industry, issues with regard to potential researcher bias have been disclosed and managed. Mentioned earlier, my description of the purpose of the study to interviewees helped elicit honest and genuine answers. With regard to general replicability, this study could be repeated if desired and the study data will be retained

and available for the next five years. It would be interesting to see if this research was repeated by someone within medical academia what challenges (or lack thereof) with enrolling interview participants in this study would occur.

Results: Research Question 1

Since the release of the IOM Policy Report (Lo & Field, 2009), to what extent have interaction and COI policies been fully complied with by United States based medical academic institutions, what were the rationale(s) and decision making considerations involved in developing such policies, and how would these institutions classify the current nature of their relationship with pharmaceutical companies as opposed to pre 2009?

Discussion

The policy analysis of 15 medical academic institutions overall showed at high rate of compliance to the 2009 IOM COI recommendations. Individual institutions were coded (scored) across all 10 2009 IOM policy recommendations with a possible total compliance score being 100. This process is depicted in Table 3 and displays each institution on the first column with scoring by IOM policy recommendation along each corresponding column and a total compliance score reported in the last column.

Table 3

IOM policy recommendation compliance scoring by institution.

Instit.	IOM Policy Recommendation										
	1	2	3	4	5	6	7	8	9	10	Total
101	10	6	10	10	10	8	10	10	0	6	80
102	10	6	10	10	10	10	10	10	10	10	96
103	10	6	10	10	10	8	10	10	10	6	90
104	10	6	10	5	10	8	10	10	10	0	79
105	10	6	2	6	10	2	10	10	2	6	64
106	10	6	10	10	10	8	10	10	10	6	90
107	10	6	8	10	10	7	10	10	0	4	75
108	10	6	10	10	10	10	10	10	10	6	92
109	10	6	10	10	10	8	10	10	6	6	86
110	10	6	10	10	10	8	10	10	10	0	84
111	10	6	10	0	10	7	10	10	2	0	65
112	10	6	10	10	10	10	10	6	0	6	78
113	10	6	10	10	10	8	10	10	10	6	90
114	10	6	8	10	10	10	10	10	10	0	84
115	10	6	8	0	10	8	10	10	10	0	72
Ave	10	6	9.1	8.1	10	8	10	9.7	6.7	4.1	81.7

The data were examined across a number of arrays and resulted in similar yet interesting results reported on Table 4 with regard to interviewed versus not interviewed institutions, public versus private, and most versus least policy links categories by institution.

Table 4

IOM compliance score across different identifiers

Category	*n*=	Range	$\bar{x}$	Median
All Institutions	15	64-96	81.7	82.0
Interviewed	4	64-96	82.5	85.0
Not Interviewed	11	65-90	81.4	84.0
Public	9	64-96	82.1	80.0
Private	6	65-90	81.2	85.0
Most Policy Links	7	84-96	87.6	90.0
Least Policy Links	8	64-90	76.5	78.5

While somewhat unorthodox to the typical qualitative process, the data analysis approach and presentation of the results in relationship to institutional compliance with the 2009 IOM Policy report shows relatively high compliance and similarity between and among different demographic categories of the institutions researched in this study. The range of compliance score from 64 - 96 ($\bar{x}$ = 81.7) suggests that policy recommendations across all institutions shifted along a normal distribution spectrum. That is, a couple of institutions very highly complied with the IOM Policy report recommendations (*n* = 2, score over 90) and a couple of institutions complied fairly well (*n* = 2, score under 70). It was interesting to observe that interviewed versus noninterviewed institutions had an $\bar{x}$ compliance score of 82.5 and 81.4 respectively and public versus private institutions had an $\bar{x}$ compliance score of 82.1 and 81.2 respectively. At a macro-level, these results

would seem to suggest that medical academic centers adopted policy changes generally consistent with the 2009 IOM Policy Report.

The segmentation of the institutions with the most policy links versus the least policy links did show some differentiation in that the schools with most policy links (n = 7) had an $\bar{x}$ compliance score of 87.6 and the schools with least policy links (n = 8) had an $\bar{x}$ compliance score of 76.5. This is not a profound observation in that it would seem to make sense that schools that had developed the most number of policy links (number of policies) would have developed policy language to more fully deal with COI issues. Therefore, it could be generally observed that schools with higher levels of COI policy development had compliance scores that were closer in alignment to the IOM's policy recommendations.

Within the parameters of each policy recommendation, some interesting themes emerged. All fifteen medical academic centers enacted policy that was comprehensive in nature, prohibited ghost writing practices, and allowed for consulting contracts at a fair market value and 14 of 15 medical schools restricted industry representative access to their respective campuses. Outside of these policy domains, the level of compliance and similarity among institutions varied by category and are discussed below.

Higher Compliance Versus Lower Compliance

Institution 105 was the school with the lowest compliance score of 64 and had a representative interviewed for this study. Participant 105 talked about some of the challenges this institution had with regard to COI policy development in that they were

trying to administer policy across four different campuses that varied between being highly medically oriented versus being more engineering oriented at other campuses. They stated that they felt they had more work to do with COI policy development and that the language was stale and had not kept up with the way academia and industry were doing things. They did, however, talk in terms that while the policy language was somewhat challenged, the institution essentially "massaged" the policies to work to arrive at compliance within the spirit of the IOM's policy recommendations and to comply with NIH reporting rules. Institution 111 had a compliance score of 65 and a representative from this institution was not interviewed for this study. Therefore, the means to more fully examine institutional motivation and decision making with regard to COI policy development and enforcement was not possible. It is interesting to note, however, that this is an institution that has historically has had very profitable industry partnerships with regard to medicine development.

Institution 102 had the highest compliance score of 96 and had an administrator interviewed for this research. Participant 102 discussed their institution's comprehensive approach to COI issues with three different committees involved in COI matters and additionally stated that, "People are sensitized to the issue of their engagement with industry and what that engagement might have on research, clinical care, and medical education." They also discussed policy development about banning industry speaker bureaus and COI policy education for faculty and staff. It is interesting to note that this institution was the only one to completely separate industry and CME activities (IOM

recommendation 10) of the 15 institutions studied. Of the administrators interviewed, this participant was the only to mention CME and discussed it in terms of banning receipt of any payments from industry for this activity. Institution 108 had the next highest compliance score of 92 and was not interviewed for this study. Again, without this vehicle to capture institutional motivation and decision making rationale, a more full analysis was not possible. It is interesting to note, however, that this institution did have a significant financial COI scandal during the 2000s when it was exposed that an influential faculty member had received millions of dollars from the pharmaceutical industry for speaking and consulting services. This institution also segmented into the higher policy links category with nine policies available for review.

Samples

The IOM Policy Report recommendation with regard to providing samples only to those patients who were economically challenged was split between eight institutions completely eliminating samples, three institutions that continued to allow samples without regard to economic status, two with a sample policy unknown, one with a managed process, and one that followed the IOM's policy recommendation. Within this policy domain, over half implemented policy that was more restrictive than the IOM's recommendations. Mentioned earlier, an equally compounding issue around sample regulations in a hospital setting with regard to storage, record keeping, dispensing, and inventories may have had a larger effect on this than just the IOM policy recommendation. Outside this issue, there was no real consistency among institutions and

this policy domain. Participant 105 was the only interviewee to mention samples in a passing comment about needing to address this further in a way that would be consistent with a formulary committee review.

Prohibiting Gifts

This policy recommendation was highly adhered to with 11 institutions prohibiting the receipt of gifts from industry. One institution allowed gifts with a $5.00 limit per gift and no more than $75.00 in gifts per company per year. Three institutions allowed a provision for faculty to receive a medical textbook from industry. This particular loophole was probably more of a holdover from the 1990s to 2000s when this was a common practice. This practice has been largely eliminated by industry today.

Prohibiting Food

Policy development with regard to the recommendation of prohibiting food to faculty and staff was adopted with a number of exceptions that still generally restricted a once very common practice. Four institutions banned food outright and six institutions allowed meals, but only if provided in conjunction with a CME event. As CME events are highly regulated and do not occur on a daily basis (even weekly at some institutions), the real effect of this highly eliminated meals being provided industry. Three institutions allowed meals within the function of being “industry sponsored”, but this could be interpreted as part of a CME event, conference, or speaker program. One institution allowed holiday snacks and one school allowed meals under the provision of a $5.00 per meal and $75.00 per company per year policy.

Continuing Medical Education

This particular policy recommendation was the least adhered to as the IOM sought to separate any industry involvement with CME activities. Only one institution adopted this policy outright and five institutions did not follow this recommendation. Eight schools elected to maintain CME support/involvement from industry, but in a managed way typically with approval to be provided by a COI office or committee. One institution did not specifically address CME in its policy, but language around consistency with ACCME standards was mentioned.

Speaker Bureaus

The particular policy recommendation to ban faculty from participation in industry speaker bureaus could best be described as a lightning bolt topic. All four interviewees mentioned this in their respective interviews as a major issue. Participant 101 when speaking about COI issues in general stated, "Fundamentally, it was about speaking engagements that were not CME related...with slide decks that were prepared by industry and this created the potential appearance of buying the faculty member." They went on to elaborate that this practice constituted large transfers of money upwards of hundreds of thousands of dollars paid to faculty per year and instituting policy to prohibit this activity was initially met with resistance. Participant 101 further stated, "We had two people that were recalcitrant, didn't see the value of the policies and engaged in relationships without disclosing them. They were discovered and they were terminated." Participant 103 added, "We had one situation were a faculty member was cancelling

clinic all the time and was probably tripling his salary and we didn't know quite how to control it." This institution also prohibited the practice of allowing faculty to participate in industry speaker bureaus.

Of the four institutions interviewed, three prohibited speaker bureau involvement and one discouraged, but did not prohibit speaking for industry. Four of the institutions studied continued to allow faculty to be involved in speaker bureaus, but were not interviewed during this study. The remaining institutions did not allow speaking for industry.

Principal Investigator (PI) and Financial Ties to Industry

The IOM specifically sought to prohibit PIs from having any financial ties to industry unless the safe conduct of the research trial in question required the expertise of that particular PI. No school specifically banned this practice and sought to manage this process through disclosure, reporting, oversight, management plans, and COI office and/or COI committee involvement. This policy was largely trumped by a different recommendation that came out of the IOM Report (Lo & Field, 2009) that specifically called on the government to more fully legislate COI issues in medicine from a disclosure, reporting, and management perspective. In August 2011, the NIH made a number of rule changes to the previous COI policy rules issued in 1995 (2011). In order for an institution to continue to receive NIH funding, individual researchers were required to disclose to their respective institutions all significant financial interests related to their organization with the annual monetary threshold reduced from $10,000 to $5,000.

The NIH also required that institutions provide reporting on COI to include policy, management, and institutional training to researchers (NIH, 2011). The change in the NIH rule was mentioned by all four interview participants as a major turning point in COI policy development as the reporting burden shifted from the individual researcher to the institution itself. Previous to this rule change, most financial ties between individual faculty and industry were under reported or not disclosed at all. Participant 105 probably summed it up best by stating, "It was probably the biggest thing I have seen happen in 15 years I have been in compliance…It switched from manage conflicts and tell us if you have a potential issue to here's how you are going to do it."

Relationship With Industry

The results from the policy and interview analysis demonstrated a general nonengagement with industry unless specifically for the purpose of conducting research. This was ferreted out not much by what was said, but more from what was not said. Potential emergent themes from the interviews around collaboration, industry partner, industry resources (information) for faculty, resources for patients, new medical information, new medicine (drug) information, were highly absent. This is not surprising when examining how COI policy was developed as an overall means to restrict interactions between industry and faculty and staff. Participant 105 directly stated, "Our institution, like many others, has locked the doors to that type of activity. We don't have pharma reps coming in and meeting with our faculty to talk about the latest pain medication. It just isn't going happen." This interviewee redirected their answer and

further stated, “On the flip side, we are really trying to bolster working with industry on the research process.” This attitude was highly prevalent across all interviews as there was a desire to interact with industry, but only to the extent that it was tied to research and research funding.

Results: Research Question 2

What are some of the effects that new COI policies have had on pharmaceutical industry research funding for United States based medical academic institutions since the implementation of the IOM Report (Lo & Field, 2009)?

Discussion

Research funding placement by the pharmaceutical industry into individual medical academic centers is not information that was publicly available during the research timeline. Provisions of the PPSA (Sunshine Act) from 2010 required industry to report all institutional and individual financial ties in medicine and only began to come online during 2014 (American Medical News, 2013). Therefore, answering Research Question 2 was not as easy as looking at previous research funding reports and examining those placements against individual institution COI policy development. Knowing this limitation, the information provided from the interviews produced some insightful and interesting results.

Research Funding

Nearly one-third of research funding provided to medical academic centers was NIH based (Dorsey et al., 2010) and was fairly consistent with information the four

interviewees provided. However, one Participant 102 reported that of their $500 million annual research budget, around $300 million of it came from the NIH. It makes sense that based on quantity and percentage of research money from the NIH, medical academic centers would be financially motivated to stay in line with NIH reporting rules and is why this was such a big topic within the realm of COI policy development, reporting, and enforcement. The NIH rule was mentioned numerous times during the participant interviews.

Funding provided by industry for medical academic centers research efforts averaged around 10% for the institutions interviewed. Participant 105 (institution compliance score = 64) actually reported the lowest percentage of pharmaceutical research at 6%. Participant 101 (institution compliance score = 80) reported the highest percentage of industry research placement at around $30 million and total research budget of $150 million at 20%. Participant 102 reported a total research budget of $500 million per year with industry support ranging anywhere from $50-$100 million per year.

COI Policy Development and Potential Effect Pharmaceutical Research Placement

The centrally defining question to this study presented to interview participants was whether or not COI policy development at their institution affected research placement by the pharmaceutical industry. The answer to this question was answered directly and indirectly throughout the interviews accordingly.

Participant 101 directly stated, “Overall our changes in COI policy did not impact research placement. Actually our funding has gone up as a result of investments in

infrastructure and adding faculty…We were very interested in speeding up IRB approvals, master contracts, and trying to make the process easier." Participant 101 went on to elaborate that as an institution they encourage faculty to be involved in research, engage with industry to do so, and feel their institution is well suited for Phase I and II clinical research. These comments are important as this institution had a compliance score of 80 (middle of entire group), but had a higher than average industry placement of research as a percentage of its total budget (20%).

Participant 102 answered, "I don't think the policies we adopted have really had an effect on research placement by the pharmaceutical industry…The bigger factor has been the regulatory (NIH rule) and IRB process involved." Participant 102 further shared that the pharmaceutical industry has not been impressed at long it to get research through the contracting and IRB process and that they felt academia wide, institutions were looking for ways to be more competitive and reduce turn-around time. This institution had the highest compliance score of 96 and the largest total research budget (all sources) of institutions at around $500 million.

Participant 103 stated, "We did have a big downturn…we were not sure if it was the economy or our strict interaction policies." Participant 103 did elaborate further that the reduction in research placement was largely a function of leadership that put restrictive policies in place and now with some current changes in leadership, has added new faculty, is looking to speed up the IRB process with weekly meetings, and has made a deliberate attempt to secure new research. This person also added that the NIH

reporting rules dramatically impacted their approach to COI issues and interaction with industry. This institution had a policy compliance score of 90 (upper third).

Participant 105 stated, “I don’t get a real sense of our policy effecting research placement either way.” Participant 105 did mention several times throughout the interview that the NIH Reporting Rule, while justified, dramatically changed their approach to COI issues but that did not necessarily have direct tie to funding placement. It is interesting to note that while this institution had the lowest policy compliance score it also had the lowest percentage of research placement (6%) by the pharmaceutical industry as a part of its total research budget.

The very apparent theme that presented itself with regard to these interviews was that COI policy development in response to AAMC/IOM guidelines largely did not impact research placement by the pharmaceutical industry. It is apparent, however, that from the perspective of these institutions, the NIH Reporting Rule and the institutional IRB process did have an impact on research placement. Consider Institution 101 were research funding levels went up as a result of not being bogged down the NIH reporting rule, streamlining the IRB process, adding infrastructure (IT), and adding faculty. Contrast this to Institution 103 that reported a down-turn in pharmaceutical research funding and attributed it the NIH Reporting Rule and restrictive COI policies. This medical school has since made some institutional changes with regard to relaxing portions of their institutional COI policy, adding faculty with interest in doing research, and speeding up the IRB process.

Summary

The results from this study show that medical academic centers were highly compliant in their adherence to the recommendations presented in the 2009 IOM Policy Report (Lo & Field, 2009) based on both a policy analysis of 15 institutions' COI policies and interviews with administrators of four of those institutions. Additionally, based on the interviews conducted, medical academia appeared to be very nonengaged in interactions with industry unless it was tied to research funding. The interviews contained an in-depth discussion on COI policy development, process, reporting, and management, but lacked genuine interest in collaboration or finding out about new medications. While limited to interview data, the development of comprehensive COI policies by academic centers has generally not had an impact on research placement by the pharmaceutical industry. It can be observed though, that institutions that were better equipped from an infrastructure perspective to effectively and efficiently speed up IRB processes and be compliant with NIH reporting rules were better poised to secure funding than other institutions. I present recommendations with regard to COI issues, industry engagement, and research placement in Chapter 5.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

The research findings I present in Chapter 5 employs an analysis of AAMC institutional policy (n = 15) and administrator interviews (n = 4) to examine COI policy development using the ACF construct. I investigated the extent to which AAMC institutions adhered to the 2009 IOM Policy Report (Lo & Field, 2009) with regard to COI policy development and potential effect on research funding placement by the pharmaceutical industry. Two key findings emerged through policy and interview reviews during the data collection and analysis phase of this research. The first key finding is that AAMC institutions highly complied with the recommendations presented in the 2009 IOM Policy Report (Lo & Field, 2009) with regard to COI policy development, reporting, and adherence. The second key finding is that COI policy development did not appear to effect research funding placement by the pharmaceutical industry into medical academia. It appears, however, that a larger phenomenon surrounding an institution's capacity to comply with new NIH reporting requirements, streamline IRB processes, and directionally align and engage in research was observed with regard to research placement by industry into academia.

Interpretation of the Findings

The findings from this study establish that United States based AAMC institutions that engage in medical research highly complied with the 2009 IOM Policy Report (Lo & Field, 2009) recommendations with regard to COI policy development, management, and

adherence. These findings did not suggest a link between COI policy development and an effect on research placement by the pharmaceutical industry into medical academic centers but rather a more complicated set of circumstances surrounding NIH research reporting rules, IRB processes, and individual institution posture and infrastructure capabilities to secure research funding.

The results from this study answer the previously unanswered question with regard to AAMC institutional change with regard to COI issues. That is, while some of the literature reports many institutions had adopted COI policies (Huddle, 2010; Rothman & Chimonas, 2008), the extent to which these policy developments were consistent with IOM policy recommendations is now established. Current institutional practice to restrict industry representative access may have addressed research bias concerns presented by previous work of Campbell et al. (2007) and Zinner et al. (2009). Previous researchers only suggested that industry interactions could potentially create research bias and this new era of access restriction potentially makes this a moot point. Maahs (2012) and Steinbrook (2009) raised the issue of restrictive interaction and COI policies being adopted by medical academia and research effectiveness and efficiency being called into question. The findings (while somewhat limited) do not suggest that this phenomenon had a correlation to research placement at the university level. McKinnon (2009) and Kitsis (2011) presented thoughts around public and private partnerships being able to fruitfully coexist through collaborative and transparent partnerships. Unfortunately, the

findings suggest that medical academia has not embraced this entirely, as these themes were highly absent during the research and analysis phase of this study.

The conceptual framework ACF (Birkland, 2001; Sabatier & Jenkins-Smith, 1988) was used as these lens upon which to design, conduct, and evaluate the research in this study. The findings are consistent with this approach in the presentation of opinions presented by interviewees that were many times heuristic in nature as well as the complexity and self-interest of the multiple parties involved with medical research. One of the major tenets of this conceptual framework is grounded on the premise that policy change typically takes a minimum of 10 years to implement and fully understand (Sabatier & Jenkins-Smith, 1988). This was demonstrated in the fact that the first major calls for COI reform started in 2006 (Breenan et al., 2006), the IOM and AAMC release of their policy recommendations was in 2009 (AAMC, 2009; Lo & Field, 2009), and the final NIH Reporting Rule came into play in 2011 (NIH, 2011); during the research timeframe (2014-2015), institutions were still making adjustments in policy relative to medical research funding.

Limitations of the Study

The study findings with regard to COI policy development across United States medical based schools being in compliance with the 2009 IOM Policy Report (Lo & Field, 2009) were fairly robust in overall compliance rates of the 15 institutions' policies evaluated. These particular findings are somewhat limited to policy development as policy effectiveness was not really studied. That is, a policy can sit on a shelf, but unless

it is actually implemented, it is otherwise meaningless. The provisions of the NIH Reporting Rule (2011) and the amount of NIH funding that medical schools receive, however, could explain a high level of motivation to comply with managing COI policies at an institutional level.

The findings concerning COI policy development and the effect on research placement by the pharmaceutical industry is challenged and limited to the extent that it is based off four interviews from administrators representing United States based 75 AAMC schools and may not apply across all institutions. Again, the overall nonengagement by academia to be involved with this study led to the number of interviews being reduced by just over half.

Recommendations

When looking at the entire body of literature with regard to COI issues in academia and the results from this study, a number of recommendations for further research can be made. First, replicating the interview portion of this study with additional topics added and administrated by the AAMC would be interesting. The nonengagement from academia to be involved in this study is not entirely known, and, therefore, conducting near replicated research through this particular association may produce higher levels of participation and provide more data rich information to analyze. Additional topics added within this study would include but not be limited to NIH reporting requirements, IRB processes, research contracting, and direct engagement and/or nonengagement with industry.

The implementation of the reporting requirements with regard to the PPSA of 2010 (Sunshine Act) only started to come online during the second half of 2014. Physician and institutional behavior with regard to having all transfers of money reported and available online may or may not have a compounding effect on interactions with industry moving forward and could be studied separately but should be examined as an additional variable for future COI studies. The Sunshine Act was mentioned several times during the interviews, but only in passing since interviewees saw no immediate impact to their institutions during the research timeline studied. Moving forward, incorporating this piece of legislation as a study variable should be considered.

The overall engagement and nonengagement between industry and academia should be examined further. McKinnon (2009) developed concepts around the future of public private partnerships and Kitsis (2011) called for a more collaborative approach to the entire concept with regard to COI issues. A qualitative study to more fully examine engagement and nonengagement between industry and academia is proposed as the results from this study suggest that a collaborative platform has not moved forward.

Implications

Positive Social Change

The capacity for medical academia and industry to produce life-saving and life-prolonging medications has important opportunities as well as profound responsibilities attached to it. Proper attempts to reduce potential conflicts of interest in medicine have largely addressed this responsibility. Unfortunately, the research presented here suggests

that some administrative and reporting requirements have stifled the efficiency of this platform. This relationship is further challenged by a nonengagement posture taken by academia. The research conducted here points for the need for medical academia to arrive at a philosophical spot where conflicts of interest in medicine are managed appropriately, but industry interactions are still possible for the benefit of treating patients and advancing medicine.

Recommendations for Practice

The findings from this study do not suggest that COI policies should be eliminated and the previous way in which academia and industry engage return. Rather, the current transparency requirements are good for all parties involved in that it establishes a more visible and purposed way in which these entities should interact. It is, however, concerning how nonengaged academia is with industry, unless research funding (and a financial benefit for the institution) is involved. When industry has limited opportunities to interact with academia, the ability to understand faculty expertise is limited. Additionally, industry representatives being able to provide valuable information and resources for the benefit of patients is diminished. Overall, this impacts the larger continuum of improving patient health. The following recommendations are provided to academia and industry:

1. Research placement is a competitive and time bound event. The FDA is requiring larger sample sizes in research, more diligent safety reporting, and longer duration of clinical trials. Given this, industry will engage with

academia or contract research organizations that have existing positive relationships, efficient contracting platforms, and a proven ability to conduct the research in a timely matter.

2. Perceived institutional expertise is not a precursor to research placement. As academia has distanced itself from industry, the ability to fully understand faculty and institutional expertise is becoming more unknown, and the opportunity to place research on this basis is diminishing. Institutions that can compliantly and transparently engage with industry for partnerships will be better equipped to leverage the expertise and talents of their faculty accordingly.
3. Industry needs to do a better job of articulating what it trying to accomplish, what it needs, and what it is looking for from the medical academic community. Part of the disconnect between industry and academia appears to be due to industry not being able to adequately articulate where it can be of value to medical academic institutions and the benefit to patients accordingly.
4. For the benefit of a more efficient research platform, academia needs to adjust to current changes in medicine, in research processes, and in disclosure requirements. Institutions that want to be competitive for securing industry research need to be prepared to make a number of infrastructure and processes changes. Efficiencies in NIH reporting requirements, more productive IRB processes, and investments in infrastructure are recommended.

Potential COI in Medical Academia

As some COI authors have argued (Breenan et al., 2006), any contact with industry creates an inherent COI. Institutions that believe this issue to be the case should be prepared to disengage with all research with industry. On the contrary, institutions that only engage with industry if research funding is involved have created their own COI issue. That is, the financial reward for research appears to trump any other meaningful engagement with industry. The reality of this dilemma should be reconciled to the middle. Medical academic institutions that engage with industry across a variety of platforms for the benefit of patient care, conduct well-controlled medical research, and do so in an open and transparent fashion appear more purposed than their counterparts that appear to only be motivated by research placement and the financial rewards of conducting that research.

Conclusion

The ability for an effective and efficient research platform for the testing and development of new medicines has historically depended on a productive partnership between academia and industry. COI policy development, while highly justified, appears to have helped produce a nonengaged relationship between these two entities. Institutions that can efficiently navigate NIH reporting requirements, streamline IRB processes, and more competitively posture themselves for research would seemed poised secure higher levels of research funding. The next iteration of COI in medicine concerns medical academic institutions' ability reconcile their approach in dealing with industry from

noninteractive to something that is closer to transparent and collaborative in nature. Research placement has become more competitive and the pharmaceutical industry has the option placing research with academia or contract research organizations. Given the historical successes of the previous partnership between industry and academia, medical academic centers that actively engage and collaborate with industry and are able to do so in an efficient and transparent manner would be poised to leverage their expertise and help advance new medication therapies for the benefit of humankind.

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Appendix A: Full Disclosure of Financial Interest

I have a significant financial interest and affiliation with the following company discussed in this dissertation:

Pfizer - Full time employment from July 2003 to current (April, 2015) as Therapeutic Specialty Representative. Standard educational assistance employee benefit of no more than $10,000 tuition reimbursement per year for continuing education.

Pfizer - 401(k) – Fully vested in retirement plan with no more than 20% of portfolio held as Pfizer stock and total account value of no more than $ 120,000

Pfizer Stock – Individual stock holdings of no more than $ 20,000

Appendix B: Email Letter to Medical Director of Academic Institution

To: Contact Name

From:

Subject: (First Request) - Research Survey – Request for Information

Walden IRB Approval Number: 02-24-14-0168299; Expiration: 02-25-2015

Dear Contact Name:

My name is Michael Maahs and I am a doctoral candidate at Walden University. I am conducting qualitative dissertation research on interaction and conflict of interest policies adopted by medical academic institutions and the potential effect on research funding placement by the pharmaceutical industry. Recent research funding reports indicate a slowdown of research placement at United States based medical academic institutions by the pharmaceutical industry during the last five to seven years. It has also been observed that many institutions have newly adopted or revised their previous interaction and conflict of interest policies with regard to contact and involvement with the pharmaceutical industry since the release of the 2009 Institution of Medicine's Report on Conflict of Interest. It is not known, however, if there is a relationship of policy development and the effect on research funding levels at the individual institution level. This qualitatively based research intends to examine the extent to which current conflict of interest policy development would be consistent with the recommendations provided in the 2009 IOM Report and the potential effect on research placement by the pharmaceutical industry. The 75 largest medical academic institutions that are engaged in medical research and are members of the American Association of Medical Colleges have been initially selected for study inclusion.

It is appropriate that I disclose that I work for Pfizer. This dissertation research is independent from my professional role at my company as I have no assigned responsibilities that deal with or interact with medical academic centers. This research project is my individual work and Pfizer has not provided research design assistance, writing, or editing. Furthermore, the outcomes from this dissertation have no bearing on my current career or job security with Pfizer.

Your time is important and I have kept the nature and depth of this initial survey as short and straightforward as possible. Information provided by you will be treated as confidential information: all results will be reported in aggregate.

The second data collection component to this study includes an interview to clarify and expand on initial information provided during the survey for those medical directors that are interested in being interviewed. For the purposes of scientific validity and for the betterment of medicine and society, please consider and indicate your interest in being involved in this portion of research project. Your assistance to help make this research as pertinent and accurate as possible is greatly appreciated.

Again, your assistance is greatly appreciated to better understand the slowdown of pharmaceutical research placement at United States based medical academic centers. If interested, institutions that volunteer to participate in this survey and interview will be provided the overall results from this study.

If you have any questions about this research, please contact me via phone at or email at. Again, thank you in advance for your assistance in allowing me to complete this research. Please fill out the attached survey and return via email.

Sincerely:

Michael K. Maahs
Doctoral Candidate, Public Policy and Administration – Health Services
Walden University

Appendix C: Online Survey

Medical Director Informed Consent and Survey on Interaction and Conflict of Interest Policies with Regard to Contact with the Pharmaceutical Industry

Informed Consent: You are invited to take part in a research study on conflict of interest policies adopted by medical academic institutions and the potential impact on research funding by the pharmaceutical industry. Participating in this survey is voluntary. The researcher is inviting medical directors from medical academic institutions to participate in this survey. This portion of the survey is part of a process called "informed consent" to allow you to understand this survey before deciding whether to participate. This study is being conducted by a researcher named Michael K. Maahs, who is a doctoral student at Walden University. Any questions or concerns about this study can be addressed to the researcher via email at or by telephone at. If you want to talk privately about your rights as a survey participant, you can call Dr. Leilani Endicott. She is the Walden University representative who can discuss this with you. Her phone number is 1-800-925-3368, extension 3121210, or email at irb@waldenu.edu. Walden University's approval number for this study is 02-24-14-016899 and it expires on 02-25-2015.

Purpose: To collect information about medical academic institution interaction and conflict of interest policies and the potential effect on research funding placement by the pharmaceutical industry from 2007 to current (2014)

Directions: Please answer each question as fully as possible. If particular information is currently available via institution website, please cut and paste the information accordingly. Any combination of free text, WordPerfect, Excel, or Adobe PDF software files are encouraged as the response media for this survey. Your responses and all information provided will be treated as confidential information: all results will be reported in aggregate. By volunteering to be a part of this survey, you can receive a copy of the results of the study if interested. At the end of the survey, please indicate if you would be willing to be a part of an interview to clarify survey responses and gather further information. Please submit all survey materials via email to

Interaction and Conflict of Interest Policies: Please provide institution interaction and/or conflict of interest policies pertaining to contact and dealings with the pharmaceutical industry that were in effect during 2007 with ongoing updates through current day (2014).

Research Funding Received by the Pharmaceutical Industry: Please report research funding received (if any) by your institution from the pharmaceutical industry expressed

in annual dollar amounts from 2007 through current day (2014). This information should be limited to research based activities and not associated with events like conference display fees, sponsorships, and/or advertising. Also, please report total research funding received (if any) by all sources from 2007 through current day (2014).

Interview: Please indicate if you are willing to be interviewed for this research study. The interview portion of this research is intended to take one hour and informed consent paperwork for the interview to be recorded will be provided/required. A typed transcript of the interview will be provided for your review and approval.
Interest In Interview Phase of Research: Yes____ No ____
Contact Information (only if yes):
Name:
Address:
Phone:
Email:

Copy of Final Research:
Individuals that provide data for this project can receive a final copy of the research if interested. Interest in final copy: Yes____ No____

Survey Return: Please submit all survey information via email to. Thank you for taking time to participate in this qualitative research study.

Appendix D: Interview Questions

Interview Questions

Question 1: Tell me a little bit about your current position with your institution? What was your function with your institution prior to 2009? Describe your involvement, if any, with regard to interaction and conflict of interest policies with the pharmaceutical industry during this timeframe? Post 2009 IOM Recommendations on Conflict of Interest through today, what has your function been with your institution? Please describe your involvement, if any, relative to interaction and conflict of interest policy development with the pharmaceutical industry during this timeframe?

Question 2: How familiar are you with the IOM 2009 Conflict of Interest Policy recommendations? What can you tell me about it? Do you think its creation was justified? What have been some of the implications of this report? How well has your institution implemented the recommended policies? With regard to current policy, what are some of the most important concerns or issues addressed when developing interaction and conflict of interest policies for your institution?

Question 3: How well does your institution's current policy addresses the concerns or issues described by the IOM Policy in 2009? Why?

Question 4: What changes has your institution made since the release of the IOM Policy in 2009? Did they go far enough? Why or why not? What future changes in current interaction and/or conflict of interest policy do you foresee for your institution? Please explain why.

Question 5: Please describe the nature of the relationship of your institution's medical research department with the pharmaceutical industry. Why do you think that is? What are some of the positive aspects of working with the pharmaceutical industry? Why? What are some of the negative aspects of working with the pharmaceutical industry? Why?

Question 6: Where there any institutional changes as a result of the 2009 IOM Policy? Where does the bulk of your research funding come from? How much of it is from the pharmaceutical industry? How do you think any changes your institution has made to interaction and conflict of interest policies have influenced funding from the pharmaceutical industry? Please elaborate. Other than interaction and conflict of interest policy development, did your institution have any circumstances that would have either positively or negatively affect research placement by the pharmaceutical industry? If yes, please identify and explain further.

Question 7: How would you describe any state or federal legislation or policy recommendation(s) that would have motivated your institution make any of the changes mentioned in question six?

Question 8: How does your institution monitor and enforce issues pertaining to conflict of interest? Generally speaking, how do you handle a conflict of interest issue when a faculty member is involved?

Question 9: Anything else? Please provide any other pertinent information with regard to interactions and conflict of interest policy and research funding placement that may not have been already captured in this survey.

Interview Follow-up: Is it okay to contact you for follow-up to clarify or follow-up any responses provided in this interview? A typed transcript of the interview will be provided to you for review and approval.

Appendix E: IRB Informed Consent Letter for Recording Interview

Consent Form for Recording Interview about
Conflict of Interest Policies Adopted by Medical Academic Institutions and the Potential Impact on Research Funding by the Pharmaceutical Industry

You are invited to take part in a research study on conflict of interest policies adopted by medical academic institutions and the potential impact on research funding by the pharmaceutical industry. The researcher is inviting administrators with decision making authority from institutions that perform medical research to be interviewed for the study. This form is part of a process called "informed consent" to allow you to understand this study before deciding whether to participate. This study is being conducted by a researcher named Michael K. Maahs, who is a doctoral student at Walden University.

Background Information:
In 2009, the IOM Report on Conflict of Interest called for medical academic institutions to adopt extensive conflict of interest policies with regard to healthcare professionals and interactions with the pharmaceutical and medical device industry. The purpose of this study is to examine the conflict of interest policies from 2007 to current (2014) adopted by medical academic institutions and the potential impact on research funding by the pharmaceutical industry.

Procedures:
If you agree to be in this study and corresponding interview, you will be asked to participate in a recorded one hour telephone interview. After the first interview, a follow-up interview may be required to clarify or expand on some the answers provided in the first interview. A typed transcript of the interview(s) will be provided to you for final review and approval.

Here are some sample questions: How familiar are you with the IOM 2009 Conflict of Interest Policy recommendations? What have been some of the implications of this report? How well has your institution implemented the recommended policies? Please describe the nature of the relationship of your institution's medical research department with the pharmaceutical industry. Why do you think that is? What are some of the positive aspects of working with the pharmaceutical industry? Why? What are some of the negative aspects of working with the pharmaceutical industry? Why? Where does the bulk of your research funding come from? How much of it is from the pharmaceutical industry? How do you think any changes your institution has made to interaction and conflict of interest policies have influenced funding from the pharmaceutical industry? Please elaborate. Other than interaction and conflict of interest policy development, did

your institution have any circumstances that would have either positively or negatively affect research placement by the pharmaceutical industry?

Voluntary Nature of the Study:
The interview for this study is voluntary. Everyone will respect your decision of whether or not you choose to be interviewed. If you decide to join the study, you can still change your mind during or after the interview. You may elect to have the interview stopped at any time and will have the option of final approval of your interview transcript.

Risks and Benefits of Being in the Study:
Being this type of study involves a commitment of your time and being asked to adequately represent the opinions and decision making process of your institution. Being in this study would not pose risk to your safety or wellbeing. The potential benefit to being involved in this study would be to better inform the medical community of the potential impact of conflict of interest policies on funded research by the pharmaceutical industry into medical academic institutions. If you have a crisis or become involved in a crisis during the interview, you can stop the interview at any time.

Payment:
This is a voluntary study and no form of payment or reimbursement in kind is provided or implied.

Privacy:
Any information you provide will be treated as confidential information. The researcher will not use your personal or institutional information for any purposes outside of scope of this research project. Also, the researcher will not include your name or anything else that could identify you or the institution you are representing. Interview recordings, transcripts, notes, and work product will be kept on a password protected USB thumb drive. Data will be kept for a period of at least 5 years, as required by the university.

Contacts and Questions:
You may ask any questions now or before the interview begins. If you have questions later, you may contact the researcher via email at or phone at. If you want to talk privately about your rights as a participant, you can call Dr. Leilani Endicott. She is the Walden University representative who can discuss this with you. Her phone number is 1-800-925-3368, extension 3121210, or via email at irb@waldenu.edu. Walden University's approval number for this study is 02-24-14-0168299 and it expires on 02-25-2015

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 replying to this email letter of consent with the words, “I consent”, I understand that I am agreeing to the terms described above.

Thank you for your time.

Michael K. Maahs
Doctoral Candidate, Public Policy and Administration – Health Services
Walden University

Appendix F: IRB Introductory Letter

To: IRB@waldenu.edu

From:

Subject: IRB Application for Michael K. Maahs

Dear Walden IRB:

My name is Michael Maahs and I am a doctoral candidate at Walden University. I am proposing qualitative dissertation research on interaction and conflict of interest policies adopted by medical academic institutions and the potential effect on research funding placement by the pharmaceutical industry. Recent research funding reports indicate a slowdown of research placement at United States based medical academic institutions by the pharmaceutical industry during the last five to seven years. It has also been observed that many institutions have newly adopted or revised their previous interaction and conflict of interest policies with regard to contact and involvement with the pharmaceutical industry since the release of the 2009 Institution of Medicine's Report on Conflict of Interest.

It is not known if there is a relationship of policy development and the effect on research funding levels at the individual institution level. This qualitatively based research intends to examine the extent to which current conflict of interest policy development would be consistent with the recommendations provided in the 2009 IOM Report and the potential impact on research placement by the pharmaceutical industry. The 75 medical academic institutions that are engaged in medical research and are members of the American Association of Medical Colleges have been initially selected for study inclusion and will be sent surveys in an attempt to gather this initial information.

The second data collection component of this study includes a voluntary institutional interview to clarify and expand on initial information provided from the survey to further understand the rationale and decision making process with regard to policy development and institutional perception on research placement. It is desired to have 10 institutions complete the interview phase of the research to then look for common and/or uncommon themes, associations, and associations on this research topic.

The attached IRB Application provides information along the entire range of important topics to include; further description of the research, potential risks and benefits, data integrity and confidentiality, potential conflicts of interest, data collection tools, description of the research participants, informed consent, checklists and electronic

signatures. I hope that you will find these items presented in good order and the entire IRB approval process will move forward in an efficient manner.

If you have any questions about my research and the submitted IRB application, please contact me via phone at. Again, thank you in advance for your assistance in allowing me to complete this research.

Sincerely:

Michael K. Maahs
Doctoral Candidate, Public Policy and Administration – Health Services
Walden University

Appendix G: Ethical Certificate

Certificate of Completion

The National Institutes of Health (NIH) Office of Extramural Research certifies that **Michael Maahs** successfully completed the NIH Web-based training course "Protecting Human Research Participants".

Date of completion: 12/16/2009

Certification Number: 352593

Appendix H: COI Policy Recommendation Coding Table

Instit.	Policy Recommenation									
	1	2	3	4	5	6	7	8	9	10
101	y	n-m	y	y	y	y-cme	y	y	n	n-m
102	y	n-m	y	y	y	y	y	y	y-ns	y
103	y	n-m	y	y	y	y-cme	y	y	y-ns	n-m
104	y	n-m	y	n-np	y	y-cme	n	y	y-ns	n
105	y	n-m	n-$	n-d	y	n-$	y	y	u	n-m
106	y	n-m	y	y	y	y-os	y	y	y-ns	n-m
107	y	n-m	y-txt	y	y	y-o/os	y	y	n	n-s
108	y	n-m	y	y	y	y	y	y	y-ns	n-m
109	y	n-m	y	y	y	y-cme	y	y	n-m	n-m
110	y	n-m	y	y	y	y-cme	y	y	y	n
111	y	n-m	y	n	y	y-o/os	y	y	u	n
112	y	n-m	y	y	y	y	y	n-m	n	n-m
113	y	n-m	y	y	y	y-hol	y	y	y-ns	n-m
114	y	n-m	y-txt	n	y	y	y	y	y-ns	n
115	y	n-m	y-txt	n	y	y-cme	y	y	y-ns	n

Key:	Points
y - yes	10
y-ns, yes- no samples allowed at all	10
y-cme, yes-CME allowed though	8
y-os, ys-off site only if sponsored by industry	8
y-txt, yes, only textbooks allowed	8
y-hol, yes, holiday snacks allowed	8
y-o/os, yes-on-site, off-site only if sponosored by industry	7
n-d, no-discouraged but not prohibited	6
n-m, no-managed	6
n-np, no non-promotional speaking only	5
n-s, no-ACCME standards mentioned	4
n-$, no -$5.00 per event, $75.00 limit per year per company	2
u-unknown	2
n - no	0

Appendix I: Preset Codes to Themes Tree

Topic: Function with institution prior to 2009 IOM Policy Report and current function with institution.

-Function:
--P1: Dean of Medical School and Vice President for Medical Affairs
--P2: Associate Dean for Regulatory Affairs
--P3, P5: Director, Conflict of Interest Office

-Time with Institution:
--P1,P5: 2005
--P2: 2006
--P3: 2009

Topic: Familiarity with 2009 IOM Policy Report, justification, and institutional policy changes made.

-Familiarity with IOM Report:
--P1, P2,P3,P5: Familiar
--P1, P2: AAMC Guidelines larger impact on policy
--P3, P5: AAMC Guidelines also an impact
--P1: Part of AAMC report on COI
--P2: Member of IOM
-Justification:
--P1,P3: Traditional financial ties and need for change
--P1,P5: Public trust issues
--P3: Evidence to suggest free gifts creates COI issue
--P3: Speaker bureaus one faculty tripled their salary while still maintaining full salary
--P5: IOM right on target with recommendations
-Policy Changes Made
--P1, P2, P3, P5: Speaker bureaus
--P1: Greater transparency in research
--P3: Eliminated free meals
--P3: Eliminated gifts
--P3: Eliminated consulting
--P3: Representative allowed access with appointment
--P5: Representatives not allowed access
--P5: Changed policies but still have to update again

Topic: Institution's current policy and how it addresses concerns from the 2009 IOM Policy report.

-P1,P5: Transparency: Needed to make changes with regard to public trust
-P1: Adherence: 90% Alignment – tie back to policy review
-P1: Adherence: Terminated two faculty that continued to speak for industry
-P2: Adherence: Pretty well, changed culture – tie back to policy review
-P5: Adherence: Disclosure and management of COI issues is key
-P5: Adherence: We are doing largely what the IOM asked us to do
-P3: Restrictive policy and negative impact on research funding

Topic: Describe current relationship with pharmaceutical industry.

-P1, P5: Encourage faculty to do research with industry.
-P3: Improving after down turn
-P3: Highly reduced interactions with industry
-P5: Sales representatives just are allowed in anymore
-P3: Opportunities to interact and collaborate for research are restricted

Topic: Positive aspects of working with the pharmaceutical industry.

-P1,P2,P3: make important medical discoveries
-P1,P2: industry partner needed to bring new therapies to market
-P2: new medications available to some patients that are still being studied

Topic: Negative aspects of working with the pharmaceutical industry.

-P1: Research Bias, Attempt to suppress research outcomes (2x)
-P2: Industry having too much a vested interest in research outcomes
-P3: Personal example of uneasy feeling at Advisory Board
-P5: Perception issues of being bought for research results

Topic: Medical research funding sources and how much of it is from the pharmaceutical industry.

-P1: $150 million a year NIH, $ 30 million year from industry, around 20%
-P2: $ 500 million a year total, $ 300 million NIH, range of $ 50-100 million from industry, around 10-20% from industry, but not entirely sure
-P3, P5: less than 10 % from industry

Topic: Changes in COI policy and impact on pharmaceutical funding placement.

-P1, P2,P5: Not really
-P3: Our COI Policies in conjunction with NIH led to downturn in research

-P2,P3,P5: NIH Rule
-P2: IRB approval process
-P2: Industry support is better reimbursed than NIH funding
-P5: NIH support dwindling creates financial issues for institutions

Topic: Other changes within institution and impact on pharmaceutical funding placement.

-P1: Research funding gone up as result of infrastructure, faculty, and efficiency investments
-P1: Research funding up as result of streamlined IRB process

Topic: State or federal legislation that has impacted COI policy.

-P1: Sunshine Act as motivator to change COI policy
-P2, P3: Sunshine Act as item of awareness
-P5: Sunshine Act has got10 a lot of at10tion, don't know real impact

Topic: COI Enforcement

-P1, P3: Monitoring tools
-P1, P2, P3: COI Committee
-P2, P5: COI Education
-P5, P2: COI Review Process
-P2, P5: Trust Model
-P2,P3,P5: COI Disclosures
-P1: Terminated to two faculty that continued to speak for industry
-P1, P2: Broad implications across all forms of funding, foundations, sponsors, government
-P2, P3: COI issues more complex
-P3: COI issues and "retail based" cash paid therapies

Appendix J: Emergent Codes to Themes Tree

Topic: Negative Perception of Pharmaceutical Industry

-P1: Industry research suppression (2x)
-P5: Medical students didn't want to be tainted by industry
-P3: Consulting, negative experience of input for marketing
-P1,P2,P3: Financial ties from speaking creating COI issues
-P2: Faculty more cautious when speaking to industry

Topic: Positive Perception of Pharmaceutical Industry

-P1: Industry has done reasonable job of repairing image from past

Topic: Role of Academia in Pharmaceutical Research
-P1, P2, P3: Expertise
-P1, P2: Industry is vehicle to get medicine to market
-P1: Phase I and II trials
-P2: Phase I, II, and III trials
-P3: Partner for investigator initiated research

Topic: Speaker Bureaus

-P1,P2,P3: Financial ties from speaking bureau creating COI issues
-P1,P2, P3: Removing faculty from appearance as "industry spokesperson"
-P1: Two faculty terminated for participation in speaker bureau
-P1: Faculty making over $100k per year in speaker bureau
-P3: Faculty speaking for 10 companies and tripling academic salary

Topic: Institution and Individual Cultural Shift with Regard to Industry Contact

P1: Shift in practice about speaker bureaus
P2: Faculty sensitized about contact with industry and COI issues
P2,P5: Culture changes about individual behavior
P2,P3: Faculty proactive on disclosure/approval with regard to COI issues
P5: Faculty engaged in what IOM wants us to be doing with regard to COI issues
P5: Medical student not wanting to be tainted by industry

Topic: Better Research

-P1: Better designed research, larger clinical trials, better safety monitoring

-P3: Collaborate with industry to conduct investigator initiated research

Topic: Collaboration

-P5: Industry and academic partnerships are a positive thing if managed correctly

Topic: NIH Reporting Rules and Impact on Research Funding

-P2: Review all applications going to public health funding for compliance
-P2,P3: NIH rule required investment for disclosure, management, and reporting
-P3, P2: NIH rule more dramatically impacted funding by industry than COI policy
-P4: NIH rule impacted process for research as whole

Topic: Institutional Challenges with IRB Efficiency

P1: Streamline IRB process
P2: Industry not impressed by length of time IRB process
P3: Making attempt to streamline IRB process