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## Truth or Consequences—Academic Physicians’ Perspective in the Management of Commercially-influenced Conflicts of Interest

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Truth or Consequences—  
Academic Physicians' Perspective  
in the Management of Commercially-influenced Conflicts of Interest

A Dissertation

Submitted to the Graduate Faculty of the  
University of New Orleans  
in partial fulfillment of the  
requirements for the degree of

Doctor of Philosophy  
in  
Educational Administration  
Higher Education

by

Melinda Lawrie Epperson

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*In memoriam,  
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LIST OF ORGANIZATIONAL ACRONYMS

ACRONYM	ORGANIZATION, CODE, ACT, or INITIATIVE
ACCME	Accreditation Council of Continuing Medical Education
ACGME	Accreditation Council for Graduate Medical Education
AdvaMed Code	Advanced Medical Technology Association
Alliance for CME	Alliance for Continuing Medical Education
AAUP	American Association of University Professors
AMA	American Medical Association
AMA CEJA	AMA Council on Ethical and Judicial Affairs
AMSA	American Medical Student Association
AAMC	Association of American Medical Colleges
AAU	Association of American Universities
FSMB	Federation of State Medical Boards
FDA	U. S. DHHS Food and Drug Administration
IOM	Institute of Medicine of the National Academies of Science
LCME	Liaison Committee on Medical Education
NFEI	National Faculty Education Initiative
NPR	National Public Radio
OIG	U. S. DHHS Office of Inspector General
PPACA	Patient Protection and Affordable Care Act
PhRMA Code	Pharmaceutical Research and Manufacturers of America
SACME	Society for Academic Continuing Medical Education
U.S. DHHS	U. S. Department of Health and Human Services

## ABSTRACT

Since the 1990s, academic physicians have been subjected to increased requirements for disclosure in their roles as educators and researchers and for conflict of interest (COI) resolution in their financial relationships with pharmaceutical, medical device, and biotech companies, collectively referred to as industry. The requirements are the result of the convergence of federal regulations, accreditation guidelines, professional and industry codes of ethics and conduct, and institutional policies. The disclosure and COI resolution requirements are managed and resolved by a review of forms and compliance with relevant guidance documents and policies. In the context of this environmental oversight, the purpose of the qualitative study was to explore physicians' perspectives of how they manage and resolve conflicts of interest in their academic roles of teaching, research, and patient care.

Minimal evidence-based research exists in the literature from the physician's viewpoint. The grounded theory study examined the research question by using an issue-contingent, ethical decision-making theoretical framework from the management literature. The data were collected using a general interview guide that consisted of three sections – general questions regarding purpose and demographics, discussion of three case scenarios (teaching, research, and clinical practice), and finally, general concluding questions to assess the environment that is indicative of the context of the study.

The theory emerged from the interview data as a refined theory representing a four-step ethical decision-making process with emphasis on the characteristics of physicians as moral agents. The study's findings further indicated that bias is a significant concern. The study identified reasons physicians enter into financial relationships with industry, the risks and benefits associated with those relationships, methods for avoiding bias, and the need for healthy academic-industry collaborative research.

Key words: Ethics, ethical decision-making, bias, influence, conflict of interest, disclosure, academic medicine, industry, medical research, qualitative research, grounded theory.

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**Chapter I**

**Introduction**

**Background**

For over twenty years, there has been an ever-increasing public concern of pharmaceutical and medical device companies influencing physicians' prescribing power and its effect on patient care and safety (Association of American Medical Colleges, 2007, 2008, 2010; American Medical Association, 2011; U. S. Food and Drug Administration Office of Policy, 1997; U. S. Department of Health and Human Services, Office of Inspector General, 2003). This concern is evidenced by a growing body of literature, ethical and professional codes, regulations, federal investigations, opinions, changes in accreditation guidelines, more stringent disclosure processes, heightened institutional compliance requirements, policies, and enactment of federal and state patient protection legislation and physician sunshine laws. Direction through these oversight mechanisms is intended to guide physicians through a robust disclosure process and, more importantly, manage and resolve without bias, any perceived or potential conflicts of interest (COIs) from financial relationships with pharmaceutical or medical device companies and biotech firms, collectively referred to as industry.

A physician's financial relationship with industry may consist of being a consultant, stockholder, member of a speakers' bureau, research grantee, patent holder, board of directors' presence, or employee as well as other arrangements that may create a potential COI.

Additionally, the physician's financial relationship extends to immediate family members (Accreditation Council for Continuing Medical Education, 2004; U. S. FDA, 1997; U. S. DHHS, OIG, 2003). Contributing a legislatively-driven transparency to the above oversight and governing systems is the recent Physician Payment Sunshine Act (H.R. 3590, Section 6002) which is a provision under the Patient Protection and Affordable Care Act (PPACA, Pub. L. 111-148, 2010). The Sunshine Act went into effect March 23, 2010 and requires pharmaceutical, medical device, and biotech firms to post on their websites (a) all funding recipients, institutional or individual, (b) the purpose or nature of the funding, e.g. research, support of continuing medical education (CME) activities, or physicians in any one or more of the roles listed above, and (c) the value of the financial relationship. The need for improved transparency, beyond the self-reported disclosure requirement, is a result of congressional investigations into an environment that has experienced significantly increased oversight and scrutiny.

### **Statement of the Problem**

In the midst of this complex and scrutinized environment is the physician or institution that has financial relationships with industry creating potential conflicts of interest (COI). The following cases and examples epitomize the concern over physicians' relationships with industry and recognition of the issue affecting individuals, institutions, and specialty associations. The first example involves the case of a Baylor College of Medicine faculty member who allowed his name to be used on a ghostwritten article about a GlaxoSmithKline's diabetic drug. A ghostwritten article is generally written by the company that a key opinion leader (KOL) presents to a journal as his or her own (Basken, 2010; Leo & Lacasse, 2010). Another example involved Merck and Schering-Plough's payment of \$400,000 distributed among fourteen prominent

university-affiliated physicians (KOLs) to promote the use of their cholesterol-lowering drug over lesser expensive alternatives (Basken, 2009b).

In 2010, several physicians in Stanford University's School of Medicine received payment for being on speakers' bureaus for pharmaceutical companies, violating Stanford's very strict industry policy that bans certain interactions with industry including free lunches, gifts, and giving promotional presentations on industry's behalf (Mangan, 2010). Emory University's psychiatry department experienced two incidents of faculty's inappropriate involvement with industry that created significant conflicts-of-interest, both with GlaxoSmithKline (Basken, 2009a). In one incident, the faculty member was receiving payment from the company while conducting a federally-funded study on the use of antidepressants in pregnant women; GlaxoSmithKline manufactures antidepressant drugs. The second incident was another faculty's failure to disclose to the university over \$800,000 that he had received from GlaxoSmithKline over seven years. As a result, Emory updated its institutional COI policy to ban industry compensation and other forms of industry interaction. In 2007, a physician received an unsolicited \$10,000 payment for the accompanying 'consulting' agreement that required his commitment to prescribe Schering-Plough's drugs (Harris, 2004).

Another example that may also have posed a threat to academic freedom involved a University of California Berkeley faculty member's research finding of the negative effects of a pesticide. The company that funded the University of California at Berkeley study, Ecorisk, attempted to influence the research outcome that the company "paid for" (Blumenstyk, 2003). These case examples involving payments for ghostwriting, prescribing power, speakers bureaus, and skewed research results are only a sample of many incidences of inappropriate financial relationships with industry and illustrate evidence of reciprocity, ingratiation, industry-

influenced control of decisions made by physicians who are considered KOLs in their specialties, and the potential lack of independence of thought and expertise in their decisions through, in some cases, failure to disclose.

According to various stakeholders, there has been an increasing need to resolve COIs in a manner that is commercially-unbiased, independent, and free from the commercial influence of pharmaceutical, medical device, or biotech companies. The current resolution process is determined by organizations or agencies that are responsible for the management of the disclosure and COI resolution process. As the literature review and environmental scanning through documentation suggests, there are many institutional industry and COI policies, federal regulations, accreditation guidelines and standards, professional recommendations, industry voluntary codes of ethics and professionalism that provide, for the most part, concrete rules, regulations, and guidance in managing and resolving COIs (ACCME, 2004; U. S. FDA, 1997; U. S. DHHS, OIG, 2003).

Unlike the codes of behavior issued by the organizations referenced above and others, Jones' (1991) decision-making model addresses the dependent nature of an issue on the decision process by viewing it through a lens of the six characteristics of moral intensity that are presented and discussed in chapter two. Moral intensity is then applied to the four sequential stages of making an ethical decision: (1) recognizing the moral issue, (2) making a moral judgment, (3) establishing moral intent, and (4) engaging in moral behavior based on Rest's 1986 model. Jones' (1991) model provides the missing component in independent, unbiased decisions by focusing on the moral aspect of the decision made by an individual who, in this study, is the academic physician involved in teaching, research, and patient care. Additionally, his model establishes the link between an individual's ethics and actions by determining the correct thing to



do within a situation, following through by acting upon one's ethical assessment without influence of environmental factors such as those previously stated, and seeking approval by oneself and/or from peers (Jones & Ryan, 1997).

### **Research Gap**

While there is a substantial number of mechanisms offered in the resolution of COIs as represented above, the literature suggests that there is a gap in the literature and research regarding an individual perspective of making an ethical decision through identifying and resolving a COI as a moral issue (AAMC, 2010; Lo & Field, 2009). Therefore, for the purpose of the study, the focus was on a process, and more specifically the academic physician's ethical decision-making process, as the unit of analysis with individual physician interviews as one data source. The study explored their approaches to and moral considerations in making ethical decisions as well as perceived COI implications with respect to their faculty roles of teaching, research, and patient care.

In any of the above-mentioned primary roles, academic physicians' financial relationship could influence a decision that affects their interaction with students, research subjects, the general population, and patients. The following hypothetical examples demonstrate the potential commercial influence and bias in each of the three roles. A faculty member may teach an equipment-based simulation skills course while owning stock in an equipment company known as Company Alpha. The pieces of equipment used in the course were from Company Alpha, Company Beta, and Company Delta. Throughout the course, the faculty member favored Company Alpha's equipment and features over the other two companies although similar. The students, as they progressed through their medical student education curriculum into residency

and then into private practice could act upon the faculty member's influence while potentially increasing the value of Company Alpha's stock. The students, now in private practice, may also not be giving their patients the benefit of determining the best equipment for their treatments.

In a research scenario, a faculty member could be the principal investigator (PI) for a diabetes research study funded by Company Epsilon, a pharmaceutical company that specializes in drugs for the treatment of diabetes. The faculty member, while conducting industry-funded research, is also on the speakers' bureau for and a consultant to Company Epsilon for which the faculty member receives financial compensation. Although the study is progressing in an unfavorable manner for Company Epsilon, the faculty member may feel obligated to the company due to the existing and generous financial relationships. Consequently, the faculty member may also feel obligated to manipulate the data in the company's favor to the possible detriment of the study participants and subsequently to the patient population-at-large.

In a third and final scenario, faculty members in an academic medical center also see patients to fulfill their clinical responsibilities. Using the financial relationships of consultant and speakers bureau in the diabetes research example above, the generous financial compensation of Company Epsilon could influence the prescribing power of faculty members to favor Company Epsilon's drug over another company whose drug may be the better choice in treating patients with certain diabetic conditions.

### **Moral Intensity, Ethics, and Academic Freedom**

As expressed by the three examples, there are two factors that may be in conflict regarding their influence on ethical decisions – the moral intensity of the issue and academic freedom. The moral intensity of the issue is represented by the teacher's biased equipment

preference, the researcher's desire to manipulate data in a manner favorable to the company, and the clinician's compromised prescribing power. Conversely, academic freedom which is intended to protect faculty autonomy, ensure integrity, serve the public interest, contribute to the public good, and is "a particular kind of liberty in a moral order" (Ryan, 1949) may be compromised in favor of the faculty members' financial gain (AAUP, 1940; Jones, 1991; Lieberwitz, 2005; Livingstone, 1974; Mangan, 1999; Rochford, 2003; Rosovsky, 1990; Ryan, 1949; Shuger, 1990).

In addition to the moral intensity and academic freedom concerns, the internal and external forces' effect on an institution and its faculty contribute to the context of the study. Among these forces that are discussed in chapter two and that were explored in my 2005 qualitative pilot study are the consequences of the commercialization of higher education, the implementation of a decentralized responsibility center model, university-industry relationships, and the need for external funding (Bok, 2003; Whalen, 1991).

## **Environmental and Organizational Change**

### **Pilot Study Overview**

The purpose of the qualitative pilot study was to identify and explore the effect of commercialization on the university departmental level. The specific emphasis was on continuing medical education (CME) departments in schools of medicine or academic medical centers within a decentralized organizational structure. Furthermore, the study examined through audio-recorded individual and focus group interviews how the various regulatory demands infused control on CME in a commercialized environment and how CME negotiated a

balance of the fiscal need for commercial involvement with the university's decentralized structure.

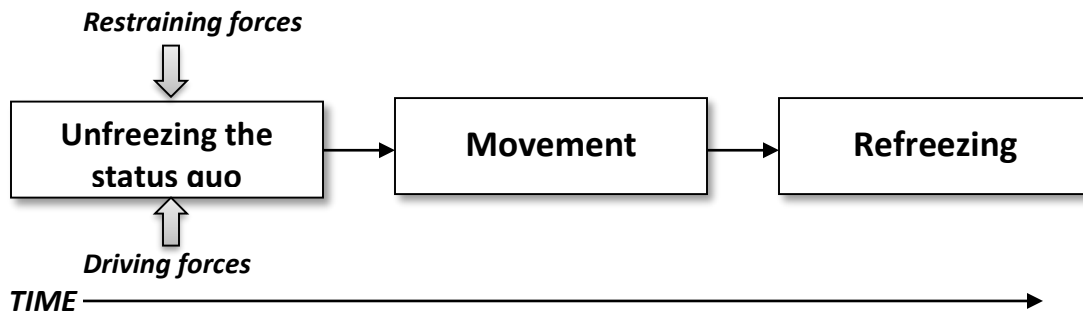
The literature review for the study revealed that commercial interests, partnerships, and influences have had an increasingly strong presence in higher education institutions since the 1980s (Bok, 2003). This trend had increased the need for external funding to replace diminishing internal and governmental sources of funding. While some post-secondary institutions were emphasizing departmental fiscal accountability through a decentralized, "every-tub-on-its-own-bottom" structure; internal stakeholders, including continuing medical education (CME) staff, were learning how to navigate a changing environment (Bok, 2003; Duderstadt & Womack, 2003; Robbins, 2003).

Bok (2003), Campbell (1997), and Stilwell (2003) identified underlying themes involved in the process and results of change. While the focus of the study was not on change itself; Bok, Campbell, and Stilwell recognized the undercurrent of change embedded in the trend of commercialization. Therefore, it was important to understand the construct of change motivating the study. The forces and results of environmental and organizational change were best exemplified by Kurt Lewin's Three-Step Change Model approach (Robbins, 2003).

Lewin's model consists of three steps – (1) unfreezing the status quo, (2) movement to a new state, and (3) refreezing the new status to make it permanent. The unfreezing step is necessary due to pressures which may occur by increasing driving forces (motivators) which direct behavior away from the status quo, by decreasing restraining forces (constraints) that hinder movement from the status quo, or by a combination of the two. The movement phase

may appear as failing and not visible since the constraining voices are more vocal. The refreezing phase provides stabilization and accomplishment.

Figure 1: Kurt Lewin's Three-Step Change Model



Source: Robbins, S. P. (2003). *Organizational behavior* (10<sup>th</sup> ed.). Upper Saddle River, NJ: Prentice-Hall.

Definitions in Lewin's Model:

- Unfreezing – Change efforts to overcome the pressures of both individual resistance and group conformity.
- Refreezing – Stabilizing a change intervention by balancing driving and restraining forces.
- Driving Forces – Forces that direct behavior away from the *status quo*
- Restraining Forces – Forces that hinder movement from the existing equilibrium.

In the context of Lewin's resistant forces, the three steps of his model were defined for the purpose of the pilot study as follows –

- Step 1: Unfreezing the status quo – (a) Ratification of the new ACCME Standards of Commercial Support on September 28, 2004 establishing greater distance and control between industry and CME; (b) change to a decentralized university structure dictating a cost-recovery fiscal climate.

- Step 2: Movement to a new state – (a) Preparation for full implementation of the new Standards by May 1, 2005 which required new policies and procedures for monitoring CME-industry relationships in addition to mechanisms for resolving conflicts of interest in the environment; and (b) developing strategic plans for seeking external funding for educational activities from the same industry relationships.
- Step 3: Refreezing the new change to make it permanent – (a) Implementation of new Standards with accomplished goals established in the Step 2 movement; (b) balance of and compliance with federal, institutional, and accreditation regulations; and (c) adjustment to a cost-recovery structure with no or significantly decreased institutional support (Robbins, 2003).

Lewin's approach is a force-field analysis and categorizes resistant forces as technical (technology, structure, and organizational interaction), political (power, money, opportunities, and recognition), and cultural (values, norms, biases, and underlying organizational assumptions) (Robbins, 2003). The three categories of resistant forces were respectively represented by the decentralized university structure as technical resistant forces, the need for funding sources and university-industry collaborations as political resistant forces, and the preservation of the traditional culture and core values of higher education as cultural resistant forces. The driving forces or motivators to direct behavior away from the status quo (Step #1 in Lewin's model) were represented by increased federal regulations and resulting policies, and the need for funding precipitated by a trend towards a decentralized structure.

As the review of current literature and discussion of the change framework reflected, the effects of commercialization on continuing medical education were complex. The environment

was changing as demonstrated through Kurt Lewin's three-step model of change (Robbins, 2003). Lewin's change model confirmed the volatility of CME and the effects it was experiencing as commercialization and decentralized institutional structures continued to position CME between a 'rock and a hard place.'

The literature review examined three aspects of the study: (1) continuing medical education (CME) – history and regulatory environment, (2) commercial influence and funding issues, and (3) context of higher education commercialization. Universities requiring CME departments to be self-supporting coupled with a more restrictive, regulatory external environment could impact how and if CME departments were able to survive.

### **Pilot Study Findings**

The research participants in the individual interviews and focus group interviews provided experiential, perceptive, and constructive commentary on the issue of commercialization and its interaction with a decentralized university structure. Each of the interviewees and focus group participants contributed perspectives that were reflective of their professional backgrounds which added depth to the findings.

The findings from the pilot study, in which CME was the unit of analysis, confirmed that the convergence of a decentralized institutional structure and the effects of commercialization increased the need for funding for CME programs and their activities. It was supported by data over a four-year period indicating a trend of increased commercial funding from 34% in 1998 to 60% in 2002 (Canadian Medical Association Journal, 2004; Croasdale, 2004; Schaffer, 2000).

Two themes emerged from the interviews and focus group. The first theme in the findings addressed the effect of commercialization on university-industry relationships and

relationship building. It demonstrated that, as the structure of universities has become more corporate, they have promoted establishing external partnerships with industry to supplement departmental budgets.

The second theme acknowledged a conflict between ethics and fiscal accountability. Because fiscal accountability is fundamental in a decentralized university structure, CME departments depend upon external funding sources for financial stability. The conflict occurs between the CME departmental need for securing funding and its ethical responsibility to separate the management of the funds from the potential influence on educational content by the funding source. In essence and as stipulated by the ACCME® Standards for Commercial Support; even though commercial interests have donated funding for a CME activity as a conference grant, they are not allowed to participate in the development or review of content or in the selection of speakers with the intent of promoting companies or their products. Influence and promotion cannot be conditions of grants.

The research participants expressed concerns over the effects and risks of the funding environment on relationships between physicians and commercial interests and between ACCME-accredited providers and commercial interests. These effects and risks were confirmed in the literature and were reflected in terms of commercial influence on physician behavior, research integrity, professional education of physicians and other healthcare professional, ethics, professionalism, and bias (Bok, 2003; Harrison, 2003; Relman, 2001). Participants appreciated the regulatory safeguards the agencies have put in place because, as one commented, "...it levels the playing field." However, with the need for external funding on the increase, it creates a delicate balance in determining how to build relationships free of bias, influence, and control and in developing a collaborative environment for the common good and for the benefit of the patient



population (Bok, 2003; Harris, 2004; Harrison; 2003; Hosansky, 2003b; Pelletier, 2004; Wilson, 2003).

Representative of the context of the study, the pilot study findings supported the environment in which the study was conducted. The findings also contributed to the focus of the study which was to investigate the process of how academic physicians make ethical decisions in their roles as teachers, researchers, and clinicians without the influence of their financial relationships with industry, i.e. “no strings attached,” or through their avoidance of financial relationships.

### **Purpose of the Study**

The purpose of this grounded theory study was to identify and investigate how physicians manage and resolve their perceived conflicts of interest (COI) in their roles as teachers, researchers, and clinicians in a changing environment of individual financial relationships with industry as well as university-industry relationships. The purpose was also to explore the process of ethical decision-making in the management and resolution of conflicts of interest, the potential moral intensity of the issue at the heart of the conflict, and the role of faculty, as moral agents, in the process.

### **Research Questions**

The study examined the following research question – How do physicians as academicians manage or resolve potential conflicts of interest in their roles as teachers, researchers, and clinicians?

Secondarily, the study examined:

- Factors that may influence ethical, commercially-unbiased academic decisions;
- Characteristics of ethical, evidence-based decisions v. commercially-influenced decisions; and
- Assessments of how relationships with industry may threaten academic freedom in ethical decision-making.

### **Significance**

The task force on clinical decision-making (AAMC, 2010) and the Institute of Medicine (Lo & Field, 2009) noted that there is a paucity of evidence-based COI research in the body of literature, including policy and systematic studies, thereby contributing to the significance of the study. The literature and research gap appeared to exist as it related to how physicians themselves, as moral agents, resolve a conflict of interest by making an ethical decision about a moral issue (Jones, 1991; Lo & Field, 2009).

Conflicts of interest are currently managed and resolved through questionnaires, surveys, and third-party evaluations, which have been created by regulators, accreditation bodies, and others who are charged with similar documentation responsibilities. The data indicating various levels of bias and influence in physicians' decisions are presented by those organizations that represent a top-down, summative view of the environment. Furthermore, the environment continues to be increasingly scrutinized by regulators, Congress, and professional organizations. The environment is also complex with numerous viewpoints and interpretations. Therefore, to minimize ambiguity of meaning, the following definitions are offered to provide clarity.

## Definitions

These definitions contribute to an understanding of concepts that are presented in discussion or explanations:

1. Academic Freedom – the custom, practice, and ideal, by which faculties may best flourish in their work as teachers and researchers; the liberty to speak, freely without persecution, in one way rather than in another, in the open and without fear or coercion; not an excuse for avoiding moral responsibility or moral debate and... a particular kind of liberty in a moral order. It is essential to researchers for the advancement of truth, to teachers for freedom in classroom discussions while avoiding controversial topics unrelated to the subject matter, and to students for freedom in learning. Academic priorities should not be influence by external interests without reviewing the consequences and consideration of the faculty (AAUP, 1940; AAUP, 1990; Kaplan & Lee, 1995; Ryan, 1949; Shuger, 1990).
2. Commercial support – financial, or in-kind, contributions given by a commercial interest, which is used to pay all or part of the costs of a continuing medical education (CME) activity or in support of research studies (ACCME, 2004; FDA, 1997).
3. (a) Conflict of interest – financial or economic issues that stem from use of funds, inappropriate influence, and the ownership of patents and licensing (Campbell, 1997).  
(b) Conflict of interest – circumstances that create a conflict of interest when an individual has an opportunity to affect CME content about products or services of a commercial interest with which he/she has a financial relationship (ACCME, 2004)  
*Updated definition* – “The ACCME considers financial relationships to create conflicts of interest in CME when individuals have both a financial relationship with a commercial

interest *and* the opportunity to affect the content of CME about the products or services of that commercial interest. The potential for maintaining or increasing the value of the financial relationship with the commercial interest creates an incentive to influence the content of the CME—an incentive to insert commercial bias” (ACCME, January 31, 2012).

(c) Conflict of interest – (FDA, 463F, 2d 600, 602)...legally, a situation in which regard for one duty leads to disregard of another (Kurt, 1990, p.6)

(d) Conflict of interest – (Institute of Medicine-IOM) “a conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest” (Lo & Field, 2009, p.46)

4. Decentralized Responsibility Center Model (RCM) – an organizational entity directly involved in accomplishing the mission of the university or in providing support that enables mission accomplishment; primary organizational unit in an RCM budgeting system that functions in a decentralized operational and financial decision-making environment (Whalen, 1991). An example of a university setting would be one of self-sufficient or cost-recovery departments that are responsible for all direct and indirect costs associated with their operating budgets and that are allowed to keep surplus revenues.
5. Ethical decision – a decision that is both legal and morally acceptable to the larger community (Jones, 1991, p. 367)
6. “Every tub on its own bottom” – Expression that originated at Harvard University. The ‘tub’ is an academic unit of a college or university and the ‘bottom’ refers to each unit

being responsible for its own bottom line including all costs it produces and all revenue it generates (Dubeck, 1997; Whalen, 1991).

7. Faculty – physicians in academic medicine whose academic roles include teaching, research, and patient care.
8. Financial Relationship – generally, it refers to those relationships in which the individual benefits financially, e.g. by receiving a salary, royalty, intellectual property rights from industry; is a consultant to or on a speakers' bureau for industry; has stock or stock options; or has a presence on a board or advisory panel. This also extends to the individual's spouse or partner and is applicable within the previous twelve months (ACCME, 2004; FDA, 1997).
9. Industry – pharmaceutical, medical device, or biotech companies or firms.
10. Moral agent – person who makes a moral decision, even though he/she may not recognize that moral issues are at stake (Jones, 1991, p. 367).
11. Moral issue – an issue central to the action or decision which must have consequences for others and must involve choice, i.e. volition on the part of the decision maker (Jones, 1991, p. 367).

Among the definitions above are four variations on what defines a conflict of interest (COI). Conflicts of interest exist in virtually all professions and organizations both of which provide policy and procedural guidance in determining what circumstances or external relationships require disclosure and how individuals and organizations may resolve potential COIs that result from disclosure. In conducting research for this study through review of the literature and face-to-face interviews, I identified fundamental, core characteristics of a COI that

could be relevant to all disciplines, not just medicine. A conflict-of-interest that stems from a financial relationship with an external entity with a vested interest in a shared goal may:

- Cloud an individual's professional judgment, objectivity, and behavior;
- Suggest the presence of undue bias and influence;
- Result in harmful consequences; and
- Require an ethical, moral resolution process.

The definition of a conflict of interest (COI) can be as narrow or as broad as circumstances or the environment dictates; but through my professional experience and research, I construed that these characteristics capture the essence of what constitutes a COI and, as such, warranted a thoughtful, qualitative study to further explore the COI resolution process. The other defined constructs or components given above represent factors that can influence faculty and institutions which may include commercial support, a decentralized structure, the 'tub' metaphor, and industry. The remaining definitions of academic freedom, ethical decision, moral agent, and moral issue place an observable focus on the individual faculty member in his or her decision-making role.

### **Overview of Methodology**

As discussed in chapter three, I conducted the study using a qualitative, grounded theory approach which Strauss & Corbin (1998) define as an existing or emerging theory that is grounded in the participants' perspectives and observations and could provide insight, enhance understanding, or generate action. The purpose of the study was to examine the *process* by which academic physicians, as moral agents, in their roles as teachers, researchers, and clinicians, may resolve and manage conflicts of interest which may result from their financial relationships with industry. Therefore, Strauss & Corbin's definition of grounded theory

confirmed that perspectives of physicians as interview participants were essential to studying an ethical decision-making process which is represented by the theoretical model and validated the use of a grounded theory methodology for the study.

The study design incorporated purposeful sampling of ten academic physicians from two academic medical centers. In order to collect rich, descriptive data for analysis, the interviewees should have participated or currently were participating in one or more financial relationships with industry. The interview protocol (Appendix I) included questions that collected demographic information to verify the academic physician profile of the de-identified research participants. Secondly, the interview participants responded to a set of questions that were based on the characteristics of moral intensity in Jones' (1991) issue-contingent ethical decision-making model and were addressed in the context of three case scenarios. Each of the case scenarios represented one of the three academic medicine roles of teaching, research, and patient care. Finally, the concluding general questions collected the participants' current viewpoints of the environment. The interviewees assessed reasons for entering into financial relationships with industry, benefits and risks, obstacles or barriers, methods of avoiding bias and conflicts of interest, the Sunshine Act effect, and factors that may influence ethical, unbiased decisions.

I applied an open coding process and constant comparison of interview data (Creswell, 2009) from which the codes evolved into nine categories (honesty, morality, human nature, bias, objectivity, proximity, volition, beliefs and actions, and decisions) and three core categories of morality, bias, and familiarity. Additionally, nine characteristics of a moral agent emerged in the refined theory.

## **Limitations**

I took precautions to minimize risks by bracketing my beliefs and opinions and allowing the voices of the participants to be heard in their own words reflecting an “insider’s” perspective or what the participants believe is true. Individuals also tend to act upon their beliefs for which there can be consequences. This philosophy also reinforces the elements of the theoretical framework (Creswell, 1998).

An additional limitation for the study evolved around the use of theoretical sampling, a purposeful sampling strategy. By using theoretical sampling, the number of interviews, ten out of a possible twenty, was conceivably small. The original goal was to conduct between twelve and twenty as long as saturation was accomplished. Saturation occurs when no new or relevant data or theoretical insights seem to emerge or add to the understanding and validation of categories (Charmaz, 2006; Corbin & Strauss, 2008; Creswell, 1998; Strauss & Corbin, 1998). The data collected from conducting ten interviews suggested that saturation was achieved. A few of the remaining ten did not respond, and others indicated that their schedules were such that they were unable to participate but were interested in the study. This was an anticipated response since physicians maintain very busy schedules in their concurrent roles of teaching, research, patient care, and sometimes the added responsibility of institutional administration. If saturation had not been reached, I would have requested a second set of interviews at each of the two institutions (Creswell, 1998; Strauss & Corbin, 1998).

## **Organization of the Dissertation**

Chapter one presents an overview of the study, providing background and rationale for conducting the study, a brief look at the literature that informed the study, a summary of the pilot



study that contributed to the context of the study, the research questions that were explored, disclosure of my limitations, and an overview of the methodology. Chapter two presents an in-depth review and synthesis of the bodies of literature in the fields of higher education, organization, and management that are pertinent to the study topic. The literature in chapter two also submits a current view of the environment, external forces and internal pressures that institutions are encountering in their navigation of the environment, the influence of historical principles that inform academic decision-making and avoidance or resolution of conflicts of interest, and finally, a discussion of the theoretical framework, an issue-contingent ethical decision-making model that provided a lens through which the reader may view the study and its findings.

Chapter three discusses the grounded theory methodology by which the study was conducted and introduces the rationale for a qualitative design by restating the purpose of the study and the research questions. The rationale justifies a constructivist, grounded theory methodology and the elimination of other qualitative methods. I present my role as the research instrument by describing my academic career, background and knowledge and by disclosing my assumptions and biases. Chapter three provides descriptions of the two institutions of higher education that were the settings for the study and outlines the research plan and process.

The research plan details the choice of purposeful sampling, participant selection, gaining institutional access, data collection, and data analysis. The data collection section describes the rationale for a general interview guide method, and the section on data analysis discusses the procedures for coding and conclusion drawing. Lastly, chapter three describes the importance of establishing trustworthiness of the study by addressing elements of credibility, confirmability, dependability, and transferability.

Chapter four presents the findings of the study and suggests a modified theory of an ethical decision-making process as it relates to academic physicians who have financial relationships with industry and how consequential conflicts of interest may affect their roles in teaching, research, and patient care. From the interviews and case discussions emerged reasons physicians enter into financial relationships with industry, individual and institutional benefits and risks of those relationships, suggestions of how to avoid bias, and a refined theory. The refined theory places primary emphasis on the moral agent characteristics existent in each of the four stages of the decision process and secondary emphasis on the moral intensity characteristics of the issue at the heart of the decision.

Chapter five reviews the purpose and significance of the study and discusses a summary of the methodology, a summary of findings, and the more recent, anticipated effect of the Sunshine Act (Open Payments), a provision of the Affordable Care Act. Chapter five also presents opportunities for future research that are either based on the findings or the existing environment in which physicians resolve perceived conflicts of interest in their academic roles of teaching, research, and patient care. Finally, I discuss implications for policy and reform.

## **Chapter II**

### **Review of the Literature**

#### **Introduction**

The purpose of chapter two is to bring together and synthesize bodies of literature relevant to the grounded theory study from the fields of higher education, organizational theory, and management. The literature review establishes the context of the study by presenting discussions on the current higher education environment, including the effect of commercialization, a decentralized institutional structure, and university-industry relationships. The discussions present the external forces that were impacting the study and viewed them from the perspectives of various stakeholder groups.

The literature presents the evolution of the current higher education environment and specifically academic medicine, how it contributes to the setting of the study, and how aspects of the commercialization of higher education and of university-industry collaborations have inherently influenced faculty, creating conflicts of interest and the need for ethical resolution without commercially-influenced bias. To establish an understanding of the need and significance for the study as well as an appreciation of the setting of the study, this chapter describes the current environment prior to reflecting on the past, discussing the ethics and elements of the current COI resolution process, and exploring the theoretical framework of ethical decision-making and the moral intensity of the study.

A brief history presents how society, institutional mission, organizational culture and climate, academic freedom, and ethics have influenced the role of faculty and academic decision-

making over time. This section of chapter two also reviews aspects of conflicts of interest and efforts of various stakeholders in managing COIs or offering guidance for resolving COIs.

Individual resolution is at the heart of the study. The literature describes unambiguous resolution requirements, recommendations, codes, and guidelines issued by federal regulatory agencies, accreditation bodies, professional societies, and industry, some of which include punitive or professional consequences. Moreover, this portion of the literature does not address the individual morality that is involved in the process of resolving a potential COI and that may result from a faculty member's financial relationship with industry.

The ethics and COI discussion introduces Jones' (1991) ethical decision-making model that may inform thoughtful consideration by the academic physician in assessing the issue and subsequent decisions. Literature from the field of management through Jones' ethical decision-making model and others suggested how an individual faculty member may approach the resolution process by identifying the issue at hand, assessing its moral intensity, and reaching an unbiased conclusion.

Jones' (1991) model is used as the theoretical framework for the study, and the moral essence of Jones' model is supported by two examples. The first example involved a psychiatrist who was being handsomely paid by Wyeth Pharmaceuticals to promote its new drug for treating depression over the use of S.S.R.I.s by giving "Lunch and Learn" presentations in doctors' offices and using slides prepared by Wyeth. Over time and becoming aware of undisclosed data regarding some of its side effects, he realized that he was minimizing discussion of hypertension risks and withdrawal symptoms, for example, because they were not part of the canned presentation. This was one of two defining moments that ended his speakers' bureau

involvement. Following a talk and being challenged by a member of the audience about hypertension risks:

I felt rattled. That psychiatrist's frown stayed with me – a mixture of skepticism and contempt. I wondered if he [audience member] saw me for what I feared I had become – a drug rep with an M.D. I began to think that the money was affecting my critical judgement (Carlat, 2007).

The other moment followed an observation by the company reps of a less-than-enthusiastic talk:

At that moment, I decided my career as an industry-sponsored speaker was over. The manager's message couldn't be clearer: I was being paid to enthusiastically endorse their drug. Once I stopped doing that, I was of little value to them, no matter how much "medical education" I provided. (Carlat, 2007)

In 2001, there were approximately 25% or 200,000 physicians who were receiving payment from drug companies to speak on behalf of the companies or promote their drugs in other manners. Since Dr. Carlat's experience in 2001, trade groups for both the pharmaceutical and medical device industries have written voluntary codes of conduct and ethics that limit this type of with physicians.

The second example from the 2010 NPR/ProPublica report corroborates the moral essence of Jones' (1991) model with the following quote from a gastroenterologist in the report:

It would really bother me. Because I perceive myself as always prescribing in the best interest of my patient, and even unconsciously if I was unduly influenced, that would

really bother me. I usually pride myself on keeping up my guard to prevent undue influence' (NPR/ProPublica, 2010, p. 4).

The physician indicates that his prescribing power could not be affected by his financial relationship with industry but, after being informed of the findings, began to wonder if he could be affected. Finally, the NPR/ProPublica (2010) report set the tone for the study and introduces chapter two by illustrating the magnitude of the issue as well as the essence of the theoretical framework through which the study was conducted.

On October 19, 2010, ProPublica, Inc. and National Public Radio (NPR) released a comprehensive report indicating that seven pharmaceutical companies paid \$257.8 million to 384 physicians and other health providers over an 18-month period during 2009-2010. For the purpose of the report, ProPublica and NPR included physicians, nurses, pharmacists, and other healthcare providers, who received a minimum of \$100,000 in fees for consulting, speaking, and other compensated activities. The seven companies of an estimated seventy-seven pharmaceutical companies have voluntarily disclosed this information in advance of the 2013 implementation of the Physician Payment Sunshine Act (H.R. 3590, Section 6002, Patient Protection and Affordable Care Act of 2009, 2010) requiring disclosure of 2012 data regarding the nature and value of the financial relationships between physicians and pharmaceutical, medical device, and biotech firms. The Physician Payment Sunshine Act became law on March 23, 2010 as part of the Patient Protection and Affordable Care Act of 2009 (PPACA, Pub. L. 111-148, 2010) and requires that companies begin collecting 2012 data by March 31, 2013 and make the information available to the public on their respective websites by September 30, 2013.

To place the magnitude of the 2010 ProPublica/NPR report into perspective; the Federation of State Medical Board (FSMB), comprised of seventy medical and osteopathic licensing boards in the U.S. and its territories, reported in its 2011 Annual Report that there were more than 850,000 licensed U.S. physicians in 2010 for whom they have verified licensing, credentialing, and disciplinary information. The 2010 ProPublica/NPR report data represents nine per cent of the estimated seventy-seven pharmaceutical companies and approximately .0005 of the approximately 850,000 licensed physician population. The report did not include population numbers for nurses and pharmacists (FSMB, 2011).

While all physicians, industry, and other healthcare professionals, to a lesser degree, are the unmistakable and observable players in a complicated environment; there are other significant players and forces involved in its evolution, context, and resolution, discussions of which follow. Additionally, and for the purpose of this qualitative study, the focus is narrowed to academic physicians, their financial relationships with industry, the potential for commercially-influenced bias in teaching, research, and patient care as well as the management and resolution of apparent conflicts of interest (COIs) that result from their financial relationships with industry.

### **Higher Education Environment**

The current higher education environment encourages medical faculty-industry financial relationships through various aspects of one's academic career – promotion and tenure, securing grants, decentralized university structures, recognition among peers, tech transfer, and collaborations that promote the recognition and reputation of the institution. In the faculty's efforts to contribute to institutional recognition and reputation, professional conflicts of interest

and commitment often emerge related to financial rewards and fees that accompany their involvement and obligations. The inherent conflict may create a tension between faculty and the tenets of academic freedom that give them the ability to responsibly and freely express themselves in research and teaching based on knowledge, research, and evidence that promote scholarly inquiry within an academic field. The tension may also be attributed to feeling ingratiated to the source of the financial relationship which may lead a faculty member to express views that may contradict scholarly evidence or his or her own professional viewpoint. This issue was a point of discussion in the 2007 symposium co-sponsored by the Association of American Medical Colleges and Baylor College of Medicine entitled “The Scientific Basis of Influence and Reciprocity.” Substantiated by the literature, my study examined this issue using Jones’ (1991) ethical decision-making model. The following background was essential in confirming the need for and significance of the study as well as providing a thorough understanding of an individual faculty member’s ethical resolution of conflicts of interest.

### **Commercialization**

Commercial interests, partnerships, and influences have been present in higher education institutions, both private and public, for decades but gained a stronger presence beginning in the 1970s and 1980s. This trend was due to a spectrum of environmental factors but was primarily attributed to a need for external funding to replace diminishing internal and governmental funding cutbacks. No longer could entities within the university structure support a fiscal climate that was not financially secure. A consequential second trend was a structural shift in higher education to a more decentralized or responsibility-centered budgeting model forcing departments to be held accountable for their bottom line. This structural shift was a change from departments having either partial or full institutional fiscal support to one that required



departmental responsibility for at least some portion of total revenues needed to conduct their academic work and cover operating budgets. It increased institutional and individual pressures to focus on the bottom line thereby initiating new perspectives regarding professional responsibilities, obligations, and expectations (AAMC & Baylor, 2007; Bok, 2003; Duderstadt & Womack, 2003; Robbins, 2003).

Faculty members who had commercial ties to one or more companies through research grants, speakers' bureaus, stock holdings, royalties or patents, and/or other financial interests were also at the core of the funding dilemma. Their financial relationships with industry had the potential of generating conflicts of interest and bias in teaching, research, and patient care. For example, medical researchers participating as PIs in studies with commercially-funded grants may either consciously or subliminally feel obligated to produce or skew findings in favor of the company. Another example would be physicians who participate on industry speakers' bureau for which they are trained to speak on behalf of the companies and promote their products. Additionally, participation on speakers' bureaus can present a difficult task of speaking on a topic from a scientific, evidence-based, non-promotional, educational perspective versus promotional on behalf of the company and its products.

Among the three accrediting bodies in the medical education continuum, the Accreditation Council for Continuing Medical Education (ACCME) requires all who participate in a Continuing Medical Education (CME) activity, regardless of role, to disclose all financial relationships with commercial interests. Disclosures are then vetted through a conflict of interest (COI) resolution process prior to faculty participation and disclosing the information to the audience (ACCME® Standards for Commercial Support, Appendix A). Additionally, the commercial supporter, pharmaceutical or medical device company, is required to complete a

letter of agreement acknowledging independent use of funds. Industry also must comply with the ACCME® Standards for Commercial Support (Appendix A) as well as relevant federal regulations, American Medical Association (AMA) Ethical Opinions (Appendix C), and voluntary industry codes of ethics. These documented safeguards are in place for the benefit of providing balanced and unbiased content being presented to the physician audience in a CME activity. The content of faculty presentations is subject to scrutiny not only by the accredited providers who hold the responsibility of maintaining balance and independence of content but also by the audiences attending the activity through the post-activity evaluation process. Control of the content of a presentation lies with the faculty and the ACCME® accredited provider to assure balance and lack of commercial bias which some would argue threatens freedom of speech and expression provisions of the First Amendment for industry (Harris, 2004; Samp, 2004).

Commercial influence and the need for balanced, unbiased content contribute to the struggle between the growing commercialized environment of higher education and its core academic mission and values. It is this larger issue for which the case of CME through the pilot study was but one illustration. The concern which is documented in the literature and discussed later in chapter two is that the traditional academic function of research may have also been compromised by commercial influence with consequences such as impairment of reputable research, pharmaceutical companies' manipulation of clinical trial data, lack of disclosure by faculty in controversial publications, ghostwriting, etc. The reality is that, in the area of research, industry funding is often the only source of support for a study, and these commercial ties may or may not cloud the physician's or researcher's judgment (Bok, 2003 & U. S. Senate Committee on Finance, 2010; Zuger, 2004).

## Academic Freedom and Commercialization

The First Amendment to the Constitution of the United States allows for freedom of speech and freedom of expression not only for individuals but, in this case, the companies as well. In 1976, a sequence of court rulings in favor of the companies' free-speech rights limited the FDA's authority over drug marketing by industry. The companies took advantage of the opportunity to increase marketing efforts and physicians' involvement as consultants or speakers who spoke on behalf of the company promoting product lines. The original tenets of academic freedom, scholarly and scientific inquiry, are grounded in the First Amendment. However, within the environment of commercialization and industry-academic relationships that exist, the principles may be at risk for both the academic physician and the companies providing funding for research, teaching, or clinical care. Among these could be allegations of fraud, kickback, or antitrust that could emerge from financial relationships between the academic physician and companies. In the higher education context and in professional practice, academic freedom principles afford faculty certain rights in the search and advancement of knowledge. Moral and ethical responsibilities to the public to seek the truth for the common good accompany those rights (AAUP, 1940; Bok, 2003; Harris, 2004; Samp, 2004).

Academic freedom's original purpose and its power provide security and protection to faculty views and institutional actions. John K. Ryan's (1949) philosophy concerning academic freedom stated that it is a particular kind of liberty in a moral order, possessing intellect, reason, and will without consequential restriction and destruction as well as freedom of expression without fear or coercion. His emphasis on academic freedom's foundation and essence in the First Amendment – *freedom of expression, information, and communication in accordance with truth and justice and the faculty's moral power and obligation to teach the truth* – support the

ethical decision-making theoretical framework within which I conducted the study. Quoting 19<sup>th</sup> century English philosopher John Stuart Mill, Shuger (1990) noted that freedom of action, unlike freedom of thought, is subject to the consequences of the “social harm” test. Balance of thought through intellectual objectivity is essential with the trend of universities becoming corporate in structure and function as well as a greater need for risk avoidance (Bok, 2003; Kaplan & Lee, 1995; Ryan, 1949; Shuger, 1990). The potential consequences of the social harm test were assessed through the theoretical framework’s six characteristics of moral intensity — magnitude of consequences, social consensus, probability of effect, temporal immediacy, proximity, and concentration of effect—which are defined and discussed later in this chapter.

Consistent with faculty responsibility expressed in the principles of academic freedom, personal opinion when stated as a professional, expert opinion also possesses consequences. This is especially true when opinions are expressed with political and moral overtones and involve substantial sums of money, thereby establishing potential conflicts of interest. Placed in the context of medical education, a physician faculty’s personal opinion may create a conflict of interest (COI) influenced by commercial interests. The COI risk may be growing within medical schools because schools and faculty appear to increasingly rely on external sources of revenues such as corporate funding. This trend may be due to reduction of institutional support, decreased funding in research dollars, cuts in Medicare, and competition for patients (Bok, 2003; Mangan, 1999; Ryan 1949; Shuger, 1990).

Recognition and concern of the COI risk is evidenced by the collective and collaborative actions of stakeholder groups to mitigate the risk. An extensive list of stakeholder groups is given below and includes organizations with release dates relevant to their respective contributions in COI risk reduction. Their actions have been expressed through university

policies, ethical opinions and recommendations from professional associations, accreditation guidelines and standards, educational initiatives, increased congressional oversight and legislation, federal regulations, and voluntary industry codes of ethics all of which are discussed later in this chapter as important background in establishing the significance of the study. Among the stakeholders and stakeholder professional groups are physicians, patients, industry, society, the Accreditation Council for Continuing Medical Education, 2004; Accreditation Council for Graduate Medical Education, 2011; Advanced Medical Technology Association, 2009; Alliance for CME & Society for Academic Continuing Medical Education, 2008; American Medical Association, 2011; Association of American Medical Colleges, 2007, 2008, & 2010; Institute of Medicine of the National Academy of Sciences, 2009; Liaison Committee for Medical Education, 2011; Pharmaceutical Research and Manufacturers of America, 2009; U. S. Department of Health and Human Services, Office of the Inspector General, 2003; U. S. Food and Drug Administration Office of Policy, 1997; and the U.S. Senate Committee on Finance, 2004 & 2010. A list of organizations and acronyms used throughout the manuscript is provided in List of Organizational Acronyms (p. x).

To begin the stakeholder discussion, it should be noted that university-industry relationships could intensify the First Amendment issue thereby reinforcing the need for disclosure from faculty. Disclosure alone does not guarantee balance, objectivity, and unbiased research or professional speaking presentations. Under the free speech provision of the First Amendment, the Washington Legal Foundation defended industry's financial support of continuing medical education (CME) programs as well as industry's right to be heard through truthful speech about products, research, and off-label use of FDA-approved products being presented (Harris, 2004; Samp, 2004). On the opposing side, Croasdale (2004) and Relman

(2003) criticized the notion of ACCME-accredited providers' accessibility to drug company speakers' bureaus for recommendations of speakers for CME activities whose views were presumed to be tainted by the company's perspective. Even though speakers for CME activities are required to disclose commercial interests and relationships, the influence may not be apparent. The concern was whether the speakers' presentations were product promotional or non-promotional without commercial bias and offered a balance of therapeutic options (FDA, 1997; ACCME, 2004).

As illustrated above, academic freedom's interaction with commercialization and the consequential issues related to COIs, mitigation efforts by stakeholders, and the ensuing need for external sources of funding creates an unpredictable environment yet one that is supportive of university-industry relationships. One of the characteristics of university-industry relationships and universities' becoming more commercialized or corporate in their organizational mission is adopting a decentralized model as described by Whalen (1991). Whalen's model places the fiscal responsibility on institutional units, departments or divisions within a college.

### **Decentralized Institutional Environment**

“Every tub on its own bottom”...the expression that originated at Harvard University epitomizes the essence of a decentralized institution. As defined in chapter one, the ‘tub’ is an academic unit of a college or university and the ‘bottom’ refers to each unit being responsible for its own bottom line and all costs it produces and all revenue it generates. A decentralized Responsibility Center Model (RCM) is defined by Whalen (1991) as an organizational entity directly involved in accomplishing the mission of the university or in providing services or support that enables mission accomplishment. In a decentralized RCM, institutions give their

departments greater budget authority and responsibility over themselves. The cost-recovery environment encourages innovation to increase revenue flow with an incentive to cut costs since departments keep all revenues that are generated. The departments are also responsible for all expenditures. Budgets are revenue-based so deficits must be eliminated. Dubeck (1997) describes three categories fundamental to a decentralized RCM – (1) departments with core missions of research, teaching, and public service, e.g. departments, colleges or schools within a university, (2) units that provide services to the primary mission departments, e.g. physical plant, library, and (3) executive management, e.g. the president’s office (Dubeck, 1997; Whalen, 1991).

Shifting the bottom-line responsibility to the department may cause two institutional-level conflicts. The first conflict could place a profit incentive against academic needs (Dubeck, 1997). Relevant to the profit-academic conflict, the second conflict could suggest a requirement to seek external funding to recover costs. This obligation can present a challenge to departments that must seek funding while complying with federal and state regulations and adhering to professional standards and guidelines. As examined in the pilot study, both conflicts do occur in the continuing medical education (CME) arena in an effort to recover or offset costs for professional medical conferences, symposia, seminars, and other types of educational activities. The CME unit has historically been considered a profit center, or at minimum a cost-recovery unit, within a university setting and generally in a school of medicine. CME is significant in academic medicine through its role in providing professional educational opportunities for physicians in practice that contribute to their maintenance of licensure and certification. The educational opportunities offer current and relevant content delivered by experts in the field of medicine and areas of specialty and sub-specialty.

It is important to note, however, that the field of academic medicine as a segment of the commercialized higher education environment is being increasingly scrutinized due, in most part, to the financial relationships that had been traditionally embraced by both the institution and individual faculty members. The second conflict, seeking external funding, promotes university-industry collaborative relationships but can also result in individual conflicts of interest for which a robust resolution process should exist (AAMC, 2008, 2010; ACCME, 2004; U.S. FDA Office of Policy, 1997; & U.S. DHHS OIG, 2003).

### **University-industry Relationships**

Many university-industry relationships have been formed for the benefit of the public good and serve a valuable purpose of which technology transfer is only one example. University-industry relationships began in the post-World War II era; but under the Bayh-Dole Act of 1980, the technology transfer process flourished. The Bayh-Dole Act offered a means of moving university research into the marketplace by encouraging university-corporate partnerships that offered tax breaks to businesses. It allows academic institutions to become conduits for cutting-edge research, to patent their research discoveries that were funded by federal money, and to license them to corporations for product development and distribution in the marketplace by replacing industrial research labs. This academic capitalism can also create conflicts among colleagues about ownership of patents and publishing as well as industry's potential influence of both (Slaughter and Rhoades, 2004). In their analysis of thirty-eight faculty interviews, Slaughter and Rhoades "found them [faculty] uncertain about the boundaries between public and private spheres, enticed by market opportunities, and plagued by conflict of interest issues" (p.31). Citing the recent BP oil spill in the Gulf of Mexico, Sheldon Krinsky (2010) raised concerns about unexpected consequences that result from federal policies, such as



Bayh-Dole, which were intended to promote university-industry research relationships. Krinsky (in Schmidt, 2010, para. 3) referred to one “unanticipated side effect as reducing public confidence in the objectivity and trustworthiness of the science” (Bok, 2003; Brainard, 2007; Dill, 1995; Lieberwitz, 2005; Slaughter & Rhoades, 2004).

The commercialized environment in which higher education is functioning with increasing university-industry relationships may undermine the traditional, core academic mission and values of the academy by making scientific knowledge and expert opinions products of higher education. The implications for institutional policy and governance evolve from the perceived tendency of industry to determine research focus that is representative in the development of a *knowledge economy*. It can also be argued that such effects may force faculty to forfeit core scholarly ideology and essential autonomy and that conflicts of interest, commitment, and internal equity may occur with industry collaboration (Bok, 2003; Campbell, 1997; Stilwell, 2003; Washburn, 2005b). Cary Nelson, president of the American Association of University Professors (AAUP), captures the essence of the concern:

Increased reliance on corporate funding—combined with the sheer power of corporations whose financial resources in some cases dwarf those of entire nations—requires us to rethink the advice we give and the policies we recommend. More detailed guidelines from the AAUP should help professors and their institutions negotiate better contracts with corporations and with the government, thereby securing faculty interests, protecting universities’ missions, and serving the public good (in Schmidt, 2010, para 4)

The environment also has implications for broad institutional policies and processes of governance as well as implications for detailed economic incentives. The economic incentives

may generate competition for the same funds between universities or between departments or faculty within the same institution (Bok, 2003; Campbell, 1997; & Stilwell, 2003).

Advocates of university-industry research collaborations acknowledge the concerns and deficiencies in the relationships but also recognize the economic and societal benefits of technological innovation and that universities and industry can work together in a cooperative and productive manner (Dill, 1995; Washburn, 2005a). However, if this is not possible, Washburn (2005a) proposed a series of four federal reforms for the benefit of universities, industry, and society: (1) independent, third-party licensing; (2) amended Bayh-Dole Act; (3) new conflict-of-interest regulations; and (4) more federal oversight of clinical research.

University-industry relationships have created a new set of norms including three types of potential conflicts. These conflicts may take the form of (1) conflict of interest – use of funds, inappropriate influence, and commingling of federal and private funds, (2) conflict of commitment or mission – misallocation of time and energy in teaching, research and public service, and (3) conflict of internal equity – departments that are favored based on ability to secure external funding and partnerships (Campbell, 1997).

### **Faculty and Academic Decisions**

Review of the literature thus far has presented an assessment of the current higher education and academic medicine environments on an institutional level. It is appropriate and informative at this point to engage in an historical reflection of faculty and how institutional mission, organizational culture and climate, ethics, and academic freedom have influenced academic decision-making over time. Secondly, an historical perspective may provide effective tools for navigating the current environment and ethically resolving conflicts of interest that may

present themselves in the academic physician's professional decisions regarding research, teaching, and patient care. Lastly, reviewing a scholarly perspective of conflicts of interest and ethics contribute to a subsequent discussion of external forces, institutional pressures, and the theoretical framework of the study.

## **Institutional Mission and Organizational Culture**

### **Mission and society.**

Throughout history, society has been generally satisfied with the missions of higher education – teaching, research, and public service with teaching the undergraduate student population as the principal goal. Examples of society's satisfaction include robust medical research, accessibility of community colleges, and prestige that accompanies attending land-grant and elite private universities. However, public opinion of higher education appears to have been waning based on a conflict between college being an absolute necessity and the rapidly increasing tuition costs in addition to the diminishing public appreciation of higher education's philanthropic mission. With declining public opinion, smaller budgets, fewer resources, and other influencing external factors; it is apparent that universities are being subjected to governmental, societal, political, and economic pressures (Callan & Immerwahr, 2008; Tierney, 1988; Weisbrod, Ballou, & Asch, 2008).

In an effort to be more responsive to these pressures, the trend for higher education accountability has forced universities to revisit their educational mission and policies that the commercialization of higher education appears to be influencing. The tension between a university's culture, values, and mission with the marketplace does not necessarily mean that either should be sacrificed. Universities can balance a mission-centered philosophy while being

market-wise in their engagement with the external community. This concern was emphasized by several of the interviewees in the focus groups conducted by Callan and Immerwahr (2008) who referred to higher education as a business with abundant revenue sources. The concern further confirmed the need for increased institutional transparency, efficiency, productivity, and accountability to society (Alexander, 2000; Bok, 2003; Callan & Immerwahr, 2008; Fitzpatrick, 2003; Zemsky, Wegner, & Massy, 2005).

“The university is expected to provide guidance for society” (Perkins, 1973a, p. 11) yet this expectation may cause difficulties for faculty and departments such as (1) acting upon an institutional commitment for which there has been no faculty involvement and (2) maintaining institutional autonomy including academic freedom for the faculty without the impact of societal demands. The institutional relationship with and commitment to society falls under public service, the third goal of a university mission. This goal came to light through the “Wisconsin Idea” in 1904 that fostered the university’s influence on families and society through the benefits of the teaching and research missions. The other goals, teaching and research, have also encountered difficulties and challenges such as obtaining sufficient tuition and donor funding as well as competing within a larger research community for funding and patent opportunities with private companies from advanced research since basic research cannot be patented. This challenge can create a conflict between mission and funding (Weisbrod, Ballou, & Asch, 2008). The agricultural programs established with the land-grant universities is a quintessential example of a successful mission in which all three goals of teaching, research, and public service to society have been achieved and continue to prosper in a cohesive manner. Relevant to the ethical decision-making model used for the study, Perkins’ (1973) assertion regarding society’s expectation of universities conveys an implicit trust that society has in higher education.

These observations and viewpoints concern higher education in general. However, the perspectives and challenges they present are applicable to academic medicine as evidenced in the discussions concerning university-industry relationships; the increasing regulatory, accreditation, and professional oversight of the environment; and the inherent tension that the environment presents to faculty and institutional missions. In the context of performance-based accountability, universities and society should never be too comfortable with each other. A certain amount of tension is healthy to the academic intellect and gives faculty and institutions opportunities to give knowledge back to society for the public good (Alexander, 2000). It may, however, be a perceived contradiction of institutional mission when academic physicians personally benefit from financial relationships with industry. This perception has influenced the need for and significance of this study. The study may reveal an understanding of how faculty should uphold institutional missions while in financial relationships with industry.

### **Institutional missions.**

From an organizational perspective, universities struggle because they strive to conduct conflicting missions within an organizational structure originally designed to support the transfer of knowledge. However, the later integration of research, public service, and a democratic community into the institutional mission created the above-mentioned conflict between mission and organizational structure and its functions. In medieval times, the original mission of teaching provided the collegial and scholarly connection between professor and student. By the nineteenth century, however, the research mission's primary purpose was to influence teaching, turning the attention of scholarship from the transfer of knowledge (teaching) to the search for new knowledge. It was large-scale research, not individual scholarship, with its external funding and partnerships that created the conflict with teaching. Opposing views existed regarding the

economic argument for transferring large-scale research outside of the university – (1) transferring to an external organization may eliminate the conflict of institutional missions, but (2) retaining within the institution may provide financial support for salaries and courses. Teaching and research, however, ultimately have become two separate institutional missions that often oppose each other in support of institutional needs (Perkins, 1973).

In research, ideas become more important than people...and external funding more important than internal budget allocations. The judgment of peers in one's field of specialization, rather than the progress of the student, becomes the critical measure of performance [of the faculty] (Perkins, 1973a, p. 7).

This quote expresses the essence of the current commercialized environment, university-industry relationships, and the importance that institutions have placed on those partnerships. The advent of large-scale research supported by external funds has affected the peer relationships among faculty and created competition among departments, has changed internal administrative and management organizational structures, and has encouraged entrepreneurial approaches and establishing relationships with members of the external funding community such as government, industry, and foundations. Organizational structures and institutional missions can be complex; however, they have provided opportunities for scholars and cultures to interact throughout history for the common good (Duryea, 1973; Perkins, 1973).

### **Organizational culture and climate.**

As with institutional missions, organizational culture and climate can influence faculty and academic decisions. To distinguish between the two concepts, Peterson and Spencer (1990, pp. 6-7) state that culture “focuses on the deeply embedded patterns of ideologies that members

have about their organization or its work,” and climate refers to “the current common patterns of important dimensions of organizational life or its members’ perceptions of and attitudes toward those dimensions.” Culture emphasizes the uniqueness of the institution, endures time, and is not easily or readily changed; whereas, climate focuses more on current attitude and is more easily and quickly changed by its members. Austin (1990) expands the definition of culture into four primary cultures that effect faculty values and behavior:

- (1) Academic Profession (core values) – its mission is to pursue, discover, produce, and disseminate knowledge, truth, and understanding; autonomy and academic freedom in research and teaching are valued in protecting creative and controversial ideas; commitment to intellectual integrity; and collegiality is the ideal framework for faculty interactions as well as institutional decision-making (p. 62).
- (2) Discipline – offers primary identification and socialization of the faculty; frames the beliefs and behaviors of the faculty (pp. 63-64).
- (3) Academy as an Organization – espouses two core values: (a) universities and colleges are involved in “good work” – knowledge for society and development of students and (b) faculty collegiality coupled with autonomy within the institution; is characterized by a compliance system, bureaucratic system resulting in accountability demands and performance outcomes of faculty; and threatens core values through external pressures (Austin & Gamson, 1983, in Austin, p. 65).
- (4) Institutional Types – typified by strong missions to produce knowledge and highly specialized research; is a strong force affecting faculty values and activities (pp. 66-67).

As discussed, missions, culture, and climate can affect faculty-student relationships; faculty institutional responsibilities of teaching and research; faculty participation in institutional decisions; and core values, customs, and traditions. Additionally, they may influence the independence of thought, freedom of inquiry and expression of faculty and community of scholars as well as the effective function of higher education that are protected by academic freedom (Austin, 1990; Millett, 1962; Perkins, 1973; Peterson & Spencer, 1990; & Sanders, 1973).

### **Academic freedom.**

In 1940, the American Association of University Professors (AAUP) released its Statement of Principles on Academic Freedom and Tenure (Appendix D). Academic freedom, with some limitations, applies to teaching and research but may also refer to the autonomy of the institution from governmental influence on policy and institutional self-governance. Faculty view academic freedom more as a professional norm, without fear of reprisal, grounded in the First Amendment of the U. S. Constitution. The statement describes the values of academic freedom that are the underpinnings to the protection of the rights of the teacher's responsibility in the transference of knowledge, the researcher's responsibility in the advancement of truth, the student's freedom to learn, and institutional autonomy (AAUP, 1940; Glenny & Dalglis, 1973; Lieberwitz, 2005; Livingstone, 1974; Mangan, 1999; Rochford, 2003; & Rosovsky, 1990).

Secondly,

The origins of the AAUP demonstrate the potential power of private corporate donors to pressure universities to serve their economic interests, as a scale of corporate donations grew from thousands to millions of dollars during the industrialization period of the early twentieth century (Hofstadter & Metzger, in Lieberwitz, 2005, p. 117-118).



In a commercialized higher education environment, protecting the independence of teaching and academic research from potential conflicting external influences is at the core of academic freedom. Due to an increased reliance on corporate funding, the spirit of academic freedom in academic medicine, particularly in research, may be affected. In response to the increased corporate involvement and influence in research, the AAUP released the following in 1999:

The freedom to pursue research and the correlative right to transmit the fruits of inquiry to the wider community—without limitations from corporate or political interests and without prior restraint or fear of subsequent punishment—are essential in the advancement of knowledge. (Mangan, 1999, p. A14).

Academic freedom is intended to protect faculty autonomy, ensure integrity, serve the public interest, and contribute to the public good without serving other interests and without recourse. To reiterate Ryan's 1949 view of academic freedom, he stated that academic freedom is a particular kind of liberty in a moral order. It possesses intellect, reason, and will without consequential restriction and destruction as well as freedom of expression without fear or coercion. It is the moral order that connected faculty decisions and perceived conflicts of interest within the protection of academic freedom to Jones' (1991) theoretical framework (Lieberwitz, 2005; Livingstone, 1974; Mangan, 1999; Rochford, 2003; Rosovsky, 1990; & Shuger, 1990).

### **Conflicts of Interest and Ethics**

To be discussed in the section on external environmental forces, Congress, professional associations and accreditation bodies have put forth much effort to establish mechanisms to manage conflicts of interest in medicine through existing and pending federal legislation,

voluntary industry codes of ethics and professionalism, and recommendations, opinions, and guidelines. The Pew Prescription Project (2007 & 2008) offered academic medical centers guidance and policy considerations in addressing conflicts of interest (COIs) in institutions in the areas of gifts, drug samples, formularies, continuing medical education, speakers bureaus, ghostwriting, consulting, and research funding. They presented model institutional policies in addition to potential external threats, internal barriers, and strategies to overcome them, much of which has been previously discussed in the areas of decentralized structures, effects of organizational culture, dependencies on external funding, faculty resistance to change, and lack of disclosure and COI knowledge.

In a broader sense, the AAUP (1990) issued its Statement on Conflicts of Interest and Research (Appendix E) due in part to increasing university-industry relationships that have resulted from reduced university budgets and a need for external funding. A key goal of the statement was to create awareness of the potential for faculty who are involved in collaborative industry research to consciously or unconsciously affect the design and outcome of research. In an effort to prevent such action, the AAUP offered the following considerations for use in the development or revision of institutional conflict-of-interest guidelines:

- (1) Any requirements for disclosure of potential conflicts of interest should be carefully focused on legitimate areas of concern and not improperly interfere with the privacy rights of faculty members and their families (AAUP, 1990, para. 4);
- (2) Faculties should ensure that any cooperative venture between members of the faculty and outside agencies, whether public or private, respects the primacy of the university's principal mission, with regard to the choice of subjects of research and the reaching and publication of results (AAUP, 1990, para. 5);

- (3) Pursuit of such joint ventures does not become an end in itself and so introduce distortions into traditional university understandings and arrangements, and external interests should not be allowed to shift the balance of academic priorities in a university without thorough debate about the consequences and without the considered judgment of appropriate faculty bodies...and a commitment to fairness (AAUP, 1990, para. 6); and
- (4) Private or government funding must be kept in proper proportion and be consistent with criteria established by the faculty (AAUP, 1990, para. 7)

The AAUP offered these safeguards for faculty. The role of the faculty, however, in promoting the institutional mission and protecting the principles of academic freedom may be affected by conflicts that are created by decisions they make when involved in institutional-industry or faculty-industry financial relationships (Lieberwitz, 2005). Dill (1982) referred to these faculty roles as value conflicts that are inherent in the relationships with industry which increase the constituencies that they serve and their influences. These value conflicts may further result in a decrease of faculty autonomy and ethical judgment.

### **External Forces and Institutional Pressures**

An historical understanding of faculty and institutional mission, culture, and academic freedom contributes to the evolution of the United States higher education system. The existing higher education environment, however, typifies commercialization, decentralized structures, and university-industry relationships that inherently foster individual and institutional conflicts of interest. Specific environmental characteristics that informed the focus of the study included an institutional need for external revenue sources, individual decision-making influenced by

commercial funding sources, and individual and institutional conflicts of interests. The 1990 AAUP Statement on Conflicts of Interest and Research (Appendix E) emphasizes the need for fairness and holding true to the institution's academic mission when engaged in research or other interaction with external organizations. Therefore, the study warranted a review of some of the external forces and institutional pressures that can affect academic medicine and physicians.

Beginning in 1997 with the U.S. FDA Office of Policy's release of its Guidance for Industry: Industry-supported Scientific and Educational Activities, physician-industry financial relationships have been increasingly monitored by three primary external forces: (1) federal regulations and congressional oversight, (2) voluntary industry codes of ethics and conduct, and (3) accreditation guidelines, professional recommendations and ethical opinions, the last of which may place institutional peer pressure on academic medical centers and their medical faculty. Regardless of the external or internal nature of the oversight, at the heart of financial relationships is industry's potential influence on physicians' decision-making in teaching, research, and patient care.

Among the most common reasons physicians may receive fees from industry include their roles as consultants, speakers trained to speak on behalf of a company, recipients of funding for research or clinical trials, members on companies' scientific advisory boards, paid researchers in industry-sponsored studies, stockholders, royalties from patents sold or assigned to companies, or being co-authors on peer-reviewed journal articles, a role recently investigated due to evidence of ghostwriting. Ghostwriting is a practice by which physicians, who are well-known as key opinion leaders (KOLs) in their specialties, lend their names as sole or lead authors to articles that were written by company employees. The U. S. Senate Committee on Finance brought this unethical practice to the attention of the National Institutes of Health (NIH)

and urged the NIH to issue conflict-of-interest guidelines for researchers (ACCME, 2004; NPR/ProPublica, 2010; Pew Prescription Project, 2007 & 2008; and U. S. Senate Committee on Finance, 2010).

The following overview of external forces and institutional pressures offers insight into the perspectives through which physicians' relationships with industry are monitored and regulated. It also provides background for the study from the viewpoints of congressional legislation and federal regulatory oversight, industry voluntary codes, accreditation guidelines and standards, ethical opinions, and professional association recommendations.

## **Federal Regulatory Oversight and Congressional Legislation**

### **United States Senate Committee on Finance.**

Since 2004, the United States Senate Committee on Finance has been investigating financial relationships between physicians and industry and releasing its findings to the public. This congressional oversight contributed to the writing and passing of the Physician Payment Sunshine Act (H.R. 3590, Section 6002) as a provision under the Patient Protection and Affordable Care Act (PPACA, Pub. L. 111-148, 2010) that went into effect March 23, 2010. The essence of the Sunshine Act is transparency, requiring industry to make all financial relationships with individuals and organizations public including the amount and nature of the compensation accessible on companies' websites. Prior to the need for legislating transparency, governmental agencies were addressing the financial relationship issue with the 1997 FDA Guidance for Industry that focused on industry-supported scientific and education activities. In a subsequent action in 2003, the Office of Inspector General of the Department of Health and Human Services released a compliance program guidance to reinforce the need for transparency

and management of physician-industry financial relationships. As described below, the OIG guidance is broader in scope than the FDA guidance but embraces its intent.

### **1997 FDA Guidance for Industry.**

In November 1997, the Office of Policy of the U.S. Department of Health and Human Services' Food and Drug Administration (FDA) issued its Guidance for Industry – “Industry-Supported Scientific and Educational Activities.” The 1997 FDA Guidance evolved from concern that industry was influencing content of medical education that should be independent and non-promotional, either directly through selection of speakers and/or topics or indirectly through industry's relationship with the educational provider. As a result, the FDA Guidance issued twelve factors to be used in evaluating programs and determining the independent nature of the content of medical education. Of the twelve factors described below, disclosure (#2) is the factor that requires identification and resolution of potential conflicts of interest for faculty:

1. Control of Content and Selection of Presenters and Moderators: the educational provider must maintain and document full control while avoiding industry-favored bias.
2. Disclosure: when applicable, this factor requires three forms of disclosure to the audience prior to delivery of the content of medical education – (a) company funding of the program in the form of educational grants to the provider; (b) the nature of financial relationships with industry or that none exists by anyone who is in a position to influence content, and (c) discussion of off-label or unapproved uses of products.
3. The Focus of the Program: the educational content must be free from commercial influence or bias, the title must accurately reflect the scope of the content, and all reasonable and relevant therapeutic options and treatment modalities must be discussed.

4. Relationship between Provider and Supporting Company: are there legal, business, or other relationships between companies and providers that would commercially influence content, e.g. company ownership of a provider?
5. Provider Involvement in Sales or Marketing: this factor considers if the provider assumes a second relationship with a company by assisting in the promotion of its products while, in its primary role, the educational provider is developing educational programs free of commercial influence, thereby creating a conflict of purpose.
6. Provider's Demonstrated Failure to Meet Standards: educational programs must meet standards of independence, balance, objectivity, or scientific rigor.
7. Multiple Presentations: this factor is encouraged by the FDA when based on an urgent topic and/or serving public health interests.
8. Audience Selection: companies may not generate lists or invitations, the intent of which may reflect sales and marketing goals, rewarding high prescribers of the companies' products or influencing key opinion leaders (KOLs).
9. Opportunity for Discussion: meaningful discussion must be provided during live programs.
10. Dissemination: this factor considers intentional, additional distribution of product information after the educational program.
11. Ancillary Promotional Activities: sales presentations, exhibits, and product promotion may not take place in the meeting space.
12. Complaints: this mechanism allows for reporting companies' attempts to influence content (U. S. DHHS FDA Office of Policy, 1997, pp 64096-64099).

The FDA Guidance further recommended documenting compliance by both companies and educational providers with the twelve factors and other parties, as appropriate, in a written, co-signed letter of agreement, which is a current standard of practice.

### **2003 DHHS OIG Compliance Program Guidance.**

In April 2003, the Office of Inspector General of the U. S. Department of Health and Human Services (OIG) issued the OIG Compliance Program Guidance for Pharmaceutical Manufacturers. The intent of the compliance guidance embraced reducing the cost of health care, improving quality of care, and preventing fraud and abuse in the federal Medicare and Medicaid healthcare programs. The OIG guidance consists of seven fundamental elements for implementation by the pharmaceutical companies for an effective compliance program:

1. Implementing written policies and procedures regarding standards of conduct, commitment to compliance, addressing issues of fraud and abuse, and sales and marketing practices;
2. Designating a compliance officer and compliance committee to develop, operate, and monitor the compliance program noted above;
3. Conducting effective training and education for industry employees;
4. Developing effective lines of communication between the compliance officer/committee and employees including a process for complaints or questions and procedures for the protection and anonymity of complainants and whistleblowers;
5. Conducting internal monitoring and auditing of compliance programs for risk mitigation;



6. Enforcing policies, standards, and procedures communicated to employees through well-publicized guidelines for those employees or entities, due to violations of the OIG Compliance Program Guidance, who are excluded from participating in federal healthcare programs; and
7. Responding promptly to detected problems or offenses of non-compliance or misconduct per the OIG Compliance Program Guidance and undertaking preventive corrective action (U.S. DHHS OIG, 2003, p. 23731-23733).

The OIG intended for compliance guidelines to be benchmarks for companies in establishing a compliance program or evaluating an existing federal compliance program. They developed the guidelines with representation and input from four major industry stakeholder groups – physicians, pharmaceutical industry, health plans, and pharmacy benefit managers. The OIG recommended that companies write a code of conduct to reiterate the ethical and legal standards that function as the underpinnings of the companies’ commitment to and implementation of a compliance program that enforces compliance with federal regulations expressed in the OIG Compliance Program Guidance.

Additionally, the OIG guidance identified specific risks of fraud and abuse in the federal Medicare and Medicaid healthcare programs. Examples of such risk included the integrity of data in determining government reimbursement rates, kickbacks, and other illegal payments. It also identified three areas of potential risks and abuse that should be monitored. These included (1) the companies’ relationships with purchasers and their agents, (2) the companies’ relationships with physicians and other persons and entities in a position to make or influence referrals, and (3) the companies’ relationships with their sales forces. The OIG addressed the last area of companies’ sales and marketing efforts by encouraging companies to commit to an

OIG-mandated compliance program that includes (a) training and monitoring its sales force for compliance with the OIG Compliance Program Guidance, (b) understanding relevant industry standards, and (c) disciplinary policies as a pre-emptive measure to avoid inappropriate, illegal, or unethical actions. It is the second relationship, *companies' relationships with physicians and other persons and entities in a position to make or influence patient referrals and prescribing power*, which contributed to an understanding of the environment of the study and also reinforced the FDA guidance previously discussed. As described in a prior section of this chapter, academic physicians may enter into financial relationships with industry for which the compensation can be very generous. Examples of physician-industry relationships are consultants, members of speakers' bureaus, or members of scientific advisory panels. The physicians who are in these financial relationships may feel an obligation to consult in the company's favor, to speak more on behalf of the company than solely from scientific evidence, or to advise in a manner that promotes the company or its products, regardless of the ethical or moral implications. Therefore, the physician-industry financial relationships may affect the physician's ethical decision-making process that was focus of the study.

As with the 1997 FDA guidance, the 2003 DHHS OIG guidance gave the following factors against which the physician-industry financial relationship should be assessed in order to fit within an existing *safe harbor* for appropriate personal services or management contracts:

- Nature of the relationship between the company and physician including any direct or indirect influence the company may have on the physician to generate business;
- Manner in which the payment is determined, whether based on the volume of value of the business, referrals, or services generated;
- Is the value of the payment in excess of fair market value?

- Potential federal program impact of the payment, affecting federal healthcare programs and utilization; and
- Potential conflicts of interest (COIs) that may diminish objectivity and professional judgment or affect patient safety or quality of care and that may encourage propagation of incomplete, inaccurate, or misleading information (U. S. DHHS OIG, 2003, p. 23737).

The final factor, potential conflicts of interest (COIs) and the effect on objectivity and professional judgment, reflects the essence of the study and theoretical framework by raising ethical and moral concerns. As discussed in this chapter, these concerns were and continue to be addressed by several stakeholder groups represented by federal legislative bodies and regulatory agencies, accreditation bodies, professional associations, industry, and physicians. The OIG guidance states that potential COIs may present themselves in various physician-industry financial relationships including:

- switching arrangements which involve payments for changing a patient's prescription to the requesting company's product from a competing product and may also have implications under the federal anti-kickback statute;
- consultancies and advisory boards which may also emerge in the physicians' roles in speaking on behalf of the company, certain research, preceptor/shadowing services, or ghostwriting articles which is also suspect under the anti-kickback statute;
- detailing, a manner by which company sales representatives educate prescribing physicians about their products, is discouraged due to anti-kickback and fraud-and-abuse implications.

- business courtesies and other gratuities that appear under the broad categories of entertainment and gifts that are bestowed upon physicians who are in a position to make or influence referrals.
- educational and research funding should be determined as being used for *bona fide* educational or research purposes and not conditioned on selection of content or faculty (U.S. DHHS OIG, 2003, p. 23738).

With reference to consultant and advisory board relationships and their related roles, the OIG suggested that full disclosure by physicians of these relationships may only mitigate, not fully eliminate, the risk of abuse. The OIG also recommended documenting the relationship in a written agreement prior to payment that verifies a legitimate need for professional services, that these services actually occurred, and that payment for the services was fair market value.

As explained in the following section and in response to the OIG recommendation, the Pharmaceutical Research and Manufacturers of America (PhRMA) and Advanced Medical Technology Association (AdvaMed) voluntary industry codes of ethics and conduct as well as institutional policies on physicians' interaction with industry; recommendations, guidelines and opinions issued by leading medical associations; and standards set forth by relevant accreditation bodies reinforce the FDA program guidance and the OIG compliance guidance.

### **Industry Voluntary Codes**

In support of the 2003 OIG Compliance Guidance, there are two predominant industry codes of ethical conduct that, albeit voluntary in nature, encourage compliance by the companies and their employees. The two codes contain similar principles although they are specific to two different segments of industry: (1) research-based pharmaceutical and biotechnology companies

and (2) medical equipment and device companies. The website for each code maintains a list of the companies who have voluntarily agreed that all of their employees will comply with the relevant code.

The code for the research-based pharmaceutical and biotechnology companies is the “Code on Interactions with Healthcare Professionals” and generally referred to as the PhRMA Code. The Pharmaceutical Research and Manufacturers of America (PhRMA), an organization that represents the research-based pharmaceutical and biotechnology companies, originally released its code in 2002. The PhRMA Code was adopted on April 18, 2002 with an effective date of July 1, 2002 and was revised in 2008 with an effective date of January 1, 2009.

The second code, “Code of Ethics on Interactions with Health Care Professionals,” is applicable to the medical equipment and device companies and generally referred to as the AdvaMed Code. The Advanced Medical Technology Association originally released the AdvaMed Code in 2005 and later revised it with an effective date of July 1, 2009. Both codes are comparable in purpose which is to support industry engagement in ethical relationships with physicians and other healthcare providers and share similarities among the following principles:

- Encouragement of member companies to adopt and comply with their respective codes;
- Effective compliance program that includes annual certification based on specific criteria, including evidence of a compliance officer, policies and procedures;
- Appropriate financial support of *bona fide* independent CME or third-party conferences, given as educational grants with conditions of modest meals and refreshments, speakers’ honoraria and travel expenses, independent control of content, faculty, and educational materials. Honoraria should be based on fair market value. The financial support

principle is consistent with the ACCME® Standards for Commercial Support (ACCME, 2004).

- Modest meals may be provided by representatives for informational (PhRMA Code) or business-related (AdvaMed Code) presentations.
- Consultancies must be documented by a written agreement indicating the nature of the services to be provided; compensation should be fair market value. This principle is consistent with the OIG Compliance Program Guidance (2003).
- The provision of entertainment and recreational items to physicians and other health care providers are no longer allowed.
- Gifts to physicians and other health care providers are no longer permitted except under the following conditions: of patient benefit or healthcare providers' educational benefit, including medical textbooks or anatomical model. \$100 maximum value applies under certain circumstances (PhRMA & AdvaMed, 2009).

The differences between the PhRMA code and AdvaMed code generally exist in the specific details related to a principle, or the code may contain a principle that is only applicable to their segment of the industry. The AdvaMed Code is broader in scope due to the equipment and device nature of the companies' product lines. For example, the AdvaMed code contains a section that details the terms and conditions for equipment training and education of healthcare providers and one that discusses evaluation and demonstration of equipment. Neither is pertinent to the pharmaceutical industry. The PhRMA Code also does not address issues related to research grants or the engagement in fraudulent practices that the AdvaMed Code addresses.

## **Recommendations, Opinions, and Accreditation Guidelines**

In addition to the regulatory oversight and the two voluntary industry codes, accreditation bodies, professional medical associations, and institutes or foundations with patient-centered care and public health foci in their missions have, to date, approached the COI environment in a policy-and-procedural manner. These organizations have offered and encouraged, for adoption and implementation, recommendations, opinions, standards, and guidelines regarding healthcare professionals' interactions with industry representatives and the potential COIs that financial relationships may create and ultimately impact patient care. Compliance with accreditation standards and guidelines is required of the accredited school or program. The intent of these organizations is to prevent inappropriate relationships and undue commercial influence and bias in research, patient care, and medical education as the following section explains.

### **Accreditation for the medical education continuum.**

There are three relevant accreditation bodies that have established criteria, standards, and policies for the purpose of providing continuity among all medical undergraduate, graduate, and continuing education programs and curricula within the United States. Oversight for the undergraduate medical education programs and curricula for the approximately 125 U.S.-based medical schools is through the Liaison Committee for Medical Education (LCME, 2011). Secondly, the Accreditation Council for Graduate Medical Education governs residency and fellowship programs, commonly referred to as graduate medical education (ACGME, 2011). Lastly, providers accredited by the Accreditation Council for Continuing Medical Education (ACCME) present continuing medical education activities to support maintenance of licensure and certification for physicians in practice.

***Accreditation Council for Continuing Medical Education (ACCME).*** Accredited providers must adhere to the Accreditation Council for Continuing Medical Education's (ACCME) Essential Areas and Elements, Standards for Commercial Support, and supplemental policies. The ACCME® is a seven organization member council consisting of the American Board of Medical Specialties (ABMS), American Hospital Association (AHA), American Medical Association (AMA), Association for Hospital Medical Education (AHME), Association of American Medical Colleges (AAMC), Council of Medical Specialty Societies (CMSS), and the Federation of State Medical Boards of the U.S., Inc. (FSMB).

Of the three accreditation bodies, the ACCME has specific requirements for disclosure and COI resolution as detailed in Standard 2 of the ACCME® Standards for Commercial Support<sup>SM</sup>, *Standards to Ensure the Independence of CME activities* (ACCME, 2011) (Appendix A). Among these requirements and responsibilities are (1) the provider's documentation that, regardless of role, everyone in a position to control the content of an educational activity has either disclosed financial relationships with commercial interests or documented the nonexistence of such; (2) disqualification of participation by individuals who refuse to disclose; (3) a mechanism developed by the provider to resolve all conflicts of interest prior to an educational activity; (4) informing the learners of all disclosures prior to an activity, and (5) management of the interaction with commercial interests to reduce potential undue commercial influence of the content. Furthermore, the ACCME® Standards for Commercial Support, grounded in the 1997 FDA Guidance, inherently establish a firewall between educational activities and promotional opportunities.

***Accreditation Council for Graduate Medical Education (ACGME).*** Even though the LCME and ACGME do not have comparable documents and policies, they fundamentally



discourage student, faculty, and staff interactions with commercial interests. The ACGME, through its Institutional Requirements, states that the institutional Graduate Medical Educational Committee (GMEC) is “...responsible for establishing and implementing policies and procedures regarding the quality of education and the work environment for all residents in all programs” (ACGME, 2011, p. 9). For example and relevant to the study, the ACGME Institutional Requirements (III.B.13) expects the GMEC to document the existence of a position statement or institutional policy that addresses residents’ interaction with industry.

In 2002, the ACGME released a white paper entitled “Principles to Guide the Relationship between Graduate Medical Education and Industry.” In the white paper, the ACGME discussed the role of professionalism, one of its six general competencies, in support of a more restrictive interaction of residents with industry representatives by defining professionalism as:

[...] an expression of the norms that guide the relationships in which physicians are engaged (Kuczewski, 2001, in ACGME, 2002, p. 4)... and identifying those traits commonly associated with professionalism as altruism, respect for others as embodied in humanistic qualities, honor, integrity, ethical behavior, accountability, excellence, a sense of duty, and advocacy (Arnold, 2001, in ACGME, 2002, p.5).

Kuczewski (2001) emphasized that medical education curricula should be inclusive of ethics and orientation to established guidelines and principles espoused by the associations and specialty societies that represent the medical profession. The ACGME 2002 white paper also encouraged emulating and exceeding the ACCME® disclosure requirements as well as abiding by the AAMC’s recommendations regarding the management of COIs in human subjects’ research.

On February 13, 2007, the ACGME Board of Directors approved the integration of six general competencies into the curriculum as a residency program requirement. The expanded definition of each competency described the expectations of residents and their responsibilities to the medical profession and the patient population. Specific to the definition of professionalism and reinforcing the principles advocated by the ACGME in its 2002 white paper,

“...residents must demonstrate a commitment to carrying out professional responsibilities and an adherence to ethical principles. Residents are expected to demonstrate: compassion, integrity, and respect for others; responsiveness to patient needs that supersedes self-interest; respect for patient privacy and autonomy; accountability to patients, society and the profession; and sensitivity and responsiveness to a diverse patient population, including but not limited to diversity in gender, age, culture, race, religion, disabilities, and sexual orientation” (ACGME, 2007) (Appendix B).

*Liaison Committee for Medical Education (LCME)*. The Association of American Medical Colleges (AAMC) and the American Medical Association (AMA) are collaborative sponsors of the LCME and have issued reports and opinions that address disclosure policies, mechanisms for COI resolution, and an individual’s conduct and interaction with industry while engaged in the practice of medicine. The implementation of industry policies in the majority of medical schools, which is discussed in a succeeding section of this chapter, reinforces the position that the AAMC and AMA have taken on these issues.

#### **American Medical Association (AMA).**

The American Medical Association originally released its 168-year-old AMA Code of Medical Ethics (Appendix C) in 1847 at the first AMA meeting in Philadelphia. As a dynamic

document, it is updated frequently by the AMA's Council on Ethical and Judicial Affairs (CEJA) as the environment and profession dictate. The code presents opinions in ten ethical areas related to the medical profession and informs physicians' ethical and professional conduct in medical education, research, and patient care. The AMA opinions relevant to this study are those regarding practice matters (Opinion 8.00), professional rights and responsibilities (Opinion 9.00), and reference to definitions of the terms "ethical" and "unethical" as used in the remaining nine areas of the code (Opinion 1.01). According to CEJA's Opinion 1.01, "ethical" refers to one's respect of moral principles and social policy involving issues of morality, and "unethical" refers to one's failure of professional conduct by not abiding by moral standards. Both descriptions strengthen the significance of the moral agent in Jones (1991) ethical decision-making model used as the theoretical framework of this study.

Within Opinions on Practice Matters (8.00), Opinion 8.03 addresses physicians' potential conflicts of interest (COIs) by stressing patient welfare and service to humanity above their financial gain and further states that COIs must be resolved to the benefit of patients. Opinions 8.031 and 8.0315 continue by addressing resolution of COIs in biomedical research and clinical trials respectively. Physicians may partner with industry in research, but the AMA stresses the necessity of ensuring objectivity, maintaining integrity, and assuring the safety of human subjects. In CEJA's Opinion 8.061, Gifts to Physicians from Industry, the AMA recognizes the importance of physicians' appropriate interaction, cautions physicians in the inappropriate acceptance of gifts, and offers ethical direction through seven detailed guidelines. In summary, the guidelines state that gifts should be of professional or patient benefit as the 2009 revised PhRMA and AdvaMed codes stipulate. The guidelines also promote scientific and objective dissemination of knowledge in professional conferences. This opinion also reflects the

disclosure requirement and other parameters governing the interaction of physicians with industry as stipulated in the 1997 FDA Guidance and Standard 3: Appropriate Use of Commercial Support of the ACCME® Standards for Commercial Support (Appendix A).

The ACCME® criteria and standards are further reflected in Opinion 9.011, Continuing Medical Education, which offers guidance to attendees, faculty, and sponsors regarding ethical participation in CME activities. Opinion 9.011 promotes participation in balanced and unbiased CME activities for the purpose and benefit of better serving patients, upholding professional standards, and sustaining ethical responsibility. It also cross references Opinion 8.061, Gifts to Physicians from Industry, as it relates to honoraria and expenses for faculty.

#### **Association of American Medical Colleges (AAMC).**

Consistent with the AMA's and accreditation bodies' views of academic medicine's interaction with industry, the Association of American Medical Colleges (AAMC) has in recent years investigated the ethical nature of physicians' financial relationships on two levels – individual and institutional. While the focus of the study is narrowed to the individual healthcare professional and, more specifically, the academic physician; application of a similar study on the institutional level would be of equal benefit and should be considered for future research. With funding from the Robert Wood Johnson Foundation and Pew Charitable Trusts, the AAMC and Baylor College of Medicine sponsored a symposium on June 12, 2007 entitled “The Scientific Basis of Influence and Reciprocity.” The four major goals of the symposium were to:

- 1) Identify, quantify, and understand influence, reciprocity, and conflicts of interest;
- 2) Develop responsible practices to manage and mitigate these conflicts;

- 3) Sustain and enhance the important contributions of industry to biomedical discovery, product development, and education through evidence-based medicine; and
- 4) Earn the public trust and protect the patient. (AAMC, 2007, p. 8)

The participants examined the goals from the following four perspectives providing conceptual clarity as well as case-based and research-based evidence to generate further inquiry:

- Neuroscience: concepts of individual trust and how special treatment can influence decisions;
- Psychology: moral standards, degrees of freedom, an individual's choice to be honest or dishonest and its effect on self-concept;
- Behavioral economics: “conflicts of interest...a clash between professional responsibilities and economic interests” (AAMC, 2007, p. 19), disclosure as a “moral license” (AAMC, 2007, p. 22), and elimination of gifts to mitigate biased decision making; and
- Implications for Public Policy: importance of understanding concepts of bounded awareness, which may be expressed as the ability to ignore what one wishes not to see and confirm what one wants to believe, unconscious bias in decision making, and bounded ethicality which Chugh, Bazerman & Banaji (2005, in AAMC, 2007, p. 25) define as “systematic and predictable ways in which humans act unethically beyond their own awareness.”

The symposium generated three task forces which convened in each of the three areas of industry funding — medical education, financial conflicts of interest in human subjects' research, and conflicts of interest in clinical care. They subsequently released the following reports with recommendations for the profession of medicine: (a) AAMC in conjunction with

the AAU on COI policies to protect patients, preserve integrity, and advance health in human subjects' research in February 2008, (b) industry funding of medical education in June 2008, and (c) physician financial relationships and clinical decision making in June 2010. The third task force responsible for clinical decision-making (AAMC, 2010) and the Institute of Medicine (Lo & Field, 2009) confirmed that there is a paucity of evidence-based COI research in the body of literature, including policy and systematic studies which contributed to the significance of this study. The need for COI research was specifically noted in the IOM consensus report as Recommendation 9.2 which suggested that the National Institutes of Health, Agency for Healthcare Research and Quality, and Department of Health and Human Services develop a research agenda on conflict of interest (Lo & Field, 2009). Collectively, the AAMC task force

- defined professionalism consistent with the ACGME's definition as involving "...a set of ethical standards and motivations on the part of individual practitioners. Among medicine's ethical principles are autonomy, objectivity, altruism, and the avoidance of conflicts of interest" (AAMC, 2008, p. 3);
- endorsed and adopted the Institute of Medicine's definition of COI which states that "a conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest" (Lo & Field, 2009, p.46);
- supported the appropriate and well-managed academic medicine-industry interaction for the public good;
- identified the need for future research related to decision-making in these relationships;
- exposed the potential negative effect of conflicts of interest in medical education, research, and patient/clinical care;

- encouraged academic medical centers to create and implement institutional policies, commonly referred to as “industry policies,” that provide specific guidance for interaction with industry by faculty, staff, trainees, and students; and finally,
- made recommendations for academic medical centers as they move forward to resolve these issues (AAMC, 2008; AAMC & AAU, 2008; AAMC, 2010; & Croasdale, 2008).

***National Faculty Education Initiative (NFEI).*** In support of the recommendations, federal regulations, and other organizational efforts to establish a thorough understanding of the environment and how to avoid COIs and inappropriate interaction with industry, the Alliance for CME (Alliance) and the Society for Academic Continuing Medical Education (SACME), in collaboration with the AAMC, launched the National Faculty Education Initiative (NFEI) in October 2008. The online educational activity which may be found at [www.nfeinitiative.org](http://www.nfeinitiative.org) offers “cased-based content to quickly and effectively educate medical faculty about federal regulations, accreditation and professional standards, and their roles and responsibilities when presenting in certified CME or commercial programs” (Alliance & SACME, 2008). The online course is beneficial to individuals’ understanding of the distinction between promotional and evidence-based content and is also designed to protect individual and organizational stakeholders and the public.

***Institutional industry policies.*** One of the AAMC (2010) recommendations encouraged academic medical centers to develop and implement institutional policies that offer guidance for interaction of industry with students, trainees, faculty, and staff and are commonly referred to as “industry policies.” The policies generally follow the institutional faculty or staff member on or off campus and include sections that provide guidance on gifts, meals and entertainment, drug samples, speaking and consulting arrangements with industry, disclosure, access and registration

procedures, and restrictions for sales representatives on the academic medical center's property or campus.

Prior to AAMC issuing the 2010 recommendations, the American Medical Student Association (AMSA) released its initial, yet subjective, "PharmFree Scorecard" in 2007. AMSA graded medical schools on an A to F scale based on whether they had a conflict of interest or industry policy that controlled the interaction of faculty and students with industry representatives. Since 2007, AMSA has collaborated with the Pew Prescription Project to develop a more thorough assessment to suggest elements that should be included in an effective policy. The purpose behind AMSA's campaign that began in 2002 was to advocate for evidence-based medicine and physicians' prescribing power that is free from the influence of industry and to implement institutional conflict-of-interest policies.

As of December 15, 2010, 140 of 152 medical institutions have participated in the Scorecard, a 92% rate, improved from 88% in 2009. Of 152 = medical schools, 19 received As (13%), 60 Bs (39%), 24 Cs (16%), 18 Ds (12%), 26 Fs (17%), and 5 'In Process' (AMSA, 2011, para 4-8).

In 2010, AMSA's grading system assessed the strength and restrictive nature of the key elements of a policy. The 2010 summary data indicated trends towards strengthening policies, thereby receiving a higher grade, as well as improvement trends by domains, e.g. gifts or samples. AMSA's efforts were intended to support the AAMC's task force recommendations released in 2008 and the Institute of Medicine's 2009 consensus report discussed below.



## **Institute of Medicine of the National Academy of Sciences (IOM).**

Consistent with the positions of the AMA, AAMC, and accreditation bodies; the Institute of Medicine of the National Academy of Sciences released a consensus report in 2009 defining the elements of a conflict of interest (COI) and identifying the need for further COI research in medical education, research and practice. The Institute of Medicine's definition of COI states that "a conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest" (Lo & Field, 2009, p.46). Also referred to as goals, obligations or rights, "primary interests include promoting and protecting the integrity of research, the welfare of patients, and the quality of education" (Lo & Field, 2009, p.47). Secondary interests are referred to as financial gain, desire for professional advancement, recognition for personal achievement, or favors to friends, family, students, or colleagues. As such, secondary interests create conflicts and potential harm when the weight of the secondary interest is inappropriate and greater than the primary interest, exercising undue influence on professional decisions and distorting the pursuit of the primary interest (Lo & Field, 2009, p.47). The IOM report also suggested that commercial support of continuing medical education (CME) activities may promote a physician faculty's sense of entitlement due to medical school debt and other financial factors (Lo & Field, 2009).

The IOM report addressed mechanisms designed to identify and assess COIs; motives and unconscious bias in decision-making; cases that demonstrate the specific nature of conflicts in education, research, and practice; and existing accreditation disclosure and COI guidelines and policies. Specific to this study and Jones' (1991) ethical decision-making model, the IOM's description of the secondary interests, e.g. unconscious bias in decision-making, supports the behavioral economics perspective explored in the AAMC / Baylor symposium (2007). For

example, both noted that some social science research suggests that even gifts of small value from industry, e.g. pens, pads, etc. may cause unconscious bias or undue commercial influence in professional judgment and decision-making (AAMC, 2007; Lo & Field, 2009; Dana & Loewenstein, 2003).

Based on its findings, the IOM concluded by offering sixteen recommendations for a spectrum of stakeholders to mitigate undue bias and commercial influence and to inform stronger COI policies. The stakeholder groups that could be affected by or involved in the implementation of the recommendations included individual healthcare professionals; academic medical centers, medical research and teaching institutions, faculty, residents, fellows, and students; pharmaceutical, medical device and biotech companies; accreditation and certification bodies; healthcare professional societies; U. S. Congress, National Institutes of Health, other federal and public agencies; and community physicians.

Two significant purposes underlying the IOM recommendations, which are outlined and classified among seven categories, include (1) protecting the integrity of professional judgment and (2) preserving public trust in a proactive versus reactive manner:

- I. General Policy – adopt and implement COI policies; strengthen disclosure policies; standardize disclosure content and formats; and create a national program for the reporting of company payments.
- II. Medical Research – restrict participation of researchers with COIs in research with human participation.

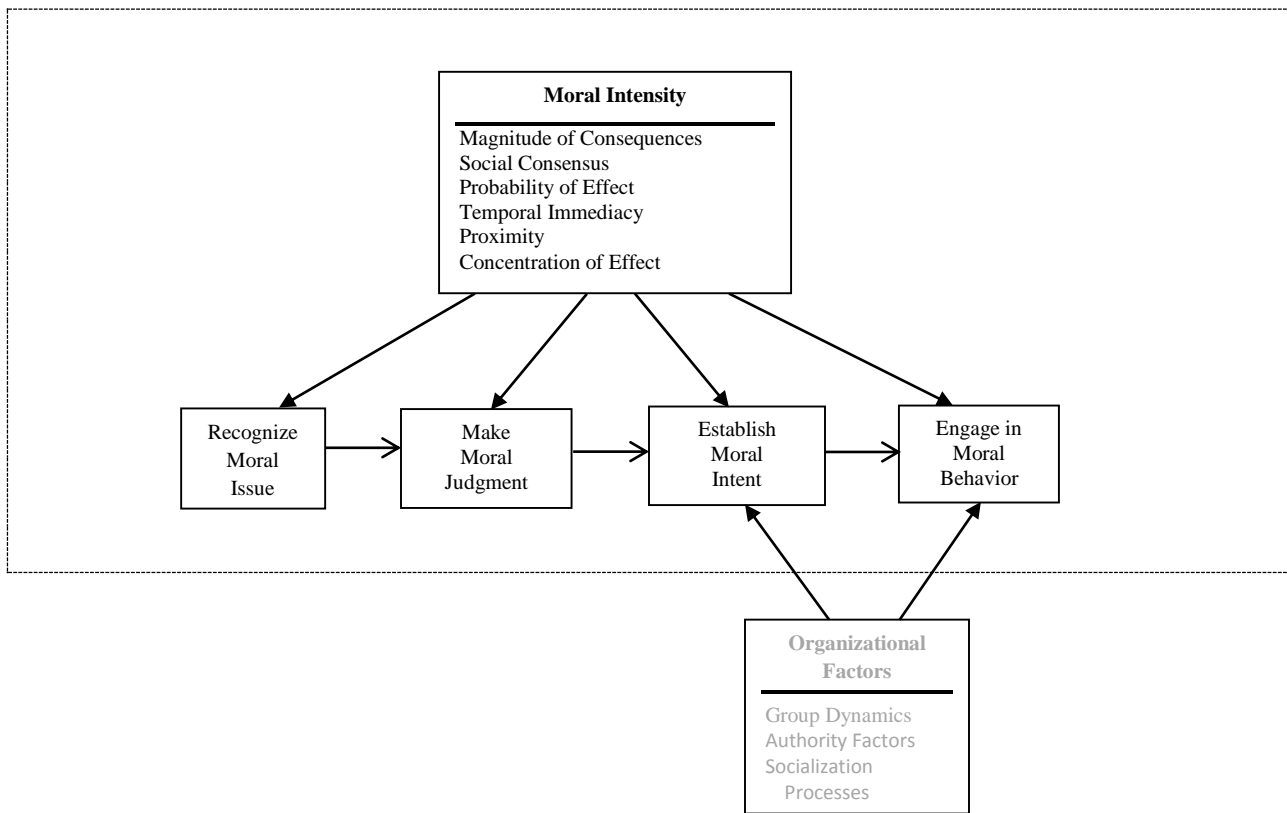
- III. Medical Education – reform relationships with industry in medical education; provide education on conflict of interest; reform the financing system for continuing medical education.
- IV. Medical Practice – reform financial relationships with industry for community physicians; reform industry interactions with physicians.
- V. Clinical Practice Guidelines – restrict industry funding and conflicts in clinical practice guideline development; create incentives for reducing conflicts for reducing conflicts in clinical practice guideline development.
- VI. Institutional Conflict of Interest Policies – create board-level responsibility for institutional COIs; revise PHS regulations to require policies on institutional COIs.
- VII. Supporting Organizations – provide additional incentives for institutions to adopt and implement policies; develop research agenda on conflict of interest (Lo & Field, 2009, pp.16-17).

### **Theoretical Framework**

The professional fields of organizational behavior and management have generated a number of ethical-decision making models for individuals in organizations. Thomas M. Jones (1991) developed one such model using J. R. Rest's 1986 model as the foundation. Jones' model centers on the issue-contingency nature of a decision with an emphasis on the moral intensity of the issue. Jones' model of ethical decision making (Figure 2) was the theoretical framework within which I conducted the study for the purpose of exploring physicians' individual perceptions of resolving potential or perceived conflicts of interest (COI). Additionally, for the purpose of this study, I excluded the organizational factors in his model which should present an opportunity for future research. The context of COIs relate to the

interaction of the physicians' relationships with industry, defined as pharmaceutical, medical device, or biotech firms. The model placed emphasis on physicians as moral decision-makers or moral agents and their ability to tap into embedded ethics and morals that influence decisions regarding research, teaching, and patient care.

Figure 2: Adapted from An Issue-Contingent Model of Ethical Decision Making in Organizations.



Source: Adapted from An Issue-Contingent Model of Ethical Decision Making in Organizations. Jones, T. M. (1991, April). Ethical decision making by individuals in organizations: An issue-contingent model. *The Academy of Management Review*, 16(2), p. 379. Used with permission from the author, Thomas M. Jones, PhD (Appendix J).

As discussed earlier in this chapter, there are regulatory agencies including the U. S. DHHS FDA and U. S. DHHS OIG; accreditation bodies, LCME, ACGME, ACCME; relevant professional and ethical recommendations and opinions by the AMA, AAMC, and IOM; voluntary industry codes, PhRMA and AdvaMed Codes; and institutional conflicts of interest or

industry policies that guide physicians in managing and resolving conflicts of interest (COIs). The lack of literature regarding the role of the individual in COI resolution suggested exploring the ethical nature and moral intensity of physicians' decision-making process used to resolve perceived COIs and to proceed with commercially unbiased responsibilities in the areas of research, teaching, and patient care (AAMC, 2008; AAMC, 2010; Lo & Field, 2009).

In developing his model, Jones (1991) conducted a synthesis of existing models among which he identified collective strengths and weaknesses. As a result, he identified the gap in the literature as the absence of the explicit moral issue itself and its characteristics which he referred to as moral intensity. He also discussed the implicit presence of the moral issue in the synthesis. Using J. R. Rest's 1986 four-component model for individual ethical decision-making and behavior as the foundation of the synthesis; he incorporated elements of L. K. Trevino's 1986 person-situation interactionist model (in Jones, 1991; Hayibor & Wasieleski, 2009) which is similar to Rest's model; Ferrell and Gresham's 1985 model of ethical decision-making in marketing relative to professional codes, corporate policy, and rewards and punishment (in Jones, 1991); Hunt and Vitell's 1986 model of ethical decision-making in marketing with an emphasis on the effect of environmental factors and personal experiences (in Jones, 1991); and Dubinsky and Loken's 1989 model of ethical decision-making in marketing based on the theory of reasoned action (in Jones, 1991). All of the models in the synthesis have elements of applicability to the study, but in researching Jones' model (1991), I determined that it was the most comprehensive and relevant framework for thoroughly exploring the research questions through examination of the process.

The four components of Rest's 1986 model were the theoretical foundation for Jones' 1991 model and required the moral agent who, in this case, is the physician to (1) recognize the

moral issue, (2) make a moral judgment, (3) establish moral intent, and (4) act on the moral concerns. The first component of recognizing the moral issue requires (a) the individual to acknowledge one's role as a moral agent, (b) that the decision involves choices (volition), and (c) that the decision or action produces consequences for or have an effect on others. In Jones' (1991, p.391) conclusions regarding his proposed issue-contingent model of ethical-decision making, he suggested that future research "should include consideration of the effect of the moral agent's failure to recognize the moral issue." The suspected failure, whether an inability to identify a moral issue or an intentional disregard of a moral issue, was taken into account.

The second component of the process requires the moral agent to make a moral judgment. Based on the varied models of moral judgment stages, social cognition, and the effect of context by Kohlberg and others; Jones (p. 384) contended that "moral reasoning is issue dependent." He validated his argument with the studies of Velasquez, Fiske and Taylor, Taylor, Weber, and others indicating that, in summary, moral reasoning is proportional to whether the moral stakes are high or low. Therefore, it is essential to understand the issue that is central to an ethical decision and how it is affected by the characteristics of moral intensity.

The third component, establish moral intent, and fourth component, act on the moral concerns, are interrelated. Jones (1991) asserted that moral intent influences moral decision-making and moral behavior which is supported by Fishbein and Ajzen's (1975, p. 381, in Jones, 1991, pp. 386, 387) arguments that "the best predictor of a person's behavior is [one's] intention to perform the behavior" and that a moral judgment, *what is morally correct*, is not the same as the decision to act upon the moral judgment. Harrington (1997) also supported Rest's moral intent component in Jones' model and the reasons for the inconsistency between what an individual knows is wrong versus one's unethical actions.

Engaging in moral behavior, the fourth component in Rest's model, may also be influenced by several factors including what Fiske and Taylor (1984, in Jones, 1991) refer to as situational forces, which are not always evident to the moral agent, such as self-serving bias based on an individual's knowledge of one's own attitudes, feelings, and intentions. Secondly, social, cultural, psychological, and physical proximity may play a considerable influencing role. The more distant an individual is from a situation and its effects, the less influence proximity will have on the moral decision. In support of the fourth component of Rest's model, Detert, Trevino, and Sweitzer (2008) explored Bandura's assertion and argument (1986, in Detert, Trevino, and Sweitzer, 2008, p. 374) "that moral disengagement explains why otherwise normal people are able to engage in unethical behavior without apparent guilt or self-censure." Bandura also suggested that individuals can "morally justify" harm to others although they know it is wrong. The authors also tied moral disengagement to Jones' 1991 model, indicating that moral intensity may be dependent upon the potential harm as a result of the decision.

Through faculty interviews, Jones' integrated model determines if and how the characteristics of the moral issue bring perceived conflicts of interest to the heart of the conflict-of-interest resolution process. Therefore, it is important to understand the evolution of the gap Jones identified as moral intensity through the characteristics of the moral issue and how moral intensity relates to supporting the evidence presented and to the context of the study (Jones, 1991; Harrington, 1997; Hayibor & Wasieleski, 2009).

### **Moral Intensity**

Moral intensity is a construct identified by Jones (1991) that focuses on the issue at the center of a decision and how it is assessed by the person making the decision without

consideration of the context of the professional organization or environment. Furthermore, the level of moral intensity may vary depending on the issue. Jones supported the significance of the moral issue through intuitive, observational, and empirical factors. The intuitive nature of the issue suggests an increased concern for decisions involving moral issues that may have an effect on individuals close to the decision-maker. Observationally, physical, psychological, cultural, or social distance affects the decision maker's perspective of the moral issue. Finally, empirical evidence suggests that ethical decision-making may be proportional to the level of the decision maker's anticipated consequences or risks (Fritzsche and Becker, 1983; Fritzsche, 1988; and Weber, 1990; in Jones, 1991).

Hayibor and Wasieleski (2009) reinforced Jones' (1991) intuitive, observational, and empirical factors through their application and probable effect of the availability heuristic on the perception of moral intensity in his model. According to Tversky & Kahneman (1973, in Hayibor & Wasieleski, 2009, p. 154; Jones, 1991), an availability heuristic "in uncertain contexts...is used to facilitate estimation of frequencies and probabilities of events," *a judgment call*, evaluating the probability of events or risks, based on what can easily be brought to mind or rationalized. Physicians, for example, may not perceive that they have conflicts of interest (COIs) that stem from financials relationship with industry as was demonstrated by the examples in chapter one. They may not immediately be able to recall colleagues that found themselves within circumstances that created COIs and subsequently encountered barriers to effective research, teaching, or patient care with minimal or no negative effects. Hayibor and Wasieleski (2009, p. 155) further proposed that "the availability heuristic effects ethical decision-making by its influence on the moral intensity of the issue" basing their research on two of the six characteristics of a moral issue identified by Jones – magnitude of consequences and social



consensus. Hayibor and Wasieleski enhanced Jones' research by concluding that by "identifying the availability of particular phenomena as potential determinants of the moral intensity of ethical issues," the availability heuristic has significant consequences for ethical decision making and promoting ethical behavior (pp.163-164). Jones (1991) identified six characteristics of moral intensity as (1) magnitude of consequences, (2) social consensus, (3) probability of effect, (4) temporal immediacy, (5) proximity, and (6) concentration of effect, each of which is defined and discussed below. The interview protocol for the study presented an opportunity to assess each case scenario and determine if there was a moral issue at the center of the decision process by taking each of the six characteristics of moral intensity into consideration.

#### **Magnitude of consequences.**

Jones (1991, p. 374) defined *magnitude of consequences* as "the sum of the harms (or benefits) done to victims (or beneficiaries) of the moral act in question." There are underlying assumptions that ethical decision-making is directly proportional to the level and nature of consequences, that a link exists between consequences and reasoning, and that a moral agent as the decision-maker has a moral component. Jones presented empirical evidence by Fritzsche and Becker (1983), Weber (1990), Fritzsche (1989), and York (1989) to support the assumptions underlying the inclusion of this characteristic. Collectively, their research suggested that serious consequences encourage ethical behavior more so than consequences of a lesser degree.

#### **Social consensus.**

Jones (1991, p. 375) defined *social consensus* as "the degree of social agreement that a proposed act is evil (or good)." In essence, "it is difficult to act ethically if a person does not know what good ethics prescribes in a situation; a high degree of social consensus reduces the

likelihood that ambiguity will exist.” Laczniak & Inderrieden’s (1987, p. 304, in Jones, p. 375) assertion supported Jones’ logic that “in order for individuals to respond appropriately to a given situation, agreement must exist as to whether or not the behavior is appropriate.” In exploring Jones’ decision-making model, Harrington (1997, p. 364) examined the social consensus characteristic of moral intensity and suggested that “the greater the level of seriousness, the more likely it is that laws will be created, as evidenced by laws for murder, theft, etc.”

While hopefully not in the same category as murder and theft, the principle still applies. Harrington’s (1997) study supported Jones’ 1991 model indicating that social consensus influences moral judgment and moral intent. In the context of this study, the increasing number of regulations, recommendations, codes of conduct, and accreditation guidelines have been established or revised in recent years. They represent the social consensus characteristic and are based on an assessment of the seriousness of potential consequences. The interview protocol further examines this effect through the case scenarios. The increased oversight is intended to shape and control ethical guidance in the interaction of physicians and industry.

### **Probability of effect.**

*Probability of effect* represents logic in a decision and is “a joint function of the probability that the [moral] act in question will actually take place and the [moral] act in question will actually cause the harm (benefit) predicted (Jones, 1991, p. 375).” Additionally, anticipated consequences of moral actions are the result of the individual’s estimation of the magnitude of consequences. The moral act in the context of the study is a physician’s decision with the intent of resolving a perceived conflict of interest in an ethical and moral manner and with consideration of the effect ranging from individuals to society as a whole. The interview

protocol probed potential harms and benefits in the case scenarios with relevance to magnitude of consequences as well as probability of effect.

### **Temporal immediacy.**

*Temporal immediacy* of the moral issue refers to “the length of time between the present and the onset of consequences of the moral act in question; shorter length of time implies greater immediacy (Jones, 1991, p. 376).” Jones supported this component with tenets of economic theory – (1) individuals tend to disregard impact of events that happen in the future and (2) as time increases between the situation and the anticipated consequences, the probability of predicted harm decreases and potentially diminishes moral urgency.

In this study, temporal immediacy is probably most evident in decisions that evolve around medical research involving human subjects. Examples include the short-term and long-term effects of certain classes of drugs, e.g. the effect of certain cholesterol-lowering statin products on the liver or the effect of certain NSAID products on stroke or heart attacks or other cardiovascular events. The interview protocol examined the effect of time in terms of future effects as it did with the proximity of personal or professional relationships which is closely related to temporal immediacy.

### **Proximity.**

To reiterate the influence of *proximity* previously discussed, Jones (1991, p. 376) stated that “the proximity of the moral issue is the feeling of nearness (social, cultural, psychological, or physical) that the moral agent has for victims (beneficiaries) of the evil (beneficial) act in question.” Proximity, as a characteristic of moral intensity, represents the intuitive and observable explanation of the effect of moral intensity of ethical decisions.

In theory, individuals and the physician decision makers may instinctively care more for those near to them, e.g. by family relationships or close friendships, than those who are distant. To support the inclusion of proximity as a characteristic of moral intensity, Jones (1991) cited Milgram's 1974 teacher-student obedience experiments in which *increased* physical proximity, the greater distance between student and teacher, *decreased* obedience. This analogy implies that physicians' close relationships with their patients would generate thoughtful decisions in the patients' best interests regarding potentially beneficial or harmful effects on their patients. Although the National Institutes of Health (NIH) provides guidance in the protection of human subjects, decisions by researchers and the effects of those decisions on a cohort of random clinical trial subjects may be less proximate, i.e. a greater distance between researcher and subjects. Another example that supports the moral nature of proximity as a characteristic is Charles Fried's analogy of 'lawyer as friend' in legal relationships in which Fried professes that "not only do attorneys often tend to develop close (proximate) relationships with their clients, but also that these relationships are morally appropriate. (Fried, 1976, in Jones, 1991, p. 377)"

### **Concentration of effect.**

Jones (1991, p. 377) defined the sixth and final characteristic of moral intensity, *concentration of effect*, as "an inverse function of the number of people affected by an act of given magnitude." Jones explained this characteristic well with an example – "cheating an individual out of a given sum of money has a greater concentration of effect than cheating an institution, i.e. a corporation or government agency out of the same amount (p. 378)." Rawls' Theory of Justice (1971, in Jones, 1991, p. 378) supported the principle expressed by the example through an assumption that those "who have a sense of the paramount importance of justice for the individual will abhor immoral acts that result in highly concentrated effects." The

study contemplates this characteristic through discussion of the effect of potential significant gain on the decision process discussed in each of three case scenarios.

## **Bias**

As the six characteristics of moral intensity affect the moral issue in the four components of an ethical or moral decision-making process, Jones (1991) suggested that two sources of biases are inherent to the process – the individual who is acting as the moral agent and organizational factors that can influence moral behavior and test the cognitive ability of the decision-maker. In referencing the work of others, Jones (1991) proposed that individual biases may present themselves in the form of an individual’s inability to process “what if” scenarios, perceive risk, recognize early indications of a problem, see oneself as an independent agent in moral situations, and possibly accept responsibility for a moral conflict. On the opposite end of the individual’s bias spectrum is an ‘illusion of control’ (Langer, 1982, in Jones, 1991) in which an individual as the moral agent overestimates one’s control in the situation leaning towards personal choices.

As discussed earlier in chapter two, accreditation, regulatory, and organizational policies provide oversight for capturing and resolving potential conflicts of interest with the intent of mitigating physician bias in teaching, research, and patient care. With these oversight mechanisms taken into consideration, the study explores the influence of personal biases, values, and morals. It is a common and accepted practice for pharmaceutical and medical device companies to recruit physicians as key opinion leaders (KOLs) who are considered experts in their respective medical specialties or sub-specialties. Industry trains its KOLs, e.g. as a member of a speakers bureau, in a manner that best represents and promotes the companies and their

interests. With recognition and increased status, KOL physicians may also presume a greater sense of control including that of making unbiased decisions in the best interest of the patient.

In summary, Jones' (1991) ethical decision-making model of issue-contingency supports that moral behavior is connected to moral decision-making, individual and organizational influencing factors, and levels of moral intensity surrounding the significance of the issue. The model also places a specific emphasis on magnitude of consequences, probability of effect, temporal immediacy, and concentration of effect. As noted earlier, the study does not consider organizational factors and their influence but this theoretical component should provide opportunities for future research. As the research instrument for the study with approximately twenty years of observation and interaction with academic physicians, I reviewed several decision-making models and determined that the issue-contingency model would provide the most meaningful opportunity to explore a process beyond what the environment dictates regarding disclosure and resolving potential conflicts of interest.

## **Conclusion**

Chapter two presented a comprehensive assessment of the context in which I conduct the grounded theory study. The literature review began with a global view of higher education and its evolution in becoming more of a corporate entity through commercialization, adopting a decentralized responsibility center model, and fostering research and other types of partnerships with business and industry. Secondly, the literature review offered an historical perspective of the principles that for centuries have defined faculty and higher education. Those principles included ethics, academic freedom, and responsibilities to society for teaching, research, and public service. The third purpose of the review was to narrow the concepts to the field of

academic medicine and present the external forces and internal pressures that have imposed scrutiny and oversight. The fourth and final goal was to connect with faculty and how, in that role and in the environment described in this chapter, one makes ethical decisions in resolving conflicts of interest for the advancement of medicine and the benefit of the common good.

## **Chapter III**

### **Methodology**

#### **Purpose of the Study**

The purpose of this qualitative, grounded theory study was to identify and investigate how physicians manage and resolve perceived conflicts of interest (COI) in their roles as teachers, researchers, and clinicians. The study was specific to individual physician's financial relationships with industry and within the context of university-industry relationships. An academic physician's financial relationship with industry may be in the form of consultancy, member of a speakers' bureau, advisory or scientific board member, recipient of research grants directly or through an institutional agreement, patent agreements, royalties, or involvement in industry-funded studies. Disclosures of a physician's financial relationships also extend to the same types of relationships that an immediate family member may have, all of which must be disclosed if the relationships have existed within the previous twelve months, regardless of whether the relationship currently exists (ACCME, 2004; AMA, 2011; U. S. FDA, 1997; & U. S. DHHS OIG, 2003).

As such, a financial relationship may hinder the faculty member's ability to make ethical decisions regarding how knowledge is framed and presented to future physicians in the classroom, how data are analyzed and manipulated in research projects or clinical trials, how a patient is treated and with which company's drugs, and ultimately how decisions could influence the effects on society. Regardless of academic discipline, the tenets of Academic Freedom (AAUP, 1940) protect faculty academic decisions. The study explored the potential of these academic decisions being commercially-influenced through individual faculty financial



relationships with industry as previously described or through involvement in university-industry relationships.

To thoroughly examine the stated purpose of the study, this chapter presents the research questions, describes the methodology for conducting the study, and explains the exclusion of other methodological approaches. I also submit the rationale for a qualitative, constructivist, grounded theory study design and discuss my role as the researcher. In the research plan section, I describe the institutional settings and detail the sampling procedures and participant selection for the study. Finally, I outline methods of data collection and analysis. The following research questions were central to confirming, refining, or developing a theory underlying the process of ethical decisions.

### **Research Questions**

The grounded theory study examined the following research question – How do physicians as academicians manage or resolve potential conflicts of interest in their roles as teachers, researchers, and clinicians?

Secondarily, the study examined:

- Factors that may influence ethical, commercially-unbiased academic decisions;
- Characteristics of ethical, evidence-based decisions v. commercially-influenced decisions; and
- Assessments of how relationships with industry may threaten academic freedom in ethical decision-making.

## **Design of the Study**

### **Rationale for a Qualitative Design**

University-industry relationships, commercialized organizational structures, and faculty financial relationships with industry are well-known and common within the environment of institutions of higher education (AAMC, 2008 & 2010; ACCME, 2004; AMA, 2011; Bok, 2003; Duderstadt & Womack, 2003; Robbins, 2003; Shuger, 1990; U. S. FDA Office of Policy, 1997; U. S. DHHS OIG, 2003; U. S. Senate Committee on Finance, 2010). As presented in chapter two, various laws and regulations, policies, guidelines, and voluntary codes of ethics and conduct govern or provide oversight mechanisms for the environment (AdvaMed, 2010; AAMC, 2008 & 2010; ACCME, 2004; ACGME, 2007; AMA, 2011; PhRMA, 2010; U. S. FDA Office of Policy, 1997; U. S. DHHS OIG, 2003; & U. S. Senate Committee on Finance, 2010). As a result, regulators, accredited organizations, and other interested stakeholder groups have created quantifiable mechanisms, e.g., questionnaires, surveys, attestations, and third-party evaluations, that are intended to ‘manage and resolve’ perceived conflicts of interest that may impact a decision in the academic areas of teaching, research, or patient care.

The above-mentioned regulators, Congress, and professional organizations continue to investigate the environment. As presented in chapter two, a literature and research gap appeared to exist regarding how physicians have historically processed the resolution of perceived conflicts of interest (COIs) but also how in the future they may manage their resolution of potential COIs. In the resolution process, physicians make ethical decisions about moral issues and, as such, the study explores physicians’ possible role as moral agents in the process (Jones, 1991; Lo & Field, 2009). Therefore, through application of Jones’ (1991) theoretical framework

to three case scenarios, the data presents evidence through interview data of how faculty as individuals may manage and resolve COIs which supported the rationale for a qualitative, grounded theory study. Strauss and Corbin (1998) define grounded theory as an existing or emerging theory that is grounded in the participants' perspectives and observations and could provide insight, enhance understanding, or generate action. Strauss & Corbin's definition of grounded theory confirms that perspectives of physicians as interview participants were essential to studying ethical decision-making.

The gap, in concert with the dynamic and interacting nature of the three constructs discussed in chapter two – university-industry relationships, commercialized organizational structures, and faculty financial relationships with industry – invited a naturalistic, inductive approach, encouraged insight and understanding, promoted rich descriptions and explanations from participants in the social context, and made the world visible for observation, interpretation, and experiencing. In the study, I approach grounded theory from a constructivist viewpoint, even though I use a theoretical framework as a guide which would indicate a positivist approach. The constructivist approach also focuses on analyzing the process of ethical decision-making, results, and influencing factors of physician actions and interaction with industry. Additionally, the constructivist approach permits physicians, as participants in their natural settings, to present various meanings and perspectives through case scenarios that confirm the social and historical significance of COI management and resolution. The participants also shared personal experiences as confirming or divergent opinions and philosophical points of view either during the discussion of the case scenarios or as concluding comments to the interview which further contributed to affirming a grounded theory methodology (Charmaz, 2006; Creswell, 2003;

Denzin & Lincoln, 2000, in Ritchie & Lewis, 2004; Glesne, 1998; Maxwell, 2005; Miles & Huberman, 1994; Ritchie & Lewis, 2004).

Scrutinizing the COI resolution process as a qualitative study contributes to a greater understanding of the concept by identifying and examining its features and how they inform the process of ethical decision-making. An analysis of the interview data provides insight into physicians' understanding of and approach to ethical decision-making.

As the researcher, I did not consider quantitative methods for the study. A quantitative approach would present a confirming or refuting picture of data outcomes of physicians' financial relationships with industry. Additionally, it would not have presented a full understanding of the processes that are inherent to making individual, ethical decisions within the context of that interaction. Applying a qualitative, grounded theory research design emphasizes process rather than solely emphasizing results which is more indicative of a quantitative approach. Processes viewed from different perspectives have duration whereas people, places, and their interactions are constantly changing and allows for interpretation of what is being studied (Charmaz, 2006; Creswell, 1998; Creswell, 2003; Glesne, 1998; Maxwell, 2005). Grounded theory provides insight into the processes that would lead to possible outcomes regarding ethical decisions, as defined in Maxwell's five intellectual goals and three practical goals.

Maxwell's (2005) five intellectual goals include (1) understanding the meaning, (2) understanding the particular context, (3) identifying unanticipated phenomena and influences, (4) understanding the process by which events and actions take place, and (5) developing causal explanations. Maxwell's three practical goals encourage (1) generating results and theories that

are understandable and experientially credible to those being studied and others, understanding the process, (2) conducting formative evaluations to improve existing practice, and (3) engaging in collaborative research with research participants. Maxwell's intellectual and practical goals support and further demonstrate the viability of a qualitative, grounded theory study.

My pilot study supported Maxwell's (2005) intellectual goals with a particular emphasis on understanding the context of my dissertation study. The purpose of the pilot study was to examine the effect of commercialization on higher education, the increasing regulatory demands placed on continuing medical education (CME), and the consequential need of CME units to balance fiscal responsibility and commercial involvement. Kurt Lewin's Three-Step Change Model (Robbins, 2003) was the lens through which the changing environment and its effects on CME were explored, placing CME units between a 'rock and a hard place.' The pilot study was also a qualitative study incorporating two individual interviews in addition to one focus group of four consisting of two faculty members, one of whom was also a departmental administrator. The other two participants included an academic administrator and a hospital administrator. All participants had regularly interacted with CME and offered different perspectives of the commercialization trend in higher education often presenting a point-counterpoint discussion.

Two findings emerged, the first of which indicated that, as higher education becomes a more corporate structure, the effect of commercialization encourages establishing external partnerships with industry to supplement budgets. The second finding recognized a struggle between the ethics of relationships with industry and departmental fiscal accountability. Both findings supported the need for further research and a more in-depth examination, beyond CME, of the environment in a broader context of faculty involvement in teaching, research, and patient

care. The pilot study also influenced the design of this study to explore ethical decision-making theory in a commercialized environment through one-on-one interviews.

### **Rationale for Constructivist Grounded Theory**

Constructivist grounded theory is an inductive approach that allows for the researcher's interpretation of data gathered during the interviews. This approach provides an abstract understanding of the interaction of the participants' multiple viewpoints of their situations and experiences with other data sources. As the researcher conducting one-on-one interviews, I have the opportunity to actively listen to how the participants construct and interpret meaning in the process of conflict of interest (COI) management and resolution through case scenarios.

Researcher reflexivity, discussed later in this chapter under Role of the Researcher, was essential because constructivists connect facts and values which reinforces Jones' (1991) ethical decision-making model as a framework for the study. A resulting theory that emerges from data analysis is, in and of itself, an interpretation that may confirm a presupposed theory, enhance or expand an existing theory, or develop a new theory (Charmaz, 2006; Creswell, 2003).

### **Consideration of Other Methodologies**

#### **Phenomenology.**

A phenomenological study promotes the exploration of the meaning of the subjective, everyday, lived experiences of individuals about a concept and, as in this study, from a constructivist perspective. This approach allows participants to express their views through open-ended questions concerning a current issue. Phenomenology explores *intentionality* which is based on Husserl's 1913 work and involves both the act and object of consciousness in human experiences. Phenomenology is also conducive for studies in the health sciences which is the

professional environment of the study (Creswell, 1998; Creswell, 2003; Patton, 2002). Creswell summarizes the procedure of a phenomenological study as follows: (a) the research should understand the philosophical perspective behind the study; (b) research questions should explore meaning and allow for description of the lived experiences; (c) data collection is from those who have actually experienced the phenomenon; and (d) data analysis should follow steps utilized in all psychological, phenomenological methods. Fundamental to phenomenology is the description of lived experiences which could vary among the participants being interviewed. Grounded theory, on the other hand, allows for continuity of data collection and analysis. As the research instrument, I accomplish this by presenting the same three case scenarios to all participants.

The focus of the study was ethical decision-making in individual resolution of conflicts of interest that present themselves to academic physicians in their roles of teaching, research, and patient care and their potential consequences. A phenomenological approach appeared to be *a propos* to the study based on the study's setting, Creswell's criteria above, and supported by a quote from Patton (2002, p.14), "doctors who look only at test results and don't also listen to their patients are making judgments with inadequate knowledge, and vice versa." Although the study appeared to be obvious for a phenomenological study; with valued guidance from my committee, I chose grounded theory methodology. Grounded theory places emphasis on the *process* of ethical-decision making as reflected in Jones' model (1991) versus focusing on the issue at the center of a conflict of interest (COI) that generates the process.

## **Case Study.**

Additionally, I considered a case study design which is defined as an in-depth investigation of a unit of analysis and of its characteristics within a bounded context. A case may be an individual, group, culture, phenomenon, or entity; and a study may consist of one case or of several. However, the focus of the study suggested the need for greater emphasis on process and anticipated outcomes rather than cases. Therefore, grounded theory was the best suited methodology for the study which examines the *process* that entails the management and resolution of conflicts of interest through ethical decision-making (Creswell, 1998; Creswell, 2003; Gay & Airasian, 2000; Lincoln & Guba, 1985; Miles & Huberman, 1994; Patton, 2002; Strauss & Corbin, 1998).

## **Role of the Researcher**

In qualitative research, the researcher or investigator is the research instrument and must establish credibility which is dependent on the researcher's skill, competence, and rigor of fieldwork while recognizing the effect of distractions. Variations in skills and objectivity should be counterbalanced by the researcher's flexibility, insight, and assumed knowledge base that is unique to being a human research instrument. For these reasons, the researcher as the instrument of inquiry should adopt a position of empathic neutrality providing a balance between detachment and being too involved. It is crucial for a qualitative researcher, as the instrument, to establish credibility and disclose assumptions and biases that could influence the study. Therefore, I describe my background and qualifications below for conducting the study. I also disclose my assumptions and biases as well as how I address them with respect to fairness and balance of perspectives and findings (Lincoln and Guba, 1981 in Patton, 2002; Patton, 2002).



## **Professional Background**

I have been a continuing medical education (CME) professional in an academic medical center since 1993 and director of CME since 2004. Prior to my current position and with the exception of three years, my professional life has been in continuing education beginning in 1979 and within a variety of disciplines that provided a breadth of professional experiences. Through my academic career, I have been exposed to three different institutional settings – a college of business in a four-year, public land-grant university, a general conference development department in a large community college, and currently, an academic medical center of a four-year private university. The diversity of these institutional settings equipped me with a greater understanding of the governance and fiscal climates inherent to each institutional type and the general, yet varied, resources, challenges, and philosophies of funding.

The organizational structure of academic medical centers (AMCs) is the setting of the study and is reflective of my current professional environment. As the research instrument and sensitive to the need for empathic neutrality; my knowledge of an AMC enhances my credibility to conduct the study through professional experience and institutional involvement with the responsibilities of:

- Employing accepted mechanisms to resolve perceived conflicts of interest (COIs) of physicians who are participating in CME activities;
- Interacting with industry, primarily pharmaceutical and medical device companies, to secure supplemental funding of CME activities;

- Assuring compliance with and maintaining documentation of accreditation as well as adhering to regulatory and institutional policy requirements in the abovementioned functions; and
- Engaging in discussions to resolve apparent COIs using the requisite regulations, policies, and accreditation tools designed for that purpose.

Contributing further to my background knowledge and qualifications is my institutional involvement on two university compliance committees, clinical and teaching/administration, in addition to the committee charged with writing a policy for physicians' interaction with industry. The policy reflects the revised PhRMA Code as well as the essence of the revised AdvaMed Code and covers issues relevant to gifts, entertainment, samples, ghostwriting, speaker bureaus, etc.

Pertinent to the focus of the study, it is important to disclose that my department received a grant from a pharmaceutical company in 2012 to conduct a non US-based evaluation study on the effects of a professional educational intervention on implementing the appropriate protocol for stroke prevention and treatment of patients with atrial fibrillation. As the principal investigator, I received no salary support or other funds from the commercial source. I disclosed my financial relationship of research support to my university and, in all CME disclosure documents, as required by the ACCME, for the life of the project and exceeding the twelve-month disclosure requirement.

With a high prevalence of stroke in China, the symposium was held in Shanghai, China with a follow-up retrospective chart review to determine efficacy of the symposium content. Individuals involved with the study included physicians and other professionals with expertise in education, evaluation analysis, cardiology/atrial fibrillation, public health, and global health

systems and policy. Since the grant was an educational grant, not a clinical research grant, and housed in my department; the IRB required that I, as the director, be the principal investigator for the study. It was my responsibility to assure independence in content development and mitigate the potential of commercial influence and bias. The IRB also required that all investigators in the study be HIPAA-compliant per university policy and CITI-certified by completing three courses offered through the Collaborative Institutional Training Initiative (CITI Program), which was established in 2000 for the purpose of supporting quality and public trust in research. The courses covered the responsible conduct of research, human subjects research (social sciences module), and conflicts of interest (COI). The COI module was case-based and encouraged the learner to be cognizant of all of the facts and to analyze and answer the questions based on the evidence.

Concurrent with receiving the commercial grant funds and preparing for implementation of the evaluation study, I was scheduling interviews, as a graduate student, for my dissertation study, completing the CITI program, and continuing my professional responsibility of resolving potential COIs for CME educational activities which made me acutely aware of being embedded in the world that I was studying. Being responsible for the integrity of these concurrent activities allowed for a triangulation of sources that continually informed and challenged me in avoiding potential conflicts of interest without bias and undue influence in each of my roles as a student, researcher, and professional. While my experience and knowledge contribute to my capability to conduct this study, they are also fundamental to the effects of my personal and professional assumptions and biases on the study. This premise is further supported by the American Psychological Association (APA) in its 2010 publication manual which states that “in all scientific disciplines, professional communications are presumed to be based on objective

interpretations of evidence and unbiased interpretation of fact...although such relations [commercial interests] do not necessarily constitute a conflict of interest, ... (APA, 2010, p. 17).”

### **Researcher Assumptions and Biases**

The challenges presented in resolving conflicts of interest and interacting with industry create a need for preserving a high degree of ethics and professionalism. This balance is sustained through disclosure, transparency, and independence, which collectively constitute an academic ‘firewall.’ If a company is willing to provide funding to an academic medical center in the form of a research grant or funding for an educational activity, the company has a vested and commercial interest in collaborating with the institution and its faculty. Industry’s involvement is documented through contracts or letters of agreement and managed by institutional conflict of interest and commitment policies and procedures, disclosure to relevant audiences, and federal regulatory oversight by the U. S. FDA (1997) and the U. S. DHHS OIG (2003). A conflict can emerge with the intent of the funds. For what purpose are funds being solicited and accepted – educational grants to offset costs, collaborative research, or other? As grantors of commercial funds, are the companies participating for physician benefit, enhancement of medical knowledge, improvement of patient care, advancing research, or product promotion?

Companies collectively referred to as industry are actively involved in conducting research studies and clinical trials with academic institutions, providing the most current, cutting-edge information for practicing physicians and other healthcare professionals whose ultimate goal is to advance science for optimal patient care. Are the findings of these studies that are released to the public reflective of untarnished data, or are the data manipulated to favor the

expected, positive outcomes of the drug or device? Potential financial risks and benefits can be associated with research findings.

My biases are embedded in these assumptions. As indicated previously, I assert that healthy university-industry relationships are important for the advancement of knowledge and science, the study of medicine, and technology transfer, thereby contributing to the marketplace. However, I struggle with specific and sometimes ambiguous views of commercialization of higher education and if the public good is always the beneficial recipient of these relationships. From an academic point of view, the long-standing tradition of the academy has changed with an increased emphasis on a corporate model in which knowledge can be viewed as a product for sale.

Taking my limitations into consideration, I sought a theoretical framework that would address moral judgment and consequences inherent to individual ethical decisions, and I selected physicians as interview participants who may currently have or have had financial relationships with industry in the past. I employed the following methods to address my biases.

### **Methods to Address Subjectivity and Bias**

I explored and continuously monitored my research subjectivity, intersubjectivity, and biases through personal and professional lenses and addressed my perspectives of the study in the discussion of my role as the researcher. By writing field notes, member-checking, and including verbatim accounts from the transcribed interviews in the findings, I monitored my subjectivity, research reflexivity, and empathic neutrality. Using direct quotes from the participants minimized the influence of my points of view and interpretation, regardless of whether they were confirming or opposing views (Charmaz, 2006; Creswell, 2003; Gay &

Airasian, 2000; Glesne, 1998; Maxwell, 2005; Miles & Huberman, 1994; Patton, 2002; Strauss & Corbin, 1998).

Through research reflexivity, I enhanced the use of verbatim quotes by reflecting about my own voice and perspectives which, in turn, contributed to establishing my credibility as the research instrument. A credible researcher's voice communicates legitimacy and trustworthiness and is 'reflexive in consciousness' (Patton, 2002). Maxwell (2005) discussed Hammersley and Atkinson's (1995) definition of 'reflexivity' as the researcher being part of the social world he or she studies. I am the researcher in that context.

Glesne and Peshkin (1992, p. 38, in Maxwell, 2005) view subjectivity as "virtuous, something to capitalize on rather than to exorcise," which better defines the role of empathic neutrality in addressing subjectivity. Empathic neutrality suggests a balance between being too involved which can affect one's judgment and remaining too distant which may lead to diminished understanding of the case (Patton, 2002). As part of my conscious inquiry process, I drew upon my experiential background of knowledge, personal observations, and understanding as well as critical subjectivity or the quality of awareness (Strauss, 1987, in Maxwell, 2005; Reason, 1988 and 1994, in Maxwell, 2005).

As my professional contributions were described above, my experience, awareness, and understanding of the study environment are intended to strengthen and add value to the study as well as credible depth to my role as the researcher, which should be viewed as an asset to the study. However, the reader should also approach the interaction of my background and the study with caution with the intent of reducing the potential for researcher bias.

## Research Plan

### Sampling

Purposeful sampling requires strategic and purposeful selection of information-rich cases and is the technique by which I selected participants for the grounded theory study, implementing a theory-based or operational construct sampling strategy (Creswell, 1998; Creswell, 2003; Miles & Huberman, 1994; Patton, 2002). “The strength of interviewing information-rich individuals allows the researcher to learn a great deal about issues of central importance to the purpose of the inquiry with insight and a more in-depth understanding (Patton, 2002, p. 230).” According to Miles and Huberman (1994), successful purposeful sampling, which is often theory-driven, requires two stipulations. The first is that the researcher should set boundaries, defining aspects of the cases that can be studied within limits of time, place and means. Upon receiving approval from the University of New Orleans’ Institutional Review Board (IRB), I acquired formal access to two institutions, one private and one public. The institutional gatekeepers identified a group of twenty medical faculty participants from which I was able to successfully schedule and conduct ten interviews (50%). I accomplished this in three ways – (1) by determining that the interview would take no more than sixty minutes unless the interviewee wished to continue the dialogue; the average interview lasted forty-five minutes; (2) by conducting the interview on the interviewees’ campuses which are representative of the setting of the study and at locations of their choosing which were usually in their academic offices or conference rooms; and (3) by establishing selection criteria to achieve a strong representative cohort of interviewees including academic roles and financial relationships with industry. Secondly, the researcher should create a framework that will assist in uncovering,

confirming, or qualifying the basic processes or constructs of the study (Miles & Huberman, 1994) which is discussed later in this chapter.

Maxwell (2005) discusses four of several important goals that Creswell (2003) identifies for purposeful selection: (1) achieving representativeness or typicality of the settings, individuals, or activities selected; (2) achieving the opposite of the first goal...capturing heterogeneity in the population; (3) deliberately examining cases that are critical for theories with which you begin the study or will develop; and (4) establishing particular comparisons to illuminate the reasons for differences between settings or individuals. The process of purposeful sampling requires two additional conditions – clear objectivity of the researcher in order for the sample to be independently examined and the opportunity for the cases to be proven or disproven (Ritchie & Lewis, 2004).

### **Participant Selection**

The participants who were identified and selected for the interviews contributed to an understanding of ethical decision-making by physicians who have financial relationships with industry. Furthermore, selecting interviewees in two academic medical centers, one private and one public, provided potential comparison and contrast of perspectives which could be affected by respective institutional, contextual settings (Creswell, 1998). I met the heterogeneity goal by interviewing physicians who represented a gender mix, a diverse range of years of experience and academic titles as well as a variety of specialties in adult and pediatric medicine (Table 1). The two selection criteria, faculty members in an academic medical center or school of medicine and financial relationships with industry, met the goals stated above.



Table 1: Faculty Participant Profile

Participant	Faculty Gender	Specialty	Institutional Type	Years in Academic Medicine
Amanda	Female	Pediatrics	Private	25
Ben	Male	Psychiatry	Private	16
Daniel	Male	Pediatrics	Private	13
David	Male	Internal Medicine	Public	25
Edward	Male	Surgery	Public	36
Grace	Female	Pediatrics	Private	10
Karen	Female	Preventive Medicine	Public	22
Jim	Male	Anesthesiology	Private	6
Molly	Female	Pediatrics	Public	18
Oliver	Male	Internal Medicine	Private	13

Of the ten participants, six (60%) were men and four (40%) were women (Table 2) which proved to be representative of the population and context of the study. The Federation of State Medical Boards (FSMB) data, reported in 2015, represent active medical licenses in the United States excluding medical residents for the 2014 calendar year (Young et al, 2015). Also in 2015 and specific to the academic setting of the study, the Association of American Medical Colleges (AAMC) data represent all clinical, medical faculty in U.S. medical schools for the 2014-2015 academic year.

Table 2: Faculty Participants by Gender

Faculty Gender	Study Participants	Licensed Physicians FSMB (2014)	U.S. Medical Faculty AAMC (2014-2015)
Female	4 (40%)	293,565 (32%)	52,179 (38.5%)
Male	6 (60%)	604,926 (66%)	83,022 (61%)
Unknown	0 (0%)	17,773 (1.9%)	73 (.5%)
Total	10 (100%)	916,264 (100%)	135,274 (100%)

The gender summary (Table 2) of the study participants is in proximate alignment with the FSMB and AAMC data. The percentage of female participants (40%) in the study is in very close alignment and, by 1.5%, exceeds the AAMC percentage of female medical faculty at 38.5%. The percentage of male participants (60%) is below the FSMB percentage of 66% but in close alignment, by 1%, with the AAMC percentage at 61%. These data indicate that the gender breakdown of the study sample (40% female and 60% male) is representative of the medical faculty population in U.S. academic medical centers (AAMC, 2015).

Consistent with purposeful sampling and one-on-one interviews, the individuals who participated were ‘information rich’ providing insight and an in-depth understanding of the conflict of interest (COI) management and resolution process. Therefore, I selected the participants by utilizing the theory-based, operational construct sampling strategy of purposeful sampling, also referred to as theoretical sampling, to examine the concept through their reactions to case scenarios, thereby contributing to an evolving theory. Theoretical sampling continues until saturation of all categories or themes occurs. The data collected from conducting ten interviews suggested that saturation was achieved (Creswell, 1998; Miles & Huberman, 1994; Patton, 2002; Strauss & Corbin, 1998).

Only the two selection criteria, previously discussed, were used to identify study participants. Age and years in academic medicine were not used as participant selection criteria for the following reason. The physician-industry relationship has evolved considerably over the last thirty years and with a more recent acceleration of restrictions, primarily by Congress, that govern the relationships. Therefore, a variety of participants from two institutions was a better representation and reflection of the population spectrum and the evolution of the process being

studied. Gatekeepers at the two sites contributed to identifying potential participants who could possibly meet the relevant criteria.

### **Institutional Descriptions**

Schools of medicine at two institutions of higher education, one public and one private, both not-for-profits, were the settings for the faculty interviews. The Carnegie Classification of Institutions of Higher Education<sup>TM</sup> in its basic classification of 2010 categorized both institutions as Research Universities, very high research activity (RU/VH). Of the 4,634 institutions that were classified in 2010, 73 public universities and 35 private, not-for-profit universities comprised the 108 (2.3%) that Carnegie categorized as RU/VH. The Carnegie Foundation for the Advancement of Teaching offers the classification framework with the goal of characterizing institutional differences and confirming sufficient representation of institutions, students, or faculty for inclusion in research studies such as this one.

With the exception of the governance distinction, public versus private not-for-profit, the two universities were very similar. Both universities have significant graduate and professional programs at the masters and doctoral levels. They have institutional conflict-of-interest policies for faculty and staff in addition to policies that govern and restrict physicians' interaction with industry. The interview participants, all ten of whom are actively engaged in research activity, frequently referenced their own policies during the interviews and, without exception, spoke of their policies with appreciation of intent and valued their contributions to the reputation of their respective universities. The policy comments were offered especially when I inquired about their past or current relationships with industry, which are noted in the participants' composite profile in chapter four.

### **Gaining Access.**

Purposeful selection of participants, who are representative of the context of the study, requires establishing clear selection criteria and rationale of the study prior to beginning the process of gaining access, negotiating relationships, and establishing rapport with participants and gatekeepers who could influence the study. I initially contacted a faculty member who is in a senior leadership role within my own institution to introduce me to a professional colleague who would fulfill the role as gatekeeper at a private institution in another state that I had identified as one of two institutions for the study based on the selection criteria noted above. Secondly, I contacted a professional colleague at a public, out-of-state institution I had identified for the study who directed me to their IRB who, after review, declined my request to conduct the study with its faculty. I subsequently contacted another public university in a different state who granted me permission to interview their faculty for my study. The gatekeeper in the private institution gave me a list of thirteen potential participants to contact, and the gatekeeper in the public institution gave me a list of seven potential participants.

The gatekeepers at both institutions were in senior leadership roles and had the authority to grant access to their institution and faculty and to establish contact with their respective IRBs. Each IRB indicated that no further review and approval was necessary. I presented the gatekeeper at each institution with a prospectus (Appendix F) for consideration of my request. The prospectus described the study including an explanation of why their institutions were selected, how the study would be conducted, assurance that disruption would be minimal, how the results would be reported, benefits from the study, and finally, that the aggregate results would be available to them upon successful completion of the study. The negotiation process required continuous and professional communication that resulted in successful formal access

and verbal confirmation that the study has merit to the field (Creswell, 1998; Creswell, 2003; Glesne, 1998; Maxwell, 2005).

Ethical access also demands that the researcher protect the confidentiality and identity of the participants. I accomplished this by de-identifying the individual participants and the institutions as well as not discussing the specifics of what is learned in the interviews but rather presenting the data in terms of general concepts and de-identified quotes which uphold confidentiality. I assured confidentiality by several methods: (a) in a letter of invitation for their participation (Appendix G), (b) mutual signing of a consent form by the participants and the researcher (Appendix H), and (c) presentation of aggregate, conceptual data in the findings. I protected identifiable participant information by de-identifying and maintaining confidentiality through the use of pseudonyms during the interview and/or with reference to Interviewee #1, Interviewee #2, etc. in the subsequent transcriptions, data analysis and discussion (Creswell, 1998; Glesne, 1998; Patton, 2002). Only descriptions of the institutions were used for the purpose of de-identifying them and adding another level of confidentiality for the participants.

### **Data Collection**

In addition to the interviews that lasted thirty to sixty minutes, data collection for the study came from two other sources – environmental scanning and supporting documents (Creswell, 2003), which were presented in chapter two. Since the documents and the environment are fundamental to the significance and purpose of the study, they were essential sources of data. Both of these data sources were primarily intended to support triangulation, serving two purposes – (1) to validate interview questions about COI policies, regulatory

environment, and physicians' financial relationships with industry, and (2) to either confirm or refute perceptions and interpretations of the participants.

The participants' responses to the concluding general questions presented observational data of their views of the professional environment. The environment, policies, and related documents from the AMA, AAMC, IOM, ACCME, ACGME AAUP, FDA, DHHS OIG and other federal regulatory and institutional sources (see List of Organizational Acronyms, p. xi.) established the context of the study and continue to serve as professional guidance and governance of the medical profession. The purpose of interviewing individuals was to discover things that cannot necessarily be observed and to allow an opportunity to hear and understand another person's perspective through the voice of the individual physician (Patton, 2002). Of the three interview approaches that Patton (2002) describes (*informal conversational interview, general interview guide approach, and standardized open-ended interview*), I implemented the general interview guide approach for individual interviews. The general interview guide approach employs a well-defined question list to be used during the interview for probing a specific subject area, which in this study is conflicts-of-interest.

When conducting one-on-one interviews, the advantages of an interview guide are three-fold: the guide (1) maximizes a limited time frame, (2) establishes continuity for a platform of emergent perspectives and experiences, and (3) provides a framework for more in-depth discussion. Doing so strengthens consistency of information gathered and assures that I, as the researcher and interviewer, use time carefully and efficiently, allowing individual perspectives and experiences to emerge (Patton, 2002).

In developing the questions for the interviews, I paid particular attention to utilizing several of Patton's (2002) six types of questions as well as what he describes as the appropriate sequence to encourage information building and maximizing interpretations of experiences. His six types of questions evolve from (1) experience and behavior, (2) opinion and values, (3) feelings, (4) knowledge, (5) senses, and (6) background/demography. It is the second (opinion and values), third (feelings), and fifth (senses) types of questions that may be the strongest in supporting Jones' (1991) issue-contingent model of individual ethical decision-making. This was due to the ethical decision-making model's focus on moral intensity and its effects on recognizing a moral issue, making a moral judgment, establishing moral intent, and engaging in moral behavior. The first (experience and behavior), fourth (knowledge), and sixth (background/demography) types of question gathered profile data of the individual participants that contributed to a composite profile.

### **Rationale for Interview Method**

Interviews provide access to observation and interaction. They provide insight, *a window on their past*, into experiences, perceptions, feelings, exposure to settings otherwise not accessible, and effects of events on their lives (Weiss, 1994). Of the several types of interviews methods considered for the study, one-on-one interviews were the most appropriate. The one-on-one interviews provided an opportunity for me, as the research instrument, to hear and share ideas and thoughts relative to the ethical decision-making in an academic setting (Creswell, 1998). Furthermore, it capitalized on the required ability of the interviewer to be an active listener, to respond to a spontaneous and unpredictable exchange, and to observe nonverbal and verbal feedback (Glesne, 1998; Patton, 2002). Glesne stresses three key features of interviewing: *structured* – specific questions to address, *open* – questions as a result of unexpected points that

are raised, and *depth-probing* – points that prompt further explanation. The individual interviews offered opportunities for structured, open, and depth-probing interactions between the interviewees and the researcher interviewer as demonstrated in the interview guide (Appendix I). Additionally, Glesne notes that the informal time after the taping ceases is a valuable learning opportunity providing casual discussion of the issue which occurred in five of the ten interviews and were very collegial conversations. For example, at the end of Mary’s interview, she inquired about my project and its goals. Beyond the brief introduction I gave at the beginning of each interview, her curiosity gave me an opportunity to articulate my ‘light-bulb’ moment, express my interest in the topic through experiential examples, and convey why I chose to study it through an ethical decision-making lens which was to give physicians a voice. She responded, “It’s an interesting topic.” I agreed.

### **Interview Guide**

The interview guide (Appendix I) consisted of stating the purpose of the study and then asking questions that, based on Patton’s (2002) six types of questions, explored individual abilities to make ethical academic decisions in the context of a commercialized and regulatory environment. The questions encouraged more probing opportunities for in-depth discussions (Glesne, 1998; Patton, 2002).

As the researcher, I piloted the interview guide with a peer debriefer within my institution to assure that the questions were unambiguous (Lincoln & Guba, 1985). The peer debriefer has a strong working knowledge of the healthcare field in which the study was conducted as well as experience in conducting grounded theory studies. She is also familiar with identifying and



resolving individual conflicts of interest (COIs) that emerge as a result of entering into a financial relationship with industry.

As suggested by Miles and Huberman (1994), to accomplish successful purposive sampling, the researcher should create a framework that will assist in uncovering, confirming, or qualifying the basic processes or constructs of the study. I accomplished this by developing an interview guide (Appendix I) that consisted of three sections: (1) general and demographic questions; (2) three case scenarios that examined the ethical decision-making model; and (3) a set of concluding questions about the environment pertinent to the study.

### **Description of Interview Scenarios.**

The case scenarios represented the three areas of academic medicine – teaching, research, and patient care – in which academic physicians could face potential conflicts. The teaching case scenario involved a well-respected faculty member who teaches a skills-based course using donated equipment from three companies. The faculty member owns stock in one of the companies and favors the use of that company’s equipment in demonstrating the procedure. The second scenario presented a faculty researcher who is involved in a commercially-funded study. The researcher has extensive financial relationships with the funding company for whom the results are not evolving in a manner favorable to the company. The researcher struggles with the unfavorable results and a sense of obligation to the company due to his financial relationships with the company. The final scenario involved an academic physician who retired from a successful career in the pharmaceutical industry (Company E) and is now clinical faculty at his/her alma mater. Because of the faculty member’s familiarity with Company E’s drugs, he/she

tends to prescribe Company E's drugs more frequently when other treatments may be equally or more effective in certain cases.

### **Collection of Data from Interview Scenarios.**

I audio-recorded the interviews (Creswell, 1998; Creswell, 2003; Patton, 2002). Doing so allowed for greater attention to the interviewee versus taking verbatim notes which can hinder active listening, for careful observation of non-verbal reactions, and for actual quotations from the participants. I began the interview with gathering participant profile information and then asking for their definition of a conflict of interest which provided a transition into the scenario segment of the interview. For reference during the interview, I gave each participant descriptions of the scenarios as each was presented and a list of questions to examine. Following their assessments of the three scenario discussions, I posed six concluding questions that addressed themes or assumptions relevant to the scenarios, such as reasons physicians enter into financial relationships with industry, risks and benefits of such, and bias avoidance. I also gave each participant an opportunity to offer additional remarks. During the interviews, I only made notes of key phrases or points for follow-up or clarification. Following the interviews, I also made notes that were reflexive or observational in nature (Patton, 2002). At the conclusion of one interview, the participant commented –

I think it's interesting to explore this. I think the manner of doing it by cases is very interesting as well. As someone who has also done qualitative research, I actually like the way you had some general questions, some cases, and the other things to digest. I think, as an interviewee, that actually facilitated the process of thinking through this (Oliver).

## Data Analysis

Data analysis in grounded theory should always occur concurrently with data collection, a cyclical process which assists with shaping the study and presents an opportunity during which the researcher should consistently write reflections for greater depth of understanding of the data. Strauss and Corbin (1998, p. 13) emphasize that “analysis is the interplay between researchers and data.” They further emphasize the importance of finding a balance between being creative while being systematic in the data analysis stage of the study. Patton (1990, in Strauss and Corbin, 1998) advises grounded theory researchers to adopt behaviors that would promote creativity such as exploring multiple possibilities and options, using nonlinear forms of thinking to encourage fresh perspectives, trusting the process, and having fun. I took precautions to minimize risks by engaging in *epoché* to refrain from my personal prejudices, beliefs, and viewpoints and in *reflexivity* to be continuously conscious and self-questioning of the same. I also categorized the data allowing the voices of the participants to be heard in their own words to minimize subjectivity (Creswell, 2003; Patton, 2002).

## Coding Procedures

In the grounded theory tradition, the systematic aspect of data analysis involves a three-step coding procedure of the interview transcriptions. The initial step of the analytical procedure includes making reflexive notes immediately upon conclusion of the interview, while listening to the audio-recorded interviews, and during transcription. In the course of re-reading the interview transcriptions, I made margin notes, identified key concepts, categories, and subcategories (properties) of information through the interviewees’ words and phrases. A few words and phrases, e.g. bias, familiarity, influence, and ‘slippery slope,’ are considered *in vivo* codes which

were the participants' distinctive terms that gave special meaning to their assessments of an ethical decision-making process (Charmaz, 2006).

I initiated the data reduction process with open coding, the first step in the coding procedure, illustrating the process being explored which, for this study, was ethical decision-making. The second step was axial coding. During this step, I identified interrelationships between concepts and categories (units of information) and narrowed down the most significant categories or central phenomena for theory development. Selective coding, the third and final step was the point at which I modified Jones' (1991) ethical decision-making model based on the perspectives of the participants (Charmaz, 2006; Corbin & Strauss, 2008; Creswell, 1998; Creswell, 2003; Patton, 2002; Strauss & Corbin, 1998). The code list presented evidence of the theoretical framework and the moral intensity characteristics of Jones' (1991) ethical decision-making model (Miles & Huberman, 1994). Coding links raw data to raw data then to contextual themes establishing the foundation for drawing and verifying findings (Coffey & Atkinson, 1996). I verified the findings through triangulation and establishing trustworthiness (Creswell, 1998; Creswell, 2003; Lincoln & Guba, 1985; Miles & Huberman, 1994; Patton, 2002).

### **Trustworthiness**

Lincoln and Guba (1985) define trustworthiness as the methods by which the researcher can persuade the audience that the study is worthy of their attention. This may be achieved by establishing confidence in the "truth" of findings, as well as the applicability, consistency and neutrality of findings (p. 218). Guba (1981a, in Lincoln and Guba, 1985) developed four qualitative terms to address and substantiate trustworthiness of a study – credibility (internal

validity), confirmability (objectivity), dependability (reliability), and transferability (external validity).

### **Credibility.**

*Credibility* of the study, which is defined in quantitative research terms as internal validity, refers to the strength of findings through the eyes of the information sources and truth value (Lincoln & Guba, 1985; Miles & Huberman, 1994). Lincoln and Guba suggest five techniques for establishing credibility of which I employed two: (1) activities intended to increase the probability of credible results through prolonged engagement, persistent observation, and triangulation; and (2) member checks. I accomplished the first technique by describing my role as the researcher and drawing on over twenty years of professional experience through studying, observing, and engaging with the culture and context in which I conducted the study (also Patton, 2002). Emphasizing the role of the researcher, Patton (2002) connects the trustworthiness of the person conducting the research and his or her competence to the trustworthiness of the data. Additionally, I achieved triangulation and contextual validation through detailed discussions in the literature review of the environment and documents that guide and govern faculty relationships with industry as well as thick descriptions by the participants which Patton (2002) and Miles and Huberman (1994) refer to as triangulation and consistency of data sources. I employed a member-check procedure, the second technique, by giving the participants an opportunity to review their respective transcripts for feedback and assuring accuracy. Two of the ten participants requested their transcripts for review and subsequently verified accuracy.

### **Confirmability.**

*Confirmability* assures objectivity by establishing researcher neutrality (Lincoln & Guba, 1985; Patton, 2002). I used triangulation and included my own written reflections to establish objectivity. Triangulation again involved collecting data from multiple sources to reduce the risk of bias and to support, confirm, or contradict the findings of the study (Creswell, 1998; Lincoln & Guba, 1985; Maxwell, 2005; Miles & Huberman, 1994; Patton, 2002). Miles and Huberman distinguished triangulation among five methods, the first four of which were classified by Denzin (1978, in Lincoln & Guba, 1985): data source, method, researcher, theory, and data type. Triangulation for the study was accomplished by methods that included interviews, environmental scanning, documents, and researcher knowledge and experience to reinforce trustworthiness with a specific emphasis on the objectivity of the researcher (Lincoln & Guba, 1985; Miles & Huberman, 1994).

### **Dependability.**

*Dependability* refers to the reliability of the study by establishing stability, consistency, and predictability. In quantitative studies, there cannot be validity without reliability; therefore, in qualitative studies, there can be no credibility without dependability (Lincoln & Guba, 1985). Lincoln and Guba suggest that, while it is not the strongest approach, the same techniques utilized to enhance credibility and confirmability can contribute to addressing stability and consistency aspects of dependability.

Miles and Huberman (1994) suggest questions to substantiate the reliability or auditability of the dependability criterion in establishing trustworthiness. Among the queries that should be addressed or described are clear research questions and a consistent study design, the

role of the researcher and status in the context of the study, triangulation of data sources, and breadth of data collection with appropriate settings and respondents.

### **Transferability.**

The fourth element of trustworthiness, *transferability*, is also referred to as external validity and generalizability in quantitative research methods (Lincoln & Guba, 1985). Transferability assumes the same feature of representativeness of the population (receiving context) while not being confined only to the researcher (sending context). Addressing the appropriateness of transferability in the study was achieved through determining the design of the study and thick description from information-rich sources through the audio-recorded, individual interviews (Lincoln & Guba, 1985; Miles & Huberman, 1994; Patton, 2002). The findings of the study should be transferable to other academic disciplines such as law, engineering, and business in which individual financial relationships with industry or university-industry relationships also exist. Regardless of the field, these relationships could generate conflicts of interest that require resolution through an ethical, unbiased decision-making process.

### **Peer Debriefers.**

Bias plays a key and dual role in my study. It is critical to the theory of ethical decision-making and was equally as critical in my role as the researcher. To mitigate my biases and assumptions and to add a secondary element to the trustworthiness of the study, I incorporated the peer debriefer technique which Lincoln and Guba (1985) explain is a disinterested peer who can reinforce credibility of the study. Lincoln and Guba outlined the advantages as well as the risks of using a peer debriefer. Among the advantages, a peer debriefer is a professional who is not involved in the study and may provide guidance in methodology, is a supportive and

considerate listener, or helps assure the researcher's honesty by playing 'devil's advocate' in all aspects of the study. The risk of using a peer debriefer evolves from the influence of the peer debriefer's perspectives and criticisms that could lessen the researcher's enthusiasm and energy about the study.

The peer debriefers for my study were professionals who have worked in the same academic institution as I and understand the environment in which the study was conducted. One peer debriefer received his PhD in higher education administration and was a fellow graduate student. My second peer debriefer received her PhD in a related educational field, has professional and experiential knowledge of the healthcare environment, and conducted her doctoral study in the qualitative, grounded theory tradition. Both of them actively listened for the purpose of strengthening the study and minimizing my biases.

### **Conclusion**

In this chapter, I presented my rationale for a qualitative, grounded theory study in exploring ethical decision-making and its impact on academic physicians as teachers, researchers, and clinicians in a regulated, scrutinized, and commercialized environment. Instituting a grounded theory study design strengthened the many voices to be heard about the process of ethical decision-making as well as of the environment which provided the context of the study. The findings are presented in chapter four and their implications for policy and future research are discussed in chapter five.



## **Chapter IV**

### **Findings**

#### **Introduction**

The purpose of the study was to develop a theory that represents how academic physicians, who have financial relationships with industry, manage or resolve potential conflicts of interest in their roles as teachers, researchers, and clinicians. Secondly, the study examined factors that influence an ethical decision-making process, characteristics of an ethical decision and how physicians' relationships with industry impact an ethical decision. The financial relationships may take various forms including, but not limited to, research funding, consultancies, speakers bureaus, scientific advisory boards, stock investments, or patent agreements. Requirements for disclosure of these financial relationships also extend to immediate family members.

Thirdly, determining if there were underlying threats to academic freedom as a result of financial relationships with industry added a potential outcome to contemplate during the discussion of the case scenarios. Through these discussions, the participants determined that academic freedom was minimally affected. Their comments regarding academic freedom are presented and discussed later in this chapter.

Using Jones' (1991) issue-contingent ethical decision-making model as the theoretical framework for the grounded theory study provided the opportunity to explore the research questions through three case scenarios in teaching, research, and patient care. The participants frequently offered their own experiential or interpretive accounts as well as divergent perspectives to clarify or enhance a discussion point or question. Finally, the participants'

vision, awareness, knowledge of the environment, and personal and professional views shared in the preliminary and concluding general questions added depth to the findings, identifying characteristics of the academic physician as a moral agent and a refined theory. In addition to reporting the data, findings, and refined theory; this chapter presents a demographic profile of the participants, their assessment of the environment, and revised characteristics of a moral agent.

### **Profile of Faculty Participants**

As described in chapter three, I contacted twenty potential participants of which ten (50%) agreed to participate in the study (Table 1). Of the ten, I interviewed four faculty members at the public institution and six at the private institution. The faculty selection provided a rich variety of combined training, professional interests, industry relationships, and specialties in both adult and pediatric medicine as well as in other non-clinical, health science disciplines including anesthesiology, cardiology, epidemiology, general pediatrics, infectious diseases, internal medicine, law, pathology, psychiatry, preventive medicine, public health, and surgery.

Three of the participants were department chairs which occasionally added an administrative dimension to the discussion. The participants' years in academic medicine ranged from six (6) to thirty-six (36) years with an average of eighteen (18) years. Eight of the participants are currently involved in research, teaching, and clinical/patient care; and two are no longer involved in patient care but are actively engaged in research and teaching. Of the ten participants, six (60%) were men and four (40%) were women (Table 2) which proved to be representative of the population and context of the study based on the FSMB (2015) and AAMC (2015) data discussed in chapter 3.

Table 2: Faculty Participants by Gender

Faculty Gender	Study Participants	Licensed Physicians FSMB (2014)	U.S. Medical Faculty AAMC (2014-2015)
Female	4 <b>(40%)</b>	293,565 (32%)	52,179 <b>(38.5%)</b>
Male	6 <b>(60%)</b>	604,926 (66%)	83,022 <b>(61%)</b>
Unknown	0 (0%)	17,773 (1.9%)	73 (.5%)
Total	10 (100%)	916,264 (100%)	135,274 (100%)

Regardless of other profile characteristics, their reasons for choosing a career in academic medicine were unequivocally the three academic missions of research, teaching, and patient care. They emphasized the importance of each with comments such as “you can only really do independent, directed research in an academic setting (Daniel);” “[I] became interested in studies that really evaluate the interventions we use, the treatments we propose...do they really work, are they worth it... how medical students are taught about the evidence that we have; if they are being taught to evaluate the evidence and how to read the literature (Karen);” and “[to] provide the best clinical care in the best sorts of environments (David).”

The participants’ composite profile represents an academic physician that supports the advancement of the field of medicine through a commitment to scholarship and research and with consideration mindful of industry’s involvement in pursuit of these two missions. The participants viewed and expressed the potential conflict between mission and having financial relationships with industry as a two-fold concern in which “a dual relationship may affect one’s objectivity in approaching a topic or...one relationship interferes with the performance of the other” (Oliver). Secondly, there was concern “when the interest of the mission of the physician is at odds with the interest of a commercial entity, and so choices are made that would advantage one entity versus another” (David). As conveyed in these quotes, the participants’ profile reflects

the academic physician's awareness and sensitivity to ethical balance in the dual academic-industry relationship when the participants identified research funding as the leading reason for industry support whether in support of clinical trials, industry-sponsored research, or investigator-initiated research. Additionally, in collaborative research with industry, the majority of funding is given directly to the institutions, not to the individual, thereby creating a natural firewall against the potential for undue influence, bias, and mission conflict. In essence, the moral and ethical responsibilities of academic physicians as scholars and researchers to various stakeholders involve independence and objectivity of thought, establishing implicit firewalls among roles, gatekeeper obligations, fiduciary commitment of trust and protection, and thoughtful balance of what one can or should not do for a company.

### **Environmental Assessment and Observations**

The study data offered an assessment of the environment and a deeper insight into what constitutes a conflict of interest (COI) and its effects on physicians and institutions by delineating reasons for entering into financial relationships with industry (Table 3) as well as associated risks and benefits. The study data also suggested potential barriers to faculty performance, how bias should be avoided, potential effect of the Sunshine provision (Open Payments) of the Affordable Care Act, which will be discussed in chapter five, and finally, what factors could influence ethical, unbiased decision-making.

In considering possible reasons physicians enter into financial relationships, the participant data presented several broad, environmental or institutionally-based, influencing factors that impact a decision to enter into a financial relationship with industry – (1) opportunities just present themselves when being in a certain specialty connects physicians to industry which can evolve into a mutually beneficial relationship, (2) the advantages of

academic-industry relationships including shared resources for the advancement of science and medicine, (3) institutional pressure to secure external funding due to a decrease in federal support of research as well as a decrease in institutional financial resources, (4) institutional culture and mission, and (5) tenure and promotion, although not considered to be a major influence. These influencing factors and other data supported specific reasons for entering into financial relationships with industry that evolved into three categories – reputation, money and funding, and research (Table 3).

*Table 3: Reasons for Entering into Financial Relationships with Industry*

<b>REPUTATION</b>	<b>MONEY &amp; FUNDING</b>	<b>RESEARCH</b>
<ul style="list-style-type: none"> <li>▪ Recognition in the professional community</li> <li>▪ Professional growth through engagement outside of day job</li> <li>▪ Contribution of expertise and background</li> <li>▪ Mutually beneficial</li> <li>▪ Shared expertise and networking</li> <li>▪ Opportunity to obtain better perspectives of a field</li> <li>▪ Ethical responsibility</li> <li>▪ Pride</li> <li>▪ Fame (narcissistic)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Student loans; debt</li> <li>▪ “Want money!”</li> <li>▪ Augmenting personal income; personal financial gain; salary supplement; minimal family income – should consider other options</li> <li>▪ Should be compensated if right person (expertise) to work with industry</li> <li>▪ Another revenue stream to institutions in support of mission; medical education is not directly supported by those who benefit from it.</li> <li>▪ Buy back more of my time for the institution</li> </ul>	<ul style="list-style-type: none"> <li>▪ Promote advances in medical science</li> <li>▪ Contribution to medicine and patient care</li> <li>▪ Bring new drugs to market</li> <li>▪ Funding very beneficial to research</li> <li>▪ Source of research support</li> <li>▪ Survival as a researcher</li> <li>▪ Supplement research portfolio</li> <li>▪ Ethical responsibility</li> <li>▪ “on the ground” with development of drugs and devices.</li> </ul>

In assessing the risks and benefits associated with each category, the data corroborated the importance of the physician’s role as a moral agent in Jones’ (1991) model and suggested

characteristics or conditions that could create an obstacle or barrier to academic performance as well as ways to avoid the financial relationship becoming an obstacle. The participants identified potential barriers or obstacles to performance that included the ability of money to shape the relationship; restrictive involvement based on institutional policies representing a firewall of sorts; the tendency to be more biased and scrutinized by peers; impaired decision-making; conflicts with interests of learners and patients; and the frequency of interaction with company representatives that could increase the physician's use of the company's product, suggesting an individual's human nature and need to express gratitude. To avoid the relationship becoming an obstacle, the data proposed that physicians must be very conscientious; should, as part of their decision-making process, assess the effect of engaging in a financial relationship with a company prior to entering into a relationship; and finally, as the participant Ben conveyed, "...in the current, more challenging environment, be alert for biases that can easily creep in."

## **Reputation**

The first of the three reason categories for entering into financial relationships with industry focuses on the individual faculty's reputation which is defined as professional and personal. The professional reasons emphasize individual recognition in the professional community, professional growth, and contributing and sharing expertise, collaboration, and perspectives. The personal aspects of a faculty member's reputation may be identified as pride or fame, in a narcissistic sense, for entering into a financial relationship with industry, e.g., as a consultant, author, member of a speakers' bureau, which the data suggest is secondary to one's professional reputation and that of the institution.

Daniel articulated professional contribution as the ability to influence industry – “...industry might be making decisions based purely on financial considerations, and physicians and other faculty members in academia can sort of educate them [industry] sometimes towards areas that we [academicians] think are important.” Oliver emphasized the value of professional gain and growth,

There is also a degree of growth that can occur by engagement in a different activity so...there is natural curiosity. I, for example, am a better doctor because of, I would say, all of the things I have done outside my day job...every single one of them either because of the people I have met.... I can think of activities I did where I met other people who helped me get a better perspective of the field and other academic physicians I had contact with.

Examples of the participant’s activities were legal review of cases or writing board review questions; however, the participant “drew the line” with speaking on behalf of industry because “...I think everybody has different things that they are seeking from these relationships” (Oliver). The comment reflects a choice or decision of not being influenced or biased by industry in activities outside the institution.

The data also connected reputation to institutional culture and climate surrounding the decision to enter into a relationship with industry and melded the professional and personal aspects –

I think every individual physician has to decide what their own criteria are, and it’s going to be influenced by the culture and environment in which they work. If they work in a place where these relationships are viewed with scrutiny, they will be more selective than

if they work in an institution or even in a microcosm of that institution where it's commonplace so...they would be more likely to join in that (Oliver).

This quote supports the study data which emphasized the importance of academic-industry relationships and respect for the institution as a community of scholars, whether the faculty role is that of a teacher, researcher, or clinician. Faculty and industry each brings different perspectives, knowledge base, and expertise to the relationship, focuses on the mutual nature of the relationship and as such, may provide an implicit balance and mitigate bias. The data also indicated, as articulated above, that characteristics of the personal reputation, such as pride and fame, are shadowed by the individual's professional reputation that contributes to and reflects the reputation of the institution and respects its culture. However, as Karen suggested, "I think some physicians feel like, as consultants, they really are helping a company to be more responsive to patients, helping a company to see that physicians really want this product." As this quote and others imply, the relationship between faculty and industry can be valuable to the professional and personal reputation of faculty as well as to their respective institutions. However, regardless of the nature of the relationship, there are potential and sometimes significant reputation risks and benefits associated with the relationship.

### **Potential Reputation Benefits.**

Potential benefits of a positive relationship with industry may include industry's grateful recognition of the supporting institution usually in research collaboration, although it is important that the funds "...be managed in a way that those funds are not benefitting that person" (Ben). Added prestige and strengthened reputations of the faculty and institution follow if good research is published in peer-reviewed journals. A positive institutional and faculty reputation



may result in investigator-initiated research that is deemed worthy of industry funding. Institutional and faculty partnership and collaboration with industry are generally viewed in a very positive manner. For faculty, the ability to influence industry in clinical areas of importance is significant in the discovery of new and effective drugs which may result in recognition by one's institution and career advancement, tenure and promotion.

### **Potential Reputation Risks.**

While the benefits offer positive recognition to the reputation of the individual and institution, potential risks can contribute to a significant, negative reputation of both. Bad research, wrong decisions in teaching and patient care due to industry bias and undue influence can taint the reputations of the institution and faculty. Academic-industry relationships may also be perceived as questionable or unethical resulting in conflicts of interest, commitment, purpose, or mission. As a result, faculty and/or institutions may be considered an extension of a company rather than regarded as independent in thought and decisions that are based on scientific evidence and best practices. Additionally, faculty or institutional objectivity may be lost and subject to bias and undue influence.

Beyond the individual and institutional risks are risks for patients and society. It is deemed wrong for patients if conflicts of interests result from a financial relationship with industry and cannot be resolved thereby resulting in care that is not optimal or cost-effective. Patient and public perspectives of faculty and institutional reputations can result in lack of public trust of the medical profession and industry.

## Money and Funding

The second reason for entering into financial relationships with industry focuses on the individual faculty's connection with money and funding which, as with reputation, may be described in professional and personal terms. The professional aspect relates more to funding or compensation such as salary supplements from consultancies, providing expertise in other roles such as research or scientific advisory boards, or as another revenue stream to the institution. As Daniel expressed,

In most institutions, there are pressures to secure external funding because, if you get money from industry, that's money the institution doesn't have to pay you. Federal dollars are more restrictive...institutions definitely seek industry support, and it's not so much for personal gain of the institution as [it is] another revenue stream to support their missions.

The quote represents explicit institutional encouragement and reasons to secure funding, but the participant also referred to the implicit encouragement that is representative of the culture of the institution. Regardless of whether faculty motivation is explicit or culturally accepted by the institution, the reasons behind securing external industry funding are the same – the lack of funding to support the high cost of medical education and shrinking federal support.

Additionally, “government funding has the highest value to the institutions but is also linked to priorities of certain conditions, certain innovations all that are drive by politics” (David). The political influence creates an inherent conflict of interest implying lack of independent decisions in awarding the funds.

The personal reasons for faculty entering into relationships with industry vary from just wanting additional money, irrespective of the purpose behind the relationship, to supplementing salary income due to minimal family income or to pay off student loans and debt. The data produced differing views of personal financial reasons:

Most people who are in academics, academic medicine, or other areas...they don't go into it to make money, otherwise, they would be in private practice; but most of us have or had lots and lots of loans...many people hundreds of thousands of dollars, and since you don't make as much in academia as you do in private industry, that is not a trivial consideration at all...so personal compensation is actually a big factor and legitimate (Daniel).

Another perspective did not see medical school debt so much as influencing decisions to be in financial relationships with industry but rather “buying back more of my time...the ability of an institution to support my efforts and my time is, I think, more important than any impact of medical debt (Jim).” Regardless of perspectives, the data suggested assessment of personal motivations as well as the potential risks and benefits of interacting with industry .

### **Potential Benefits Associated with Money and Funding.**

The benefits of money and funding are stronger for institutions mainly because the revenue to the institution supports research whether through funding a study, physician investigator salary support, or being a research site. Additionally, successful study findings may result in patents and tech transfer which would generate a richer source of revenue to the institution. For the individual physician, the benefit is a significant increase in earnings to supplement a university salary. As with Dr. Carlat's example (2007), he supplemented his

\$140,000 private practice income with approximately \$30,000 from the Wyeth “Lunch and Learn” talks in 2001.

### **Potential Risks Associated with Money and Funding.**

The data suggested that risks associated with money were related more to the individual and could create unresolvable conflicts of interest (COI). Viewing Dr. Carlat’s (2007) example described in chapter two as a risk instead of a benefit,

“I began thinking that the money was affecting my judgement. I was willing to dance around the truth in order to make the drug reps happy. Receiving \$750 checks for chatting with some doctors during a lunch break was such easy money that it left me giddy. Like an addiction, it was very hard to give up.”

In addition to Wyeth, Dr. Carlat gave a couple of talks for Forest Pharmaceuticals. Also reflective of the risks associated with money, Amanda (participant) advocated that holding stock in a company that produces products that the stockholder physician uses and prescribes has “zero benefit” and creates a significant COI. Another risk involved a physician just wanting additional revenue without regard for what role he or she has in the industry relationship which may result in a lack of independence of thought or action and being subject to industry bias. As will be discussed under research, the role of physicians in industry relationships and interaction among individual multiple roles are important considerations in supporting independent, unbiased thinking, conduct, and decisions as well as mitigating risks and conflicts of interest.

## Research

The third and final reason faculty enter into relationships with industry involves research and is the most prominent of the three. The three primary reasons, reputation, money and funding, and research categorize individual reasons for entering into relationships with industry, but they also have overlapping and interconnected features. Research, for example, can have a tremendous effect on reputation and funding opportunities for both faculty and institutions. The data also indicated that establishing and maintaining ethical responsibility was a reason for securing a positive reputation of faculty and institutions as well as conducting responsible research with industry. NIH policies and courses, institutional policies, and programs such as the Collaborative Institutional Training Initiative (CITI) provide compliance mechanisms and assure adherence to accepted research standards and practices. Institutional policies may not allow faculty who have industry funding for research to have other financial relationships or roles with the funding company to avoid bias, undue influence, and a conflict of purpose or mission. For example, having stock in a company with which a physician is conducting research creates a conflict of interest as one participant stated, “the desire to make money from that [relationship] is a direct COI with your patients, with the interests of your learners or of your patients” (Amanda). Additionally, “...for researchers, they often have to really develop relationship with companies. If they do that, they have to be researchers and not do other things” (Ben). In essence, the participant data suggested that in order to conduct ethical, responsible research, physician investigators should resolve all conflicts of interest including participation in other roles with the funding company such as consultant, speaker’s bureau, or owning stock which could reap financial gain from a successful study outcome.

Notwithstanding the concerns expressed above, the data strongly supported the research benefit of academic-industry relationships with physicians or institutions for the purpose of advancing science through shared, collaborative research as expressed through the participants' beliefs. "I think shared expertise and networking is also a very important and valuable reason [to enter into a financial relationship with industry]. We clearly need both industry and academia to, for example, bring new drugs to market" (Daniel). Additionally, "physicians want drugs to come to market and they want to give their expertise to make sure that drugs are coming to market or vaccines are coming in an appropriate manner" (Grace). Another participant, David, pointed out that "some people view industry-funded research as tainted while others view it as entrepreneurial; but regardless, many view it as necessary to move things forward...especially the area of research."

For the institution, the research and funding partnership with industry is very beneficial to the research enterprise by promoting advances in medical science, contributing to improved patient care by, e.g., bringing new and effective drugs to market. Industry may also be able to provide resources other than funding that institutions may not be able to obtain. For the individual faculty researcher, having industry funding for research studies provides a significant source of revenue that supports the faculty and institution, helps build research portfolios, and contributes to survival as a researcher.

The participants discussed potential research harms with concern and how bad, unethical decision-making can generate adverse effects on physicians, patients, the public-at-large, institutions, and faith in research findings. Expanding upon the effect of ethical responsibility as it relates to reputation and research, one participant's comment was reflective of the moral agent in Jones' model (1991), "I really consider corporate sponsorship not different from federal or

government or foundations. It's not bad money, but they [physician researchers] have to really work as researchers and be true to what they are and what they should be" (Ben). Funding from industry is different from federal and state government or foundation funding with the main difference being organizational mission. Industry's structure is corporate; and therefore, one of its goals is to generate profit for the company and its stockholders. The company, however, is also generally purpose-driven by disease states in a specialty, e.g. diabetes. Government and foundation funding, however, first identifies and supports the clinical or medical need for patients and society with a financial focus on cost-recovery which requires tight budget controls so that the not-for-profit research grant funds cover or offset research study expenses. Because of these organizational differences, researchers, regardless of funding sources, must be moral researchers, first and foremost without regard for the source of funding. In other words, let the data and evidence speak for themselves and produce an outcome, negative or positive, which is beneficial to and informs the medical profession, patients, society, and industry.

### **Potential Research Benefits.**

The benefits of academic-industry shared research can have significant effects especially in the discovery of new drugs that can result in patents and financial gain for faculty, institutions, and companies. Industry funding can provide infrastructure for clinical trials and contribute to opportunities to develop local expertise/techniques especially for benefit of patients and trainees. Industry-funded research can also fill time and provide resources between larger NIH studies and clinical trials.

In addition to the financial and resource benefits, there is a social benefit. "The interesting thing is that...getting research grants for development of new drugs or new devices

can create generalizable new knowledge...if you can be sure that they [researchers] are doing the study right and analyzing the data right, there is a real social benefit of that” (Amanda). Shared research should also support and respect the institutional mission and be reflected in the physician faculty’s role as a research study investigator.

### **Potential Research Risks.**

Benefits and risks accompany all research; however, the risks associated with industry-funded research can produce damaging effects on physicians, patients, the public-at-large, institutions, and faith in research as previously discussed. These effects can result from tainted research, inappropriate conflict-of-interest (COI) management, industry-biased or influenced data reporting and research findings, or research misconduct. The purpose of the compliance and oversight mechanisms of the NIH and others are intended to provide guidance for preventing these harmful effects. Oversight is conducted through mechanisms such as required education, IRB review and approval processes, data safety monitoring boards, and institutional research policies and procedures. From a financial perspective, if all funding goes away; the lost revenue potential can be significant for the researcher and the institution through, for example, loss of patenting opportunities and technology transfer. This statement reflects the resource-rich nature of industry-funded research and how lack of funding would hinder the discovery of new drugs and medical devices.

### **Bias Avoidance**

The participants expressed concern for undue commercial bias and influence in the missions of academic medicine, teaching, research, and patient care, and the importance of being responsible and alert to the daily battle of potential conflicts of purpose in the three roles of



educator, researcher, and clinician. The data and literature indicated that it is human nature to think that individuals don't have conflicts of interest, can never be biased or influenced, or are necessarily good at recognizing bias and influence. This observation of human nature suggests that even subtle influences can prejudice decision-making ability. The participants offered consideration of methods for avoiding bias and proposed good *litmus tests* for detecting and mitigating bias and undue influence. Their suggestions fell into two different approaches that should work interactively with each other. The first is a pragmatic approach which promotes an understanding of what bias is through education, policies, and procedures. They emphasized the importance of participating in training about bias in COIs, becoming educated about bias in general, and being aware of "how we think as people in the first place" (Ben).

The second should be an intuitive and reflective approach which requires recognizing the moral agency aspect of being honest to oneself and alert to a consistent presence of bias that can create a conflict of interest, purpose, and/or mission. As one participant, Edward, expressed:

I think that [avoiding bias] is just behaving like hopefully your mother taught you, to be fair and objective, and I would think that with all the education that people at this level have, they should know enough to exclude bias. Saying that, I'm fully aware that what I'm expressing is an ideal that too often is not met.

The moral agency characteristics in Table 4 below delineate the study participants' main concerns of undue bias and influence, morality, and familiarity representing core values in a basic social process (Glaser, 1998).

Table 4: Methods for Bias Avoidance

PROCEDURAL	MORAL AGENCY
<ul style="list-style-type: none"> <li>• Conduct an annual review of disclosures and potential COIs (process).</li> </ul>	<ul style="list-style-type: none"> <li>• Be honest with yourself; acknowledge inability to be fair &amp; objective (3).</li> </ul>
<ul style="list-style-type: none"> <li>• Observe practical, real-time, full disclosure in all professional roles (2).</li> </ul>	<ul style="list-style-type: none"> <li>• “Behave like hopefully your mother taught you...to be fair and objective.”</li> </ul>
<ul style="list-style-type: none"> <li>• Assess purpose and merit of research and the benefit to society v. personal financial remuneration.</li> </ul>	<ul style="list-style-type: none"> <li>• Ask yourself ‘are you a good person? Do you have a moral compass?’</li> </ul>
<ul style="list-style-type: none"> <li>• Consider investing in a different industry.</li> </ul>	<ul style="list-style-type: none"> <li>• Behave in the same manner for family, friends, or society (proximity).</li> </ul>
<ul style="list-style-type: none"> <li>• Exert caution with research data collection &amp; analysis.</li> </ul>	<ul style="list-style-type: none"> <li>• Be open and honest about the ‘why’ of actions: “Am I doing the best for students, patients, others?” (2)</li> </ul>
<ul style="list-style-type: none"> <li>• Effectively use institutional guidelines and policies for individual guidance.</li> </ul>	<ul style="list-style-type: none"> <li>• Assess possible issues of professionalism in other roles that may contribute to a COI.</li> </ul>
<ul style="list-style-type: none"> <li>• Involve a third, objective party for bias mitigation.</li> </ul>	<ul style="list-style-type: none"> <li>• Reflect on decisions/choices before an issue arises; recognize human imperfection. (2)</li> </ul>
<ul style="list-style-type: none"> <li>• Completely eliminate all gifts from industry.</li> </ul>	<ul style="list-style-type: none"> <li>• Submit to the ‘local newspaper’ test – “can I defend my decision?”</li> </ul>
<ul style="list-style-type: none"> <li>• Recognize what one can/cannot do with financial relationships; be willing to not participate, if necessary.</li> </ul>	<ul style="list-style-type: none"> <li>• Carefully consider all aspects and effects of decision beyond immediate situation.</li> </ul>
<ul style="list-style-type: none"> <li>• Make decisions that are very transparent.</li> </ul>	<ul style="list-style-type: none"> <li>• Feel comfortable with your decision.</li> </ul>

### Theory Development

Jones’ (1991) ethical decision-making model was the process representing the unit of analysis for the grounded theory study and guided the development of the interview protocol (Appendix I). Jones’ model, which was described and discussed in chapter two, consists of four components, requiring the moral agent to (1) recognize the moral issue, (2) make a moral judgment, (3) establish moral intent, and (4) act on the moral concerns. Jones identified moral intensity as a construct that focuses on the issue at the center of the decision. Jones’ six

characteristics of moral intensity included (1) magnitude of consequences, (2) social consensus, (3) probability of effect, (4) temporal immediacy, (5) proximity, and (6) concentration of effect. Building on the six characteristics, the interview protocol offered an opportunity to assess each case scenario and determine if there was a moral issue at the center of the decision process and how physicians, as moral agents, recognized and assessed the moral issue.

### **Themes from Academic Physicians' Responses to COI Scenarios**

The participants' assessments of the cases and study data generated three themes – morality, bias, and familiarity – and contributed to the development of moral agent characteristics that could impact the roles and responsibilities of the physician as a teacher, researcher, or clinician. Table 5 displays the three themes, sub-themes which further delineate the themes, and elements of the sub-themes which are descriptive terms or phrases that the participants cited frequently and independently. The number of times participants mentioned each descriptor is noted in parenthesis following the term or phrase. The nine sub-themes are honesty, morality, and human nature for the *morality* theme; bias, objectivity, and proximity for the *bias* theme; and volition, beliefs and actions, and decisions for the *familiarity* theme.

Although the themes of morality, bias, and familiarity are also considered sub-themes and used as descriptions in the elements; they best represent the collective nature of each theme. Morality represents how individuals conduct themselves in personal and professional decision-making and accordingly encompasses characteristics and effects that relate to human nature, capacity to be honest, and variable aspects of morality. Therefore, for this discussion, morality is a theme, a primary sub-theme, and an element.

Similar to morality, bias is a collective term that embodies a theme, a predominant sub-theme, and a descriptor of the sub-theme which is reinforced in two of the moral agent characteristics. As discussed previously in this chapter, bias was a major concern of all participants and required a discussion that suggested procedural and moral approaches for avoiding bias.

As with morality and bias, the term familiarity exemplifies the essence of the third theme and can possess both positive and negative effects. Applicable to the sub-theme proximity, familiarity poses a concern about physicians who would, for example, treat a close family member different than a patient. In the context of this study, proximity refers to the closeness of the relationship between a physician and family members, friends, patients, research participants, students, or society-at-large as explored in the case scenarios and how a physician's financial relationship with industry may affect personal or professional relationships. Familiarity also impacts volition, a sub-theme, culminating with a decision that is affected by one's beliefs, actions, and choices.

Table 5: Development of Themes

<b><u>THEMES</u></b>	<b><u>MORALITY</u></b>			<b><u>BIAS</u></b>			<b><u>FAMILIARITY</u></b>		
<b>Sub-Themes</b>	<b>HONESTY</b>	<b>MORALITY</b>	<b>HUMAN NATURE</b>	<b>BIAS</b>	<b>OBJECTIVITY</b>	<b>PROXIMITY</b>	<b>VOLITION</b>	<b>BELIEFS &amp; ACTIONS</b>	<b>DECISIONS</b>
<b>Elements of Themes</b>  <i>(Participant Descriptors)</i>	Honesty / being honest (3)  Truth (2)  Fiduciary responsibility (2)  Reputation (2)  Integrity  Credibility  Accountability  Awareness	Morality (11): -Moral  -Moral person  -Moral compass  -Recognized as a moral, ethical teacher  -Moral duty  -Moral obligation  Ethics / ethical / ethical principles (4)  Peer pressure	Human Nature  Being "human"  Financial pressure  Culture  Good person?	Bias (9)  Influence / undue influence (9)  Full / absolute disclosure (6)  Mission Conflict  Relevance of COI  Corruption  Damage  Fraud  Morally bankrupt?	Objectivity / being Objective (5)  Fair (3)  Balance (3)  Independence / independent (3)  Unfairness to company (2)  Autonomy  Impartiality	Familiarity / Preference: benefit or harm (9)  Duty to patient  Patient trust  Harm to students, patients, society, etc.  Treat all the same; "right thing to do"  Sacred trust	Familiarity / Preference: benefit or harm (9)  Evidence (listen to...) (3)  Obligation to company (3)  "Slippery slope" (2)  Scientific integrity  Clouded judgment  Intention  Experience/expertise  Moral problem / issue / dilemma  Compliance: appearance v. spirit  Consequences	Ethics / ethical / ethical principles (4)  Professional obligation / responsibility (3)  Effect on behavior  Mission (physician)  Role (physician)  Role performance  Leadership  Modeling  Professional trust  Professionalism	Unbiased / unbiased decision-making (5)  Transparency (4)  Transparent (2)  Gatekeeper responsibilities  Local newspaper "test"  Moral decision  Residual effects
<b>Moral Agent Characteristics</b>  <i>(representing sub-themes)</i>	Honesty with self and others	Enduring moral compass	Recognition of human imperfection	Continual awareness of biases & potential conflicts	Fairness and objectivity	Respect for proximity effect	Constant reflection of choices / consequences	Congruence of moral beliefs and actions	Transparent, unbiased decisions

## **Morality**

The participants expressed and questioned moral issues and concerns by discussing the three case scenarios in terms of the physician's moral duty and obligation, ethics, truth, and integrity. In support of morality as a theme, the AMA Code of Medical Ethics Opinion 1.01 (Appendix C) states that "ethical" refers to one's respect of moral principles and social policy involving issues of morality, and "unethical" refers to one's failure of professional conduct by not abiding by moral standards. This theme encompasses three sub-themes – honesty, morality, and human nature – which represent the individual physician's self-reflection of beliefs, morals, and ethics.

[...] what is more important here – being recognized as a moral, ethical teacher who really doesn't have that conflict, or do you continue to resolve those conflicts every time you teach?" So, my advice would be "resolve this, move on, and avoid that conflict in the first place (Ben).

Moral issues and responsibility were evident in all three cases, but this quote expresses the essence of awareness and responsibility. In offering advice to the faculty in the teaching case, the role of teacher could be replaced with researcher or clinician and apply to the heart of one's ethical and moral obligation.

## **Bias**

The theme of bias was equally as prominent in all three case scenario discussions exploring the effects of undue influence, mission conflict, objectivity, and patient trust on the physician's ability to make an unbiased decision. The sub-themes of bias represent a more

descriptive, detailed interpretation of bias and how it interacts with objectivity and proximity. The bias theme also represents how the individual physician interacts with others and the professional environment as the following quote from the research case scenario demonstrates:

OK, I have a long-standing relationship with this company in many different roles. I cannot be objective. Yes, I think I am a scientist. I'm objective, but we are all human. I think the faculty member should have recognized that 'I cannot be objective' so the future effect is 'I am not going to be able to objectively serve as an investigator for this study' (Daniel).

In the physician researcher's different roles with the company funding the research study, he or she could, for example, be a consultant, be on a speakers' bureau, or own stock, any of which would create a conflict of interest and commitment. As the participant data has suggested, institutional policies are critical and probably the most effective in avoiding conflicts especially in research. However, the principle still applies in the management and resolution of all conflicts of interest.

### **Familiarity**

Familiarity, the third theme, gleaned differing opinions among the participants, viewing it as both a potential harm and benefit with particular relevance to proximity and volition. The familiarity effect on proximity and volition was described as a duty to patients and that physicians should treat all the same whether a family member, society, or patient. Additionally, the participants emphasized the importance of listening to the evidence and being aware of consequences of choices in making decisions. Familiarity can be a benefit and have a positive influence when equated to professional knowledge, confidence, preference, and expertise.

Familiarity was also viewed as a harm when the best drug for treatment or alternatives are not considered or selected which may be the result of a physician's financial relationship with a company whose drugs the physician prescribes more frequently than other options.

The theme of familiarity involves sub-themes or final steps in the end phase of an ethical decision-making process which are represented by volition, beliefs and actions, and decisions. The third theme of familiarity is the culmination of the individual physician acting upon his or her introspection (morality) and interaction with others and the professional environment (bias). Jones' (1991) model establishes the link between an individual's ethics and actions which involves determining the correct thing to do within a situation, following through by acting upon one's ethical assessment without influence of environmental factors, and seeking approval of oneself and/or from peers (Jones & Ryan, 1997). The third theme further suggests an undercurrent of reflection, interaction and action by continuously contemplating the moral agent characteristics in the ethical-decision making process. Familiarity had the greatest effect in the clinical case scenario as the following quotes illustrate, identifying the benefits and potential harm:

[Physicians] will tend to pick one [drug] and stick with that one, usually independent of any conflict of interest. It is just because they develop a familiarity with it; and that is a benefit because...if you use the same drug in a number of patients over a long period of time, you really become...you have a degree of expertise with the benefit and the side effects and sort of just the practical, hands-on use of it in patients (Daniel).

The harm to the patient is that they are not getting the optimal treatment. The harm to society is that it may be adding to overall medical costs. Benefits to the patients here



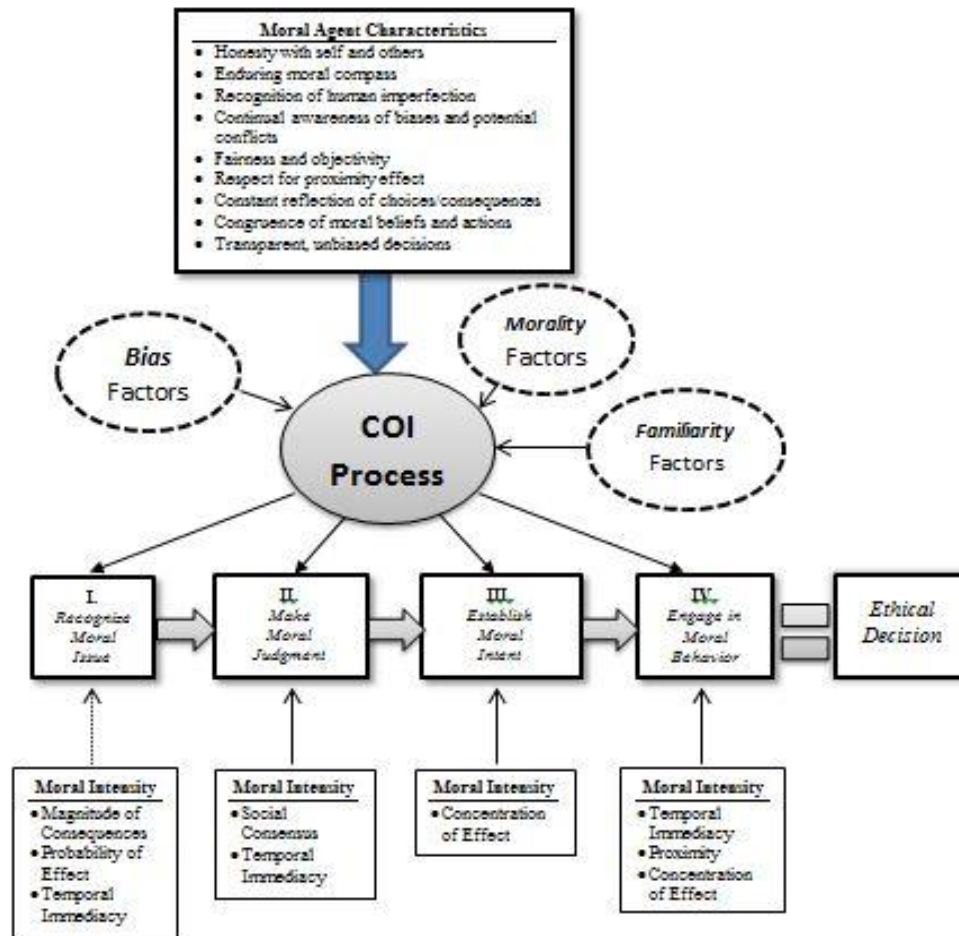
would be familiarity...the physician has tremendous experience and familiarity with Company E's product lines and is probably perhaps more able to help patients use those products compared to others (Jim).

In these quotes, familiarity is synonymous with knowledge, experience, and expertise. However, familiarity in these terms is also narrowed to one drug or one line of products that could result in not prescribing the best drug for a condition, or as in the teaching case, have a delayed and potentially negative effect. The faculty member in the teaching case scenario preferred to use equipment from one company instead of exposing the students to equipment from several companies. In this particular case, it also created a conflict of interest due to his owning stock in the preferred company. The effect on the students may not present itself until they go into practice with limited knowledge of one company's equipment.

### **Theory Refinement**

In refining Jones' (1991) model, the study data generated nine moral agent characteristics (Table 5 and Figure 3) from the elements of the themes. The moral agent characteristics are applied to the role of the physician, whether as a teacher, researcher, or clinician, in each of the four steps of the ethical decision-making process. The characteristics represent the sub-themes and emphasize the physician's ethical and moral responsibility in making decisions. Moreover, depending on the setting of the case scenario, not every characteristic of moral intensity in Jones' model had the same effect on each step in the process. As discussed in chapter two, Jones identified moral intensity as a construct that focuses on the issue at the heart of a decision and how the decision-maker assesses the moral intensity without consideration of professional or environmental context.

Figure 3: Modified Ethical Decision-Making Model for Resolving Conflicts of Interest



Source: Modified from An Issue-Contingent Model of Ethical Decision Making in Organizations. Jones, T. M. (1991, April). Ethical decision making by individuals in organizations: An issue-contingent model. *The Academy of Management Review*, 16(2), p. 379. Used with permission from the author, Thomas M. Jones, PhD (Appendix J).

With that in mind, I identified one or more characteristics of moral intensity that appeared to have a dominant effect on each step of the process which is illustrated and discussed below. The refined components of the ethical decision-making model include the moral agent characteristics produced by the study data, the addition of the final step of making an ethical decision, and a suggested redistribution of the moral intensity characteristics.

## **Moral intensity effect on the process of ethical decision-making**

### **Step I – Recognize moral issue.**

Three characteristics of moral intensity – magnitude of consequences, probability of effect, and temporal immediacy, which are expressed in terms of harms, benefits, and future effects, should be taken into consideration when the decision-maker is in the first step of the process, *recognizing the moral issue*. As Jones (1991) indicated, this is the point at which an individual acknowledges his or her role as a moral agent and should take into account that ethical decision-making may be proportional to the potential consequences, suggesting that potentially serious consequences encourage ethical behavior, produce harms and/or benefits to various stakeholders, and have short or long-term negative effects as Karen (participant) indicated regarding research:

[...] can harm a lot of people. It could also come back to hurt the university if there was some sort of fraud or problem with scientific integrity or the way it was presented; and that could hurt the whole standing of the university as far as funding in the future...besides his own career. It could hurt the institution, hurt patients, and while he might help the company, ultimately, it could hurt the company too.

The participants affirmed this assertion especially with their responses to the research case scenario in which they stated clearly that there is no justification for biased research or obligation for findings other than what the data suggest could result in harm, as stated above, to research participants, patients, institutions, companies, and society. With obligation to the company described by Molly and David as a “slippery slope”, the researcher and possibly the institution could be branded due to scientific misconduct. Other participants recognized

potential harms to healthcare systems, the overall enterprise of industry-sponsored research, and the scientific process as well as possible patient and public loss of trust in physicians and the profession. The harm to society could also result in increased medical costs.

The data from the teaching scenario suggested that favoring one company's equipment would produce harm to students and trainees by teaching and creating choice preferences or biases as well as entering the profession with limited knowledge that could affect them later in their practices. By limiting exposure, the faculty member is not offering a full educational experience and sets a poor example for the learners. As one participant stated, this is an example of "inaccuracy at best and dishonesty at worst in teaching if all companies are equal." There is embedded harm to other companies through omission of their equipment which could affect institutional reputation if purchasing agreements are in place.

From the clinical case scenario, the data identified harm to patients as the primary consequence from favoring one company's products and was expressed as patients not getting optimal treatment, which another participant labeled as a moral issue or "one's duty as a physician" (Oliver). Oliver also expressed and supported the need for unbiased, evidence-based clinical care and the lack of oversight:

In practice, there is a whole spectrum of ability to practice; that's just the way it is, and it's always going to be that. There is no way to make sure everybody is practicing at the absolute highest level. That is tested from time to time. When people come up for accreditation, they have to have their peers vouch for them that 'yes,' they have an acceptable practice standard. I think it's only through those occasional tests that we get a 'check-in.'

This quote identifies a flaw in the healthcare system that would assure balance and continuity of practice in addition to identifying practice patterns that could represent inadvertent or intentional bias in prescribing patterns or balance in treatment options.

One leading benefit involved physician familiarity which was best conveyed in the teaching and clinical case scenarios and had positive and negative conditions. In the teaching scenario, familiarity was identified as preference of equipment used by the faculty instructor and represented extensive knowledge and expertise. One participant, however, suggested a *negative benefit* based on the faculty member's stock in the favored company's equipment as a potential financial benefit to the faculty member. This would, however, be negative for the students or trainees by their not being exposed to equipment from various companies. In both cases, Amanda suggested that the faculty member "should consider divesting" and relative to the clinical case, "be more self-aware."

In the clinical case scenario, 'positive' familiarity was identified as the physicians' ability to pick a drug and stay with it based on experience or expertise with the drug even if they have no financial relationships with industry. This approach can provide an advantage for a patient by the physician prescribing favorite drugs for different conditions, "all drugs equal, prescribe what is familiar" (David). The negative aspect of familiarity is that, all drugs *not* equal, prescribing what is familiar is not necessarily what is best; physicians should consider effects and consequences before prescribing.

### **Step II – Make moral judgment.**

Social consensus and temporal immediacy were two of the moral intensity characteristics that appeared applicable to the second step in the process, *making a moral judgment*, the point at

which an individual would exercise moral reasoning and define what is considered morally correct. Social consensus suggests that moral reasoning may be proportional, issue dependent, or context dependent. A high degree of social agreement was essential at this point to confirm the ethical appropriateness of the behavior. As with the first step, consideration of short or long-term consequences (temporal immediacy) implied that moral urgency correlated with the time between the present and the onset of consequences indicating that the greater amount of time, the less urgent (Jones, 1991). The teaching case illustrated more of a potential delayed effect or potential consequences into the future, e.g. when the trainees are in practice with potentially limited knowledge and limited familiarity of equipment for the benefit of their patients. The participants thought that institutional policies, more so than federal regulations, should have the greatest impact in assuring an unbiased breadth of training...“what we learn in training heavily influences what we do in practice” (Oliver). The data suggested that policies should also reflect the culture of the institution and have conflict of interest (COI) policies that define disclosure and COIs, heighten awareness, and offer guidance, processes, and education about COIs. Everyone has biases, and “most academics, we take pride in... ‘we’re independent; we’re not merely a shell for industry” (Daniel).

This same sense of being independent decision-makers was evident in the clinical case scenario. The data indicated that prescribing patterns that are favorable or disproportionate to industry are currently hard to detect, manage, and monitor because preferences happen in practice without necessarily knowing why or what influenced the choice. As one participant, Karen, noted, “we teach young doctors; we say ‘beware of where this information is coming from and what the bias is for why this one [drug] is better than the other.” The participants suggested methods for consideration that could mitigate bias such as identifying prescribing

patterns and biases toward drugs by reviewing physician EMRs and pharmacy records and cross-referencing preferences with institutional disclosures. Another method involved peer review and creating a culture of education and interaction among peers and consultants.

As with the Step I above, the research case illustrated the greatest effect of social consensus. Unlike the teaching and clinical case scenarios, the participants felt that federal oversight had the most potential for avoiding damaging consequences since it is the common denominator for all clinical research. Examples of federal oversight and regulatory mechanisms are the Clinical Trial Registry (CTR), Data Safety Monitoring Boards (DSMB), and Institutional Review Boards (IRB) which are designed to protect faculty in their academic and research roles. The IRBs may be the most influential because of its representative presence within the institution connecting institutional policy with federal research requirements and guidance to “ensure that the data are being...that the study is conducted ethically and appropriately, and that things are not inappropriately misconstrued” (Jim). If faculty are receiving industry funds to support a study, the data strongly indicated that faculty should be forbidden from having any other financial relationship with a company, described as the “most incredible potential risk for corruption” (David), to avoid creating a COI by feeling obligated to the company for favorable findings which represents natural characteristics of *being human* and *being grateful*.

Humans, all of us, think we are more objective than we are. We think we can be objective and that we can be truthful. [In a financial relationship], you do become friendly with people and develop positive relationships, and nobody likes to give bad news. So, you're both in a position of giving bad news to your friends in the company... “oh, your drug does not really work”...and you are hurting yourself because...you're not going to have the same financial benefit (Daniel).

This quote demonstrates why policies and regulations are in place, which is to fulfill research's social responsibility through implementing safeguards to review data in an unbiased manner, determining how findings will be disclosed, and reporting accurate, positive or negative findings.

### **Step III – Establish moral intent.**

The moral intensity characteristic, concentration of effect, had the most significant effect on the third step, *establishing moral intent*. Fishbein and Ajzen (1975, p. 381, in Jones, 1991, pp. 386, 387) suggested that “the best predictor of a person’s behavior is [one’s] intention to perform the behavior” which reinforced a tension that can exist between what people believe and do. Due to the faculty’s financial relationship with the company in the teaching case, one participant, David, described the case as a “*slippery slope* between *teaching* people and *selling* people.” It is important that students understand disclosure and what constitutes a conflict of interest and its implications. The institution has an important role in recognizing, mitigating, and managing COIs with students, allowing for a learning experience outside the clinical curriculum. The data suggested that with the students in mind, faculty should revisit their COIs frequently and inform their students on a regular basis of any financial relationships and how their disclosures or COIs, real or perceived, may reveal bias.

The data suggested that there is a high degree of faculty autonomy in research, especially in the data analysis phase, giving the researchers the opportunity to make decisions that may be biased and subject to undue influence from industry. Research can be difficult to monitor. Data analysis, for example, can be monitored by a Data Safety Monitoring Board (DSMB) to assure appropriate analysis and concentration of effect on the findings. The big issue as discussed



previously is that, if a physician is participating in an industry-funded study, he or she should not have any other financial relationships with that company due to the risk of company influence.

In fact, there [would be] concern that their [faculty] decision-making about treatment of the study and how they are going to be reporting it is being influenced by those relationships in their decision-making process (Jim).

There [could be] a perception that the relationship with a company will be reduced if, for example, he proceeded with publishing unfavorable findings. One could also imagine a scenario where the company increases investment in this person to try to influence the outcome of this particular decision (Oliver).

These viewpoints were expressed by other participants as well. One participant reminded researchers that they shouldn't need to be reminded of their ethical responsibilities. However, and without exception, the participants often and respectfully referenced their own institutional policies and procedures and how the policies establish firewalls to prohibit conditions, such as multiple financial relationships, from occurring when engaged in industry-funded research.

In the clinical setting, transparency and full and frequent disclosure with patients is essential in the same manner as with students. The participants proposed that physicians disclose to every patient because patients could lose trust if, for example, they know that their physician has stock in a company that manufactures the drug that their physician is prescribing to them frequently. It is important for physicians to be sure that patients understand what they are taking and feel comfortable with their care. As Oliver stated, "I think it's more about the moral obligation as a physician prescriber to keep up with the literature and do what's best for the patient."

#### **Step IV – Engage in moral behavior.**

Three of the moral intensity characteristics appeared to have an influencing effect on the fourth and final step, *engaging in moral behavior*, which was the point of acting on moral concerns and then making an ethical decision. Temporal immediacy, proximity, and concentration of effect represent and emphasize distance in terms of levels of urgency (time), social, cultural, psychological, or physical proximity (relationships), and the potential number of people affected (concentration). Responses to all three cases accentuated the fact that it should not matter whether the effects or consequences are immediate or in the distance future, whether the relationship is a family member, patient, or society-at-large, and whether the decision affects one person or a population. Additionally, faculty members should disclose relationships with industry; and as one participant commented...“once disclosed, the individual should consider what are the consequences of my conflict? The *appearance* of complying is different than the *spirit* of complying” (David). It is important for physicians to be open with disclosure and potential COIs and aware of evidence in support of engaging in moral behavior and making ethical decisions and of the need to overcome and challenge one’s own biases.

Concerning the proximity characteristic, individuals should be considered “morally bankrupt” (David) if they treat close or distant relationships differently; care should be the same regardless. “The ‘bar’ should be similar regardless of friend or patient; high level of responsibility when prescribing for either” (Oliver). Physicians must be familiar with disclosure requirements, effect of their professional opinions, and expectations in their official role. The data suggested that disclosure may not be *expected* with a close relationship, such as a family member; however, it should be *required* with patients, as previously noted, because the physician-patient relationship is considered a “sacred trust,” thereby putting the patient’s best

interest first and foremost. The data identified one potential negative effect concerning proximity in research – the potential for corruption. A researcher may advise a friend not to take a drug but may present it favorably to others with possible harm to the reputation of the researcher, institution, and company involved in the study. This is contrary to the participants' consensus view that treatment should be the same, regardless of the relationship to the physician, and whether it affects one person or a cohort of research study participants and level of urgency.

### **Academic Freedom Concerns**

Although not addressed in Jones' (1991) model, consideration of the effect of academic freedom on ethical decision-making is certainly related to the model and process and provided a different lens through which the decision-making process may be examined in the context of academic medicine. When considering a decision-making model and process in resolving conflicts of interest (COIs) as my research focus, I recalled a professional experience several years ago when an invited speaker challenged the requirement for disclosure and subjective resolution of his COI. He felt that I was violating his academic freedom rights because 'everyone has biases' and that he should be allowed to express his views. I agreed in principle but stated that I was only interested in resolving his commercially-influenced biases that could impact what should otherwise be an independent, unbiased, balanced, and evidence-based presentation. He had several financial relationships with industry. As I reflected upon our conversation and discussed it with my peers, I began to wonder if he had a valid point. As a result, I researched academic freedom during the literature search and its potential for having an impact on an individual's ethical decision-making process for COI resolution.

Resources such as the American Association of University Professors (AAUP), J. K. Ryan (1949), and others revealed enough evidence to include a secondary research question regarding academic freedom that addressed the concern as well as a question in the interview protocol. The research question contemplated if and / or how faculty perceive that their academic freedom is threatened in their relationships with industry. During the discussions, the participants expressed viewpoints concerning potential threats to academic freedom in each of the three case scenarios. Ryan's (1949) definition of academic freedom, "a particular kind of liberty in a moral order," supported exploring the possible effect, positive or negative, of academic freedom on Jones' (1991) model.

According to the AAUP 1940 Statement of Principles on Academic Freedom and Tenure, academic freedom intends to protect faculty autonomy in the search for 'truth' through teaching, research, and when representing a discipline or a community of professional scholars to the public. Relevant to the current environment and the study, the AAUP released the following in 1999 regarding corporate involvement in research:

The freedom to pursue research and the correlative right to transmit the fruits of inquiry to the wider community—without limitations from corporate or political interests and without prior restraint or fear of subsequent punishment—are essential in the advancement of knowledge. (Mangan, 1999, p. A14).

One participant suggested that if academic-industry relationships were disengaged due to circumstances that suggest abuse of academic freedom, e.g. the freedom to report negative findings; the collaborative nature of research and moving new and effective products and innovations into the marketplace could be compromised and be an ultimate loss to society.

In general, the interview data suggested that academic freedom concerns were not significantly evident in the case scenarios. The participants expressed greater concern for physicians assuming responsibility in being mindful of preferences, influence, and bias in resolving conflicts of interest. They emphasized the importance of being transparent and not advocating for or favoring specific products. Their views about academic freedom were not necessarily specific to the cases. One participant referred to a “limitation of some freedom” but not academic freedom through institutional policies inferring that institutional policies actually protect, rather than restrict, scholarly inquiry. The institution “sets the tone” (Amanda). Another participant agreed that in higher education, one should be able to speak what he or she considers the truth, but “academic freedom is not a complete license to say whatever one wants to say either” (Daniel); and as another stated, “[there] needs to be a balance between freedom and potential COIs...you don’t get to do just whatever you want just because you are in an academic setting so the freedom needs to be within limits” (Grace). With reference to the research case scenario, there were comments alluding to academic freedom’s strength behind the ability to “publish irrespective of what the findings show” (Oliver) and to report negative findings of a study. The interview data also suggested that academic freedom may have minimal effect under actual circumstances, indicating that physicians’ awareness of their biases and how to resolve conflicts of interest would have greater impact in their academic roles of teaching, research, and patient care.

### **Conclusion**

The study examined the primary research question *how do physicians as academicians manage or resolve potential conflicts of interest in their roles as teachers, researchers, and clinicians?* Additionally, the study examined *factors that may influence ethical, commercially-*

*unbiased academic decisions* as well as *characteristics of ethical, evidence-based decisions v. commercially-influenced decisions*. As discussed above, the study also assessed the potential effect of academic freedom on their relationships with industry which provided informative data but was deemed inconsequential to the study.

Through their own words and descriptions, the physicians who participated in the study contributed to the purpose and significance of the study and to answering the research questions by articulating, in a meaningful way, a comprehensive list of moral agency traits for refinement of Jones' (1991) model. Their thoughtful viewpoints and observations confirmed that academic physicians are or should be aware of their moral and ethical duty to resolve conflicts of interest in their roles as researchers, teachers, and clinicians. They stressed that policies, federal regulations, and accreditation guidelines, to some degree, support academic physicians' disclosure and COI resolution with frameworks that encourage considerate, appropriate, and ethical choices for all, regardless of whether 'all' is defined as family, friends, patients, research participants, or society. They further emphasized the importance of the responsibilities of leadership, modeling, professionalism, and integrity that are essential in academic physicians' interactions with trainees and the physicians of the future.

During the case scenario discussions, bias was the main concern explicitly expressed by all, which they agreed had the greatest impact in dealing with issues of familiarity and expertise, and specifically, were they rationalizing their actions. They indicated that, at minimum, full, absolute, continual disclosure, and conflict of interest (COI) mitigation were imperative whether caring for patients or interacting with research participants or a classroom of medical students and trainees. Doing so empowers the medical students, trainees, research participants, and

patients to understand and contribute to their own assessments of the healthcare situation and decisions that affect them.

## **Chapter V**

### **Discussion**

#### **Purpose of Study**

Various concerned stakeholders and stakeholder groups continue to examine conflicts of interest (COIs) that may result from physicians' financial relationship with industry and how COIs potentially affect patient treatment and satisfaction, prescription costs, and society as a whole. Stakeholders are represented by patients, researchers, physicians, and other healthcare professionals and have a vested interest in the successful and thoughtful navigation of an ethical disclosure and COI resolution process. Interested stakeholder groups are represented by federal regulators, Congress, professional associations, accreditation bodies, institutions of higher education, industry and other related and interested groups such as insurance providers and patient advocacy groups. The stakeholder groups shoulder the responsibility, oversight, and evolution of disclosure and COI resolution requirements through regulations, guidelines, policies, and voluntary codes of ethics.

These regulatory and procedural mechanisms are designed to provide continuity in the control and management of disclosure and COI resolution. The Institute of Medicine (IOM) and Association of American Medical Colleges (AAMC), based on their assessment of the environment in 2009 and 2010 respectively, indicated that there was a need for evidence-based COI research. Therefore, a key purpose of this study was to understand how physicians themselves, as moral agents, resolve conflicts of interest through an ethical decision-making process.



The physician participants in the study had been or continue to be involved in their academic roles of teaching, research, and patient care with research being the most active engagement. They were fully aware of the potential of commercial bias and undue influence that exists in academic medicine and the responsibility physicians have in mitigating that effect through disclosure, COI resolution, and more importantly, through individual moral beliefs and actions as illustrated by the refined ethical decision-making theory (Figure 3).

The paucity of evidence-based literature presented a research opportunity to contribute to that gap. The purpose of the study was to develop a theory that represents how academic physicians, as moral agents, identify, manage, and resolve perceived conflicts of interest (COI) in their academic roles as teachers, researchers, and clinicians. A secondary purpose was to assess if financial relationships with industry may threaten academic freedom in ethical decision-making. The study concluded that academic freedom was inconsequential to COI resolution.

## **Summary of Findings**

### **Reasons for Physician Relationships with Industry**

Preliminary to theory development was learning why physicians enter into financial relationships with industry. The findings identified reasons (Table 3) as well as risks and benefits that may be associated with those relationships. The reasons evolved into three categories – reputation, money and funding, and research. The findings presented *reputation* in a predominantly positive manner in terms of professional recognition and growth, contribution of expertise, or a mutual benefit to both the physician and company. The findings assessed *money and funding* from two perspectives – personal and professional. An example of a personal reason may be supplementing one's salary for the purpose of reducing personal debt, e.g.

medical school tuition loans. Professional reasons were generally focused on providing additional revenue streams to the university in support of institutional mission and research.

*Research* was the strongest reason of the three and supported collaboration with industry to bring new drugs to market, promoting advancement in medical science, and contributing to improved patient care. Research also encompassed residual, positive effects on *reputation* to the individual physician scientist and institution as well as the value of receiving external *funding* to support research. University-industry research collaboration is considered a significant benefit that brings with it recognition, prestige, institutional research support, and mission support. These three reasons give us a picture of why academic physicians engage in financial relationships with industry. Acknowledging this relationship through disclosure is the first step in resolving any potential conflict of interest.

The findings identified risks associated with these relationships that could have a substantial effect on the individual or institution through tainted research, evidence of bias, or misconduct resulting in damaging public or societal perceptions of the academic physician's or institutional relationship with industry. Perkins (1973) stressed an implicit trust that society has in higher education and the accompanying responsibility that higher education has in providing guidance for society, a principle that underlies a physician's decision to enter into financial relationships with industry. In addition to the physician and institutional responsibility to society, the findings indicated that institutional culture and climate also influence physicians' decisions to enter into financial relationships with industry as the following viewpoint suggests:

I think every individual physician has to decide what their own criteria are, and it's going to be influenced by the culture and environment in which they work. If they work in a

place where these relationships are viewed with scrutiny, they will be more selective than if they work in an institution...where it's more commonplace....(Oliver)

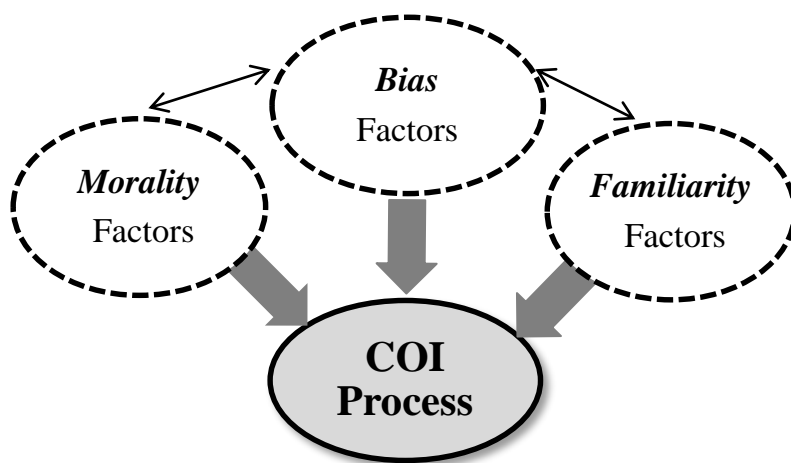
The literature supported this view and the influence of culture and climate on faculty decisions and behavior. Peterson and Spencer (1990) define climate as the common patterns and current attitudes of the institution; whereas, culture focuses on embedded ideologies and uniqueness of the institution, both of which are expressed in the participant's viewpoint. Additionally, Austin's (1990) definition of culture is implicit in the quote signifying the complexity of a physician's decision to enter into a relationship with industry. Austin identified four aspects of culture – mission and collegiality of the academic profession, identification and socialization of the faculty, the academy's responsibility to do “good work” (also Perkins, 1973), and institutional missions of producing knowledge and research. As the literature suggests, the quote above emphasizes the importance of the physician's and institution's responsibility to society and respect for institutional mission, culture, and climate.

### **Influence of Morality, Bias, and Familiarity**

The findings resulted in three themes representing factors that can influence ethical decisions regarding conflicts of interest in the academic physician's teaching, research, and patient care roles and responsibilities. I outlined the three themes of *morality, bias, and familiarity* (Table 5) with sub-themes, described the sub-themes with elements, and then articulated them as characteristics of a moral agent in the refined theory, recommending that these characteristics should be consistently present in all steps of the decision-making process as I have illustrated in the modified theory (Figure 3). I applied the nine moral agent characteristics to all four steps of the decision-making model with the intent of assisting the decision-makers in

constant reflection of their role as a moral agent as they navigate the COI process. As briefly illustrated in Figure 4 below and described in detail in Table 5 in chapter four, all three factors influence decision-making in the COI resolution process, but they also can influence each other. Morality factors express an individual's core values and beliefs; they epitomize the essence of who we are. Our moral character affects our professional conduct, may induce bias, or affect how we approach decisions in an objective and trusting manner. Factors of familiarity involve our ability to make choices that interact with our beliefs and actions, resulting in ethical and moral decisions.

*Figure 4. Influencing Factors of Morality, Bias, and Familiarity*



**Morality Factors.**

Morality speaks to the heart of what an individual espouses and is expressed as one's moral obligation, commitment to truth, and recognition of being a 'good person.' These representative elements of morality generated three sub-themes involving honesty, ethical principles, and human nature. As with the 2007 Symposium hosted by Baylor College of Medicine and the AAMC, "The Scientific Basis of Influence and Reciprocity," the AMA Code

of Medical Ethics Opinion 1.01 (Appendix C) reinforces this theme by focusing on the physician's moral and ethical responsibility with reference to one's respect of moral principles. The AMA Code also identifies unethical behavior as failure to abide by moral standards in one's professional conduct.

### **Moral Agent Characteristics Associated with Morality.**

The three characteristics associated with Morality include:

- Honesty with self and others,
- Enduring moral compass, and
- Recognition of human imperfection

The three morality characteristics support physicians' ability to conduct themselves with an awareness of truth, moral responsibility, and human nature. Honesty was associated with terms such as awareness, truth, integrity, and credibility. Honesty is a core value in the COI resolution process that drives the ability to assess a situation or relationship with objectivity and make a moral and ethical decision. The lack of honesty undermines the trustworthiness and objectivity of a decision. Similar to the effect of honesty, the findings describe the second, and strongest, characteristic as the essence of moral duty, moral obligation, and ethical principles with the third characteristic acknowledging the influence of 'being human' on decisions and the need to recognize the good and the bad aspects of 'being human.'

### **Bias Factors.**

Bias was the main concern expressed by all participants and, as such, developed as one of the three themes that contributed to theory refinement. Bias was evident in all three case scenarios and was described in terms of undue influence, lack of objectivity and independence,

and potential harm to patients and society. Because bias was a substantial concern of the participants and central to the study, the findings acknowledged that even subtle influences can prejudice decision-making and cause harmful effects which the following quote illustrates:

I think it's a daily struggle. Every day is an optimization algorithm for thinking 'has this achieved the best overall outcome for all of these missions [teaching, research, patient care], and if I devote myself to this, what deleterious effects potentially will that have on these other missions that I'm supposed to be involved in.' (David)

In support of this ever present struggle of recognizing and avoiding bias in decision-making, the findings revealed methods for bias avoidance (Table 4) through procedural aspects of identifying and resolving conflicts of interest (COIs) and the application of moral agency attributes that foster bias avoidance. The procedural methods recognize the importance of full disclosure, assessing merit of research, effective use of policies and guidelines, and providing education about COIs and bias. The procedural methods are supported by the regulations, policies, guidelines, and codes discussed in the assessment of the environment in the chapter two. These external controls are essential to the management of COIs. They level the playing field by establishing standards that require submission to the same disclosure and COI resolution process of all who are involved in conducting medical research or developing content for a continuing medical education symposium, for example. The following quote emphasizes the importance and need for a regulatory environment,

[...] there is a lot of potential for misconduct and bad things; and as much as I abhor red tape and bureaucracy, there has got to be some regulation of this. There is simply no way to expect people to completely regulate themselves (Daniel).

The medical education accreditation bodies and medical associations offer guidance and mechanisms to implement the regulatory requirements for physicians and other individuals involved in research, medical education, and patient care. These organizations have conducted research in the areas of bias and ethics and released opinions and recommendation that support the need for an understanding of the disclosure and COI resolution and embrace the effect of the moral agent characteristics that evolved in the study on bias avoidance and ethical decision-making in the COI process. For example, the AMA's Council on Ethical and Judicial Affairs offers ten ethical areas regarding professional and ethical conduct in medical education, research, and patient care. The AAMC identifies conflicts of interest as "a clash between professional responsibilities and economic interests (2007, p. 19)," and disclosure as a "moral license" (2007, p. 22). In 2009, the IOM released a consensus report that defined elements of a conflict of interest and recommended methods for mitigating undue bias and commercial influence for the purpose of protecting the integrity of professional judgment and proactively preserving public trust.

Similar to the moral agent characteristics applied in the refined theory, the findings recognized moral attributes for avoiding bias (Table 4) such as the importance of being honest, of treating everyone the same (proximity), of reflecting on choices before issues arise, and of remembering "how we think as people in the first place" (Ben). The participants suggested several litmus tests for avoiding or eliminating bias in the decision-making process. Examples include asking yourself "are you a good person" (Ben); theoretically submitting your decision to the local newspaper test; considering "how is this going to look or wondering if I'm going to have to defend [my decision]" (Amanda); and continually asking yourself "am I doing the best for this patient, not the best for me, and in research...what I think is the truth or the most valid

interpretation of the results” (Karen). Avoiding bias involves a continual awareness as stated in one of the characteristics. It is critical to have an opportunity to make sure that you are making the right decision for the right reasons in a fair and objective manner, without bias. My litmus test, as I shared with one of the participants, is if I hesitate, there is generally a valid reason to step back and to consider reviewing and assessing my impending decision, regardless of its focus and whether it affects my personal or professional life.

### **Moral Agent Characteristics Associated with Bias.**

The three characteristics associated with Bias involve:

- Continual awareness of biases and potential conflicts,
- Fairness and objectivity, and
- Respect for proximity

The first bias characteristic is the most prominent among the three and recognizes the potential of undue commercial influence, mission conflict, and the damage that can occur from either. This characteristic also suggests the need for full and absolute disclosure and the relevance of identifying and resolving conflicts of interest which is supported by the regulatory and guidance documents and policies that exist in the environment, as discussed above. The second characteristic relates to objectivity and addresses the need for fairness in the process with respect for all stakeholders. In addition to fairness, I described objectivity as balanced, independent, or impartial. This is especially true in medical research and in the delivery of content in medical education. The third characteristic addresses “the right thing to do” for all, regardless of personal or professional relationships and one’s financial relationship with industry. This was



especially evident in the patient care case scenario in which ‘duty to patient’ and ‘patient trust’ were described as a “sacred trust.”

### **Familiarity Factors.**

The findings recognize familiarity, the third and final theme, in terms of being either potentially harmful or beneficial. Familiarity was considered beneficial when equated to expertise and when decisions are made based on professional knowledge, confidence, or preference. It was viewed as a harm when the best drug or treatment or alternatives are not considered or selected, suggesting that a decision may be unduly biased or influenced due to a financial relationship with a company whose drugs the physician is prescribing. This example reflects the clinical care case scenario in which the physician had retired from industry and returned to clinical practice. The physician was very familiar with the drug he frequently prescribed which was manufactured by his former employer. However, prescribing that drug may or may not be the best for the patient. This example represents a COI that is not easily resolved as well as the potential harm to the patient.

As expressed by this example, familiarity can be a positive or negative influence in the choices we make resulting in a decision that should be the best for the patient, in this case, and not just because that’s ‘what I know and prefer.’ Familiarity establishes the link between one’s beliefs and actions, determining the right thing to do (volition), and consequently, making a decision that is ethical. In making a decision to resolve a COI, it’s critical to weigh all options for those the decision will affect, whether they are patients, students, or professional colleagues. With reference to this case scenario, the study findings indicated the tracking prescribing patterns

in the current healthcare system is difficult but suggested that tracking through electronic medical records may be a method to identify unusual prescribing patterns in the future.

### **Moral Agent Characteristics Associated with Familiarity.**

The three characteristics associated with familiarity require:

- Constant reflection of choices/consequences,
- Congruence of moral beliefs and actions, and
- Transparent, unbiased decisions.

The first characteristic identifies the point at which actions are considered based upon reflection of the characteristics associated with morality and bias. This characteristic involving choice requires listening to the evidence behind the impending decision, relying on professional expertise, and being aware of potential clouded judgment and consequences. The second characteristic associated with familiarity suggests the point in the process where ethics and professional responsibility influence behavior. It is linked with physician mission and role performance. The third characteristic, decisions, is intended to confirm that the decision will be unbiased, transparent, and moral as David suggested,

[...] making decisions that are very transparent and making sure that you are making a decision, that you are OK if other people know, that you can stand by your decisions in a transparent way.

A few of the nine characteristics based on *morality*, *bias*, and *familiarity* may be more obvious in some steps of the decision-making process than others. However, the decision-maker should consider all characteristics of his / her role as a moral agent in all four steps of the process. Doing so should result in a decision made for the right reasons and based on moral,

ethical, and unbiased criteria. In reference to the research, Daniel summed up the essence of making ethical decisions:

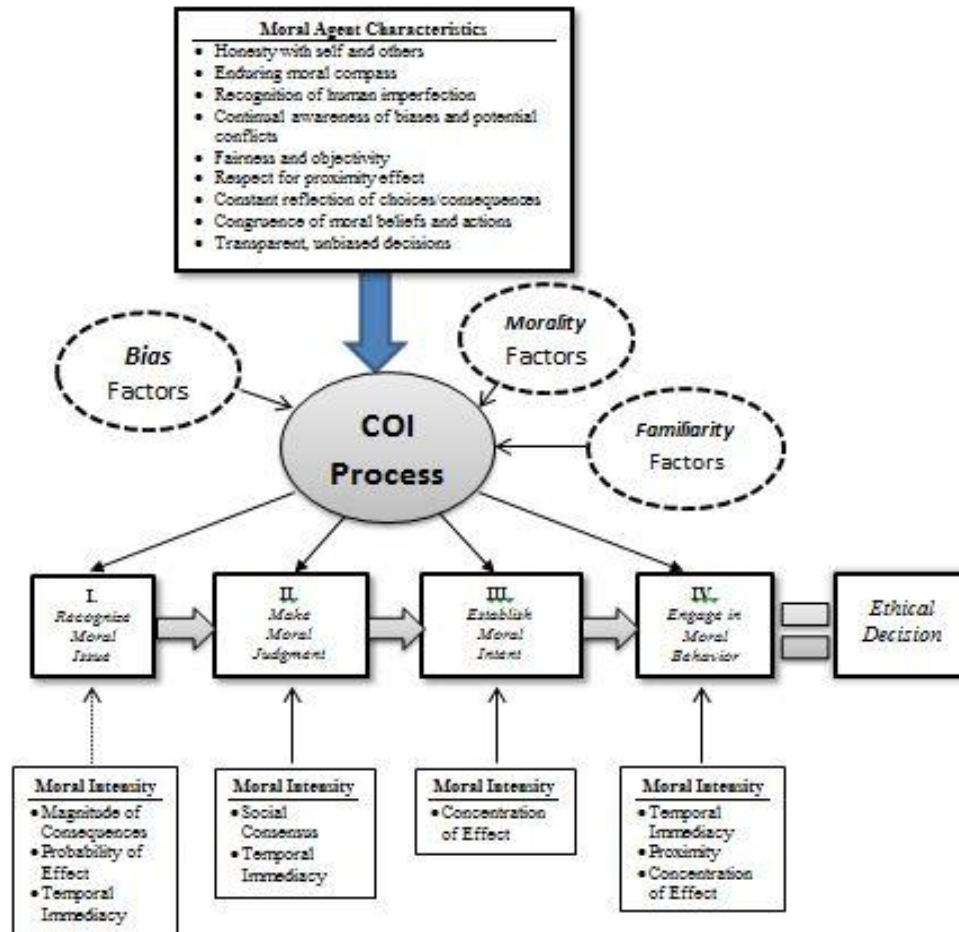
[...] I think if you think about all of the aspects of it in trying to make an ethically correct decision, it's not just about one trial. It's the perception and the relationship of the public and the people doing the trial, and the public with the drug companies, and people's faith in research and public science. There are a lot of factors, and I think that is one important part of making a good ethical decision...just to actually take the time to think about those factors beyond the immediate, obvious factors.

Although specific to a research setting, the underlying principle in the quote also applies to teaching, patient care, and professional relationships, regardless of any financial relationships with industry. It is important to think through the consequences of a decision in the COI resolution process and its potential effects on students, research study participants, patients, and society.

### **Ethical Decision-Making Model in the COI Process**

As a result of conducting this study, I have developed the belief that consideration of factors related to morality, bias, and familiarity should offer a basis for providing thoughtful reflection as individuals proceed through the steps involved in the COI resolution process. The steps, adapted from Jones' (1991) model involve a sequential order of (1) recognizing a moral issue, (2) making a moral judgment, (3) establishing moral intent, and (4) engaging in moral behavior that results in an ethical decision.

Figure 3: Modified Ethical Decision-Making Model for Resolving Conflicts of Interest



Source: Modified from An Issue-Contingent Model of Ethical Decision Making in Organizations. Jones, T. M. (1991, April). Ethical decision making by individuals in organizations: An issue-contingent model. *The Academy of Management Review*, 16(2), p. 379. Used with permission from the author, Thomas M. Jones, PhD (Appendix J).

During the first step, the decision-maker acknowledges her/his role as a moral agent and potential consequences, whether harmful or beneficial. The findings recognized that the second step requires moral reasoning, determining what is morally correct, and recognizing that ‘being human’ has its imperfections. The third step can create tension between what the decision-maker

actually believes and his/her actions. This step was summed up in the teaching case scenario as a “slippery slope between *teaching* people and *selling* people” (David). The fourth step represents the decision-maker’s choice to act upon moral beliefs and make an ethical decision, the essence of which was best also described by David, “the *appearance* of complying is different than the *spirit* of complying.” With continuous reflection on issues related to the influence of morality, bias, and familiarity; ethical decisions in the COI resolution process should produce decisions that are based on truth, objectivity, and professional knowledge and expertise.

### **Moral Intensity Effect**

Jones (1991) identified moral intensity as a construct that focuses on the issue at the heart of a decision and the possible inability of the decision-maker to recognize the moral issue or assess its moral intensity which in this study would be the issue that creates a COI and requires resolution. With that in mind and as exhibited in Figure 3, I identified one or more characteristics of moral intensity that I determined to have a predominant effect on each step of the process, suggesting a redistribution of the moral intensity characteristics. In my study, I did not place primary focus on recognizing or assessing the core moral issue at the heart of the decision but propose consideration of such for future research at which point the six moral intensity characteristics should have a more significant impact on a study.

### **Implications for Practice and Policy**

The stakeholder groups identified in the study continue to refine conflict of interest (COI) regulations and general guidelines as well as offer ethical guidance to physicians, other healthcare professionals, and non-healthcare professionals who contribute complementary expertise to the healthcare field. Guidelines alone are inadequate in reducing conflicts of

interest, ensuring unbiased education, and reducing healthcare costs (Coleman et al, 2006).

Institutional policies, however, are designed to protect the institution and the scholarly ideology and autonomy of its faculty, but their purpose is also to define what constitutes a COI and offer guidance on how to manage and resolve COIs and avoid bias. It is a goal of this study that the findings will contribute to and inform revision of policies, procedures, and processes in the management of conflicts of interest through sequential steps of identifying, assessing, and resolving COIs.

It is important for individuals and institutions to recognize that disclosure is the first step, not the only step, in a process that is designed to be transparent and resolve perceived conflicts-of-interest as a result of financial relationships with industry. Understanding the full process from an ethical decision-making perspective, as discussed in this study, is essential for identifying conflicts of interest, their potential effects, and how to manage them in a manner that is balanced, free of bias and undue commercial influence. For the benefit of many affected stakeholders, whether they are students, research participants, patients, peers, or society; academic medical centers should offer education and case-based training in ethics, ethical decision-making, and how to identify, resolve, and manage a conflict of interest or commitment. In support of the need for education and training and as an adjunct to institutional conflict-of-interest committees, an ethics policy and committee of faculty and other institutional leaders could assume oversight of the training and contribute to the resolution step in the COI process. The training should be required of all faculty and residents with refresher courses offered every few years or more frequently as deemed necessary. The training should also contribute to addressing situations or complaints involving perceived ethical misconduct. Additionally, institutions should consider creating a firewall in their COI policies, as some already have, that

prohibits multiple financial relationships with industry, especially when research funding support or academic-industry research collaboration is involved. Doing so would inhibit potential conflicts of purpose or mission.

The findings also encourage policy writers and the authors of ethical and professional conduct codes to listen to physicians and consider their voice in how the COI process should be navigated and what factors influence the process and decision, such as those presented in this study. The findings accentuate the importance of understanding how we, as human beings first and foremost, process issues imbedded in a moral and ethical context which should support a more objective and independent approach to the COI resolution process.

### **Sunshine Act**

Among the regulations referenced above that may influence the COI process is the recently enacted Sunshine Act, a provision of the Patient Protection and Affordable Care Act. I sought the participants' views on existing or potential effects of the Sunshine Act on physicians' financial relationships with industry. Their knowledge of the legislation ranged from none to comprehensive with most participants having minimal knowledge of it. After explaining the act, they generally considered that the effect will be virtually none at this point. The Sunshine Act places the burden of disclosing physician and institutional financial relationships with industry on the companies. The companies must post all funding recipients, the nature of the funding, e.g. research, and the value of the funding. As a result of congressional investigations that began in 2004, the act was predicated by the need for improved transparency.

The participants' viewpoints speculated that financial relationships with industry will continue as is and some will sever the relationships to avoid having it made public, *'out in the*

*sunshine.*’ One participant observed that “...some colleagues...have told me that they wear it as a ‘badge of honor’ while others...have morally moved themselves to accept it and say ‘that’s just how the world works’” (Ben). The general opinion suggests that it should be a deterrent to financial relationships with industry or at least an opportunity to pause and consider the effects on one’s professional role. An opportunity for future research of the effect of the Sunshine Act is evident because its implementation is ongoing and outcomes data are not available at this point.

### **Future research**

In addition to the future research potential of the Sunshine Act, several other opportunities emerged for future research. The focus of the study has considered the individual physician’s financial relationship with industry; however, institutions also have relationships with industry primarily in the forms of grants to fund research initiative, university-industry research collaboration, or program grants. As with the individual financial relationships, there are inherent conflicts of interest that may exist in these institutional level relationships; therefore, application of a similar study may have merit.

In my study, I examined the *process* of making ethical decisions through a grounded theory approach based on Jones’ (1991) model. Jones’ model and my refined theory offer several opportunities for further research. Jones (p. 391) suggested that future research “should include consideration of the effect of the moral agent’s failure to recognize the moral issue.” Recognizing the moral issue is the first step or component in the decision-making model which is fundamental to an effective navigation of the process. Future research should also consider whether ethics is proportional or rationalized in consideration of an issue, situation, or circumstances. Additionally, I excluded the organizational factors of Jones’ model from the



study which includes constructs of group dynamics, authority factors, and socialization processes. The effects of these organizational factors on ethical decision-making and in the context of the COI resolution process may reveal the impact of peer influence as well as the effect of institutional culture and climate.

Due to a relatively small sample in this study, a replication of the study would be valuable in continuing the discussion among stakeholders in determining how academic physicians assess and resolve potential conflicts of interest because as several participants indicated, we all have biases. Furthermore, it would give them an ongoing voice in the dialogue and an opportunity to consider the moral agent responsibility that exists in all of us. The study purpose and methodology should be generalizable to other professions and academic disciplines, such as law, business, engineering, or education, in which financial relationships exist between external organizations and faculty. Conflicts of interest (COIs) in these fields could be represented by financial relationships such as consulting agreements with private firms in the legal, management, or engineering communities. COIs could also present themselves through stocks and stock options with e.g., oil and gas companies or book publishing companies. As with medicine, these examples could create a conflict of interest with the individual faculty member but could also result in a conflict of commitment between time and effort dedicated to academic responsibilities and secondary, external commitments that are more financially beneficial. Many universities address external allocations of time and effort in their institutional policies to avoid an imbalance of responsibilities between internal and external professional roles. With the appropriate balance, the external relationship can be viewed as a complement to the faculty member's academic role and institutional mission as well as an academic-industry collaborative opportunity for both faculty and institution.

## **Conclusion**

Bias and conflicts of interest have existed over time in many aspects of our lives, but as I discussed with the speaker who suggested that I was violating his academic freedom, I was only concerned with his bias that may be inappropriately influenced by industry thereby creating a conflict of interest (COI) that may not be conducive to resolution. At the heart of COI resolution is an ethical decision-making process in a manner such as the refined theory demonstrated with the findings from my study. The academic physicians who agreed to participate in my study expanded my understanding of the role and responsibilities of individuals as moral agents in a refined theory of ethical decision-making that may contribute to the literature.

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## Appendices

### Appendix A



**Standards for Commercial Support: Standards to Ensure Independence in CM**  
Published on Accreditation Council for Continuing Medical Education  
(<http://www.accme.org>)

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#### Standards for Commercial Support: Standards to Ensure Independence in CME Activities

##### [Standard 1: Independence](#)

Standard 1.1 A CME provider must ensure that the following decisions were made free of the control of a commercial interest. (See [www.accme.org](http://www.accme.org) for a definition of a "commercial interest" and some exemptions.) (a) Identification of CME needs; (b) Determination of educational objectives; (c) Selection and presentation of content; (d) Selection of all persons and organizations that will be in a position to control the content of the CME; (e) Selection of educational methods; (f) Evaluation of the activity.

Standard 1.2 A commercial interest cannot take the role of non-accredited partner in a joint provider relationship.

##### [Standard 2: Resolution of Personal Conflicts of Interest](#)

Standard 2.1 The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines "relevant" financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

Standard 2.2 An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

Standard 2.3 The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.

##### [Standard 3: Appropriate Use of Commercial Support](#)

Standard 3.1 The provider must make all decisions regarding the disposition and disbursement of commercial support.

Standard 3.2 A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services.

Standard 3.3 All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.

Standard 3.4 The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider's educational partner or a joint provider.

Standard 3.5 The written agreement must specify the commercial interest that is the source of commercial support.

Standard 3.6 Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.

Standard 3.7 The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.

Standard 3.8 The provider, the joint provider, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the provider's written policies and procedures.

Standard 3.9 No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint provider, or any others involved with the supported activity.

## Appendix A (continued)



### Standards for Commercial Support: Standards to Ensure Independence in CM Published on Accreditation Council for Continuing Medical Education (<http://www.accme.org>)

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Standard 3.10 If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

Standard 3.11 Social events or meals at CME activities cannot compete with or take precedence over the educational events.

Standard 3.12 The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint provider or educational partner.

Standard 3.13 The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support.

#### Standard 4: Appropriate Management of Associated Commercial Promotion

Standard 4.1 Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.

Standard 4.2 Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME. For print, advertisements and promotional materials will not be interleaved within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face and are not paid for by the commercial supporters of the CME activity. For computer based, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleaved between computer 'windows' or screens of the CME content. (Supplemented February 2014; the information that follows previously appeared in ACCME policies. No changes have been made to the language.) Also, ACCME-accredited providers may not place their CME activities on a Web site owned or controlled by a commercial interest. With clear notification that the learner is leaving the educational Web site, links from the Web site of an ACCME accredited provider to pharmaceutical and device manufacturers' product Web sites are permitted before or after the educational content of a CME activity, but shall not be embedded in the educational content of a CME activity. Advertising of any type is prohibited within the educational content of CME activities on the Internet including, but not limited to, banner ads, subliminal ads, and pop-up window ads. For computer based CME activities, advertisements and promotional materials may not be visible on the screen at the same time as the CME content and not interleaved between computer windows or screens of the CME content. For audio and video recording, advertisements and promotional materials will not be included within the CME. There will be no 'commercial breaks.' For live, face-to-face CME, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity. (Supplemented, February 2014; the information that follows previously appeared in ACCME policies. No changes have been made to the language.) For Journal-based CME, None of the elements of journal-based CME can contain any advertising or product group messages of commercial interests. The learner must not encounter advertising within the pages of the article or within the pages of the related questions or evaluation materials.

Standard 4.3 Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, corporate logo, trade name or a product-group message of an ACCME-defined commercial interest.

Standard 4.4 Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product-promotion material or product-specific advertisement.

Standard 4.5 A provider cannot use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities.

## Appendix A (continued)



**Standards for Commercial Support: Standards to Ensure Independence in CM**  
Published on Accreditation Council for Continuing Medical Education  
(<http://www.accme.org>)

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### Standard 5: Content and Format without Commercial Bias

Standard 5.1 The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

Standard 5.2 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company.

### Standard 6: Disclosures Relevant to Potential Commercial Bias

Standard 6.1 An individual must disclose to learners any relevant financial relationship(s), to include the following information: The name of the individual; The name of the commercial interest(s); The nature of the relationship the person has with each commercial interest.

Standard 6.2 For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

Standard 6.3 The source of all support from commercial interests must be disclosed to learners. When commercial support is "in-kind" the nature of the support must be disclosed to learners.

Standard 6.4 'Disclosure' must never include the use of a corporate logo, trade name or a product-group message of an ACCME-defined commercial interest.

Standard 6.5 A provider must disclose the above information to learners prior to the beginning of the educational activity.

#### **Source URL:**

<http://www.accme.org/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support>

# Appendix B

## ACGME Core Competencies

### Common Program Requirements: General Competencies

Approved by the ACGME Board February 13, 2007

#### ACGME Competencies

The program must integrate the following ACGME competencies into the curriculum:

- **Patient Care**

Residents must be able to provide patient care that is compassionate, appropriate, and effective for the treatment of health problems and the promotion of health. Residents are expected to:

[as further specified by the RC]

- **Medical Knowledge**

Residents must demonstrate knowledge of established and evolving biomedical, clinical, epidemiological and social-behavioral sciences, as well as the application of this knowledge to patient care. Residents are expected to:

[as further specified by the RC]

- **Practice-based Learning and Improvement**

Residents must demonstrate the ability to investigate and evaluate their care of patients, to appraise and assimilate scientific evidence, and to continuously improve patient care based on constant self-evaluation and life-long learning. Residents are expected to develop skills and habits to be able to meet the following goals:

- identify strengths, deficiencies, and limits in one's knowledge and expertise;
- set learning and improvement goals;
- identify and perform appropriate learning activities;
- systematically analyze practice using quality improvement methods, and implement changes with the goal of practice improvement;
- incorporate formative evaluation feedback into daily practice;

## Appendix B (continued)

- locate, appraise, and assimilate evidence from scientific studies related to their patients' health problems;
- use information technology to optimize learning; and,
- participate in the education of patients, families, students, residents and other health professionals.

[as further specified by the RC]

- **Interpersonal and Communication Skills**

Residents must demonstrate interpersonal and communication skills that result in the effective exchange of information and collaboration with patients, their families, and health professionals. Residents are expected to:

- communicate effectively with patients, families, and the public, as appropriate, across a broad range of socioeconomic and cultural backgrounds;
- communicate effectively with physicians, other health professionals, and health related agencies;
- work effectively as a member or leader of a health care team or other professional group;
- act in a consultative role to other physicians and health professionals; and,
- maintain comprehensive, timely, and legible medical records, if applicable.

[as further specified by the RC]

- **Professionalism**

Residents must demonstrate a commitment to carrying out professional responsibilities and an adherence to ethical principles. Residents are expected to demonstrate:

- compassion, integrity, and respect for others;
- responsiveness to patient needs that supersedes self-interest;
- respect for patient privacy and autonomy;
- accountability to patients, society and the profession; and,



## Appendix B (*continued*)

- sensitivity and responsiveness to a diverse patient population, including but not limited to diversity in gender, age, culture, race, religion, disabilities, and sexual orientation.

[as further specified by the RC]

- **Systems-based Practice**

Residents must demonstrate an awareness of and responsiveness to the larger context and system of health care, as well as the ability to call effectively on other resources in the system to provide optimal health care. Residents are expected to:

- work effectively in various health care delivery settings and systems relevant to their clinical specialty;
- coordinate patient care within the health care system relevant to their clinical specialty;
- incorporate considerations of cost awareness and risk-benefit analysis in patient and/or population-based care as appropriate;
- advocate for quality patient care and optimal patient care systems;
- work in interprofessional teams to enhance patient safety and improve patient care quality; and
- participate in identifying system errors and implementing potential systems solutions.

[as further specified by the RC]

## Appendix C

### AMA Code of Medical Ethics

#### Principles of Medical Ethics

*Adopted June 1957; revised June 1980; revised June 2001.*

##### Preamble

The medical profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient. As a member of this profession, a physician must recognize responsibility to patients first and foremost, as well as to society, to other health professionals, and to self. The following Principles adopted by the American Medical Association are not laws, but standards of conduct which define the essentials of honorable behavior for the physician.

##### Principles of medical ethics

I. A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.

II. A physician shall uphold the standards of professionalism, be honest in all professional interactions, and strive to report physicians deficient in character or competence, or engaging in fraud or deception, to appropriate entities.

III. A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.

IV. A physician shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidences and privacy within the constraints of the law.

V. A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.

VI. A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical care.

VII. A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.

VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.

IX. A physician shall support access to medical care for all people.

##### Opinion 1.01 - Terminology

*Issued prior to April 1977; Updated June 1994 and June 1996.*

The term "ethical" is used in opinions of the Council on Ethical and Judicial Affairs to refer to matters involving (1) moral principles or practices and (2) matters of social policy involving issues of morality in the practice of medicine. The term "unethical" is used to refer to professional conduct which fails to conform to these moral standards or policies.

## Appendix C (continued)

Many of the Council's opinions lay out specific duties and obligations for physicians. Violation of these principles and opinions represents unethical conduct and may justify disciplinary action such as censure, suspension, or expulsion from medical society membership. (II)

### Opinion 8.03 - Conflicts of Interest: Guidelines

*Issued July 1986; Updated June 1994*

Under no circumstances may physicians place their own financial interests above the welfare of their patients. The primary objective of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration. For a physician to unnecessarily hospitalize a patient, prescribe a drug, or conduct diagnostic tests for the physician's financial benefit is unethical. If a conflict develops between the physician's financial interest and the physician's responsibilities to the patient, the conflict must be resolved to the patient's benefit. (II)

### Opinion 8.061 - Gifts to Physicians from Industry

*The previous Opinion 8.061, also entitled "Gifts to Physicians From Industry," issued June 1992, updated June 1996 and June 1998, was replaced by the current Opinion 8.061, "Gifts to Physician From Industry." Adopted November 2013.*

Relationships among physicians and professional medical organizations and pharmaceutical, biotechnology, and medical device companies help drive innovation in patient care and contribute to the economic well-being of the community to the ultimate benefit of patients and the public. However, an increasingly urgent challenge for both medicine and industry is to devise ways to preserve strong, productive collaborations at the same time that they take clear effective action to prevent relationships that damage public trust and tarnish the reputation of both parties.

Gifts to physicians from industry create conditions that carry the risk of subtly biasing—or being perceived to bias—professional judgment in the care of patients.

To preserve the trust that is fundamental to the patient-physician relationship and public confidence in the profession, physicians should:

- (a) Decline cash gifts in any amount from an entity that has a direct interest in physicians' treatment recommendations.
- (b) Decline any gifts for which reciprocity is expected or implied.
- (c) Accept an in-kind gift for the physician's practice only when the gift:
  - (i) will directly benefit patients, including patient education; and
  - (ii) is of minimal value.
- (d) Academic institutions and residency and fellowship programs may accept special funding on behalf of trainees to support medical students', residents', and fellows' participation in professional meetings, including educational meetings, provided:
  - (i) the program identifies recipients based on independent institutional criteria; and
  - (ii) funds are distributed to recipients without specific attribution to sponsors. (II)

## Appendix C (continued)

### Opinion 9.011 - Continuing Medical Education

*Issued December 1993. Updated June 1996. Updated June 2013 based on the report "Amendment to E-9.011, 'Continuing Medical Education,'" adopted November 2012.*

Physicians should strive to further their medical education throughout their careers, to ensure that they serve patients to the best of their abilities and live up to professional standards of excellence.

Participating in certified continuing medical education (CME) activities is critical to fulfilling this professional commitment to lifelong learning. As attendees of CME activities, physicians should:

- (a) Select activities that are of high quality and are appropriate for the physician's educational needs.
  - (b) Choose activities that are carried out in keeping with ethical guidelines and applicable professional standards.
  - (c) Claim only the credit commensurate with the extent of participation in the CME activity.
  - (d) Decline any subsidy offered by a commercial entity other than the physician's employer to compensate the physician for time spent or expenses of participating in a CME activity.
- (I, V)

## Appendix D

### *Selected Text and related Endnotes from* **AAUP 1940 Statement of Principles on Academic Freedom and Tenure**

*In 1915 the Committee on Academic Freedom and Academic Tenure of the American Association of University Professors formulated a statement of principles on academic freedom and academic tenure known as the 1915 Declaration of Principles, which was officially endorsed by the Association at its Second Annual Meeting held in Washington, D.C., December 31, 1915, and January 1, 1916.*

*In 1925 the American Council on Education called a conference of representatives of a number of its constituent members, among them the American Association of University Professors, for the purpose of formulating a shorter statement of principles on academic freedom and tenure. The statement formulated at this conference, known as the 1925 Conference Statement on Academic Freedom and Tenure, was endorsed by the Association of American Colleges (now the Association of American Colleges and Universities) in 1925 and by the American Association of University Professors in 1926.*

*In 1940, following a series of joint conferences begun in 1934, representatives of the American Association of University Professors and of the Association of American Colleges (now the Association of American Colleges and Universities) agreed upon a restatement of principles set forth in the 1925 Conference Statement on Academic Freedom and Tenure. This restatement is known to the profession as the 1940 Statement of Principles on Academic Freedom and Tenure.*

*Following extensive discussions on the 1940 Statement of Principles on Academic Freedom and Tenure with leading educational associations and with individual faculty members and administrators, a joint committee of the AAUP and the Association of American Colleges met during 1969 to reevaluate this key policy statement. On the basis of the comments received, and the discussions that ensued, the joint committee felt the preferable approach was to formulate interpretations of the 1940 Statement from the experience gained in implementing and applying it for over thirty years and of adapting it to current needs.*

*The committee submitted to the two associations for their consideration Interpretive Comments that are included below as footnotes to the 1940 Statement.<sup>1</sup> These interpretations were adopted by the Council of the American Association of University Professors in April 1970 and endorsed by the Fifty- Sixth Annual Meeting as Association Policy.*

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The purpose of this statement is to promote public understanding and support of academic freedom and tenure and agreement upon procedures to ensure them in colleges and universities. Institutions of higher education are conducted for the common good and not to further the interest of either the individual teacher or the institution as a whole.<sup>2</sup> The common good depends upon the free search for truth and its free exposition.

Academic freedom is essential to these purposes and applies to both teaching and research. Freedom in research is fundamental to the advancement of truth. Academic freedom in its teaching aspect is fundamental for the protection of the rights of the teacher in teaching and of the student to freedom in learning. It carries with it duties correlative with rights.<sup>3</sup>

Tenure is a means to certain ends; specifically: (1) freedom of teaching and research and of extramural activities, and (2) a sufficient degree of economic security to make the profession attractive to men and women of ability. Freedom and economic security, hence, tenure, are indispensable to the success of an institution in fulfilling its obligations to its students and to society.

## Appendix D (continued)

### Academic Freedom

1. Teachers are entitled to full freedom in research and in the publication of the results, subject to the adequate performance of their other academic duties; but research for pecuniary return should be based upon an understanding with the authorities of the institution.
2. Teachers are entitled to freedom in the classroom in discussing their subject, but they should be careful not to introduce into their teaching controversial matter which has no relation to their subject.<sup>4</sup> Limitations of academic freedom because of religious or other aims of the institution should be clearly stated in writing at the time of the appointment.<sup>5</sup>
3. College and university teachers are citizens, members of a learned profession, and officers of an educational institution. When they speak or write as citizens, they should be free from institutional censorship or discipline, but their special position in the community imposes special obligations. As scholars and educational officers, they should remember that the public may judge their profession and their institution by their utterances. Hence they should at all times be accurate, should exercise appropriate restraint, should show respect for the opinions of others, and should make every effort to indicate that they are not speaking for the institution.<sup>6</sup>

### Endnotes:

1. The Introduction to the Interpretive Comments notes: In the thirty years since their promulgation, the principles of the 1940 “Statement of Principles on Academic Freedom and Tenure” have undergone a substantial amount of refinement. This has evolved through a variety of processes, including customary acceptance, understandings mutually arrived at between institutions and professors or their representatives, investigations and reports by the American Association of University Professors, and formulations of statements by that association either alone or in conjunction with the Association of American Colleges. These comments represent the attempt of the two associations, as the original sponsors of the 1940 “Statement,” to formulate the most important of these refinements. Their incorporation here as Interpretive Comments is based upon the premise that the 1940 “Statement” is not a static code but a fundamental document designed to set a framework of norms to guide adaptations to changing times and circumstances.

Also, there have been relevant developments in the law itself reflecting a growing insistence by the courts on due process within the academic community which parallels the essential concepts of the 1940 “Statement”; particularly relevant is the identification by the Supreme Court of academic freedom as a right protected by the First Amendment. As the Supreme Court said in *Keyishian v. Board of Regents*, 385 US 589 (1967), “Our Nation is deeply committed to safeguarding academic freedom, which is of transcendent value to all of us and not merely to the teachers concerned. That freedom is therefore a special concern of the First Amendment, which does not tolerate laws that cast a pall of orthodoxy over the classroom.” [Back to text.](#)

2. The word “teacher” as used in this document is understood to include the investigator who is attached to an academic institution without teaching duties. [Back to text.](#)

3. First 1970 comment: The Association of American Colleges and the American Association of University Professors have long recognized that membership in the academic profession carries with it special responsibilities. Both associations either separately or jointly have consistently affirmed these responsibilities in major policy statements, providing guidance to professors in their utterances as citizens, in the exercise of their responsibilities to the institution and to students, and in their conduct when resigning from their institution or when undertaking government-sponsored research. Of particular relevance is the “[Statement on Professional Ethics](#)” adopted in 1966 as Association policy (AAUP, *Policy Documents and Reports*, 11th ed. [Baltimore: Johns Hopkins University Press, 2015], 145– 46). [Back to text.](#)

## Appendix D (*continued*)

4. Second 1970 comment: The intent of this statement is not to discourage what is “controversial.” Controversy is at the heart of the free academic inquiry which the entire statement is designed to foster. The passage serves to underscore the need for teachers to avoid persistently intruding material which has no relation to their subject. [Back to text.](#)

5. Third 1970 comment: Most church-related institutions no longer need or desire the departure from the principle of academic freedom implied in the 1940 “Statement,” and we do not now endorse such a departure. [Back to text.](#)

6. Fourth 1970 comment: This paragraph is the subject of an interpretation adopted by the sponsors of the 1940 “Statement” immediately following its endorsement:

If the administration of a college or university feels that a teacher has not observed the admonitions of paragraph 3 of the section on Academic Freedom and believes that the extramural utterances of the teacher have been such as to raise grave doubts concerning the teacher’s fitness for his or her position, it may proceed to file charges under paragraph 4 of the section on Academic Tenure. In pressing such charges, the administration should remember that teachers are citizens and should be accorded the freedom of citizens. In such cases the administration must assume full responsibility, and the American Association of University Professors and the Association of American Colleges are free to make an investigation.

## Appendix E

### AAUP 1990 Statement on Conflicts of Interest and Research

# Statement on Conflicts of Interest

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*The statement that follows was approved for publication by the Association's Committee on Professional Ethics in June 1990.*

American universities and colleges have long been engaged with the institutions of the wider society, to their mutual benefit. Universities have trained ministers, teachers, corporate leaders, and public servants, and have taken on wider responsibilities in research and administration for state and federal governments. The years after World War II brought both quantitative and qualitative change in this relationship as a result of the global responsibilities assumed by the United States and of the strikingly new importance attained by science. This change was symbolized and advanced by an immense increase in federal and state funding for higher education and in investment by private foundations. Now, as universities have entered an era of more stringent budgetary limitations, yet another major shift has occurred—to greater reliance on private funding and to a closer symbiosis between universities and industry.

The many opportunities offered to both university researchers and the private sector by sweeping developments in certain areas of science and technology have led to new concerns in both universities and government. One such concern, about freedom to do research and to publish the results, has rightly exercised universities in deliberations about whether or not to undertake such joint efforts and on what terms. More recently, the question of conflict of interest has been raised anew, with regard to the pressures that financial interests of faculty members participating in extra-university enterprises may exert, consciously or not, on the design and the outcome of the research.

The American Association of University Professors has addressed these questions in the past, and we believe it important to reaffirm the 1965 joint statement of the AAUP and the American Council on Education, *On Preventing Conflicts of Interest in Government-Sponsored Research at Universities*, and to commend the 1983 report of an Association subcommittee on *Corporate Funding of Academic Research*.<sup>1</sup> The latter report, avowedly tentative and anticipating a fuller statement at a later time, properly assumed that the initiative must lie with university faculties for drawing up such conflict-of-interest guidelines as are appropriate to each campus, with due regard for the proper disclosure of a faculty member's involvement in off-campus enterprises, in terms of investment, ownership, or consultative status; for the use of university personnel, including students; and for the disposition of potential profits.

Recent developments have suggested the following considerations to be taken into account by faculties involved in developing or revising such guidelines.

Government proposals for policing possible conflicts of interest have been overwhelmingly rejected by the academic community as involving a massive, unneeded enlargement of the government's role on the campus. Faculties must be careful, however, to ensure that they do not defensively propose a similar bureaucratic burden differing only in the locus of administration. Any requirements for disclosure of potential conflicts of interest should be carefully focused on legitimate areas of concern and not improperly interfere with the privacy rights of faculty members and their families.

Because the central business of the university remains teaching and research unfettered by extra-university dictates, faculties should ensure that any cooperative venture between members of the faculty and outside agencies, whether public or private, respects the primacy of the university's principal mission, with regard to the choice of subjects of research and the reaching and publication of results.

Faculties should make certain that the pursuit of such joint ventures does not become an end in itself and so introduce distortions into traditional university understandings and arrangements. Private and public agencies have a direct interest in only a few fields of research and in



## Appendix E (*continued*)

only certain questions within those fields. Accordingly, external interests should not be allowed to shift the balance of academic priorities in a university without thorough debate about the consequences and without the considered judgment of appropriate faculty bodies. So, too, care must be taken to avoid contravening a commitment to fairness by widening disparities—in teaching loads, student supervision, or budgetary allocation—between departments engaged in such outside activity and those not less central to the nature of a university, which have, or can have, no such engagement.

The ability to procure private or government funding may in certain circumstances be an appropriate consideration in making judgments about salaries, tenure, and promotion, but it must be kept in proper proportion and be consistent with criteria established by the faculty. Guidelines concerning intra-university research support should guard against making its availability dependent, solely or predominantly, on the likelihood that the research so supported will result in obtaining outside funding.

### **Note**

1. *Academe: Bulletin of the AAUP* 69 (November–December 1983): 18a–23a.

## Appendix F

IRB-approved Institutional Prospectus



DEPARTMENT OF EDUCATIONAL LEADERSHIP,  
COUNSELING AND FOUNDATIONS

[date]

[Name/address]

Dear [name]:

I am currently a PhD candidate at the University of New Orleans in the Higher Education Administration program, Department of Educational Leadership, Counseling, and Foundations. I am in the process of fulfilling the university and college degree requirements for completion of the program.

I am writing to ask if you would allow me to conduct taped interviews with six to ten faculty members that should last approximately 60 minutes as a component of my qualitative research study and dissertation entitled **Truth or Consequences—Academic Physicians’ Perspective in the Management of Commercially-influenced Conflicts of Interest: An Issue-Contingent Ethical Decision-Making Model**. The study will focus on conflicts of interest that emerge from academic physicians’ financial relationships with industry, i.e. pharmaceutical, medical device, or biotech firms in their roles of teaching, research, and patient care. The faculty responses will be framed as perspectives to case scenarios, not their real-life experiences.

I will follow all federal regulations regarding conducting research involving human subjects and have attached relevant documentation for your review in allowing my access to your institution and faculty. Additionally, please advise if further review and approval is required by your Institutional Review Board.

If you have additional questions and/or would like to receive a summary of my findings, I may be reached at 504-442-2143 (cell) or at [mleppers@uno.edu](mailto:mleppers@uno.edu). Additionally, if you wish to discuss the study or requirements with my major professor and dissertation committee chair, Belinda M. Cambre, JD, PhD; you may reach her at 504-280-3210 or at [bmcambre@uno.edu](mailto:bmcambre@uno.edu). Thank you for your consideration of my request, and I look forward to hearing from you.

Best regards,

Melinda Epperson, M.Ed., CMP  
504-442-2143 (cell)  
[mleppers@uno.edu](mailto:mleppers@uno.edu)

Attachments: Institutional Prospectus  
Participant Recruitment Flyer  
UNO IRB Approval letter  
Interview Consent Form

## Appendix F (continued)

### Institutional Prospectus

**Purpose:** The purpose of this qualitative research study is to explore academic physicians' perspectives in the management of conflicts of interest (COI) that emerge from financial relationships with industry, i.e. pharmaceutical, medical device, or biotech firms. Your academic medical institution was selected based on three sets of criteria:

- (1) Either of the following descriptions applies:
  - (a) a relatively new medical school accredited within the past ten years OR
  - (b) a long-standing academic medical institution
- (2) Type of governance:
  - (a) private OR
  - (b) publicly-funded, i.e. state institution.
- (3) Willingness to participate in a study that may contribute to
  - (a) the literature and a better understanding of the environment AND
  - (b) policy reform and change

**Research Activities at the site during the study:** With the institutional administration's permission, I will conduct one-on-one interviews with identified faculty who have met the selection criteria. The interviews will be conducted with minimal disruption and with respect to confidentiality of data and participant identity. Please refer to the attached Interview Consent Form that provides additional details regarding participant selection, terms of participation, access to information, and the benefits and risks that may result from participation in the study.

**Findings:** Also noted in the attached Interview Consent Form, the results of the study will be reported in aggregate without any identifiable information to protect the participants and the institution with which they are affiliated.

**Institutional Benefits:** As explained in the Interview Consent Form, there are minimal risks to conducting this study. A sample of benefits that the study may provide include further discussion with faculty of the research topic, a better understanding of the university-industry environment, the barriers that faculty may encounter in industry relationships, and an opportunity to inform institutional policy.

## **Appendix F (continued)**

[Flyer wording, if applicable]

Faculty Study Participants Requested

for a

Qualitative Dissertation Study

*How do physicians as academicians manage or resolve potential conflicts of interest in their roles as teachers, researchers, and clinicians?*

Participate and contribute to the body of literature through your

faculty perspectives of case scenarios during a single,

60-minute interview between [date] and [date].

### **Participant Criteria**

Medical Faculty who are:

- involved in the three roles of teaching, research, and patient care
  - have or have had one or multiple financial relationships\* with industry (biotech firms, pharmaceutical or medical device companies)
- [\*For example: speakers' bureau, consultant, stock or stock options, research grants, etc.]*

Please call or email by [date] with questions and/or

to schedule an interview date and time.

### **CONTACT**

Melinda Epperson (PhD candidate)

504-442-2143

[mleppers@uno.edu](mailto:mleppers@uno.edu) or [mlecmp@aol.com](mailto:mlecmp@aol.com)

## Appendix G

IRB-approved Interview Request Letter



DEPARTMENT OF EDUCATIONAL LEADERSHIP,  
COUNSELING AND FOUNDATIONS

[Date]

Dear Dr. [name]:

I am currently a PhD candidate at the University of New Orleans in the Higher Education Administration program, Department of Educational Leadership, Counseling, and Foundations. I am in the process of fulfilling the university and college degree requirements for completion of the program.

I am writing to ask if you would allow me to conduct a taped interview with you as a component of my qualitative research study and dissertation entitled **Truth or Consequences—Academic Physicians’ Perspective in the Management of Commercially-influenced Conflicts of Interest: An Issue-Contingent Ethical Decision-Making Model**. The study will focus on conflicts of interest that emerge from academic physicians’ financial relationships with industry, i.e. pharmaceutical, medical device, or biotech firms in their roles of teaching, research, and patient care.

If you are willing to participate, I have included a consent form defining the parameters of the interview and how I will use the information and perspectives that you will contribute. I appreciate your consideration of my request and I will assure confidentiality of your identity and of your responses as noted in the attached consent form. If you agree to be interviewed, I will contact you to arrange a time convenient with your schedule. I ask that you call or email me to let me know of your willingness to participate. My contact information is given below.

If you have additional questions and/or would like to receive a summary of my findings, I may be reached at 504-442-2143 (cell) or at [mleppers@uno.edu](mailto:mleppers@uno.edu). Additionally, if you wish to discuss the study or requirements with my major professor and dissertation committee chair, Belinda M. Cambre, JD, PhD; you may reach her at (225-931-8852), [bcambre@cox.net](mailto:bcambre@cox.net), or [bmcambre@uno.edu](mailto:bmcambre@uno.edu). I look forward to talking with you.

Best regards,

Melinda Epperson, M.Ed., CMP  
504-442-2143 (cell)  
[mleppers@uno.edu](mailto:mleppers@uno.edu)

## Appendix H

IRB-approved Interview Consent Form



DEPARTMENT OF EDUCATIONAL LEADERSHIP,  
COUNSELING AND FOUNDATIONS

### Interview Consent Form

#### Conditions of interview participation:

1. **Purpose:** The purpose of this qualitative grounded theory study is to explore academic physicians' perspectives in the management of conflicts of interest (COI) that emerge from financial relationships with industry, i.e. pharmaceutical, medical device, or biotech firms.
2. **Selection and Participant Rights:** The selection of an academic physician engaged in the academic roles of teaching, research, and patient care for the single, individual interview provides a faculty member's perspective of how one may manage and resolve any potential COIs in case scenarios in the areas of teaching, research, and patient care. The interview will be taped and transcribed maintaining confidentiality of identity and with due respect to anonymity of responses. You will be described only by your academic role (faculty level, specialty, type of institution, e.g. academic medical center, school/college of medicine, teaching hospital, etc., other administrative/faculty responsibilities, and general descriptive demographics) in the institution with no reference to a specific department or institution.
3. **Access/Confidentiality/Anonymity:** The graduate student-interviewer, Melinda Epperson, will omit your name and all other identifying features in transcription as well as discussion of the interview technique of qualitative research in the dissertation, assuring confidentiality. You will only be identified with a pseudonym of your choosing or with an assigned interviewee #. This interview is for my dissertation and resulting presentations or publications for which your identity will be protected. All written notes, records, and electronic documents, i.e. tapes or CDs of interviews will be protected in a locked cabinet in my office for a period of three (3) years after which all will be shredded or destroyed in an appropriate manner.
4. **Participation:** Your participation in the interview for the study is strictly voluntary and will last no longer than 60 minutes. I will take notes during the interview to supplement the audio-taping. Once transcribed, I will ask you to review my transcription for accuracy. Your signature below acknowledges your willingness and agreement to participate and to answer the questions to the extent of your knowledge and experience, contributing to the integrity of the study. Please understand that your role is strictly voluntary and that you may choose at any time to discontinue your participation in the interview and the study. There is minimal risk, but if you decide to withdraw, your decision will not affect any future contact with the University of New Orleans or impact on the study.

## Appendix H (continued)

5. **Benefits and Risks:** The benefits to you in participating include learning new perspectives, ideas, opinions concerning how an academic physician as an individual manages conflicts of interest (COI) that emerge from financial relationships with industry, i.e. pharmaceutical, medical device, or biotech firms.. As an experienced faculty and/or administrator, you may as well enlighten and further my understanding of the environment. Although there is minimal risk, you may discover opinions that would differ from previously conceived perspectives. Additionally, disclosure of your responses may be damaging to your financial standing, employability, or reputation. I will protect your identity and the confidentiality of your participation as indicated above in #3. The additional benefit of your participation is to society and may contribute to future research and/or inform policy.

Any questions regarding my study may be directed to Belinda M. Cambre, JD, PhD (225-931-8852), [bcambre@cox.net](mailto:bcambre@cox.net), or [bmcambre@uno.edu](mailto:bmcambre@uno.edu). Thank you for participating.

*I have read and understand the conditions of participating in the interview exercise and am willing to participate.*

*Signature*

*Participant Interviewee:* \_\_\_\_\_ Date: \_\_\_\_\_

**Name Printed:** \_\_\_\_\_

*I have explained the conditions of participating to the best of my ability and have answered questions concerning participation.*

*Signature*

*Student Interviewer:* \_\_\_\_\_ Date: \_\_\_\_\_

**Name Printed:** Melinda Lawrie Epperson, M.Ed., CMP

# Appendix I

## IRB-approved Interview Guide

### Interview Guide

**PART A—Purpose and demographics:** The purpose of this study is to explore and gain insight into how academic physicians, who have financial relationships with industry, make ethical decisions in resolving potential conflicts of interest (COIs). Therefore, the objectives of the interview, based on three case scenarios, are to:

- (1) Hear your perspectives of the decision-making process that physicians may use in resolving COIs;
- (2) Identify factors that may influence the decision-making process;
- (3) Generally understand how the decision-making process may or may not affect an academic physician, who has financial relationships with industry, in his or her roles as research, teaching, and patient care; and
- (4) Synthesize observations of the environment.

Your insight as both clinician and faculty will be valuable. Thank you for your willingness to participate in the interview. Please provide the following background information about yourself:

- a. Specialty
- b. Years in practice
- c. Years in academic medicine, if different than years in practice
- d. Why you chose to participate in academic medicine
- e. How many years you have had financial relationships with industry
- f. The nature of those relationships, e.g. speakers' bureau, consultant, research funding, stock or stock options, advisory boards, other.
- g. How would you generally define conflict of interest as it relates to physicians' financial relationships with industry?

**PART B—Case Scenarios:** [NOTE: The following questions will be presented with each of three case scenarios in teaching, research, and clinical/patient care.]

In making ethical decisions in this scenario, did or how should have the physician considered the following? Please feel free to answer with other examples:

- a. Is there a moral issue at the center of his/her decision? (*moral intensity*<sup>1</sup>)
- b. What potential harms and benefits should the physician have considered and based on what criteria? (*magnitude of consequences and probability of effect*<sup>1</sup>)
- c. What could be the effect of institutional policies, federal regulations, accreditation guidelines, etc., on the physician's decisions, and what could determine the level of effect, e.g. strong influencing effect or minimal consideration? (*social consensus*<sup>1</sup>)
- d. Did or should have the physician consider(ed) future effects or consequences of his/her decisions? Why? Examples? (*temporal immediacy*<sup>1</sup>)
- e. Would his/her decisions be different for a close friend than, for example, a class of patients, a cohort of students, society, etc.? (*proximity*<sup>1</sup>)
- f. How would the decision be affected if the potential for significant financial gain were apparent? (*concentration of effect*<sup>1</sup>)
- g. Any advice that you would offer him/her?



## Appendix I (continued)

**PART C—General environmental assessment:** The following are concluding questions for the purpose of gaining your assessment of the current environment. Taking the three scenarios we have discussed into consideration, please offer your professional perspectives about the following:

1. What are the possible reasons physicians enter into financial relationship(s) with industry? If not mentioned, will present the follow-up questions below for reaction:
  - a. Q1: Reputation?
  - b. Q2: loans (debt-load) from medical school?
  - c. Q3: institutional pressures to secure external funding?
  - d. Q4: tenure rewarded by department/institution for securing external funding?
2. What are the benefit(s) for a physician and his/her institution? Risks?
3. Do financial relationships present obstacles or barriers to physicians' performance in research, teaching, and patient care?
  - a. Q1: ...such as?
  - b. Q2: Do or could they impact independent and professional judgment in interaction with (i) professional colleagues, (ii) research subjects, (iii) students, and (iv) patients?
4. How does/should a physician avoid bias and COIs in (a) teaching, (b) research, and (c) patient care?
5. Is the Sunshine Act a deterrent to physicians entering into financial relationships? Why or why not?
6. One final question...what factors have you observed that may influence ethical, unbiased decisions? What could be a good litmus test?

In concluding the interview, I want to give you the opportunity to offer additional opinions, perspectives, or observations concerning ethical decision-making either in reference to the case scenarios we discussed or the environment in general.

Thank you again for your time, your observations, and for participating in my study! I will be happy to share the aggregate findings with you.

<sup>1</sup> Jones, T. M. (1991, April). Ethical decision making by individuals in organizations: An issue-contingent model. *The Academy of Management Review*, 16(2), 366-395.

## Appendix J

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**Epperson, Melinda L**

---

**From:** Thomas Jones <rebozo@u.washington.edu>  
**Sent:** Thursday, October 14, 2010 11:09 AM  
**To:** Epperson, Melinda L  
**Subject:** Re: Dissertation & ethical D/M model

Ms. Epperson,

I'm not sure that you even need my permission to use the issue-contingent model, but if so, I hereby grant it. Proper citations/references should be all you need.

My research has moved in different directions since that article was published, but if you would like to talk to me anyway, let me know and we can set up a time.

Good luck with your research.

Professor Jones

----- Original Message -----

**From:** [Epperson, Melinda L](mailto:Epperson, Melinda L)  
**To:** [rebozo@u.washington.edu](mailto:rebozo@u.washington.edu)  
**Sent:** Wednesday, October 13, 2010 1:27 PM  
**Subject:** Dissertation & ethical D/M model

Dear Dr. Jones,

I am a PhD candidate in the Higher Education Administration program at the University of New Orleans. I am very interested in your issue-contingent model of ethical decision-making as the theoretical framework for my qualitative study and dissertation. The general theme of my study is physicians' ethical decision-making regarding management and resolution of COIs in the context of their financial relationships with industry, i.e. pharmaceutical and medical device companies. There are many guidelines, regulations, policies, etc. that govern the resolution process and environment but very little about how the physician individually identifies and manages a perceived COI.

I would like to ask your permission to use your model for my study and would be happy to answer any questions you may have or briefly discuss this with you by phone. Please let me know if this is agreeable with you; and if so, please give me a phone number as well as a good day and time to call you. I am on Central Daylight Time.

I look forward to hearing from you.

Sincerely,  
Melinda Epperson

~~~~~  
Melinda Epperson, M.Ed., CMP  
Director  
Center for Continuing Education  
Tulane University Health Sciences  
New Orleans, Louisiana  
504.988.6445 (direct line)

*For upcoming CME activities, please go to <http://tulane.edu/cce>*

## Appendix J (continued)



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## Appendix K

NIH Certificate of Completion



**Human Participant Protections Education for Research Teams**

### Completion Certificate

---

This is to certify that

**Melinda Epperson**

has completed the **Human Participants Protection Education for Research Teams** online course, sponsored by the National Institutes of Health (NIH), on 07/15/2002.

This course included the following:

- key historical events and current issues that impact guidelines and legislation on human participant protection in research.
  - ethical principles and guidelines that should assist in resolving the ethical issues inherent in the conduct of research with human participants.
  - the use of key ethical principles and federal regulations to protect human participants at various stages in the research process.
  - a description of guidelines for the protection of special populations in research.
  - a definition of informed consent and components necessary for a valid consent.
  - a description of the role of the IRB in the research process.
  - the roles, responsibilities, and interactions of federal agencies, institutions, and researchers in conducting research with human participants.
- 

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## Appendix L

UNO IRB Human Subjects Approval

***University Committee for the Protection  
of Human Subjects in Research  
University of New Orleans***

---

*Campus Correspondence*

Principal Investigator: Belinda M. Cambre  
Co-Investigator: Melinda Lawrie Epperson  
Date: January 14, 2013  
Protocol Title: "Truth of Consequences- Academic Physicians' Perspective  
in the Management of Commercially-influenced Conflicts of  
Interest: An Issue-contingent Ethical Decision-making  
Model"  
IRB#: 08Oct12

The IRB has deemed that the research and procedures are compliant with the University of New Orleans and federal guidelines. The above referenced human subjects protocol has been reviewed and approved using expedited procedures (under 45 CFR 46.116(a) category (7)).

Approval is only valid for one year from the approval date. Any changes to the procedures or protocols must be reviewed and approved by the IRB prior to implementation. Use the IRB number listed on this letter in all future correspondence regarding this proposal.

If an adverse, unforeseen event occurs (e.g., physical, social, or emotional harm), you are required to inform the IRB as soon as possible after the event.

Best wishes on your project!

Sincerely,



Robert D. Laird, Ph.D., Chair  
UNO Committee for the Protection of Human Subjects in Research

## Vita

### Melinda Lawrie Epperson

The author holds a BS degree in Secondary Education (French and English) from University of Tennessee at Martin, a Master's degree (MEd) in Higher Education Administration from the University of New Orleans. Her formal education is complemented by her designation as a Certified Meeting Professional (CMP). With conference development and management being an essential component of continuing education, she obtained her initial CMP designation in 1992 and has recertified every five years. With her most recent recertification in 2012, she will be eligible for an *emeritus* recertification in 2017.

She began her Tulane University continuing education career as Program Coordinator in May 1993 followed by positions as Program Manager, Assistant Director, and Interim Director and was appointed director in March 2004. Her professional experience includes 33 of the last 36 years in academic-based continuing education with positions in the University of Kentucky's College of Business and Economics in Lexington, Kentucky and Valencia Community College in Orlando, Florida in addition to her current position in Tulane University.

The author's current professional memberships include the Society for Academic CME (SACME), Association for the Study of Higher Education (ASHE), International Association of Continuing Education and Training (IACET), and Meeting Professionals International (MPI).