To the Graduate Council:

I am submitting herewith a dissertation written by Michael Lee Manolakis entitled "Conflict of Interest in the Pharmacy Benefits Management Industry." I have examined the final copy of this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy, with a major in Philosophy.

Glenn C. Graber, Major Professor

We have read this dissertation
and recommend its acceptance.

Accepted for the Council:

Associate Vice Chancellor
and Dean of The Graduate School

CONFLICT OF INTEREST

IN

THE PHARMACY BENEFITS MANAGEMENT INDUSTRY

A Dissertation

Presented for the

Doctor of Philosophy

Degree

The University of Tennessee, Knoxville

Michael Lee Manolakis

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DEDICATION

This dissertation is dedicated to my family. To my mother, Pat, who first suggested graduate school, and who instilled in me as a child the confidence necessary to complete this project as an adult. To my wife, Patti, for her never ending support, patience, and love. To my son, Charlie, for big hugs when I needed them. To my son, Steven, for smiles at the eleventh hour. To my brother-of-another-mother, James, for long distance inspiration. And to my dog, Madison, for hanging out with me in the middle of the night.

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ABSTRACT

"Conflict of Interest in the Pharmacy Benefits Management Industry" is concerned with conflicts of interest encountered by pharmacists working for pharmacy benefit management companies. Pharmacy benefit management companies (PBMs) provide outpatient pharmacy management services to managed health care organizations, employers, state government organizations, and insurers. It is estimated that 100 to 115 million persons in the United States have their health plan's pharmacy benefit managed by a PBM. Three major PBMs were recently purchased by pharmaceutical manufacturers for a collective $12 billion. The pharmacist who works for a PBM faces a variety of potential conflicts of interest. Consequently, key questions include how these conflicts should be understood and appropriately managed.

Four analyses of conflict of interest are reviewed, with a focus on the works of Neil Leubke and Michael Davis. The debate between these philosophers centered around a number of key distinctions, including whether objective and subjective interests should count in defining a conflict, and whether the key consideration should be the correctness of decision making or the possible loss of trust from the fiduciary relationship. The author argues that a modified version of Leubke's position is the stronger understanding of conflict of interest.

Four practice scenarios shared by PBM pharmacists are evaluated in light of possible conflicts of interest. In each scenario, possible harms to patients and the

PBM's customers are reviewed. The author argues that the relationship between the patient and the PBM pharmacist is fiduciary in nature, and consequently, trust is placed at risk when the pharmacist is involved in a conflict of interest.

A variety of strategies for managing conflicts of interest are reviewed. These include reliance on personal integrity and a code of ethics, and regulatory controls. With a focus on retaining integrity, maintaining the patient-pharmacist relationship, and appropriately managing drug expenditures, the author argues for a refocusing of the profession's Code of Ethics, the development of professional guidelines, collective action by the PBMs to create ethical standards, and oversight of managed pharmacy by consumers as necessary for the pharmacist to appropriately manage conflicts of interest.

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CHAPTER I

A Historical Look at the Pharmacist's Role

In the August 14, 1995, edition of the *Federal Register*, the Food and Drug Administration announced its intention to hold hearings on the potential implications of changes in its pharmaceutical marketing policies.[1] The focus of these hearings, held in October 1995, was on drug marketing and information exchange in light of the growth of managed care. Janet Woodcock, Director of the FDA's Center for Drug Evaluation and Research, opened the session by telling attendees that the agency was considering whether policy changes should be implemented because the effects of managed care had reached beyond the delivery and marketing of health care. She went on to note that managed care had also caused changes in the traditional physician-patient relationship, and in the physician's role as gatekeeper and prescriber of drugs.

Although a variety of concerns drove the FDA to organize these hearings, two of the key issues were that managed care organizations have become the prime audience for drug companies, and the acquisition of pharmacy benefit management companies (PBMs) by drug companies, has altered most, if not all, traditional prescription drug sales and marketing practices.[2] Of key concern for the purpose of this dissertation is that within the context of the pharmacy benefit management company, which is a business I will explain

[1] See Hubbard (1995).

[2] See Wechsler (1995).

later in this chapter, the pharmacist has become a key decision maker regarding drug product selection and promotion within managed health plans. It is my contention that the methods by which the pharmacy benefit management company does business generate an interest that potentially threatens the patient-PBM pharmacist relationship; and further, that the creation of this potentially adverse interest, as well as strategies for resolving the possible conflict of interest, should be, but have not been, fully explored.

Pharmacy benefit management companies provide outpatient pharmacy management services to managed health care organizations, employers, state government organizations, and other insurers.[3] They have evolved from playing a third party role that focused almost exclusively on the processing of prescription drug claims to their present function of providing services that include prescription drug claim processing, program eligibility verification, utilization review, and cost containment services. More than 50% of employers and a significant number of insurance carriers and Health Maintenance Organizations (HMOs) have turned to pharmacy benefits managers to assist them with managing the prescription drug portion of the health benefit they offer.[4] It is crucial to recognize that management of the outpatient drug benefit is a significant challenge for businesses, as annual expenditures for outpatient prescription drugs have increased from $21.4 billion to approximately $50 billion over the past 10 years.[5]

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[3] See Cascade (1995).

[4] From this point forward I will refer to any managed care organizations as an MCO, unless specifically quoting or drawing from an author. It is important to point out that MCOs include HMOs and other types of organizations.

[5] See Schulman (1996), p.906.

Pharmacy benefit management companies contain costs through a number of strategies; however, they derive the biggest savings by leveraging their market size against other market elements. For example, PBMs can drive down prescription drug acquisition costs by negotiating discounts off the average wholesale cost from an independent or chain pharmacy by providing them with an increase in the volume of traffic that enters their store.[6] Likewise, because of the tremendous number of prescriptions the PBM dispenses through its mail service facility, it can secure substantial price discounts from pharmaceutical product wholesalers. Because PBMs have been so successful at improving cost management, the number of persons they cover has grown dramatically. It is estimated that 100 to 115 million persons in the United States have their health plan's pharmacy benefit managed by a PBM.[7] The largest PBMs, which include PCS Health Systems, Medco Containment Services, Diversified Pharmaceutical Services, Caremark, and ValueRx, are believed to manage the benefits for more than 80% of these enrollees. Estimates suggest that half the U.S. population, or 135 million people, could be receiving PBM services by 1997.[8]

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[6] The rationale behind this idea is that members of the health plan that utilize the PBM will have to use the PBM's network of pharmacies to have their prescriptions filled. Consequently, the pharmacy that contracts with the PBM will have new customers by virtue of the fact that the health plan's members will shop at their store. Plan members can always use a pharmacy of their choice, but there is a financial incentive to purchase their prescription in the pharmacy network.

[7] See Schulman (1996); also see GAO (1995), p.3.

[8] See Cascade (1995), p. 6.

As with the managed health care industry in general, PBMs have experienced exponential growth in terms of persons covered and dollars managed over the past few years. Managed care has also changed structurally through mergers and acquisitions during this time, and PBMs are no exception. Integration has occurred vertically and horizontally within the PBM industry, with the objective always being the same -- to achieve greater margins through increased market share and /or economies of scale.[9] This integration has changed the basic structure of the pharmacy benefits management industry. The corporate and clinical staff of PBMs prior to integration were required to balance client and business interests, which is not to suggest that conflicts of interest did not exist. However, PBM staff members in the post-integration period finds themselves dealing with an additional business interest, specifically the interests driven by their parent-owner. It has been suggested that these interests compromise the PBMs' role, and consequently, conflict of interest is a common topic of discussion, and government oversight now plays a role to assure that unfair methods of competition are not enacted.[10, 11]

Stemming from these changes, the PBM function that is perhaps most at risk for compromise is the clinically appropriate development and management of the drug formulary. A formulary is a preferred list of drugs that is typically categorized by therapeutic class: for example, nonsteroidal anti-inflammatory drugs. The drugs on the

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[9] See Cascade (1995), p. 8.

[10] See Southwick (1995), p. S9.

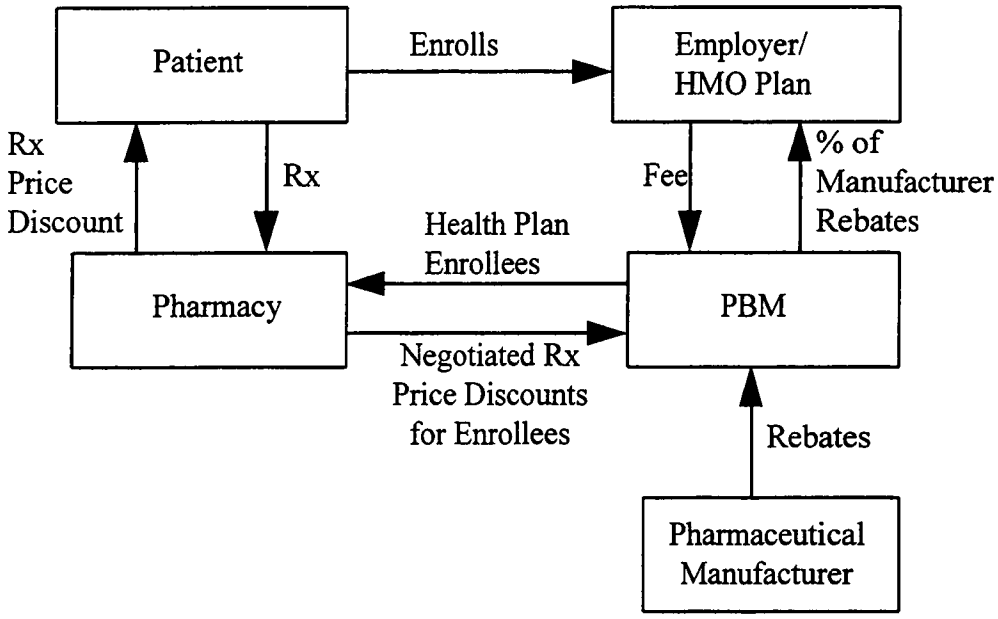
[11] See GAO (1995), p. 2.

formulary are considered to be "preferred" based on clinical and economic reasons. The PBM will generally use its panel of physicians and pharmacists to review drugs for formulary consideration. Formularies can be used to promote the prescribing and dispensing of selected brand name products, as well as less expensive generic drugs. The PBM will typically profile physician prescribing and pharmacist dispensing patterns to assess their compliance with the formulary, and will intervene through education programming to enhance compliance. By modifying the provider's patterns of prescribing and dispensing away from more expensive agents, PBMs effectively accrue hard dollar savings for their customers by reducing the amount spent on the prescription at the point of sale.[12]

PBMs are effective formulary managers, which pharmaceutical manufacturers have recognized. In addition, because PBMs have been able to move market share for selected drugs, manufacturers offer PBMs drug rebates in return for inclusion on the formulary. Rebate dollars are then usually passed on to customers at a percentage share or guaranteed rate, thereby generating additional savings for the customer and leaving a

[12] Hard dollar savings are the costs saved that can be directly measured. For example, a health plan may have spent $20 million in one therapeutic class over a period of 12 months. After an intervention program is put in place to reduce the drug spend in that therapeutic class, and correcting for inflation and other factors, the drug spend might be measured at $19 million the next year. Hard dollar savings equal $1 million. Soft dollar savings are the costs saved from reduced hospitalization rates, decreased physician office visits, and decreased emergency room use. Assumptions based on research literature are required to estimate program savings stemming from the intervention program.

margin for the PBM. The diagram below highlights the manufacturer and rebate activity and other key areas where a PBM can generate savings for its customers.[13]



The PBM's pre-integration role has been compromised, and arguably to a large extent lost, because pharmaceutical manufacturers have been vertically integrated into the market for PBM services. The pre-integration role primarily encompassed managing the administrative aspects of the prescription drug benefit for a health plan, and working to bring down escalating prescription drug costs and utilization trends. As an independent company, the pre-integration period PBM (including the pharmacists that worked for it) was able to serve its customers' best interests with a lesser degree of interests that might compromise its role. All of this changed in November 1993 when Merck & Company

[13] See GAO (1995), p. 6.

purchased Medco Containment Services. This was followed by the SmithKline Beecham purchase of Diversified Pharmaceutical Services in May of 1994, and the Eli Lilly purchase of PCS in November 1994. Collectively, these manufacturers paid more than $12 billion for these three PBMs, with the idea that enhanced competitive advantage would enable them to maintain or grow profits in a rapidly changing market. These manufacturers were clearly looking for a beneficial position on the PBM's formulary, as well as opportunities to gain market share increases through new sales and marketing strategies.

Response to these purchases was swift with the FDA hearings noted earlier and the GAO report on PBMs delivered to Representative Ron Wyden one month later. Reaction to the takeovers in the professional pharmacy press was critical and skeptical. One national pharmacy journal editor wrote that the "fox was [now] guarding the henhouse." The Federal Trade Commission also inserted itself into this discussion based on the relationship between drug sales and formularies. The FTC reviewed all three mergers on antitrust grounds to determine the possible impact they might have on competition. It did not question the Merck and SmithKline Beecham acquisitions, but did challenge the Lilly acquisition of PCS. As a result, FTC entered into a consent agreement with Lilly that established safeguards against potential anti-competitive effects, and noted that it would continue to monitor the integration activities between all drug manufacturers and PBMs.[14]

[14] Although it is not totally clear why the FTC directly challenged the Lilly acquisition of PCS; a Lilly memorandum which indicated that efforts were underway to control distribution through an

Caught in the current of this change are the individual pharmacists who are employed by PBMs. Finding themselves acting somewhere outside the traditional patient-pharmacist relationship, these pharmacists often shoulder tremendous responsibility, particularly when one considers the broad impact that their decisions can have. For example, assume that an employer representing a 300,000 enrollee health plan turns over the management of its drug program to a PBM, and the PBM (with the employer's consent) puts a disease management program into place that results in prescribers changing the way they prescribe for that disease category. The pharmacist responsible for developing and implementing that program has in all likelihood affected the pharmaceutical management of more individuals in one year than he or she might have over the course of his or her professional career, assuming he or she practiced in a more traditional setting like a retail pharmacy. A morally interesting question that results from this example is, how do we characterize the relationship that this pharmacist has with the individuals in the health plan? Since the pharmacist is making decisions requiring professional knowledge and judgment to improve care and maximize patient outcomes, it appears on the surface that we could characterize the relationship as fiduciary, and morally, if not legally, binding. If so, how do we analyze morally challenging problems that may result when interests adverse to the relationship emerge?

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internal business unit, as well as a major internal Lilly reorganization that occurred shortly after the intended purchase was announced, may have pushed the regulators into action. See Gibaldi (1995). Anticompetitive concerns were expressed by pharmacy associations from the onset of the acquisitions, and they continue today. See Zolkos (1996).

And to what resource should these pharmacists turn for moral guidance when faced with these challenges? Should it be their Code of Ethics, or perhaps some sort of legislation? In any event, the PBM pharmacist's role is characterized by change and challenge, and the conflicts of interest stemming from these changes are what I will explore in the pages of this dissertation. Before continuing, it is important to clarify what is meant by a fiduciary relationship.

An analysis of the professional and client relationship completed by Michael Bayles helps to clarify key elements of the fiduciary relationship.[15] Both parties in this relationship maintain a level of responsibility and have judgments that are given consideration. Since the professional maintains an expert knowledge base, which puts him or her in a more advantageous position, he or she maintains special obligations to the client. The client, who is the weaker party in the relationship, depends on the professional in ways that the professional does not depend on the client. Consequently, the client ideally should trust the professional. I will more fully describe my views on trust later in this chapter.

The client's consent and judgment are required in the decision making process; however, the client depends on the professional to supply information upon which he or she can make consent decisions. The term "consent" is critical in understanding the fiduciary relationship. This is because the professional's role is to propose courses of action to which the client consents, rather than having the professional decide.

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[15] See Bayles (1981), p. 118.

Joseph Ellin brings this point out in his discussion of the fiduciary relationship.[16] Ellin adopts Szasz and Hollender's principle of distinguishing professional-client models according to the location of control.[17] The fiduciary model begins with a recognition that the two parties have unequal power and control. Next, if we believe that the professional is superior to the client, then we must ascertain whether the professional is using the client for his or her own ends, or whether the professional is working for the client. If the former, then we have the exploitation model; and if the latter, we have the fiduciary model. By contrast, if the client is superior to the professional, then we have what Ellis calls the agency model, or Judith Swazey calls the consumer model.[18] In this model the client determines the ends and the professional acts to achieve them. I prefer Swazey's label for this model as it clearly distinguishes it from the formal use of the agency model that is discussed in Chapter II.

The professional in the fiduciary relationship provides ideas and information, and the client agrees or disagrees with the recommendation(s). This is not an arms length negotiation where two people are equally contributing to the formulation of a plan, as in the contract model. For the fiduciary relationship to be effective, the client must trust that the professional has accurately analyzed the problem(s), offered the complete range of solutions, recognized and analyzed to the best of his or her ability the consequences, perhaps made recommendations, and worked honestly and loyally for the client's best

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[16] See Ellin (1982), p. 134.

[17] See Szasz and Hollender (1956), pp. 585-92.

[18] See Ellin (1982), p. 138, note 21.

interests. Since the client does not have the level of expertise necessary to verify the accuracy of the analysis and most (if not all) of the conclusions, the professional has the obligation to assure that the trust which the client has given is justified.

Clients should be consulted at appropriate times during the decision making process. These times might be set in conjunction with an annual review process related to ongoing issues, and on a more frequent basis for acute needs and concerns. What needs to be recognized by the professional is that these discussions must occur when the client believes they are appropriate. The professional in a fiduciary relationship has the discretion to act on issues of a technical nature, and on issues that have client-specific value implications. It may be within the professional's discretion to act on technical issues without advising the client, particularly if the client has no knowledge of the technical issue; but, the professional does not maintain the discretion to act on issues that have value implications without the consent of the client.

What exactly do we mean by the trust that is given to the professional by the client? Rem Edwards defined trust to mean "confidence that we can depend on the competence, integrity, support, care, and concern of another."[19] If this definition is acceptable, we are left with two further questions. How are the various components of trust defined, for example competence? Second, why is trust so important?

Competence means the state of being competent, in other words, having the requisite abilities to perform a certain task. This component of trust reflects the

[19] Edwards (1988), p. 77.

knowledge that was gained during formal training, as well as the experiential knowledge gained during post-graduate training and from practice. Competence is shown by many professionals through the display of credentials, whether it is a diploma or a license to practice.

Sissela Bok points out that *integrity* comes from the same roots that form "intact" and "untouched," and that integrity is often used in relation to truthfulness and fair dealings.[20] William F. May argued that "integrity marks the professional who is upright or integral (whole)."[21] Uprightness refers to moral posture. May sees this as a refusal to identify self-serving opportunities at the expense of clients or colleagues. Likewise, it is the refusal to give in to a powerful client, an influential colleague, or some outside pressure. Wholeness or completeness of character is the element that does not permit the split between word and deed. May asserts that this wholeness makes possible the fiduciary bond between professional and client.[22]

Turning to analysis that has been undertaken in the nursing profession, Martin Benjamin and Joy Curtis identify integrity as one of the qualities most admired in others, and one that many try to cultivate in themselves.[23] The person of integrity provides responses to various matters that are not arbitrary or unpredictable; rather they are principled. New situations are responded to with a consistency that reflects responses to

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[20] See Bok (1978), p. 27.

[21] May (1980), p. 409.

[22] May believes that integrity is a key professional virtue. Other virtues include perseverance, public-spiritedness, veracity, fidelity, benevolence, and humility. See May (1980), pp. 408-10.

[23] See Benjamin and Curtis (1986), p. 17.

previous situations. This "principled continuity of conduct" becomes part of their identity, and the more this becomes integrated into their daily responses to situations, the more they are considered to be persons of integrity.

Christine Mitchell, also a nurse, provides another analysis of integrity.[24] She argues that there are at least five dimensions to moral integrity. These include truthfulness, fairness, pureness, fittingness, and wholeness. Truthfulness, or honesty, is described with respect to self and others. People lack integrity if they are self-deceptive or deceptive with others. Fairness is characterized as being unprejudiced, unbiased, and impartial. Pureness describes the characteristic of being uncorrupted or undefiled, where actions reflect a consistent and uncorrupted spirit. Fittingness focuses on the formal requirement of interdependence and harmony among integral parts of a unit. Wholeness refers to solidarity and completeness, which is found on an individual and group level. A key point in Mitchell's analysis is that the elements of integrity refer to the self in terms of character, and the self in relation to others as a group.

Drawing from these analyses we can conclude that persons with integrity are principled in that they are truthful, honest, and fair -- they have an upright moral posture. In addition, these characteristics are demonstrated in a consistent manner. This consistency is shown in word and deed with respect to self, and in relation to others. Carol Gilligan brings out the points of moral posture and consistency in the following discussion, which is drawn from *In a Different Voice*:

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[24] See Mitchell (1982), pp. 64-71.

> Yet, in view of her continuing equation of morality with caring for others and her continuing belief that "acts that are self-sacrificing and that are done for other people or the good of humanity are good acts," her abandonment of the principle of not hurting others was tantamount to an abandonment of moral concern. Recognizing the rightness of her decision but also realizing its painful consequences, she can see no way to maintain her integrity while adhering to an ethic of care in relationships. Seeking to avoid conflict and compromise in choice by "just doing what is right for you," she is in fact left with a feeling of compromise about herself.[25]

Support can be understood in at least two ways. First, trusting that someone will support you might mean trusting that he or she will provide financial support in a time of need. Support can also refer to some degree of emotional assistance during times of need.

Care can also be understood in a variety of ways. One may look to Gilligan's discussion of an ethic of care. In her view the world is made up of a network of relationships, and an awareness of the "connection[s] between people give rise to a recognition of responsibility for one another, a perception of the need for response."[26] Gilligan's rich understanding of care can be contrasted with the strict definition of care that focuses on feeling interested or concerned. *Concern*, which is a synonym of care, implies a troubled state of mind that stems from a personal interest.

This brief review of the components of trust is intended to provide a sense of the rich and complex nature of trust. It is in no way meant to be an exhaustive analysis of trust, as that could be the subject of an entire dissertation. I hope this analysis shows that

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[25] Gilligan (1982), p. 135.

[26] Gilligan (1982), p. 30.

trust is cultivated within relationships through one's thoughts, words, and actions. Trust is valuable because it enables patients to communicate private information, and place their welfare in the hands of a health care professional. Within the context of health care, trust makes the fiduciary relationship possible.[27] May described the role that trust plays as follows:

> Professional services in the so-called helping professions are directed to subjects whose needs are in the nature of the case unpredictable....These needs cannot be exhaustively specified in advance for each patient or client. The professions therefore must be ready to cope with the contingent, the unexpected....These services moreover are more likely to be effective in achieving the desired therapeutic result if they are delivered in the context of a fiduciary relationship that the patient or client can really trust.[28]

Professionals do have a special fiduciary relationship with their clients that should be controlled by the professional because of his or her level of knowledge to serve the best interest of the client. Trust binds this relationship, but not a blind trust; rather it is a reasoned trust that grows out of previous actions demonstrated by the professional, as well as from others in that profession. This is the gift that the client gives to the professional. If the client does not trust the professional because he or she is cynical, the fiduciary relationship does not end, nor do its obligations. This is because the source of the obligations also have roots to the larger society. The sources of this indebtedness include at least federal and state funding utilized for tuition, the individuals who allowed

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[27] The importance of understanding the role that trust plays in the patient-pharmacist relationship will be clarified in later chapters. In anticipation, I believe that trust is an essential element in analyzing conflicts of interest in health care and similar fiduciary relationships.

[28] May (1977), p. 92.

themselves to be patients for students and residents, and the professional's school for selecting them when applicants outnumber candidates and demand outweighs supply.

This analysis of the theoretical underpinnings of the fiduciary relationship will be applied in later chapters to help clarify relevant practical considerations for the PBM pharmacists. At this point I believe it is important to place our discussion about the pharmacist's role in context.

Although medicinal agents have been available to the public from the early days of our country's history, pharmacy can trace some its earliest professional roots to the organization of the Philadelphia College of Pharmacy in 1821. This college was organized as a reaction to local physicians who were exclusively designating certain apothecaries as "masters" of the pharmaceutical arts. Even though their training during this time focused specifically on the manufacturing of pharmaceuticals, pharmacists of the 1850s found themselves in a tense situation with physicians over the issue of selling patent medicines over the counter.[29] This was because physicians perceived pharmacists to be direct competitors to their business. What is most striking about this period in American pharmacy is the recognition that a pharmacist who prescribed and directly provided a drug to a patient was acting in the role of primary care provider -- a role associated with an extremely high level of moral responsibility. However, even though pharmacists had taken on a high level of responsibility, they would not retain this primary care role as the profession evolved.

[29] See Higby (1996), pp. 24-25.

State Boards of Pharmacy were developed in the late 1800s with the specific function of providing professional licensure. State schools of pharmacy were built, and although the focus was on manufacturing practices, application of manufacturing techniques in practice was fading. This was the beginning of the drugstore era, a time when soda fountains were introduced to pharmacies and dispensing areas were moved to the back of the store. Unfortunately for pharmacy, the profession also faced its first division, with one constituency focused on academic initiatives and the other on the practice of pharmacy itself. The pharmacist's role at this time began to center around dispensing and the physician's role focused on prescribing, with the two not overlapping unless an emergency was apparent.

The early part of the twentieth century found pharmacy concentrating on education. The shift was driven by two key events. First, Abraham Flexner, a respected medical education reformer, declared that pharmacy was not a profession. He argued that although pharmacists did contribute to society through their specialized skill, physicians bore the responsibility for the medicines they ordered.[30] Shortly after Flexner's charge was made, the War Department declared that registered pharmacists would no longer routinely receive commissions because their professional education was so minimal. Pharmacy responded swiftly with education initiatives that increased the minimum education period from two years in 1910 to four years in 1928. By 1949, the call was for a six-year Doctor of Pharmacy degree. Ironically, as pharmacy turned to the schools for

[30] See Higby (1996), pp. 34-35.

help in establishing the profession, the schools remained primarily focused on manufacturing, which was a production activity that the emerging pharmaceutical industry was quickly commercializing and using to make a profit. The traditional core activity of pharmacists, the art of manufacturing, was moving out of the pharmacy, and the pharmacists who could do little more than focus on the prepackaged product they dispensed were left behind.

In the 1950s many new products were released into the market, products that could eradicate diseases rather than just treat the symptoms. Examples of these products include antibiotics such as tetracycline (1950), erythromycin (1952), warfarin (1954), and hydrocortisone (1952). As a result, the number of prescriptions increased by more than 50% over the course of the 1950s, and pharmacy's "count and pour" era was born. This time in pharmacy's history is marked by a focus on moving the product, viewing the person on the other side of the counter as a customer, and maximizing profits based on margin. Pharmacists dismissed themselves from responsibility for the patient, a fact that they described in the 1952 version of their Code of Ethics:

> The pharmacist does not discuss the use or therapeutic effects or composition of a prescription with a patient. When such questions are asked, he suggests that the qualified practitioner is the proper person with whom such matters should be discussed.[31]

The mid-1960s marked the beginning of pharmacy's transition back to accountability for patient outcomes. This was driven by the emergence of the "clinical pharmacy" era, which began around 1965 and for the next fifteen years helped to shape

[31] Buerki (1985), p. 61.

the role of the clinical pharmacist as the health care practitioner who was expert in drug information. This role took shape in the institutional setting, and slowly moved into the retail setting. The American Pharmaceutical Association's Code of Ethics again provides a snapshot of prevailing attitudes, and in the opening sentence of its 1969 revision the Code proudly noted that the health and safety of the patient shall be of first consideration. Although pharmacy had changed its focus away from the product and toward the information on how best the products could be used, the pharmacist's role was not yet defined to include accountability for patient outcomes.

The latest turn started when Charles Hepler and Linda Strand presented their definition of "pharmaceutical care" in 1989.[32] They stated, "Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life." This idea, which a large majority of practitioner groups within the profession of pharmacy has embraced, clearly redefines the role of the pharmacist by moving the patient into the center of the pharmacist's professional endeavor. And it is during the period of the developing pharmaceutical care model that the role of the PBM pharmacist has emerged; consequently, it should be of no surprise that this role is associated with a high level of responsibility for patient outcomes, even though direct patient contact is minimized.

As this brief sketch of the history of pharmacy reveals, the pharmacist's professional role and the patient-pharmacist relationship have changed dramatically over

[32] Hepler and Strand (1989), p. 26.

the past 150 years. It could be argued that a clear notion of key professional responsibility is still emerging; but as I noted earlier, I believe pharmacists at one time maintained a set of key patient-focused responsibilities, which they could not preserve. Regardless, as pharmacists have acquired the level of professional responsibility and accountability that accompany pharmaceutical care, the interests that can generate moral conflicts for pharmacists have escalated as well. The PBM pharmacist finds himself or herself in a similar role today. The PBM pharmacist's role has emerged not from a focus on the distribution of a product, but from the PBM's need to have someone with expert clinical knowledge apply it in the management of a client's prescription drug benefit. The emphasis is still on the patient; however, rather than being on a single patient and a single prescription, it must spread across thousands in a patient population. This is the most fundamental change to the traditional patient-pharmacist relationship. Another change has to do with professional satisfaction, which must now be derived from seeing a percentage decrease in a health plan's drug spending, or perhaps a decrease in hospitalizations resulting from drug-induced therapy problems, rather than from seeing or hearing that a person feels better.

For PBM pharmacists, conflicting interests might be generated when the interests of the individuals they serve are placed at risk by a pharmaceutical manufacturer / PBM owner whose drive to advance market share of their drug pushes the pharmacist to consider the parent company's drug when clinical superiority over a less expensive agent has not been shown, or improved cost effectiveness of the therapy has not been demonstrated. In contrast to the pharmacist of a generation ago, potential conflicting

interests are not limited to those that may arise between the pharmacist and the patient, which were often financial. The PBM pharmacist practices in a setting where conflicts of interest can also divide loyalty between the patient and a third party--in this case the company that employs the pharmacist.

In the 1950s, a community pharmacist would make additional revenue by marking up his or her purchase costs for a drug. An entirely self-interested pharmacist whose pharmacy exclusively served a large geographic area might have marked prescription costs up so high that patients could barely afford to pay. If the pharmacist had refused to lower his or her price for a patient who needed care, but could not afford the cost of the prescription, they might have been considered morally blameworthy. The conflict in this case is between the pharmacist's personal financial interest and the patient's need.

Different elements create the conflict for the pharmacist who works for the PBM. He or she is salaried, and perhaps has a bonus plan or stock options that show gain when the PBM increases profits; consequently, the interests that may compromise the pharmacist's actions stem (albeit not exclusively) from a third party. The challenge for the PBM pharmacist is to appropriately manage these conflicts so ethical integrity can be maintained. The question is: how? Before answering that question, the parameters of these conflicts for the pharmacist must be identified. Pharmacy has not yet started this conversation. The profession of pharmacy has not yet defined what comprises a conflict of interest, nor has it taken a look at how these conflicts impact the PBM pharmacist. Based solely on the sheer volume of lives that the PBM pharmacist affects, it is essential that the profession of pharmacy take action to ensure that the management techniques

used by PBMs are administered in a way that protects patients and the integrity of the patient-pharmacist relationship. Therefore, the purpose of my dissertation is to clarify these conflicts and propose a strategy for managing them. To that end, let us move on to defining a conflict of interest.

CHAPTER II

What Is a Conflict of Interest?

"...perhaps no other ethical concept in business is so elusive and subject to dispute."

-John Boatright, 1993b

In this chapter, I have three main objectives. First, I will attempt to state and explain the differing views on conflict of interest put forth by Michael Davis, Neil Leubke, and John Boatright. Second, I will try to defend Leubke's view, including some of his moral prescriptions, against a number of objections. The objections I will discuss stem from Davis's critique of Leubke's 1987 article, "Conflict Of Interest as a Moral Category." Third, I will focus on two points that I believe are weaknesses in Leubke's argument.

Davis's article entitled "Conflict of Interest" was published in 1982 in response to Joseph Margolis's 1978 paper on conflict of interest.[33] Davis was highly critical of Margolis, noting that his analysis was "importantly different" and "significantly better" than Margolis's "flawed" paper. In my opinion, Davis correctly identified his analysis as a successful criticism of Margolis; however, he could not have anticipated another important feature of his work. Specifically, it was the beginning of what would become

[33] See Davis (1982).

an ongoing and enlightening discussion of conflict of interest. This three-way discussion between Davis, Leubke, and Boatright spans six articles over a ten-year period.

Davis first draws the reader's attention to the legal ethics' literature in his criticism of Margolis. He points out that even though Margolis's interpretation of the notion of a conflict of interest as an avoidable exploiting of conflicting roles was groundbreaking, it was not a groundbreaking analysis of conflict of interest.[34] The literature of legal ethics, written well before Margolis's article, already contained analyses of the subject, which focused on the conflict as a situation that tended to undermine independent professional judgment.[35] This point emphasizes a key distinction between Margolis and Davis; specifically, Margolis viewed conflicts of interest as a situation *between* roles, where Davis saw the conflict as one *within* a role.[36]

Davis drew on the American Bar Association's Code of Professional Responsibility for his analysis, which he called the "lawyer's analysis." According to this Code, a conflict of interest requires a formal role with occupants and at least one interest tending to interfere with proper action within that role. The key is that the lawyer exercises professional judgment within that role, and that his or her judgment purports to

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[34] Davis credits Margolis with breaking new ground because Margolis was focused on the "notion" of a conflict of interest, rather than on examples of conflicts of interest. By supplying an analysis of conflict of interest, Margolis made a significant contribution to the literature.

[35] See Davis (1982), p. 16.

[36] According to Margolis, "There are no conflicts of interest between persons solely as persons; a conflict of interest is entirely intrapersonal, confined to the relationship between the roles that any particular person occupies; plural persons may exhibit only conflicting interests." See Margolis (1978), p. 370.

be independent, in that the lawyer provides his or her client with the full extent of his or her relevant knowledge and training within legal boundaries. Of course, the client must be someone other than the lawyer. The "interest" in the conflict describes any influence, loyalty, or concern that may compromise the lawyer's ability to act for the client. So, the conflict of interest is viewed as a problem of professional judgment, with the conflict seen as a collision between competent judgment and something that might make the lawyer unable to function with the judgment his or her role requires.[37]

The lawyer's analysis goes further to distinguish among three kinds of conflicts of interest. Actual conflicts occur when the interest is quite likely to adversely affect the advice the lawyer would provide. When an interest generates a latent conflict, the conflict is already present but it requires a change in circumstances to become actual. Potential conflicts are those that a lawyer can reasonably foresee, and changes in circumstances would be necessary for it to become a latent conflict. Davis illustrates this distinction with an example drawn from government.

Consider the case of a lawyer who is contemplating running for Congress, who represents Native American interests in his or her practice, and whose district would include Native Americans that have a claim against the federal government. The lawyer could reasonably foresee this constituency becoming dissatisfied with the court's actions and taking its case to Congress for direct action. This lawyer already has a potential conflict of interest. If the lawyer ran and won a Congressional seat, the potential conflict

[37] See Davis (1982), p.18.

would become latent in that a reasonable probability exists that the lawyer-Congressperson might be called upon to advise on the claim in which his or her interest as a member of Congress may make his or her judgment as a lawyer unreliable. As long as the Native Americans remain satisfied with the court's action, he or she does not have an actual conflict; but when the lawyer is put in the position of advising on the claim, then an actual conflict of interest exists.[38]

There are two interesting points of distinction between Margolis's position and that of the Code. First, although the Code does not treat each kind of conflict equally, it looks with doubt *upon all three*. It flatly condemns actual and latent conflicts, but allows the lawyer to enter into a potential conflict as long as the interest is disclosed and the client's consent is secured. This point differentiates the Code from Margolis, who believes that "[pursuing] a course of conduct that leads to [an actual] conflict of interest is not itself a mark of any wrongdoing on the agent's part."[39] Under the Code, action of this type without consent would be subject to discipline. Second, Margolis makes the point that the only permissible response to a conflict of interest situation is to divest from the conflict.[40] This position is more extreme than the Code's, which exempts lawyers who have provided disclosure to their client regarding potential conflicts from discipline under the Code. For example, if a lawyer maintains personal investments in the main

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[38] See Davis (1982), p. 19.

[39] Davis (1982), p. 20. Modifications of text are from Davis.

[40] According to Margolis, "Relative to a conflict of interest, wrongdoing concerns only an agent's failure, when acting relevantly, to divest himself of a relationship of roles that constitutes the conflict." See Margolis (1978), p. 363.

competitor of a client for whom he or she is asked to write a contract (a potential conflict), the lawyer can proceed for the client as long as disclosure and consent are secured. Without this, actions to move forward would be inappropriate under the Code. If the potential conflict becomes latent (assuming the contract involved working with financial information directly related to the personal investments), the lawyer could still continue, *if the client retained him or her* (emphasis added). According to Margolis; however, the only option at this point would be divestiture. As Davis points out, we can see from this example that the Code is more in tune with the pragmatic aspects of practice and the difficulties associated with divesting.[41]

The key point that Davis draws from his analysis of the ABA Code of Professional Responsibility is that wrongness of a conflict of interest stems from the impairment of the lawyer's ability (acting in the role of lawyer) to provide independent professional judgment for his or her client. This applies to actual and latent conflicts, and in such cases the lawyer either should refuse to represent the client or disclose the conflict and seek consent. Part of the responsibility of being a lawyer is to look for conflicts. Although recognition does not by itself remove the conflict, by reasonably foreseeing the conflict he or she has performed competently, and (at minimum) not betrayed the trust of his or her client.[42]

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[41] See Davis (1982), p. 20.

[42] The point has been made to me that a certain degree of professional dedication can drive a lawyer to act such that impairment of judgment is not apparent, even though adverse interests exist. Take for example the case of a legislator who has to vote on a bill that would adversely affect his or her business. In this case the legislator voted for the bill, as he/she was convinced

Davis provides us with his preliminary definition of a conflict of interest based on the lawyer's analysis. He believes that his definition can be generalized to fit business and professional ethics. His preliminary definition follows:

> A person has a conflict of interest if a) he is in a relationship with another requiring him to exercise judgment in that other's service, and b) he has an interest tending to interfere with the proper exercise of judgment in that relationship.[43]

What is of critical importance to note is that there is no reference to role. Davis's concern is not with roles as such; rather, it is on a role that includes a relationship requiring *the exercise of judgment in the service of another* (emphasis added). "Judgment" is understood as the capacity to properly make decisions that a clerk with a book of rules and access to all relevant facts would not likely make. "Interest" is understood broadly to include all the influences, loyalties, concerns, emotions, or other factors that can make competent judgment less reliable than it might otherwise be.[44] To return to role for a moment, as highlighted above, Davis's concern is with judgment and not on role in characterizing conflict of interest. He believes that roles are part of his definition by implication, but not formal roles. The role he sees is the role, whether it be formal or

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that it was the right thing to do, despite his/her business suffering. I believe that this is an example of a latent conflict as there is a reasonable probability of an adverse effect; however, because of the legislator's strong commitment to do what was right, the circumstances did not exist to make it an actual conflict. This case supports the Code's position that disclosure of conflicts (including actual or latent) is a viable alternative to Margolis's position of strict divestiture in face of conflict.

[43] Davis (1982), p. 21.

[44] See Davis (1982), p. 23.

informal, that involves the exercise of judgment on behalf of another. Davis desires to characterize roles broadly, which he describes as allowing role its "full elasticity." These points will be revisited later in this chapter as they represent targets for critical evaluation by Boatright, and particularly by Leubke.

Davis recasts his preliminary definition into the following generalized analysis:

A person P1 has a conflict of interest in role R if, and only if:

a. P1 occupies R;

b. R requires exercise of (competent) judgment with regard to certain questions Q;

c. A person's occupying R justifies another person relying on the occupant's judgment being exercised in the other's service with regard to Q;

d. Person P2 is justified in relying on P1's judgment in R with regard to Q (in part at least) because P1 occupies R; and

e. P1 is (actually, latently, or potentially) subject to influences, loyalties, temptations, or other interests tending to make P1's (competent) judgment in R with regard to Q less likely to benefit P2 than P1's occupying R justifies P2 in expecting.[45]

By focusing our attention on the proper exercise of judgment within a role, Davis has characterized the conflict of interest by first defining the relevant role (points a-d), and then introducing the conflict (point e). With this approach he has developed an argument for defining conflicts of interest that closely parallels the lawyer's analysis, and allows for conflicts to continue after full disclosure and consent are secured. In addition, Davis's

[45] Davis (1982), p. 24.

position does not require that the conflict be avoidable, which distinguishes his analysis from Margolis. Consequently, by focusing on judgment within the role, and not the role itself, Davis has advanced the conversation regarding conflict of interest, but as I noted earlier, this was just the beginning of what would become an interesting conversation.

Leubke provided the first response to Davis in a 1987 article entitled "Conflict Of Interest as a Moral Category."[46] His break from Davis's position is clear from the start:

> I claim that what is morally at stake in CI (conflict of interest) cases is a potential violation of trust on the part of the party having the CI and a corresponding "situational" basis for the other party to withhold or limit reliance. What is not at stake, except accidentally, is the quality of judgment, the strength of affections or desires, or the uses of information.[47]

Leubke has tried to move our attention away from the correctness of decision-making (which was Davis's key concern regarding the exercise of judgment) to the trust that binds the two parties.

Leubke's primary purpose in writing about conflict of interest is to describe the meaning of conflict of interest as a moral category.[48] His belief is that even though many situations are now called "conflicts of interest," the use of the term has become vague and ambiguous. Consequently, by using the label "conflict of interest" inaccurately, the relevant moral issues are obscured. Appreciating the fact that Leubke is attempting to distinguish "conflict of interest as a moral category" from the broader use of the term "conflict of interest" is critically important to understanding his argument.

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[46] See Leubke (1987).

[47] Leubke (1987), p. 66.

[48] See Leubke (1987), p. 66.

Leubke defines an interest as some material right, benefit, asset, or share possessed by a fiduciary, or by another person with whom the fiduciary is legally or closely associated, for example family members, business partners, or employer.[49] The interest might bias advice, influence efforts to aid or protect, or lead to an outcome that is adverse to the relationship's purpose. It is important to recognize that he is defining interest as objective rather than subjective.[50] What Leubke does not want to include in the category of interests are affections for another person, feelings of sympathy for some cause, a desire for some area of activity, or any other interest in the psychological sense of a feeling or desire. He grounds his decision in part on what most courts have decided when considering the question of interest, which is on the objective aspect of interest, and not on subjective desires or dispositions.[51, 52] Leubke also argues that broadening the

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[49] See Leubke (1987), p. 69.

[50] A point that will be brought out in a later chapter is that the interests that can potentially cause a moral category conflict of interest for the PBM pharmacist are objectively measurable. These interests are financial in nature and are possessed by the PBM, who is the pharmacist's employer.

[51] See Leubke (1993), p. 48.

[52] A point that Leubke brings out in a critical footnote helps us to understand the distinction between objective and subjective interests. Subjective interests do help us label a situation a "conflict of interest," a point that Glenn Graber has brought out in conversation on this subject. Take for example the case of city councilwoman who votes to spend large sums of money to refurbish a certain city park because her grandson loves to play there, although it would better serve the larger public interest if the money was spent to fund inner-city playgrounds. We can say with certainty in this case that her subjective interest motivated her to vote as she did. However, as Leubke tries to argue, subjective interests are not sufficient to label a situation a moral category conflict of interest. Attention will be focused on this point later in this chapter,

definition of interest to cover all cases where a personal desire can create a moral category conflict of interest carries the concept well beyond its paradigmatic use. Again, Leubke's break from Davis is sharp, as Davis considered both objective and subjective interests when characterizing conflicts. In Leubke's words, "subjective factors...contra Davis...do not seem to me to be defining characteristics of conflict-of-interest situations."[53]

In Leubke's view, "Any person or group capable of deliberate judgment or action and who acts or is empowered to act in a fiduciary role can have a moral category conflict of interest."[54] The fiduciary is the party who is trusted or relied upon to advise, aid, act on the behalf of, or protect the interest of the other party in the relationship.[55] Trust is given by the party whose interest is being protected, but it may also be given by a third party, as in the case of an incompetent person. The fiduciary relationship is voluntarily

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but I believe we can conclude that the result of the councilwoman's actions are better described as stemming from being a poor public official, rather than stemming from a moral category conflict of interest. Leubke tries to argue that we can also call this situation a conflict of interest, however, the term is being used in the broader fashion. See Leubke (1987), page 79, footnote 7 for more detail.

[53] Leubke (1993), p. 49.

[54] Leubke (1987), p. 68.

[55] Leubke does not make the following point, but I believe he would agree that it is the "best" interest of the other party that is being protected. As pointed out in Chapter I, best interest is what I view as being protected.

undertaken, and can be either legally or morally recognized. The more clearly defined the relationship, the easier it is to identify cases of moral category conflict of interest.[56]

A moral category conflict of interest occurs when the fiduciary party has an interest that is adverse, or is likely to become adverse, to the reason for which reliance was initially placed.[57] The interest might influence efforts to appropriately advise or protect the interest of another party. The aspect of Leubke's position that is similar to Davis's is a recognition of "latent" or "potential" conflicts, although Leubke uses the phrase "likely to become." One key aspect of Leubke's position is the necessity of having the fiduciary's interest actually or potentially threaten the fiduciary relationship. It is not necessary that there be an actual conflict between two opposing interests for a conflict of interest to occur. By knowing what a conflict of interest is, we can identify one when we can make two descriptive judgments; the first concerns identifying a

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[56] Although this point will be brought out later in this dissertation, I believe an example is helpful here. When considering the patient-pharmacist relationship, specifically the dispensing and counseling role of the community pharmacist, I believe the fiduciary relationship is clearly defined. The relationship is less clearly defined when one considers the PBM pharmacist who may never actually see the patient whose drug history he / she is evaluating for clinical appropriateness and safety.

[57] It is possible to read Leubke's point as focused on the judgments made by the fiduciary to safeguard another's interest. If this is so, then one could argue that Leubke's position collapses into Davis's account. This is not the case. Leubke is clear that any person who is capable of deliberate judgment and who acts in a fiduciary role can have a conflict of interest. To this point Davis would agree. What distinguishes the moral category conflict has to do with the interest within the fiduciary relationship, and its impact on trust -- it does not have to do with judgment (as with Davis).

specific fiduciary relationship, and the second concerns the adverse interest. As it becomes easier to make these judgments, it becomes easier to make moral judgments regarding the conflict of interest.

One example that Leubke offers to distinguish between a conflict of interest and a moral category conflict of interest is that of a stockbroker who excessively buys and sells the stocks within his or her clients' portfolios to earn extra commissions. As the scenario is described so far, there is no interest in the objective sense that would create a moral category conflict of interest. The stockbroker is simply greedy and unprincipled. The situation could be called a conflict of interest, but that would be using the term in a broad fashion. As Leubke points out, "...there is no 'interest' in the objective sense that diverts [the stockbroker's] loyal [ty] any more than is present in ordinary acts of thievery."[58] However, if the stockbroker's firm pressured the broker to churn his or her accounts under the threat of nonpromotion or release, then the stockbroker's actions would be interpreted as a moral category conflict of interest -- a conflict created by the firm's policies.

Leubke then draws a number of moral prescriptions based on his definition. As with moral dilemmas generally, it is not wrong to have, be in, or find oneself in a conflict of interest; however, it is generally wrong to knowingly enter or knowingly fail to avoid a conflict of interest. To this point, Leubke agrees with Davis and rejects Margolis. This action is wrong because it betrays trust in that particular case and positively contributes to

[58] Leubke (1987), pp. 77-78.

a general level of distrust. Recognizing that conflicts of interest are at times unavoidable, Leubke concludes that it is also wrong to enter into a conflict of interest when "informed avoidance" was possible, unless a greater wrong is committed by the avoidance.[59] For example, in the situation where a scarcity of lawyers existed, a lawyer who might be excused from a case based on a conflict would be allowed to represent a client who might otherwise not have representation. It is also wrong to knowingly place a party into a moral category conflict of interest; but unknowingly placing a party in this situation, while unfortunate, is not usually regarded as morally blameworthy. With respect to this moral prescription, I am not fully convinced by Leubke's argument and will return to it later in this chapter.

Once an individual is involved in a moral category conflict of interest, Leubke tries to argue that the individual can either extricate himself or herself from the situation via withdrawal from the fiduciary relationship, abandonment of the material interest (e.g., selling stock), or partial limitation of the fiduciary relationship (e.g., abstaining from voting); or he or she can remain in the situation, but act to minimize the threat to the fiduciary relationship via disclosure and consent. The threat to trust in the relationship is minimized through disclosure because informed consent creates an opportunity to

[59] See Leubke (1987), p. 70. The phrase "informed avoidance" can be confusing, but I believe Leubke is attempting to describe the situation where the lawyer recognizes the conflict, or is "informed," and could avoid it based on that knowledge. The word "informed" has to do with internal recognition, not a public announcement.

preserve good faith. Again, Leubke has agreed with Davis and rejected Margolis, who claimed that the only possible response to an actual conflict of interest was divesting.

The final moral prescription involves giving the appearance of having a moral category conflict of interest. Leubke views this as wrong, as it threatens to destroy not only current, but also future, fiduciary relationships. This is particularly true of health care professionals whose success depends on maintaining the trust of the individuals they serve. This clearly applies in individual fiduciary relationships, and the case could be argued that if the violation of trust was so heinous, then possibly all future relationships with that professional might be jeopardized. This does not imply that every future fiduciary relationship is destroyed.

Of course, other factors like greed and dishonesty can have an impact on future fiduciary relationships, but as Leubke points out, moral category conflicts of interest are "essentially *unrelated* to any specific character traits" (Leubke's emphasis).[60] Moral category conflicts of interest are fundamentally an issue of threatening trust; they do not have to do with specific character traits, and therefore cannot be generalized to any one

[60] Leubke (1987), p. 72. This point at first appears counter-intuitive, particularly because of the relationship between trust and character. Leubke properly points out that vices like dishonesty and greed can negatively affect fiduciary relationships; however, we need to keep in mind that Leubke is attempting to analyze conflict of interest in a very narrow manner. For Leubke, the key to understanding conflicts of interest, and their relation to character traits, is to see that moral category conflicts can and do occur independently of specific character traits, all of which assists Leubke in describing conflict of interest as a moral category. His point is not to separate character traits from conflicts of interest; rather, it is to distinguish them for the purpose of clarifying what makes up the conflict.

person or group. This is a critically important point for Leubke. With this argument he is trying to show that fiduciary relationships can be adversely impacted by factors such as dishonesty; and these factors may play a role in moral category conflicts of interest. In cases where these traits are manifested, the term "conflict of interest" may be used, although this would be a broad use of the term. It is not the trait, however, that drives the moral category conflict of interest, which is the narrower category that Leubke believes is important to distinguish, and is one that I believe is worth our attention. By relying on his distinction, we are able to clearly see when trust is being placed at risk, and why it is at risk. As Leubke points out, "...moral category conflicts of interest present a specifically situational type of challenge to trust."[61] If one accepts that a fiduciary relationship has moral worth, and to destroy the trust that binds this relationship is prima facie wrong, then Leubke's moral category provides us a method to justify moral blame.

Leubke's second key distinction is among contexts, which he uses to further distinguish between moral category conflicts of interest and uses of the term "conflict of interest" to label other concerns.[62] The four contexts are the "sociological," the "commercial," the "professional/public service," and the "judicial." His aim is to locate the place of moral category conflicts of interest within the various contexts in which the term "conflict of interest" is currently used.

In the "sociological" context, the concern is to describe a conflict between value commitments or policy preferences of persons or groups. The term "conflict of interest"

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[61] Leubke (1987), p. 72.

[62] See Leubke (1987), pp. 75-78.

is used in a broad, morally neutral manner. One of the examples Leubke cites is from the literature of the social sciences where conflict of interest is defined as "the state of incompatibility of the goals of two or more actors." This broad use of the term, while helpful in identifying the concern, is vague in moral descriptions.[63]

The "commercial" context is concerned with disloyalties by employees to employers or by vendors to suppliers. Some cases, which include speaking negatively about the firm, are hard to document, but real. Other cases involve moonlighting and personal use of confidential information, which are more common and easier to document. By calling an action a "conflict of interest" in this context is to condemn it or render it suspect at minimum. In other words, the term acts as a moral designator. Unlike the sociological context, the term includes examples of moral category conflicts of interest as well as others. One example that Leubke offers is the case of an employee who is recruited by another employer, under the condition that he or she bring confidential corporate information with him or her. This would be an example of a moral category conflict of interest since the interest, which is the new job, would threaten the existing fiduciary relationship with the current employer. Alternatively, if the employee sold trade secrets to make some additional money, then he or she has committed a moral wrong and shown the vice of greed, but he or she has not committed a moral category conflict of interest.[64]

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[63] See Leubke (1987), p. 75.

[64] See Leubke (1987), pp. 76-77.

The third context is the "professional/public service" in which there is a *specific* fiduciary relationship (Leubke's emphasis). Discussions in this context tend to focus on abuse of public office or obligations of loyalty. Leubke tries to argue that a case of disloyalty to a client's interest or abuse of office might not be a moral category conflict of interest, even though it is a moral wrong. Like the previous context, the term "conflict of interest" is being used as a moral designator; however, its use may be broader. The example he offers is of the stockbroker who churns accounts that I referred to earlier in this chapter. So, the "professional/public" context, while supplying paradigm examples of moral category conflicts of interest, sometimes uses the term in the broader manner. I am not completely convinced by Leubke's argument on this point and will return to it later in this chapter.[65]

The "judicial" is the fourth context described by Leubke. The judicial context is concerned with maintaining the court's standards of fairness and integrity to justify the confidence that the public places in the law and the justice system. An example of a judicial context moral category conflict of interest would be the disqualification of an attorney, judge, or witness on the grounds that some objective interest threatened to compromise their role in the judicial process. Leubke tries to argue that all conflicts of interest in the "judicial" context are moral category conflicts.[66]

Considering his analysis and characterization of conflicts of interest, Leubke alleges three problems with Davis's analysis. They involve the analysis of judgment, use

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[65] See Leubke (1987), pp. 77-78.

[66] See Leubke (1987), p. 78.

of the term *interest*, and a lack of condemnation for giving the appearance of a conflict of interest.[67] As noted earlier in this chapter, Davis relies heavily on judgment in his analysis of conflicts because he believes that the inability to correctly make a decision on another's behalf is the hallmark of a conflict of interest. It is this point that Leubke calls into question: specifically, that it is the correctness of a decision that is morally at stake in a conflict of interest. Leubke's assertion is that trust, not correctness, is what we risk morally, and by risking trust we threaten the fiduciary relationship. In response one might ask whether we betray the trust if we make an incorrect decision to benefit ourselves? I believe Leubke would respond by returning to his category distinction. If we make an incorrect decision to benefit ourselves, and there was no objective interest pressuring us to make this decision, then although we may label this a conflict of interest in the broad sense, it is probably better characterized as action that is considered morally suspect at the least. Should there be some material interest pressuring the individual to make the "incorrect" decision (and threaten the fiduciary relationship), then it would be considered a moral category conflict of interest.

The second criticism has to do with Davis's broad definition of interest, which includes objective and subjective concerns. As noted, Davis expressly downplays interests in favor of judgment when characterizing conflicts; he allows for a broad understanding of interests, since they impact the quality of judgment and thereby generate a conflict. Leubke believes that this position is inconsistent with the legal literature that

[67] I will clarify why I believe Leubke's position is stronger than Davis's position later in this chapter. My goal at this point is to articulate their arguments and responses.

Davis claims he is following, since the courts have relied on the objective sense of interests to the exclusion of subjective interests. As Leubke points out, subjective interests often are not clear, and incorporating them into the discussion broadens the category of conflict of interest beyond the bounds of standard or effective usage.

One question that might be raised is why we should agree with Leubke and limit ourselves to interests as outlined in the legal literature, or perhaps more specifically, why we should rely strictly on objective interests when defining the moral category of conflict of interest, assuming that Leubke's review of the law and the conclusion that the courts predominantly rely on objective (or measurable) interests is accurate. To answer this question requires a recognition that the phrase *conflict of interest* is used in a variety of ways, some of which are loose interpretations, and others that fall within Leubke's characterization of conflict of interest as a moral category. For example, moonlighting for a competitor would be seen as a moral category conflict; whereas moonlighting as a clown (although it might be frowned upon) would certainly not constitute a moral category conflict. By relying on objective interests, we are able to distinguish between various settings where the term *conflict of interest* is used. This helps us more precisely to analyze situations and identify the relevant moral issues. I also believe this distinction will be helpful in analyzing the conflicts of interest present in the PBM pharmacist's professional setting. By distinguishing between conflicts based on interests, we may be better able to assist PBM pharmacists in managing their actions once involved in a conflict of interest. I will return to this point at the end of this chapter.

Leubke's third critical point has to do with his assertion regarding the wrongness of giving the appearance of a conflict of interest. This was one of his moral prescriptions, which stemmed from the threat to trust generated by the appearance of a conflict. Leubke believes that by focusing on quality of judgment, Davis cannot find fault with the appearance of a conflict because in situations where it only appears that the quality of judgment is impaired, the quality of the judgment has not actually been impaired; consequently, there is nothing morally wrong with the situation. In contrast, when the threat is to trust, then the moral prescription against giving the appearance of a conflict is appropriate.

As it turned out, Davis and Leubke agreed on the wrongness of giving the appearance of a conflict of interest, which is a position that Davis articulated in a 1988 reprint of his original article.[68] Davis clarified his position by noting that creating an appearance has the same effect as a real wrongdoing, namely that individuals have to react to it, and in the end the only difference between the appearance and a real conflict is that the energy spent to respond to the appearance was wasted. An example of this would be asking a bank teller to "hand over the money" during a routine counter transaction. If this act was performed in such a way that the teller believed the request to be real, then this would clearly be a form of wrongdoing, and would cause anxiety and unnecessary actions at a minimum. Noting their agreement, I concur with both in that giving the

[68] See Beauchamp and Bowie (1988), pp. 482-87.

appearance is wrong for it not only leads to unnecessary effort, but that effort also leads to distrust.

Boatright entered this discussion in 1992 with the publication of his essay "Conflict of Interest: An Agency Analysis."[69] His analysis of conflict of interest is similar to Leubke's; however, he diverges from both Davis and Leubke by analyzing the relationship between the two parties involved in a conflict as an agency relation. Boatright candidly admits from the outset of his essay that agency theory is not a substitute for ethical theory, but he claims that the agency relation can be useful for discussing ethical issues because it provides a model for understanding some of the roles that individuals occupy in business, as well as the duties and rights that attend these roles. The model for the agency relation was developed from the law of agency theory, as it specifies the reciprocal rights and duties of agents and principals. The law of agency is justified on the grounds that the relation of agent and principal is created by contractual agreement.[70]

Like Davis and Leubke, Boatright is not satisfied with discussions of conflict of interest that focus strictly on conflicting roles. He believes that the conflict of a role obligation with a personal interest or with another role obligation is not sufficient to call the situation a conflict of interest. One example he uses is with accounting: an

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[69] See Boatright (1992).

[70] Boatright is viewing the agent as it is narrowly defined in the law of agency. The fiduciary in a fiduciary relationship may also be viewed as an agent, which includes the characteristics that define moral agency such as rationality, autonomy, and self-interest.

accountant has an obligation to keep information confidential and to disclose it when important matters of public interest are at hand. Boatright sees this not as a conflict of interest, but as one of conflicting obligations since the conflict is a systematic feature of the accountant's situation that cannot be altered by an individual. What makes a situation sufficient to be called a conflict of interest is the inclusion of a qualification that the obligation in a conflict of interest be an obligation to act in the interest of another. The key to Boatright's analysis is a recognition that the obligation is characterized as a role obligation and is an obligation to act in the interest of another -- this obligation coincides with the obligation in the agency relation.

Boatright defines a conflict of interest as occurring when a personal interest prevents an individual who is obligated to act in someone else's interest from doing so. In addition, a conflict of interest can occur between two obligations when a person has conflicting obligations to act in the interest of two different parties. The caveat is that the obligations must stem from the agency relation.[71] Like Leubke, Boatright defines interests as objectively measurable, noting that a person has an interest in something when he or she stands to gain a benefit or advantage from that thing. Advantages and benefits are further clarified to be things that are tangible, such as some kind of financial gain. Interests can also reside with a third party, for example a family member or close associate, who probably would stand to gain in some way from the situation. Again reflecting Leubke's argument, Boatright tries to argue that subjective interests do not play

[71] See Boatright (1992), p. 191.

a role in defining conflicts of interest. He says, "Merely satisfying a desire...would not seem to be enough [for identifying a conflict of interest]."[72]

I believe Boatright's analysis weakens in his reliance on the notion that the obligation in a conflict of interest is an obligation to act in the interest of another, which "exactly coincides with the obligation in an agency relation."[73] Boatright is attempting to move the discussion beyond consideration of conflicting role obligations as conflicts of interest, which is consistent with Davis and Leubke; however, I am not convinced that interpreting the patient-health care practitioner relationship as one defined solely by reciprocal rights and duties is accomplishing anything but selling short the robust nature of this relationship. Clearly rights and duties apply, but trust is integral to the relation between patient and provider, and to drop this from the discussion is to miss a critical element in understanding conflicts of interest.

Consequently, although I find Boatright's analysis interesting, I do not believe that his characterization of conflict of interest is applicable for describing and discussing conflicts of interest among PBM pharmacists. Boatright might agree, for he states in his opening that his analysis applies only to conflicts of interest in the business world. The narrowing makes sense when one considers that the agency relation finds its grounding in contractual agreement between consenting parties. Contracts are the underpinning of the majority of business relationships, but they are not the foundation of the patient-

[72] Boatright (1992), p. 192.

[73] Boatright (1992), p. 191.

pharmacist relationship.[74] PBM pharmacists find themselves acting within a well-defined business context, and operating programs that are described in contract language; but when working with a particular patient in a case management scenario, or reviewing an anonymous patient's drug history for safety concerns, the business needs described in contract language are superseded by concern for the best interests of the individual for whom the clinical activity is being done. This level of professional concern for a broad number of patients is characteristic of the new patient-PBM pharmacist relationship described in Chapter I. If this description is acceptable, it becomes clear why the PBM pharmacist, although constrained by contract language in terms of the variety of programs he or she can employ, is not strictly guided by contract language when considering patient concerns within the context of an authorized clinical program. Since contract language does not completely characterize the relationship, I do not believe Boatright's analysis applies although it may be adequate for the business world. Therefore, I will leave his analysis for now and move on to the dialogue continued by Davis and Leubke.

With the differing views of Davis and Leubke described, I will attempt to articulate Davis's critical response to Leubke, as well as Leubke's rebuttal. Davis,

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[74] Robert Veatch (See Veatch, 1981) has articulated the contract theory of medical ethics as an alternative to a medical ethic that is based on a professionally articulated code of principles. Veatch speaks of contracts in medical ethics like they are a marriage contract; namely, a "rich mix of religious communal faithfulness as well as an element of legal requiredness." See Veatch, page 7. It is important to point out that my use of "contract" is not intended to reflect Veatch's notion of a contract; rather, I am focusing strictly on contracts as they apply in defining business relationships.

Leubke, and Boatright revisited the issues involved in defining conflicts of interest in the 1993 edition of the *Business & Professional Ethics Journal.*[75]

In general terms, Davis understands Leubke to be arguing that his interpretation of conflict of interest makes the analysis too broad, thereby adding into the discussion cases that would better be described in other terms. In addition, Davis reads Leubke as accusing him of underrating the moral dimension of conflicts of interest. Specifically, Davis responds to two points of criticism: first, his inclusion of subjective interests; and second, his failure to comprehend of the relationship as a fiduciary one.

Davis replies to the first point by claiming that Leubke made two mistakes in his analysis, the first concerning what the standard of standard usage is, and the second concerning what the status of standard usage is. Regarding standard usage, Davis begins by asking what is standard for evaluating conflicts of interest? He points out that in his discussion he relied on the American Bar Association's Code of Ethics, and not on court opinion, which Leubke used to sharpen his argument for excluding subjective interests. Davis believes that it is more appropriate to begin discussions from the lawyer's perspective than with the court's opinion, because lawyers have access to more subjective information than judges ever do. Davis asks us to reconsider an example put forth by Leubke, which Leubke asserts would be a conflict of interest under Davis's analysis. The example has to do with a parent who delays getting needed medical attention for his or her child out of a desire to take a weekend trip instead. Although Leubke rejects this as a

[75] See Davis (1993).

conflict of interest, Davis asks why we should not accept it as one. He further postulates that by using the language of conflict of interest, we are aided in seeing some of the aspects that are troubling about this case. Davis uses both of these elements to make his final point, which is that the standard usage is not yet settled; therefore, his analysis cannot be wrong. As Davis puts it, "Where is the absurdity?"[76]

The other mistake has to do with the status of the usage Leubke considers standard. Davis asks us to consider whether the courts might be mistaken in relying only on objective interests, and consequently, that Leubke's position is flawed because he has uncritically accepted court opinion. In addition, he points out that a small number of courts have relied on subjective claims, particularly in homicide cases having to do with self-defense. Davis contends that since the courts are not yet settled on what the practice should be, and since some have accepted subjective interests to a small degree, then why should he not incorporate this element into his analysis of conflict of interest?

Davis also considers whether Leubke's notion of the fiduciary relation is not more appropriate than his own for assessing conflicts of interest. In response to his question he states, "I think not. Unlike [Boatright's] agency relation, the fiduciary relation is not so much a category as a catch basin. Vermin multiply beneath the murky water."[77] Davis believes Leubke's description of the relation is so broad that it would count situations as conflicts of interest when they would be better described in other terms, although he offers no examples. He suggests dropping the reference to fiduciary altogether, and

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[76] Davis (1993), p. 24.

[77] Davis (1993), p. 32.

focusing more precisely on what he sees as the relevant issue: namely, that the crucial relation is the one in which one party exercises judgment on the behalf of another party.[78]

In considering Neil Leubke's response to Davis, I will also add my own critical points to the discussion. Leubke articulates three areas of response, the first having to do with the question of standard usage; the second, the disagreement over interest; and the third, the disagreement over the essential features of a conflict of interest.[79]

With regard to standard usage and Davis's accusation of the error of "method" regarding his reliance on court opinion rather than the standards found in the lawyer's code of ethics, Leubke gently points out that standard usage is a mess, and not much exists in the literature to assist the discussion. In addition, Leubke does not find lawyers to be univocal on questions of ethics and therefore does not have confidence regarding the helpfulness of their Code. Finally, since neither Davis nor Leubke are lexicographers, a point that they both agree on, this should not be a concern.

Leubke next addresses a key concern with his restriction of interests to objective concerns. Although the courts have <u>not</u> admitted subjective interests into conflict of interest cases and have been known to admit subjective interests into some homicide cases, Leubke believes this is not evidence that the courts are timid in using subjective interests; rather, they recognize when these interests do and do not add value. Leubke sees this restriction by the court as advantageous to his argument. Furthermore, by broadening the definition of conflict of interest to include subjective concerns, the

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[78] See Davis (1993), p. 32.

[79] See Leubke (1993).

category is stretched way beyond its typical use. In stern retort Leubke states, "Here is a vermin-breeding catch-basin far larger than my fiduciary relation."[80]

It is philosophically interesting that Davis accuses Leubke of blurring the concept by relying on fiduciary relationship, and as just noted, Leubke accuses Davis of blurring the concept by including subjective interests. Certainly both could be correct in their assessment since the possible blurring of the concept has a different root in each claim, however, I do not believe this is the case. The question then becomes, who, if either, is blurring the concept? Consider again the case of the parent and the weekend trip. Davis asserts that conflict of interest language is helpful in explaining the troubling element about the situation that is difficult to express in other terms. I disagree, and to this point I concur with Leubke, who appropriately characterizes the situation as an ordinary case of self-interest versus paternal obligation.[81] Conflict of interest language would require us to consider solutions such as withdrawing from the situation or disclosure and consent. Davis asks us to consider turning the decision over to another party, but this is ludicrous. A parent's decision to go away for a weekend and delay the child's access to medical care would be morally reprehensible. To claim that the situation can be described as a conflict of interest is to minimize what is wrong with the parent's decision making in this case, and certainly blurs and weakens the concept. This is not to say that calling any situation a conflict of interest is to minimize its importance. Certainly conflicts can be very

[80] Leubke (1993), p. 49.

[81] See Leubke (1993), p. 48.

serious. In this situation, however, characterizing the parent's decision as a conflict of interest minimizes the morally troubling element.

On the other hand, Leubke's characterization of the fiduciary relation is helpful in identifying those relationships that can be subjects of conflict of interest. In contrast to the catch-basin that Davis describes, Leubke's broad definition is an excellent starting point from which to identify the parties in the relationship, and as Leubke points out (and Davis neglects to recognize), in cases of contracts or standard professional practice, the more clearly defined the fiduciary relation is, the more apparent are the instances of conflict of interest.[82] Consequently, it appears that Davis, rather than Leubke, is blurring the concept.[83]

The final point of criticism that Leubke addresses has to do with what he views as the essential moral features of conflict of interest. Whereas Davis understands the crucial term to be *judgment*, and more specifically the capacity to make decisions correctly, Leubke sees the moral issue as trust, not correctness.[84, 85] This point of difference affords us the best opportunity to assess these two characterizations of conflict of interest because it offers what I believe is the clearest insight into the authors' thought processes. By focusing on the correctness of judgment, and asking us to apply this definition to professional ethics in general, I believe that Davis is reinforcing the traditional

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[82] See Leubke (1987), p. 68.

[83] Although neither Davis nor Leubke explicitly state that the relationship between the parent and the child is fiduciary, I believe they would agree that fiduciary obligations apply.

[84] See Davis (1982), p. 22.

[85] See Leubke (1993), p. 49, and Leubke (1987), p. 74.

paternalistic model of the patient-professional relationship. To think in terms of health care, his discussion suggests that the relationship between patient and professional is one of dependence, and when morally inappropriate actions create a conflict of interest, the conflict occurred because the professional lost his or her moral compass and made a judgment error. The solution to this situation is wholly reactive -- disclose, gain consent, or divest.

On the other hand, Leubke's description suggests a different kind of relationship between patient and professional, and a different strategy to manage conflicts. He asks us to consider how disclosure in the situation of the parent who desires the weekend trip "would serve to preserve and restore trust."[86] By placing trust at the moral center, Leubke is asking us to view the patient-professional relationship as one in which each member contributes toward a shared goal(s), even though each brings a different level of expertise and unique value set to the discussion. Consequently, when an interest interferes with the relationship, the gift of trust given by the patient to the professional is, or ought to be, threatened. Viewing conflicts of interest in such a way suggests (1) that the structure of the health care system should provide the opportunity to gain trust, (2) that the focus of the health care professional be on the relationship he or she maintains with patients, (3) that dependence be minimized by helping patients understand their drug therapy, as well as therapy alternatives, and (4) that individuals be empowered decision makers. Consequently, to knowingly enter or knowingly fail to avoid a conflict of

[86] Leubke (1993), p. 48.

interest can now be viewed clearly as a moral issue, one that directly threatens the moral fiber of professional relationships -- namely, the trust that binds together patients, families, friends, and health care workers.[87]

Leubke has focused our attention on the threat to trust, but what is the implication for his analysis of conflict of interest if we consider one of the components of trust, namely integrity? A key question to ask is whether one's integrity is violated or threatened when one has conflicting interests? Mitchell tries to argue that her integrity is violated when she has to respond to an order from a physician that may be different from her own understanding of the patient's best interests.[88] This violation stems from a loss of pureness since she would not be able to maintain coherence between what she thinks should be done and what she is doing. I do not agree with the conclusion of Mitchell's absolutist analysis, but I do see a significant threat to integrity raised by the conflicting interests. The threat to integrity does not imply that any harm will automatically occur. One may find himself or herself tempted to pursue an interest that adversely affects an individual, but can resist the temptation and act in accordance with the appropriate interest. In the case of the PBM pharmacist, this might mean resisting the temptation to advance a financial interest and choosing to serve the best interest of the patient.

By identifying the possible threat to integrity, and the associated possible threat to trust, we are able to identify a strength of Davis's analysis. His focus on the proper

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[87] I am indebted to the feminist insights on health care ethics provided by Susan Sherwin, and I hope the intended sharing of themes is clear. See Sherwin (1992).

[88] See Mitchell (1982), pp. 68-9.

exercise of judgment in the service of another accounts for the threat to integrity because of its concern with the correctness of decision making. This raises the question of whether Davis's analysis is more appropriate than Leubke's? In responding to a challenge raised by Davis to identify a conflict of interest that did not involve the exercise of judgment, Leubke wrote, "Of course, all fiduciaries are expected to exercise judgment on behalf of another, so I cannot give the example of a never-judging fiduciary that Davis challenges me to produce."[89] Davis has identified an essential element of conflicts of interest that involve a fiduciary, namely that a decision is made. But from a moral perspective it is not clouded judgment that is most interesting. What is most interesting is the relationship between trust and conflict of interest. There is a correlation between integrity and trust. Specifically, if one's integrity is threatened, then the basis for trust is threatened; and if integrity is subsequently lost, then the basis for trust is lost. Since moral category conflicts of interest are fundamentally an issue of threatening trust, so too are they an issue of threatening integrity. Consequently, even though Davis's analysis more readily accounts for this issue of threatened integrity, so does Leubke.

Although I believe that Leubke's position is stronger than Davis', I am not convinced by all of his arguments. My first criticism has to do with Leubke's application of moral category conflicts in the "professional/public service" context. As I noted earlier, I believe the distinction between moral category conflicts of interest and use of the term "conflict of interest" adds value to discussions on the subject of conflict of

[89] Leubke (1993), p. 49.

interest. It allows one to consider the details of a case at a finer level, and as it applies in Leubke's analysis, it allows us to take a closer look at the threat to trust. But in the "professional/public service" context, the distinction appears to break down in ways that it does not in the "sociological" context. In the "sociological" context we see broad uses of the term "conflict of interest." By employing a distinction that allows us to distinguish between threatening trust and loosely using the term, value is added. But in the "professional/public service" context it does not appear that this same value can be generated. Consider again Leubke's unprincipled stockbroker who excessively churns accounts for monetary gain. The argument follows that since there is no objective interest pushing him to churn the accounts, there is no moral category conflict of interest. But how does this help us? There is still a conflict of interest, and it is hard to imagine clients who would trust their broker after finding out that the broker was churning their accounts for selfish financial reasons.[90] Trust has been violated, and the fiduciary relationship has been placed at risk. Consequently, it does not appear that Leubke has located a place for moral category conflicts of interest in this context. So, why consider the distinction valuable?

The distinction adds value in this context because it illuminates the risk to the fiduciary relationship, which is a point that Leubke does not bring out. Conflicts of interest exist to varying degrees, and when an adverse interest can be objectively measured, we are able to evaluate the severity of the risk and the burden it would place on

[90] I believe that Leubke would agree that there is a conflict of interest, but he would argue that the term is being used broadly.

maintaining the fiduciary relationship. In other words, the greater the strength of the incentive, the more likely it will create a serious conflict of interest that could lead to potential harm. For example, when the stockbroker was acting in his or her own interest to increase personal wealth, a conflict of interest existed that placed the fiduciary relationship at risk. If the broker's company put a policy into place that required the stockbroker to churn their accounts, then the fiduciary relationship was placed at a higher level of risk. If the corporate policy indicated churn or be fired, then risk would be maximized. A conflict of interest existed in each case; but when we were able to identify the objective interest, we were better able to assess the risk.

If fiduciaries ignore a moral category conflict of interest, then they deserve moral blame. As Leubke points out, to label a situation a moral category conflict of interest is to "provide a prima facie reason (i) for restriction (self or external) of the person's activities and (ii) for partial disclosure of the person's financial, commercial, political, or familial relationships."[91] If objective interests of high risk are ignored, we may assess the highest degree of moral blame and related sanctions. Consequently, by clarifying the conflict of interest and the risk, we are better able to guide and advise the professional in how to manage through the conflict. This is where I see the value of the distinction as it applies to the "professional/public service" context. This criticism does not deny Leubke the moral category distinction in this context, rather it identifies an additional reason why it should be retained.

[91] Leubke (1987), p. 66.

A second criticism of Leubke focuses on his reliance on disclosure and consent as part of the solution to acting within a conflict of interest. While I believe these two actions are part of the solution, I believe that Leubke ends his discussion prematurely, particularly when considering conflicts in the "professional/public service" context. Disclosure and consent in and of themselves are not the entire solution to a conflict of interest. They are certainly key elements, but they need to be complemented by professional guidelines for action, and possibly by public policy guidelines. This point will be brought out in Chapter V.

In working through the question of what constitutes a conflict of interest, we have covered much ground. I have argued that a conflict of interest requires a fiduciary relationship, and that a potentially adverse interest must threaten this relationship to create the conflict. This interest can either be of a subjective or objective nature. I have also tried to argue that an appropriate characterization of a conflict of interest is one that focuses on the relationship of trust. To this point I agree with Leubke. In addition, although conflicts of interest can be associated with subjective interests, use of the term is often broad and is not necessarily indicative of any moral wrongdoing. Only objective interests can place a fiduciary in a moral category conflict of interest, which allows for an assessment of moral wrongdoing. To this point my conclusion is consistent with Leubke on the question of interests, but also extends beyond his discussion by using objective interests to assess risk. Now that a conflict of interest has been defined, let us return to the potential conflicts of interest in which the PBM pharmacist may find himself or herself.

CHAPTER III

The Patient-PBM Pharmacist Relationship

Arnold Relman argued in a 1980 article entitled "The New Medical-Industrial Complex" that the most important development in health care was the burgeoning new industry that was supplying health care services for profit.[92] Whether the service was diagnostic, hospital, home, or emergency care, this "medical-industrial complex," while theoretically more efficient than its nonprofit competitors, created a variety of potential problems; cream-skimming (i.e., profit by concentrating on providing the most profitable services to the best-paying patients, and leaving the rest of the business opportunities to the nonprofit hospitals), emphasizing technology at the expense of personal care, and exerting influence on national health policy.[93] Recognizing that the use of medical resources had increased greatly over the past few decades, Relman characterized the major challenge facing the health care establishment as how to moderate the use of these resources, and yet protect equity, access, and quality -- a challenge potentially complicated by the growth of the private health care industry.

Relman's characterization of the challenges facing medicine in 1980 certainly resonate in pharmacy in the 1990s, particularly when considering pharmacy benefit management companies. He defined the new medical-industrial complex as "a large and

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[92] See Relman (1980).

[93] See Relman (1980), pp. 968-69.

growing network of private corporations engaged in the business of supplying health care services to patients for a profit -- services heretofore provided by nonprofit institutions or individual practitioners."[94] In a 1995 article appearing in *Pharmacotherapy*, Milo Gibaldi described PBMs as "companies that market competitively priced drugs and pharmacy services to managed care organizations and other comprehensive health plans."[95] I believe the resemblance between Relman's "complex" and the PBM is clear, but if more evidence is necessary, consider that PBMs are for-profit corporations, which through their efforts to drive down drug expenditures have contributed (albeit not exclusively) to the closing of many independent retail pharmacies. Consequently, Relman and others who have written on the commercialization of medicine provide material from which we can learn about these changes, and possibly provide us with lessons we can apply to understanding the commercialization of pharmacy, which has been driven in large part by the growth in the PBM industry.[96]

Although Relman worried that the medical-industrial complex would place the interests of the stockholders before the interests of the public, his main focus was on the role that physicians in particular and the medical profession in general should play as

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[94] Relman (1980), p. 963.

[95] Gibaldi (1995), p. 265.

[96] Rodwin describes the commercialization in medicine as the transition from the period when a physician carried a black bag and made token wages through to the present in which the money economy has penetrated nearly every facet of the medical system. See Rodwin (1993), pp. 11-13. In pharmacy, we find a parallel with the pharmacist of a few decades ago who made a living as a sole proprietor of a pharmacy transitioning through to the development of the corporate structure that manages the majority of the practice of pharmacy today.

private enterprise takes an increasing share of the health care market.[97] In Relman's view, health care is unique for three reasons: one, it is different than most commodities sold in the marketplace, in that public funding and insurance pay a substantial percentage of the bills; second, consumers do not have the usual incentives to be discriminating purchasers; and third, patients are at a knowledge deficit when it comes to making decisions about their care. Based on these reasons, Relman argued that physicians ought to be charged with regulation of the health care market as they work in the interest of their patients.[98] What distinguished his argument from others was his call for physicians to have no economic conflict of interest while representing their patients in the new medical marketplace, meaning that they would have no monetary interest in the medical-industrial complex.[99] The physician's role is to balance priorities in the new private health care market, such that the needs of patients (i.e., services) and society (i.e., controlling health care expenditures) are placed before the corporate need to increase profits. Relman's suggestion that the physician play the role of regulator in a changing marketplace is certainly provocative. It clearly directs a challenge at medicine, for it asks the many practicing physicians with investments in for-profit health care businesses to

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[97] See Relman (1980), p. 967.

[98] Relman views the "best kind of regulation of the health-care market com[ing] from the informed judgments of physicians working for the interests of their patients." Actions would include curbing procedures that are unnecessary or inefficient, and developing those procedures that most effectively use the resources set aside for health-care. He tries to argue that overuse "can be eliminated only by taking a more critical view of what we do and of how we use our health-care resources." See Relman (1980), p. 967.

[99] See Relman (1980), p. 967.

divest those interests, as well as asks physicians to curtail future investment. Society and the for-profit businesses must also ask whether they are willing to accept this arrangement. Relman's argument appears grounded in the long-standing tradition of medicine, since it suggests maintenance of a patient-physician relationship in which the physician, as regulator and key decision maker, remains rather autonomous. But what if the physician was not the regulator of the market, and the driver of decision making became the corporation, thereby diminishing physician autonomy?

In *The Social Transformation of American Medicine*, Paul Starr suggests that medicine is moving toward a state of corporate-driven decision making and limited physician autonomy.[100] In laying out his position he notes, "Corporations have begun to integrate a hitherto decentralized hospital system, enter a variety of other health care businesses, and consolidate ownership and control in what may eventually become an industry dominated by huge health care conglomerates."[101] In addition to broadening the discussion beyond the for-profit corporate move into the medical institutions that Relman described, Starr also distinguishes five separate dimensions in describing these changes:

1. *Change in type of ownership and control*: the shift from nonprofit and governmental organizations to for-profit companies in health care.

2. *Horizontal integration*: the decline of freestanding institutions and rise of multi-institutional systems, and the consequent shift in the locus of control from community boards to regional and national health care corporations.

3. *Diversification and corporate restructuring*: the shift from single-unit organizations operating in one market to "polycorporate" and conglomerate enterprises, often organized under holding companies, sometimes with both

[100] See Starr (1982), pp. 420-49.

[101] Starr (1982), p. 428.

nonprofit and for-profit subsidiaries involved in a variety of different health care markets.

4. *Vertical integration*: the shift from single-level-of-care organizations, such as acute-care hospitals, to organizations that embrace the various phases and levels of care, such as HMOs.

5. *Industry concentration*: the increasing concentrations of ownership and control of health services in regional markets and the nation as a whole.[102]

Unlike Relman, who articulated actions for physicians to take, Starr describes the physician and his or her changing role in the transforming system. He reviews how the profession of medicine was previously able to resist corporate competition and control through its collective organization, authority, and position as mediator between patients, hospitals, and third party payers. Even though their authority and position are still maintained, physicians have become much weaker since employers and government have become critical intermediaries and drivers in the system by successfully pressuring medicine to minimize its costs to society.[103] Starr also notes that individual physicians are no longer as opposed to corporate medicine as they once were because of some of the lifestyle advantages that corporate medicine offers over solo practice. One of these advantages has to do with a preference for practicing in groups within organization that offer regular staff hours for physicians. The break from solo practice is also reflected in the membership of the American Medical Association, which reported in the early 1980's that a large percentage of their members were involved in some sort of corporate

[102] Starr (1982), p. 429.

[103] See Starr (1982), p. 445.

practice.[104] Recognizing that this shift in their membership base reflected the tremendous growth of corporate medicine, the AMA gave up their outright opposition to corporate medicine and narrowed their focus to organizational interference in medical decisions. Starr clarifies that even though corporations will never be able to have total control over the physician, corporate practice will lead to a loss of autonomy that will be felt by physicians as they consider the duration of their careers, and their work routines, performance standards, and evaluations. In addition, since physicians will not be running the institutions in which they work, they will have to begin accepting and integrating a corporate outlook into their practices. As Starr points out, "The rise of a corporate ethos in medical care is already one of the most significant consequences of the changing structure of medical care."[105] Starr's description of the physician as corporate employee -- "one who accepts management's outlook and integrates it into their everyday work" -- stands in sharp contrast to Relman's view of the relatively autonomous physician.[106]

Edmund Pellegrino offered a slightly different perspective than Starr in a 1983 interview that appeared in *Hospital Progress*.[107] Recognizing first that trust between patient and provider is an essential ingredient to healing, and that conflicts of interest will become a greater problem as competition increases within health care, Pellegrino urges physicians to stay true to their discipline. Their first consideration must be to advocate

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[104] See Starr (1982), p. 446.

[105] Starr (1982), p. 448.

[106] Starr (1982), p. 448.

[107] See Pellegrino (1983), pp. 650-52.

for their patient, although their practice patterns of utilization should be therapeutically rational and fiscally responsible. He recognizes that competition can generate problems due to overutilization of services, as well as encouraging underutilization through practice models that value treating large volumes of patients at low unit costs. Pellegrino's position appears aligned with Relman's, since Pellegrino's model maintains the physician at a higher level of autonomy as advocate and decision maker for his or her patient within the context of a changing market.

Relman, Starr, and Pellegrino provide us with three different ways to understand the physician's evolving role within a marketplace where for-profit competition is driving fundamental change. My objective in presenting these three positions is not to defend one over the other two; rather, it is to gain insight into the physician's changing role and use this information in developing a strategy for resolving the conflicts generated by competition and cost containment. The question is, what can we learn from Relman, Starr, and Pellegrino about the professional's role that we can apply to assist the PBM pharmacist? If the goal of the PBM is to drive cost efficiencies and quality improvements into the delivery of the pharmacy benefit, then the critical ethical issue for PBM pharmacists is whether they should attempt to maintain the highest possible degree of fiduciary relationship with their patients by taking actions that maximize their autonomy, or simply accept the role of corporate employee with a reduced level of autonomy and focus on helping the PBM maximize cost savings. Perhaps the resolution should be a blend of the two approaches. In preview, my suggested answer is a compromise between

these two extremes; the goal is to maintain the patient's best interests, preserve the pharmacist's integrity, and optimize cost effectiveness.

The answer to these questions assumes that a fiduciary relationship exists between the patient and the PBM pharmacist; however, this has not yet been demonstrated. Therefore, before we answer the question posed, we must resolve what relationship, if any, does the PBM pharmacist have with the employees or MCO members whose drug therapy they manage, and how should we understand that relationship? If a relationship can be established, then we can begin to assess different functional activities in which the PBM pharmacist engages and the possible conflicts of interest associated with these activities.

In defining their model of pharmaceutical care in 1989, Hepler and Strand identified pharmacy's mandate as helping patients obtain the best possible results from drug therapy, including protection from harm.[108] They call the philosophy of practice within which this mandate would be achieved "pharmaceutical care," and define it as the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's life. These outcomes include curing the disease, eliminating or reducing symptoms, slowing or eliminating the disease process, or preventing the disease. The critical point in Hepler and Strand's position is that the pharmacist directly accepts responsibility for the quality of the care he or she provides. The basic relationship between pharmacist and patient in the pharmaceutical care model is viewed as "a

[108] See Hepler and Strand (1989), p. 24.

covenant, a mutually beneficial exchange in which a patient promises to grant authority to the provider, and the provider promises competence and commitment to the patient."[109]

The latest version of the American Pharmaceutical Association's (APhA) Code of Ethics, which was approved by the membership in 1994, describes certain moral obligations and virtues that support the pharmaceutical care model, but also expands upon its ethical underpinnings. The first position statement of the current APhA Code points out the covenantal nature of the patient-pharmacist relationship, noting that "A pharmacist respects the covenantal relationship between the patient and pharmacist." The follow-up explanatory note states, "Considering the patient-pharmacist relationship as a covenant means that each pharmacist has moral obligations in response to the gift of trust received from society. In return for this gift, the pharmacist promises to help individuals achieve optimum benefit from their medications, to be committed to their welfare, and to maintain their trust." [110] If society became distrustful of pharmacists because of a rash of misconduct, the obligations of pharmacists would not be diminished. These obligations might even be heightened temporarily in an effort to gain back some of the trust that was

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[109] Hepler and Strand (1989), p. 26. William May discussed the theological term "covenant" in his 1975 article, "Code, covenant, contract, or philanthropy," which appeared in the December issue of the Hastings Center Report. In a nutshell, covenant ethics describes a patient-professional relationship whose service aspect is responsive to the members of society, and has an aspect of giving oneself freely to the patient that is a measure beyond self-interest. Veatch points out that a covenant "[I]s based on an actual or anticipated specific exchange between "partners"; an exchange of gifts, labor, or services. It is reciprocal. The lives of both parties are shaped by the promising." See Veatch (1981), p. 90.

[110] See Fink (1994), p. 80. See Appendix III for the full text of the APhA Code of Ethics.

lost in order to shore up the fiduciary relationship. In addition, the APhA Code would still be valid for it reflects not only the duties owed to patients, but also the indebtedness that the pharmacist has to the larger society. These duties and obligations reflect the codal and covenantal ideals of the helping professions generally, including pharmacy, and they are not swayed by the inappropriate behavior of some of its members.

Not only does this reflect Hepler and Strand's position, but it also points out the fiduciary aspect of the patient-pharmacist relationship. Recall that in Chapter I the fiduciary relationship was characterized in part by the advantage that the professional maintains because of an expert knowledge base. This advantage created special obligations to the client, which lead to a dependency on the professional. Consequently, clients must trust the professional to act in their best interest. The APhA Code reflects this through its recognition of the need to maintain trust, and the promise to achieve optimum benefit from medications. Leubke used the word *fiduciary* to "connote any party in whom trust is reposed for the purpose of aiding, acting on behalf of, or protecting the interest of another party," which is consistent with the APhA Code.[111] The Code highlights other ethical underpinnings of the practice of pharmacy, including respecting patient autonomy, maintaining professional competence, respecting the values and abilities of colleagues and other health professionals, and possessing the virtues of caring, compassion, honesty, and integrity. What should be clear is that the traditional patient-

[111] Leubke (1987), p. 68.

pharmacist relationship is a morally recognized fiduciary relationship whose primary purpose is to assist individuals in maximizing their drug therapy.[112]

Managed care has challenged all of the traditional notions of the patient-practitioner relationship, which is a claim that draws support from the 1995 articles released by the American Medical Association's Council on Ethical and Judicial Affairs[113] and the Council on Graduate Medical Education.[114] The Council on Graduate Medical Education described five key findings as a result of its analysis of the physician workforce and medical education in light of the rapid growth of managed health care. Among these findings were the recognition that (1) the growth rate of managed care is likely to continue or accelerate in the future; (2) there is an increased need for generalist physicians; (3) financial support for graduate medical education may diminish due to changes in the health care ; (4) the growth of managed care will magnify current education deficiencies (specifically those driven off a fee-for-service practice model), and finally; (5) many barriers exist that impede the changes necessary to train the physician workforce for managed care. What I believe is significant about this report is the fact that medical educators have publicly recognized that managed care does change the practice of medicine, and these changes are so significant that they need to be addressed at the level of physician training.

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[112] "Traditional" is intended to refer to the relationship that is established and maintained by the community and institutional pharmacist.

[113] See Council (1995).

[114] See Rivo (1995).

The Council on Ethical and Judicial Affairs pointed out the specific implications of these changes for everyday practice: the potential conflicts that could occur when the physician is placed in the position of balancing the interests of one patient with the interests of other patients, and the potential clash between patient and physician via incentives to limit care.[115] In the first case, the managed care plan can create potential conflicts by requiring the physician to use pre-developed guidelines to determine when services should be offered. In the second case, the physician may have a strong financial incentive to limit care, and the greater the incentive (i.e., the higher percentage or their salary placed at risk) the greater the likelihood that harm may result. As the Council makes clear, "It is therefore essential that the profession and society act now to ensure that managed care techniques are implemented in a way that *protects patients and the integrity of the patient-physician relationship.*"[116]

John La Puma and David Schiedermayer, both physicians, point out that managed care organizations (MCOs) make at least two ethical assumptions. The first is that the doctor-patient relationship will be fiduciary and nonadversarial, and the second is that equality of access is the proper ethical concept for resolving resource allocation questions.[117] La Puma and Schiedermayer recognize the fiduciary role as trusting and

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[115] See Council (1995), pp. 331 and 333. This point also lends support to the idea I suggested in Chapter II regarding assessments of risk based on objective interests. In this case the conflict of interest is driven by the employer's policy to place a percentage of salary at risk, which drives up the risk to the patient as the percentage increases.

[116] Council (1995), p. 330. Italics added.

[117] See La Puma and Schiedermayer (1996).

covenantal, although the basis for the relationship is determined by a sort of contract. In addition, they recognize that the physician is in an advocacy role for the patient, but that there are limits to that role, and that patients, as well as their physicians, must recognize these limits.[118] The notion of equality of access has to do with consistency of decision making across patient populations, which is critical to the business strategy of the MCO.

La Puma and Schiedermayer make a critical point in further defining the relationship, noting that "the nature of the doctor-patient relationship in the MCO is not intended to be ethically distinct from the doctor-patient relationship in indemnity systems."[119] Doctors still treat one unique and valued patient at a time; however, cost management is a key point of focus as it is embedded in the structure of the MCO. They also make one other critical point, which I believe is of the utmost importance. First, they characterize the relationship as "doctor-patient-MCO," and then describe the obligation of the doctor to hold the MCO accountable to its ethical responsibility for assuring access.[120] This point has applicability to the PBM pharmacists relationship with their employer and obligations that follow from this relationship. I will bring this point out later in this

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[118] See La Puma and Schiedermayer (1996), p. 170. An example of a limit may be the exclusion of a highly expensive procedure, such as a bone marrow transplant, when the medical necessity of the procedure cannot be certified. MCOs cannot legally exclude such services based on cost alone. They must be described in the coverage language as experimental or investigational. This is an important point because in traditional indemnity plans exclusion of services based on cost is allowed. The limit would be justified by the MCO as a prudent use of limited resources, and one which allows for basic services to be spread across a wider population.

[119] La Puma and Schiedermayer (1996), p. 168.

[120] See La Puma and Schiedermayer (1996), p. 168.

dissertation. The value of this insight is that it reflects the most fundamental and important parameter change to all of the traditional descriptions of the patient-physician relationship. Regardless of whether we were following the paternalistic model, the informative or engineering model, the interpretive model, or the deliberative model,[121] in the case of competent adults, the scope of the relationship was not understood to include anyone other than the patient and the physician. This is critically important because it suggests that strategies to resolve moral conflicts that rely on a bilateral relationship may be conceptually flawed, if the patient-provider relationship is indeed multilateral.[122] In addition, by requiring the physician to hold the MCO accountable, La Puma and

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[121] See Emanuel (1992), pp. 2221-222. In the paternalistic model, the physician acts as the patient's guardian, articulating and implementing what is best for the patient. In the informative model, the objective of the patient-physician interaction is for the physician to provide the patient with all relevant information, for the patient to select the medical interventions he or she wants, and for the physician to carry out the selected interventions. In the interpretive model, the aim of the interaction is to elucidate the patient's values and what he or she actually wants, and to help the patient select the available medical interventions that realize these values. In the deliberative model, the aim of the interaction is to help the patient determine and choose the best health-related values that can be realized in the clinical situation.

[122] Dr. Alan Hilman, who directs the Center for Health Policy at the University of Pennsylvania, indirectly confirms this point in an analysis of payments by pharmaceutical manufacturers to pharmacists for recommending drug switches at the patient level. In discussing the PBMs who were purchased by manufacturers Hilman notes, "[PBMs] were bought so they can have pharmacists and telemarketing people call [physicians] and try to get prescriptions changed. That is exactly the opposite of what they were at least theoretically doing when they were independent. It's not a good development." Hilman's recognition of the patient, pharmacist, and PBM in his analysis is consistent with the idea that a multi-lateral evaluation of moral issues is required. See Kolata (1994).

Schiedermayer are declaring that not only does the plan member have responsibility for the actions and policies of his or her plan, but that the physician also shares in that responsibility. If we couple this point with the idea that a fiduciary relationship is in place, we begin to see what the managed care version of the patient-professional relationship looks like. The relationship is still viable; however, the professional is now obligated to work in the best interest of their patient, and focus on balancing population needs against individual needs. This is different because prior to managed care there were few, and often times no, limits to advocating for a single patient.

Where does this leave the PBM pharmacist? He or she is obviously working in a managed care setting, with a professional ethic that characterizes the patient relationship as fiduciary with a primary focus on maximizing the benefits of drug therapy. However, within the context of the PBM, the practice setting is in no way traditional. What distinguishes this setting from the traditional pharmacy setting is the role of the PBM, and the need for the pharmacist to take responsibility for holding the PBM accountable for its actions. In addition, the practice setting is different because (with rare exceptions) the pharmacist will never see the faces of the individuals for whom clinical interventions are provided. In some cases, clinical knowledge may be applied with the realization that their decisions may impact nearly one million lives in a population, but the pharmacist will never know an individual name. In other cases, the pharmacist applies his or her knowledge in the review of a drug history for clinical safety, and on top of the drug history page is a unique patient identification number. In this scenario, there is at least a person involved to whom we can point by an identifier. One question is, can we say that

these individuals, whether one or one million, are the pharmacist's patients? My answer to this question is yes.

If the pharmacist's obligation is to maximize the value of drug therapy, and the PBM pharmacist is contributing as an active member of the health care team to help attain this goal, then why not agree that the beneficiary of the pharmacist's activity is his or her patient? In the most clear-cut example, when the PBM pharmacist is responsible for a case management program that requires discussing individual patient cases (including drug and disease histories) with the prescribing physician, and his or her focus is on certifying the medical necessity of the drug in question, then it seems obvious that the member of the plan whose case the pharmacist is managing can be understood to be his or her patient. The PBM pharmacist is certainly concerned about cost management, but there are quality parameters he or she is monitoring as well.

Consider an actual case involving the drug growth hormone, which can have severe side effects when the dose is too high. The pharmacist reviewing the case of a 16-year-old child learned that the patient was growth hormone deficient, which is an appropriate indication for use. In addition, the pharmacist calculated that the physician was prescribing twice the usual dose. The physician tried to argue that this was medically necessary because of a belief that doubling the dose would be of additional benefit during the last stages of growth. This argument could not be supported by any research in the medical literature. In this case the pharmacist would not certify medical necessity, unless the doctor agreed to lower the dose. The primary motivation for not certifying medical necessity was the safety of the child, who the pharmacist viewed as his patient. As it

turned out, the reduction in the dose corresponded to a $60,000 savings to the health plan. From the perspective of the employer who hired the PBM to perform this case review function, the case was appropriately managed because the trust that the employer placed in the PBM to manage cost and assure safe drug use was upheld. Consequently, since trust was placed in the PBM pharmacist by the employer for the purpose of protecting the interest of another party (specifically, the child of an employee), I believe it is appropriate to say that a fiduciary relationship existed between the child and the pharmacist. And because of the pharmacist's application of knowledge on the child's behalf to maximize the drug treatment in a competent and caring manner, the pharmacist can say without reservation that his actions in the interest of the child - the patient - were ethically defensible.[123]

It is my contention that when a managed care plan or employer contracts with a PBM to manage its pharmacy benefit, they are placing trust in the PBM pharmacist on behalf of their members or employees. As long as clinically sound reasoning underpins pharmacists' decision making processes, the individuals for whom they are applying their knowledge can be considered their patient. Furthermore, this applies regardless of whether the PBM pharmacist's focus on patient concerns is maximized or minimized;

[123] It is possible that the person the pharmacist is helping does not trust him or her. In this case, the fiduciary relationship stays intact since the pharmacist is still obligated to act on the behalf of, aid, or advise that person. The obligations of health professionals do not cease just because the person they attend does not place trust in them. If the level of distrust was so high, and it jeopardized care, then the pharmacist would be obligated to find another pharmacist to provide pharmaceutical care.

and this applies equally to situations where the PBM pharmacist is focused on one individual or on a large population of members.[124] The idea behind maximized and minimized patient concerns will be explained shortly.

To restate my contention from another perspective: would you not want the PBM pharmacist who is responsible for reviewing your drug history profile to care for you as he or she would for a patient whose pharmaceutical care he or she was delivering in a corner drugstore? More to the point, should the pharmacist's obligation to maximize drug therapy vary by work location? I think not. Furthermore, should the fact that the PBM pharmacist never sees the patient's face matter? The answer is no, and one needs only to look at hospital pharmacy to support this claim. In many cases, the hospital pharmacist never sees the actual patient who receives the antibiotic he or she prepared or the drug that he or she put into a delivery cart. But should that pharmacist ethically dissociate himself or herself from that person, and claim that since he or she did not see

[124] I realize that these are controversial claims, and will offer actual program examples in an attempt to support the points I have asserted. I would urge an open mind in considering the points I have made, for the practice environment I am describing is real, and a framework for discussing ethical concerns within the PBM industry is not readily available. It is extremely difficult to characterize the ethical issues inherent in the industry such that the purchasers of a PBM's services can make an informed decision during the PBM selection process regarding the ethical integrity of the clinical staff and their programs. A comparison would be the evaluation that occurs of the PBM's customer service center, in which the prospective customer listens to random calls, checks call wait times, percent of busy signals, and lost calls (to name a few of the evaluative criteria) in an effort to understand the PBM's capability and experience in this area. These are an example of some of the criteria with which customers assess PBMs -- they are not available for assessing ethical integrity.

the individual's face, this person was not his or her patient? The answer is certainly no. The patient trusts that the pharmacist who prepared the drug did so properly, and consequently moral obligations and ethical accountability apply. So, if not seeing the person's face for whom clinical knowledge is being applied in the hospital setting does not disqualify the pharmacist from the moral obligations of the patient-pharmacist relationship, then why should the actions of the PBM pharmacist be evaluated any differently? The fact that the PBM pharmacist works outside of the pharmaceutical care paradigm described by Hepler and Strand does not nullify the reality that he or she is serving patients just like any other clinical pharmacist.

This is analogous to the reasoning required to justify activities as part of medicine as one moves away from the medical paradigm. Jonsen and Jameton describe the medical paradigm as follows:

a. diagnosis and treatment
b. of an illness or injury
c. for an individual
d. who presents a complaint
e. within the context of an established therapeutic relationship.[125]

An interaction between a patient and a physician that has all of these characteristics can be called practicing real medicine, much the same as the following can be described as practicing real pharmacy:

a. responsibly providing drug therapy
b. for the purpose of achieving definite outcomes
c. that improve a patient's life.[126]

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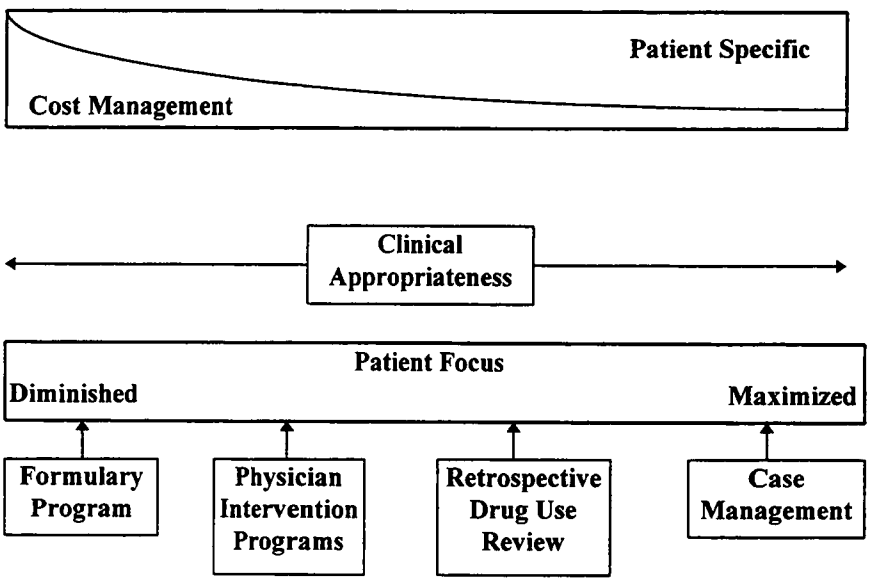
[125] Graber, Beasley, Eaddy (1985), p. 118.

[126] Hepler and Strand (1989), p 26.

Justification is required for each move away from either of these paradigms. An example in medicine is clinical research, which is justified since the gaining of new medical knowledge is central to the core activity of practice. PBM pharmacists do participate in the provision of drug therapy, and the goal of the PBM pharmacist is to achieve definite outcomes; however, it may or may not be possible to attribute their actions to a single patient's life.[127] Consequently, although the practice of pharmacy in the PBM setting has moved away from the paradigm, it is related to the core activities.

In an effort to support the claims I have made regarding the patient-PBM pharmacists relationship, consider the diagram below and the four practice scenarios in which the PBM pharmacist characteristically finds himself or herself:



[127] With respect to the provision of drug therapy, the PBM pharmacist who practices in the mail service setting dispenses drugs just like his or her counterparts in the community or hospital setting. In addition, the PBM pharmacist is called upon regularly to apply his or her clinical knowledge base to individual reviews of drug therapy cases.

The top box depicts the focus of the clinical programs that the PBM pharmacist can actively design, implement, and administer. These programs range from a cost management to a patient-specific focus. It is important to point out that although the focus on cost management is minimized in the more patient-specific programs, the focus on improving the cost effectiveness of the pharmacy benefit is always present since it is embedded in the PBM's business strategy. Clinical appropriateness, which is reflected in the next box down, is the foundation for all clinical programs, much as it is for all drug treatment decisions made in the inpatient and outpatient settings. Whether the program involves selecting a drug product that can affect thousands, or making a medical necessity determination in a specific case, clinically sound reasoning must be used to determine cost effective and therapeutically appropriate drug selection. It is important to emphasize that a patient focus always exists within the context of PBM's clinical programs, which is the point of the next box. However, this focus increases as we move from cost management to patient-specific programs. When the key driver of the program is cost management, the pharmacist's focus on patient concerns is clearly minimized, but it is not absent. The PBM pharmacist may be developing a cost management program that will impact millions of lives; and although a great majority (if not all) of these lives will always be nameless, the pharmacist is held to the obligations of the fiduciary relationship. Conversely, when the PBM pharmacist is considering the medical necessity of a drug treatment plan in a case management program, patient focus is maximized. In some cases the pharmacist may speak with the patient over the phone and correspond directly through the mail. These discussions can vary from a courteous "thank you" to a hostile

confrontation over the limits of the prescription drug benefit the PBM is responsible for managing. Regardless of the nature of the discussion, the PBM pharmacist's focus on the patient is maximized and the attention to cost management is minimized.[128]

The bottom boxes in the diagram on page 77 depict four characteristic clinical programs that PBMs operate. These include formulary programs, physician intervention programs, retrospective drug use review, and case management. I will close this chapter by briefly reviewing the patient-PBM pharmacist relationship within each of these programs.

Before I begin this discussion, I would like to point out that the PBM pharmacist does have an obligation to assure that the PBM works in an ethical manner in upholding its corporate obligation to provide and support clinically appropriate and cost effective drug therapy for employers and managed care customers. Consequently, I would like to follow La Puma and Schiedermayer's lead, and refer to the patient-pharmacist relationship as the patient-pharmacist-PBM relationship. The pharmacist does have a relationship and corresponding obligations to the customer, which is a point I will attend to more fully in the next chapter. It could be argued that the pharmacist's obligations to the patient (or employee) and the employer should remain distinct. While this clearly

[128] This is an important point because it highlights the fact that PBM pharmacists can and do interact directly with individuals in the management of their drug therapy. Later in the discussion I will focus on the advocacy role that the PBM pharmacist should play, and the close relationship he or she can have with the patient. Even though cost considerations are present in patient-specific programs (either built into guidelines or through policy), the focus on the patient is what is most important in making clinical decisions regarding the drug therapy.

distinguishes the pharmacist's obligations, I believe it masks the critical obligation(s), which is between the patient and the pharmacist. Even with programs that are being employed to benefit the corporate customer or health plan, and which patients may not know about because they are not impacted personally, the best interest of the patient is not necessarily sacrificed. Consequently, I will focus on the patient-pharmacist relationship, and will clarify the customer relationship where appropriate.

The patient-specific obligations that the pharmacist maintains reside within the context of the fiduciary relationship that I have been discussing in this chapter. The trust that binds the fiduciary relationship is seeded during the sales process when the PBM first meets the prospective customer. With few exceptions, PBMs will present their clinical programs to the prospect during the proposal stage. If the prospect accepts the proposed bid, the trust that developed during the evaluative phase is then passed to the PBM pharmacist. This trust is initially given by the corporate customer on behalf of its employees. To employees whose medical condition puts them in touch with one of the PBM's pharmacists, that trust can either be strengthened or weakened based on the pharmacist's actions and the outcome of the encounter. So, even though the employee is a competent adult, the corporate customer makes the pharmacist a fiduciary for their employees through the contracting process. In another sense, the codal and covenantal obligations that each pharmacist has for his or her patients takes over once that contract is signed, and consequent fiduciary obligations begin.

This shift to patient-pharmacist-PBM is meant to reflect the complexity of the pharmacist's role, which is to serve as both advocate for the patient and employee of the

PBM. As employee, the pharmacist is obligated to remain within the bounds of the customer's benefit when working with an individual employee. As La Puma and Schiedermayer pointed out, consistency is critical in managed care. As advocate, the pharmacist must do everything possible to assure that the patient receives the best quality pharmaceutical care, and that within the limits of the plan the pharmacist helps that patient to receive this level of care. In this role, the pharmacist may be required to stand up against the PBM if morally inappropriate choices are being made that violate clinical appropriateness, but perhaps maximize corporate profits. The pharmacist should also inform employers, MCOs, and patients about drug therapies that are not covered under the plan, but may be beneficial for the treatment of a disease state. Likewise, payers have the responsibility of informing their members about the limits of their pharmacy benefit so they know what they can and cannot expect under the benefit design and can actively lobby their employer to change the benefit where appropriate. For the duration of this dissertation, I will refer to the relationship as the patient-pharmacist-PBM relationship.

In case management programs, patient focus is maximized since the program requires the pharmacist to work on certifying the medical necessity of a particular patient's drug therapy. Clinically appropriate guidelines underpin the algorithms utilized in the decision making process, algorithms that have been reviewed for accuracy and completeness by internal and external physician experts.[129] Within case management

[129] The algorithm for human growth hormone begins with questions about the stated indication for use, and proceeds to questions regarding age, weight, and gender. Radiological bone age examinations are reviewed, as well as tests to determine endogenous growth hormone levels.

programs the relationship between patient and pharmacist perhaps most closely parallels the traditional patient-pharmacist relationship, since the pharmacist is shouldering the responsibility for the patient's drug therapy, as well as taking care to safeguard confidentiality.

Retrospective drug use review consists of a monthly review of a patient's drug history with the goal of identifying and alerting the prescribing physician(s) about potential drug therapy problems. One major PBM sends an average of 12,000 letters to physicians each month alerting them of potential drug therapy problems with their patients. Each letter is patient specific, and includes a patient-specific drug history profile showing all drugs that patient has received using his or her pharmacy benefit in the past 18 months (if that much history is present in the data file). Prior to mailing any letters, a pharmacist reviews each drug history profile and letter as part of the quality assurance process. Each drug history profile contains a patient identification number, but does not contain a name. At the final stage of the program, the patient's name is incorporated into the letter.

This program retains a patient focus, although it is not maximized since the likelihood that the patient would ever contact the reviewing pharmacist is less than one percent. Clinically appropriate judgment is applied in the review process, and the clinical review is undertaken on behalf of the patient whose identification number is on the top of

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Growth height and rate are also recorded. This information is assessed and a determination of medical necessity is made. Certain genetic disorders require growth hormone treatment as part of the overall care plan. They require a similar evaluation.

the profile. The corporate customer places trust in the PBM's clinical staff to assure that potential drug therapy problems are identified and corrected, and that cost effectiveness of the benefit is impacted by eliminating unnecessary prescriptions. This program serves to demonstrate the pharmacist's obligations to the customer, and the obligations to the patient. As indicated earlier, the key relationship is between patient and pharmacist because this is the individual whose best interest is ultimately being served.

Physician intervention programs involve aggregating 12 to 18 months of prescription drug claim history for a corporate customer's entire benefit population, which may range from 50 employees to 700,000 lives. This aggregate drug history profile is then analyzed to determine aberrant prescribing patterns that are driving costs upward or are potentially clinically inappropriate. Interventions in the form of mailings, phone calls, and face-to-face visits are then directed at these physicians to modify prescribing practices. In the majority of cases prescribing does change; however, in some cases appropriate medical reasoning justifies variation from the norm.

The focus on the patient begins to diminish in physician intervention programs as the emphasis shifts toward cost management. The pharmacist's relationship with the patient begins to move away from the paradigm described earlier since the pharmacist must now look at populations rather than individuals. Still, when deciding which drug to recommend to physicians as first line therapy within the context of disease state management program, or when crafting a message about an appropriate therapy that may be sent to 1,000 physicians representing 5,000 patients, the pharmacist is still utilizing his or her clinical knowledge base to make judgments regarding drug therapy that will be

applied to individuals via the prescribing physician. Although this activity is not directed at specific individuals within the health plan, the customer entrusts the PBM and its clinical staff to appropriately manage the clinical intervention programs. PBMs are evaluated on this capability during the bidding process, and they expend a great deal of energy assuring that programs are consistent with the latest medical literature and useful to the provider. Consequently, even though the relationship is away from the paradigm, the foundation of the relationship is still built on a trust that the pharmacist will serve the best interest of the health plan members or the employees of a corporate customer.

The fourth kind of program characteristic of PBMs is a formulary management program. A formulary is a preferred list of drugs that the health plan has approved for its members. Many managed health care plans will cover prescription drugs that are on the formulary, requiring only that the member to pay a nominal co-payment or percentage co-payment. However, if the member (or physician) demands that the prescription be filled with a non-formulary drug, and no medically necessary reason can be provided to support going off the formulary, then the member will be financially penalized, usually by being required to assume most (if not all) of the cost of the drug.[130] Typically a managed care organization will have its own staff of physicians and pharmacists that will review and sign off on the list of drugs included in the formulary. Employers, for their part, will rely

[130] It is important to recognize that restricted formularies have been in place in the hospital setting for more than two decades, and to date their use is universally accepted as a highly effective approach to managing the use and cost of drugs in the inpatient setting. The use of restricted formularies in the outpatient setting is a recent (albeit controversial) trend that continues to grow, and will probably be felt strongly over the next five years.

on the PBM's clinical staff to facilitate clinical review. The formulary is usually delivered to all physicians in the program, and in some cases is provided to the members of the plan. Drugs listed on the formulary are judged to be clinically effective and cost effective agents for the treatment of most disease states. In cases where a non-formulary drug is required, if a similar drug is not available or the patient has experienced treatment failure with a formulary drug, an appeal process exists to facilitate authorization of the non-formulary drug. A comprehensive formulary program usually includes a clinical information newsletter that is sent to physicians which also updates them regarding formulary changes. Formularies are also tied to rebates from pharmaceutical manufacturers, which are linked with the movement of market share for the manufacturer's drug. The PBM and the customer usually share the rebates either on a percentage or guaranteed amount basis. Consequently, the formulary serves as a source of revenue for the plan, and can serve to offset other administrative costs.

A formulary program stretches the patient relationship the farthest for the PBM pharmacist. It is not an exaggeration to say that the formulary will impact more than 20 million individuals, and in the case of the largest PBMs, this number can exceed 40 million.[131] Despite the number of individuals involved, the PBM pharmacist is still applying his or her clinical knowledge base and making professional judgments in an effort to determine which drugs are the most appropriate for the formulary. The pharmacist recognizes that eventually an individual physician will make a prescribing

[131] See GAO (1995).

decision for a patient based on the information provided in the formulary. As such, the trust that the corporate customer placed in the PBM, as well as the prescribing physician's trust that the drug on the formulary is clinically safe and indeed the most cost effective agent, is at stake. So, even though the patient focus is minimized, and the cost management focus is maximized, the PBM pharmacist's concern is still to a small degree focused on the person in the health plan whose physician will be influenced by the formulary -- a person who should be considered his or her patient. To view this admittedly tenuous relationship as anything different than fiduciary is to miss the point that the pharmacist's clinical knowledge is being applied to serve the best interest of patients as measured by clinical and cost effectiveness parameters.[132] This point holds even though the number of patients may reach into the millions.[133]

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[132] Clinical parameters would focus on product selection by the physician, and which drugs were selected for different populations. For example, certain drugs should not be used as a first-line agent in an elderly population. The formulary program can serve as a vehicle to deliver this message to physicians which allows for outcomes measurements. Cost effectiveness parameters also look at product selection, but consider the cost implications rather than clinical (or drug safety) parameters. For example by selecting a less costly, yet equally effective, generic drug, the out of pocket expenses for the patient can be significantly reduced. This is easily measured and is generally seen as a positive outcome.

[133] The overriding concern with a formulary program is cost management, but this does not mean that patient concerns are completely overridden. I discussed the clinical drug evaluation that the pharmacist facilitates, but there is also an appeal process built into restricted formulary programs that allow patients (and physicians) access to non-formulary drugs when they are unavailable under the plan. Managed care plans are required to have appeal mechanisms in place for members. If one was not in place, or was difficult to access, the pharmacist is obligated to assist the patient (or physician) in gaining access and working through the process.

In this chapter I have attempted to show that a fiduciary relationship exists between the patient and the pharmacist working for the PBM. This relationship, although contractually based, is assumed to be trusting and covenantal.[134] Based on the contractual nature of this relationship, the pharmacist has legal obligations to work in the best interest of the patient (or employee). However, to focus merely on the contractual obligations minimizes the rich nature of the patient-pharmacist relationship as it applies in the PBM setting. Trust is given to the PBM pharmacist, and it is this trust that binds the fiduciary relationship. Acting as a fiduciary, the pharmacist sets as his or her goal to maximize the drug therapy of individual patients, even though those who benefit from the administration of clinical programs may remain anonymous. The professional responsibilities include balancing the needs of a population against those of an individual, which stems from the relationship's managed care context. If one accepts that this relationship has been established, then the question becomes, what interests can adversely affect the relationship such that a conflict of interest is generated? This is the subject of Chapter IV.

[134] Gallup's annual assessment of honesty and ethical standards resulted in pharmacists finishing first for the seventh consecutive year, with 66% of Americans rating them very high or high. Pharmacists were followed by clergy (56%), dentists (54%), physicians (54%), engineers (53%), and college teachers (52%). See McAneny (1995).

CHAPTER IV

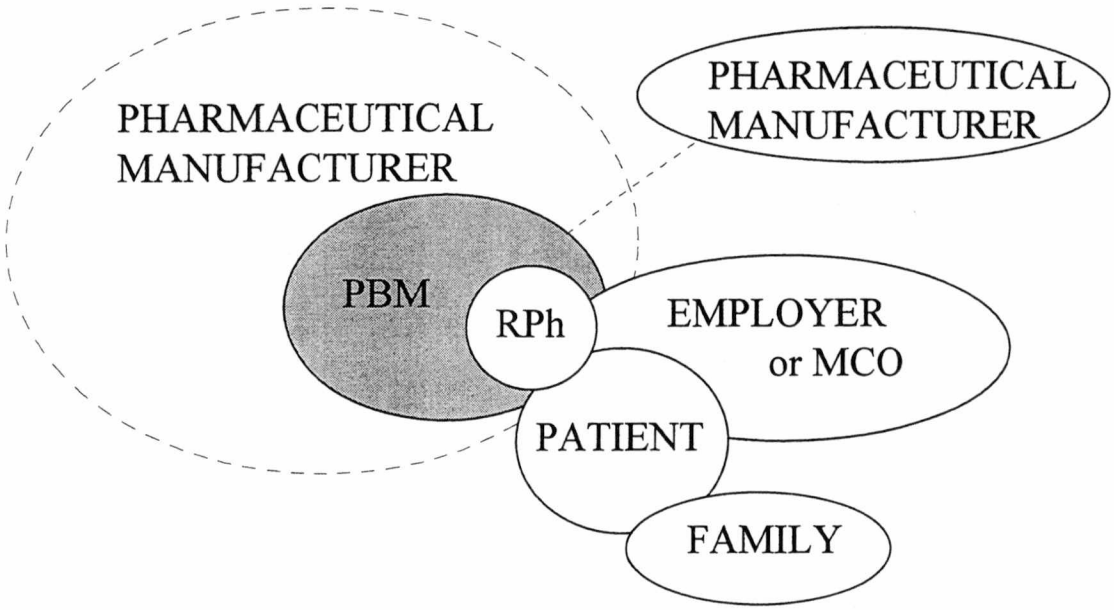
Identifying the Conflicts of Interest

In the opening chapter I suggested that the PBM pharmacist works in an environment in which a new interest has developed that potentially threatens the patient-pharmacist relationship. The additional conflicts of interest that arise with PBMs parallel conflicts that have developed in managed care medicine. In managed care medicine, as in managed care pharmacy, these conflicts of interest stem in part from divided loyalties between patients and a third party.

Some of the more dramatic changes in the practice of medicine can be tracked by following the history of prospective payment systems, the introduction of federal diagnostic-related groups (DRGs), and more recently by the proliferation of, and the enormous enrollment in, for-profit and not-for-profit managed care organizations. Pharmacy has seen its practice change with the growth of managed care, particularly as pharmacies have centralized within the MCO model. However, the most significant changes in the practice of pharmacy have been driven by the growth of the manufacturer owned PBMs, which have heightened conditions for conflicts of interest. In this chapter, I will detail four clinical management programs, clarify the potentially adverse interests, and describe the potential conflicts of interest inherent in each program.

In the previous chapter, I described the patient-PBM pharmacist relationship as the "patient-pharmacist-PBM" relationship. Before describing the potential conflicts of

interest that affect this relationship, I would like to revisit the previous discussion and more fully characterize the relationships that exist in the managed pharmacy setting. Recall that a conflict of interest occurs when the fiduciary party has an interest that is adverse, or likely to become adverse, to the reason for which reliance was initially placed. The following diagram helps to depict these relationships:



The pharmacist is an employee of the PBM, which may or may not be owned by a pharmaceutical manufacturer; consequently, the pharmacist may or may not actually be an employee of a pharmaceutical manufacturer. An employer or managed care organization contracts with the PBM to provide pharmacy benefit management services to its employees or members. It is important to note that in cases of pharmaceutical company ownership the employer or MCO has an indirect relationship with the

pharmaceutical manufacturer. The dashed line from the PBM to the pharmaceutical manufacturer reflects contractual relationships that the PBM may or may not have in place with pharmaceutical manufacturers. These contracts can specify rebate dollars to the PBM for helping to grow market share for the manufacturer, or may be in the form of unrestricted education grants to create and administer provider education regarding the treatment of specific diseases. The business relationship between the employer or MCO and the PBM creates the contractually-based relationship that underpins the PBM pharmacist's relationship with employees or MCO members, who are the pharmacist's patients. As noted in the previous chapter, the PBM pharmacist is obligated to act in the best interest of the patient, but these actions must also be within the bounds of the relationship that the employer or MCO has articulated in its contract with the PBM. The patient-pharmacist relationship is a fiduciary one, and is assumed to be trusting and covenantal.[135] In addition, since most prescription benefit plans have coverage for families, the PBM pharmacist can also have a relationship with a family member. The employee or MCO member's relationship with the employer or the MCO is primarily a business relationship. The MCO may be present because the employer has turned over management of the full health benefit to the MCO, which has brought in the PBM specifically to manage the pharmacy benefit. Alternatively, the employer may have carved out the pharmacy portion from its total health benefit, and contracted directly with the PBM for pharmacy benefit management services. The employer often contracts with a PBM under specific requirements described in a negotiated benefit package, which is

[135] These conclusions are based on arguments presented in Chapter III.

the case with union benefit plans. The part of this diagram most relevant to the adverse interests present are the circles that encompass or intersect with the pharmacist, which create interesting constraints and challenges that are described more fully in this chapter.

What stands out in this diagram is the sheer complexity of the practice and management relationships in which the PBM pharmacist finds himself or herself. Comparisons can be drawn with the practice of medicine, which has seen an escalation in management controls stemming from the rise of managed care, and perhaps more generally through the commercialization of medicine. This is especially true in the areas of practice and utilization review, as well as third party payment and billing. The commercialization of pharmacy has driven similar changes. The traditional situation in which the community pharmacist purchased drugs directly from a manufacturer, and then resold them to a patient on a fee basis, has been replaced by a system in which purchasing is done on a mass scale, and reimbursement rates for drug products and services are often established by the PBM. An analogous situation has occurred in medicine in that the traditional fee-for-service model has been replaced by a primary care provider, or gatekeeper, system that pays physicians a capitated rate per patient. This diagram and these examples illustrate that the effort to earn a living through professional practice, which was once managed primarily by the pharmacist or physician, is now part of a larger business strategy, and that the individual decision making framework has largely been replaced by corporate management directives that operate within an organizational structure. Consider the following comment about the PBM industry made in 1994 by Roy Vagelos, then Chief Executive Officer of Merck:

> PBMs like Medco offer lower-priced drugs to plan sponsors by creating limited formularies, or lists of drugs that physicians are encouraged to prescribe based on therapeutic and cost factors. When medically appropriate, formularies favor less expensive drugs and encourage the substitution of generic pharmaceuticals for branded varieties. In classic terms of competition, we could see that the power of the buyers was growing: through their formularies, PBMs were changing the competitive dynamic of our marketplace by bringing together the person who chooses the drug and the person who pays for the drug. In the pharmaceutical industry, we have traditionally marketed our products by sending salespeople to doctor's offices to tell them about new drugs. It became clear to us that the emergence of managed care and PBMs like Medco, with their ability to intervene in the prescribing and dispensing process, was introducing a whole new dimension to pharmaceutical marketing.[136]

As medicine has become commercialized, traditional patient care interests have become pitted against corporate managed care interests to enhance profits through tight control and utilization of medical services.[137] In pharmacy, a similar situation has occurred with the potentially adverse interest being generated by the PBM's drive for profit, which is driven in part through clinical management programs and distribution control.[138] This interest is compounded when a pharmaceutical manufacturer is the owner of the PBM. Besides generating interests that potentially compromise the trust between the patient and the PBM pharmacist, the process of commercialization in pharmacy is also driving other changes. Charles Dougherty, in his article "The Costs of

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[136] Nichols (1994), p. 110.

[137] See Waymack (1990) and Levey (1985) for additional commentary on this point. Also, Hillman et al. (1989) undertook a research study to quantify the impact that financial incentives have on resource use. The medical literature is rich with articles on this subject.

[138] See Gibaldi (1995) and Schulman et al. (1996). Unlike the medical literature, the literature on pharmacy ethics has not addressed these issues extensively.

Commercial Medicine," described a number of the key effects that commercialization has had upon the profession of medicine.[139] With respect to relationships among providers, the traditional relationship was to treat each other as colleagues, and to share experiences and findings openly. However, in the corporate context information is considered proprietary; sharing can be viewed as disloyalty to the firm, and thus cooperation is limited.[140] It is interesting to note how accurately this describes the business relationships that exist between pharmacists who work for competing PBMs. Relations are friendly and cordial, but discourse about business is limited by the fact that program discussions quickly reach a proprietary level, and consequently cease. This is particularly evident at professional pharmacy meetings -- where public presentations on drug management programs remain at a rudimentary level year after year.

Robert Veatch has written about this phenomenon, specifically with regard to the use of outdated information.[141] He describes the different ways the physician and the businessperson handle a situation where they recognize that another person is using outdated information. The physician bears the moral obligation to enlighten a colleague,

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[139] See Dougherty (1990), pp. 276-77.

[140] The PBM marketplace is extremely competitive, and information about program design, development, and administration are considered proprietary because these elements can distinguish your programs and services in a competitive bid situation. Even though much of the information that makes up the program (e.g., clinical drug information) is public, how that information is used makes it proprietary. Consequently, discussions about drug management programs are very limited in the PBM setting, whereas clinical program innovations in a community or hospital setting might be widely shared.

[141] See Veatch (1983), pp. 145-46.

and perhaps even ensure that he or she bring the standard of care up to a competent level. There is nothing in business ethics, however, that motivates the competitor to educate the other person about his or her out-of-date information. In fact, this would probably be used as a competitive advantage. Although Veatch's point may be exaggerated, he describes an attitude regarding drug management programs that is prevalent in managed care pharmacy today. Clinical drug information is public and shared, but how that information is used by the PBM to enhance its business is not shared.

Dougherty, among others, also describes the "process of deprofessionalization," or the "profound change in the meaning of professionalism," that medicine is going through.[142] He notes that as more physicians become employees of margin driven corporations, control of the clinical setting shifts into the hands of managers and investors. This shift has diluted the tradition of placing the patient's interest first. Dougherty also points out that medicine's ability to rely on self-regulation is being lost in the process of change. As sociologist Eliot Friedson pointed out, "The only truly important and uniform criterion for distinguishing professions from other occupations is the fact of autonomy -- a position of legitimate control over work."[143] Dan Brock and Allen Buchanan have also discussed medicine's loss of professional dominance, which they suggest is being driven by two major factors -- the institutionalization of medicine and the increased pressure for cost containment in a more competitive environment.[144]

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[142] See Dougherty (1990), pp. 277-78.

[143] Agich (1987), p. 131.

[144] See Brock and Buchanan (1986), p. 239.

Dougherty's conclusion is that traditional lines of authority of medicine, which are horizontal and evolve from professional socialization, are being replaced by "commercial lines of authority that tend to be vertical and rely on administrative values of efficiency and standardization."[145] Although we can't assume that these changes in professional authority will lower the quality of the health care delivered to patients, which is a key insight provided by Brock and Buchanan, these changes clearly raise questions about conflicting interests. For the PBM pharmacist, administrative or corporate values are driven mainly by opportunities to improve corporate profits. As with medicine, we can't assume that quality will be lowered; however, we can begin to see why the conflicts of interest that the PBM pharmacist faces can occur, or can be intensified.[146]

An important reference point for this discussion is the nature of the *traditional* relationship between patient and pharmacist. The fundamental moral principles in the

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[145] Dougherty (1990), p. 278.

[146] Decreases in quality could be measured through cost, therapeutic, or humanistic outcome measures. When considering a cost evaluation, predicted endpoints may show a decrease in the rise of costs (or perhaps an increase in key therapeutic areas in which drug costs should increase as part of improved disease management, e.g. asthma). If these endpoints are not realized, it could be argued that the quality of the drug benefit has been lowered. The same holds for therapeutic (or clinical) outcomes, in which our target may be decreased use of the emergency room by individuals with severe asthma. This endpoint could be realized through changes in drug therapy that increase drug expenditures, but improve overall quality of the program (and probably decrease total health care costs). Alternatively, quality would be grossly lowered if PBMs were excluding drugs from their formulary that were shown to be safe and effective, and then were not providing physicians and patients with a clear opportunity to appeal a denial of coverage. In this case, the PBM (and its clinical staff) is morally at fault for failing to meet its fiduciary obligations.

Code of Ethics for Pharmacists are beneficence and respect for patient autonomy. In addition, the Code describes the virtues of caring, compassion, and honesty.[147] These principles and virtues serve as the backbone of the Code that has been adopted by community and hospital pharmacists, as well as managed care pharmacists. I have already discussed the key change in the patient-pharmacist relationship driven by the PBM pharmacist's need to focus on many patients rather than just one. Another essential difference between practicing pharmacy in a PBM and traditional patient care settings is the influence on decision making by factors distinct from the patient, physician, and pharmacist. Prior to managed care, decisions that a pharmacist might have made either with or for a patient would have been done in collaboration with the patient, or with the patient and his or her physician. An example might have been when a drug was too expensive for the patient to afford, and the pharmacist called the physician to suggest a less expensive alternative. Once effectiveness was verified by the physician, the alternative was typically accepted. The key is that decision making was not influenced or controlled by anyone outside of the patient, physician, or pharmacist. What this suggests is that the rise in managed care, including PBMs, has placed respect for autonomy at risk since decision making is moving away from the patient and his or her care giver. In preview, I will be suggesting guidelines that build upon the APhA Code of Ethics to help PBM pharmacists manage conflicts of interest.

[147] See Fink, (1994), p. 80. See Appendix III for the full text of the APhA Code of Ethics.

In managed care pharmacy, control over decision making (or at least influence over decision making) moves either to the PBM, the MCO, or the employer. The driver of this change in managed care has been the redistribution of financial risk. Where payment was once made by the patient, it has been transferred from the employer to the MCO, and in some cases risk is assumed at the physician level. In cases where financial risk is assumed by the MCO, control over treatment, including prescribing and dispensing, is influenced by the MCO. This has created conflicts of interest in medicine over access to care, access to specialists, selection of primary care provider, and incentives to overutilize and underutilize services. As PBMs begin to follow the model employed by MCOs, and begin to accept more financial risk, the possibility for conflict of interest grows. Recalling the previous discussion of integrity, it will become more and more difficult for the PBM pharmacist to maintain the consistent display of principled action with respect to self, and in relation to others, that characterizes the person of integrity.

In addition to displaying actions that lead to a retention of trust, there is also the issue of actions that do not merit continued trust. Just as financial pressures increase the potential for conflicts of interest, they also increase opportunities to complete actions that do not merit continued trust. If a client is informed of this action, the disclosure may or may not create enough good will to maintain the fiduciary relationship. However, if the client is not informed of the action, one cannot assume that trust would have been maintained. In fact, it is the case that the action did not merit a continuation of trust. Consequently, we can identify a category of actions that might result in losing trust,

assuming they were known by the patient, employer, or MCO. These actions could involve a PBM-driven mandate that the pharmacist knows is not in the patient's best interest. Assuming that the pharmacist allowed the mandate to impact their client, and he or she did not advocate for their client, then integrity was not only threatened, it was lost. An example might be the inclusion of an educational message in a clinical mailing to physicians that encourages the use of a drug that is therapeutically appropriate, maximizes the PBM's profit, but increases the out of pocket expenses for the patient. In this case, since the client and patient might never know about the mailing or its intended effect, the adverse interest would not be an obvious threat to trust. However, the pharmacist has done something that no longer merits trust. Recall that the relationship between integrity and trust was discussed in Chapter II.[148] This discussion pointed out that if integrity is lost, then the basis for trust is also lost. However, if integrity is lost, and the basis for trust is not lost because the precipitating action is not known, then the retained trust is undeserved. Continuing to act on this trust is perhaps a more flagrant moral wrong than what might result from the conflict of interest. Consequently, the role that integrity plays in managing conflicts of interest cannot be underestimated. I will return to the notion of integrity in Chapter V.

Let us now consider the potential conflicts of interest that the PBM pharmacist may face when administering typical clinical management programs. These programs

[148] This relationship was discussed on pages 53-54.

include case management, retrospective drug use review, physician intervention programs, and a formulary management program.

CASE MANAGEMENT

Case management programs are designed to manage the utilization of extremely high cost drug therapies on a per patient basis. For example, one year of therapy with the drug human growth hormone can cost a health plan $25,000 to $40,000. Another drug, immune globulin, can cost a plan anywhere from a few hundred dollars to nearly $100,000 per patient in a single year. Both of these drugs are commonly used in the outpatient health care setting in which the PBM operates, and both have well-documented patterns of use that are not considered to be "medically necessary." Medical necessity is characterized by one major PBM as those indications for use that have been approved by the Food and Drug Administration, as well as uses where safety and efficacy have been documented in the medical literature generally accepted by the professional medical community. When an employer or MCO decides that it does not want to extend benefit coverage to uses that are not considered medically necessary, it can ask the PBM to implement a case management program. The PBM pharmacist is then charged with the responsibility of reviewing individual cases and making certifications of medical necessity. These case reviews typically follow a protocol-driven review in which the outcome is either to certify or not certify medical necessity. Payment for the prescription is covered by the health plan for cases that are certified as medically necessary. Appeal

mechanisms for the patient and the physician are implemented for cases in which medical necessity is not certified.

I will outline two conflict of interest forms that could occur in a case management program. The first is a fee-for-service form that I will call Case Management - A. The second is a capitated form that I will call Case Management - B. The relationship that develops between the PBM pharmacist and the patient in a case management program most closely resembles the traditional patient-pharmacist relationship. This is because the PBM pharmacist usually learns something about the patient's medical history, often has discussions with the patient or his or her surrogate, and provides pharmaceutical care to the patient via quality checks in the case review process.[149] Since the patient-pharmacist-PBM relationship parallels the traditional patient-pharmacist relationship, it should not be surprising that one potentially adverse interest closely resembles interests associated with traditional conflicts in health care. I am specifically referring to the overutilization of services, and in the case of the PBM pharmacist the adverse interest can be driven by the PBM's desire to dispense a product because it is a revenue source. This is characteristic of Case Management - A. When PBMs don't move drug products, they

[149] An example of providing pharmaceutical care was a case review of a 16-year-old male who was receiving growth hormone for documented growth hormone deficiency, which is an appropriate indication for use, but was receiving twice the amount recommended by the Food and Drug Administration. When the physician was questioned about the high dose during the case review, he stated that the doubled dose was intended to maximize the outcome. This reason was not supported by any medical literature, and placed the patient at risk for side effects from excess growth hormone. Medical necessity was certified once the physician agreed to modify the dose to the appropriate amount. This case was also discussed in Chapter III, pages 74-75.

don't generate any revenue; therefore, the incentive for the PBM pharmacist is to facilitate the movement of products. PBMs do not accrue any significant revenue from a service fee associated with case management. This adverse interest, and the conflict it drives, is analogous to the conflict of interest in which the physician finds himself or herself in the fee-for-service system. Specifically, physicians have an incentive to overutilize services because their profits will be increased. The incentive to overutilize drug products can conflict with the patient's interest in several ways: first, it can lead to drug utilization where associated costs can outweigh the medical benefits; second, it could lead to higher financial costs for the patient than otherwise would have occurred; third, it could lead to higher health care costs for the entire plan, which might drive up co-payment costs for all plan members; and fourth, it can lead to unnecessary individual health risks.[150]

The alternative does exist that the PBM pharmacist could be provided with a financial incentive to not certify medical necessity, which characterizes Case Management - B. This incentive structure can occur with capitation. It requires attention because capitated arrangements are increasingly being created between managed care plans and PBMs. Under these arrangements the PBM is paid a fixed dollar amount per member per month for total drug expenditures. In this case, it is in the PBM's interest to

[150] "Costs" is meant to be understood broadly, unless specified as *financial costs*. In its broader context, costs can include treatment required for side effects, increased visits to the physician or hospital, increased use of laboratory testing, increased use of ancillary services (e.g., home care nursing), and humanistic factors such as impairment of quality of life.

limit utilization, because any dollars saved under the capitated rate become profit. Likewise, dollars spent above the capitated rate represent lost revenue.

There are examples of this incentive structure being used in the managed care industry in which patients' interests have been minimized, if not neglected. Recent examples come from the insurance industry's efforts to deny coverage for expensive bone marrow transplants. In one case, senior staff members had bonus incentives linked to the number of cases that were not certified. These kinds of incentives grossly conflict with patients' interest for appropriate care.[151] Although I am unaware of this kind of gross conflict occurring in managed pharmacy, focus on the potential problem should not cease. The upside of patient-specific management of expensive therapies is that substantial savings can be derived; however, the downside is that patient interests can be ignored. The line between the two is thin in the Case Management - B form, which is the source of my concern regarding the potential conflicts of interest.

RETROSPECTIVE DRUG USE REVIEW

Retrospective drug use review programs follow one of two approaches. First, the PBM can profile the entire health plan's membership on a regularly scheduled basis for the purpose of identifying and alerting the prescribing physician(s) about potential drug therapy problems. For the larger PBMs, this monthly process can result in more than 10,000 letters going to physicians. The types of drug therapy problems that are detected

[151] I consider these financial incentives gross because they reward the health care provider for behavior that contradicts (or at a minimum threatens) the basic duty of non-maleficence.

during the review process include drug-drug interactions, drug-disease interactions, overutilization of drug therapy, and underutilization (or noncompliance) of drug therapy. An example of a potential drug therapy problem detected upon retrospective review is the dispensing of a non-steroidal anti-inflammatory drug (e.g., ibuprofen) to a patient who is receiving chronic anti-ulcer treatment. The problem is that the ibuprofen may worsen the gastrointestinal disease that is being treated with the anti-ulcer drug. This problem is commonly seen when a patient sees multiple physicians, and does not provide all physicians with a complete drug history. Retrospective drug use review helps to solve these problems by informing the providers about the potential drug therapy problem.

The second approach the PBM can use is to screen the prescription drug claims history database for a specific therapy problem, and then alert physicians about potential problems on a patient-specific basis. For example, the PBM may decide to screen for overutilization of anti-ulcer drug therapy, which is a common problem since patients tend to stay on high dose anti-ulcer therapy for extended periods of time.[152] The clinical issue is not that patients are staying on these drugs for too long, but that they are being maintained at too high a dose. The result is an increased exposure to a drug without demonstrated benefit, and unnecessary costs for the health plan. Consequently, the PBM

[152] PBMs also screen for underutilization (or noncompliance) of drug therapy, and identify potential problems to physicians on a patient-specific basis. In these cases, utilization of drug therapy often increases (which drives up drug expenditures); however, value is added because total health care costs may decrease as a result of improved compliance with drug therapy. Value may be seen as a reduction in chronic disease complications, and an associated decrease in the utilization of health care services.

can help drive quality improvements into the pharmacy benefit, and typically derive cost savings through retrospective drug use review programs. The experience of one major PBM has shown that in sixty-five percent of cases, the education letter that was sent to the physician(s) resulted in a positive change. Positive change is measured by a decrease in dose, a change to a more appropriate drug, or a switch to a more cost-effective drug. Historical results demonstrate that these changes correlate to a two percent decrease in the health plan's total drug expenditure.

The adverse interest in retrospective drug use review programs is for the PBM to skew or ignore the data analysis such that education letters sent to physicians push an agenda that de-emphasizes improvements in quality of care. Specifically, the PBM could reduce the number of letters going to physicians by minimizing the use of information drawn from the data. By not informing providers about potential therapy problems, the PBM may help to maintain higher levels of drug utilization, which potentially improves profits. Alternatively, the PBM could selectively ignore data that show inappropriate utilization in high cost drug therapy categories, and again minimize changes so that revenues are not affected. If the PBM was operating in a capitated arrangement, it could adopt a full-court press approach, and send out every possible letter so that drug expenditures were reduced the greatest possible amount. The target here is to keep drug expenditures under the capitated amount. These adverse interests, and the conflicts they drive, parallel the overutilization and underutilization scenarios described in the case management description. The incentive to overutilize can conflict with the patient's interest in three ways: first, it can lead to potentially harmful drug therapy problems that

might worsen health and generate increases in total health care costs; second, costs to the patient are higher due to additional co-payments at the point of sale; third, overall costs to the health plan are increased; and fourth, unnecessary health risks could occur. The incentive to underutilize conflicts with the patient's interest to receive optimal care, particularly if the physician interrupts the patient's drug therapy as a result of an education letter. This is unlikely, but the potential exists. Although these programs are retrospective in nature, and the likelihood of driving substantial change is decreased by the fact that every identified problem has already occurred, the goal of the program is to drive future prescribing changes, and therefore future patients can be hurt. The other two programs discussed in this chapter are prospective in nature, and therefore present the opportunity to create large-scale change.

Case management and retrospective drug use review programs may contribute to shifting the attention of the PBM pharmacist away from the patient's interests. The adverse interests, which can lead to enhanced revenue for the PBM, are clearly measurable. Even though case management is only applicable to a small percentage of the population, and the impact of retrospective drug use review is limited by the very nature of the program, shifts in the PBM pharmacists' patient-focused behavior can adversely affect the trust that underlies the patient-pharmacist-PBM relationship. Brock and Buchanan's framework can be applied to the patient-pharmacist-PBM relationship to assess this impact.[153] The first question to ask is has the pharmacist's behavior actually

[153] See Brock and Buchanan (1986), p. 245.

been affected by the adverse interest? Second, even if outward behavior does not change, is there a change in the motivation, and perhaps a change in others' perceptions of those motivations, that may be important? If the PBM pharmacist is perceived to be acting in the PBM's interest to the exclusion of the patient -- even if no adverse interests were acted upon -- it is reasonable to expect an erosion in the level of belief that the PBM pharmacist would act in the patient's best interest.

The value of this framework is that it allows us to understand how the adverse interest generated by the PBM's drive for profit, whether or not it is acted upon by the PBM pharmacist, represents a threat to the trust that the patient (and the employer or MCO) places in the pharmacist. In analyzing conflicts of interest, it is not enough to simply measure actual changes in behavior. We must also be cognizant of the perceptions of those who place trust in the PBM pharmacist. This is because it is generally wrong to knowingly enter or knowingly fail to avoid a conflict of interest, and it is generally wrong to give the appearance of a conflict of interest. Recall Davis's point that giving the appearance of a conflict of interest leads to unnecessary effort; and Leubke's point that giving the appearance leads to distrust. Trust is important because it binds and makes possible the fiduciary aspect of the patient-pharmacist-PBM relationship, and it is morally at stake in conflicts of interest. Therefore, conflicts of interest demand attention whether actual or potential.

PHYSICIAN INTERVENTION PROGRAMS

Like retrospective drug use review, physician intervention programs operate using various methods; but unlike the retrospective programs, they are conducted prospectively, using information to create change before a prescription is dispensed. The methods employed can either be educational in focus, or can involve direct intervention. In the education program format, the PBM aggregates prescription claims data and identifies prescribing patterns that lie outside the norm. For example, analysis of twelve months of data may show that a certain physician is prescribing a very costly antibiotic for ninety-five percent of his or her patients with a given diagnosis, while the other network physicians are using this drug only forty-five percent of the time. In this case, the PBM will contact the prescribing physician and attempt to modify prescribing behavior through clinical education, so that the most expensive antibiotic is prescribed appropriately in future cases.[154] This type of prescribing behavior is commonly seen in the outpatient setting where a pharmaceutical manufacturer's representative has influenced the physician's prescribing behavior by detailing the physician about his or her company's drug.[155] The PBM's activity is often called "counter-detailing," or "academic detailing,"

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[154] It may be the case that the physician's use of the expensive drug is completely appropriate. In the example noted above, pediatricians will frequently require expensive antibiotics for a large percentage of their patients because of antibiotic resistance. Specialists, however, are not typically the target of the education intervention. Rather, the PBM focuses on general practitioners, who write prescriptions across many therapeutic drug categories because of the nature of their practices.

[155] "Detailing" is accomplished by the pharmaceutical manufacturer's sales representative and involves selling the physician on the particular advantages of their employer's product. These

since the purpose of the educational session is to provide the physician with objective information about the appropriate uses and cost of a drug. It is important to point out that physician education programs also highlight therapy alternatives that can drive up short- and long-term drug expenditures. An example of a short term increase is the treatment of ulcers, and one major PBM's recommendation to physicians that a curative approach be taken as an alternative to the treatment of symptoms. The curative approach, which uses a combination of drugs to eradicate a strain of bacteria known to cause ulcers, is more expensive in the short term, but may lead to an overall reduction in medical and pharmacy expenditures, if the ulcer is cured. The approach is a relatively new treatment alternative, and applies to a large number of patients with ulcers. An example of a long term increase is with the treatment of asthma, and the PBMs effort to enhance prescribing compliance with generally accepted best practice standards. If these practices are accepted, utilization of asthma medications will increase, drug costs to the plan will increase, but total medical costs should decrease over time.

In the direct intervention format of physician intervention programs, the PBM uses its control of the distribution channels to make changes to a current prescription prior to dispensing. The distribution channels through which a prescription can pass include the retail and mail settings. In the retail setting, the PBM maintains limited control over the prescription being dispensed, as it is responsible for paying the prescription claim at the point of sale. Consequently, the prescription is subject to a

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advantages may be clinical or economic. The sales message is developed by the manufacturer with the intended purpose of increasing their product's market share.

series of on-line clinical review edits that provide the PBM with an opportunity to change the prescription to a less expensive generic alternative, or a chemically equivalent brand name drug.[156] This activity can either be accomplished by placing payment of the prescription drug claim on hold while a PBM pharmacist attempts to make a change to the prescription, or the PBM may directly contract with the retail network pharmacies to make a change. In the mail setting, the PBM has complete control over the dispensing process, and therefore can recommend changes with a much higher success rate. This is because the PBM pharmacist practicing in the mail setting has additional time to call physicians and discuss possible changes to the prescription.[157] This activity should not be construed as practicing medicine since pharmacists cannot make switches without the physician's authorization.

The potentially adverse interest stems from the PBM's interest in generating profit. Since both intervention formats have the potential to create large-scale change, the adverse interest is enhanced when the PBM is owned by a pharmaceutical manufacturer. The incentive for the PBM pharmacist is not limited to increasing overall utilization, but also to drive utilization of specific drugs that may additionally enhance profits.

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[156] "On-line clinical review edits" occur during the process of prescription claim payment. This process occurs electronically, and is facilitated by the PBM. While program eligibility is being verified, and prescription costs are being calculated, the prescription is also reviewed for possible drug interactions and for switch opportunities. The computer system will prompt the pharmacist with a message indicating that a formulary or generic drug may be available as an alternative. This on-line review occurs in a matter of seconds.

[157] Studies show that physicians agree to requests that a patient be switched to a similar drug 80 percent of the time. See Kolata (1994).

Specifically, if the PBM is owned by a pharmaceutical manufacturer, then it may be in the financial interest of the PBM pharmacist to move the drugs that are produced by his or her employer. The PBM may also have a rebate arrangement with a manufacturer that drives additional revenue for helping to move market share. These incentives to move specific, or preferred, drugs can conflict with the patient's interest and, to a remarkable degree, with the employer's or MCO's interests. The incentive can conflict with the patient's interest by leading to higher financial costs for the patient resulting from higher co-payments, and possibly to a decrease in health status and higher drug therapy costs for the entire health plan.[158] This is particularly true when one considers what the actions of an independently-owned PBM might be in a switch opportunity, as opposed to what a pharmaceutical manufacturer-owned PBM might do in a similar situation. When performing switches, the latter might consider the customer who has contracted with the PBM as a means to an end. Specifically, the employees or members could be viewed simply as switch opportunities for the PBM to increase profits. The interest in these programs can be measured in the form of revenue dollars, as well as enhancements in market share. The following diagram helps to make this point:

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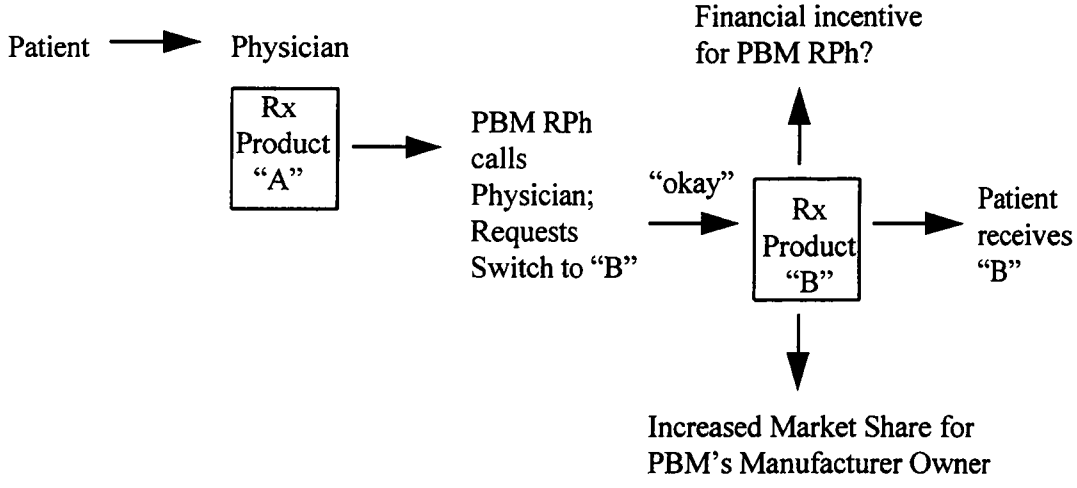
[158] It is important to note that the PBM's ability to switch to a less costly drug is a substantial source of savings for the patient and the plan, which is a process that is medically appropriate in many cases. PBMs can recommend switches from a brand product to its generic version, and from one brand product to another brand product. These switches may be to a chemically equivalent product that is made by another manufacturer, but can also be chemically distinct products within the same therapeutic class. In cases where switches of this kind are recommended, clinical efficacy is of first consideration, but cost savings are always an underlying factor.



As noted in Chapter I, the three major PBMs were purchased by pharmaceutical manufacturers in 1993 and 1994 for a collective sum of over $12 billion. The purpose of these acquisitions was simply to move market share. Roy Vagelos, in responding to a question about why Merck bought Medco, answered, "We saw a tremendous opportunity to create a new model for the pharmaceutical industry that would simultaneously improve the quality of health care, help contain costs, and increase Merck's market share."[159] Since 1994, Merck has been very successful at moving market share, and in the second quarter of 1996 posted a thirteen percent increase in profits to $972.1 million.[160] In the same article Merck credited its Merck-Medco Managed Care business with bolstering its sales gains. J.P. Morgan medical analyst Carl Seiden, commenting on Merck in a recent Wall Street Journal article estimates "...that Merck sells $375 million in drugs through Medco that it wouldn't have otherwise been able to sell," and that the "...$350 million in

[159] Nichols (1994), p. 106.

[160] See Kumar Naj (1996).

annual pretax profit [is] enough to more than cover an estimated $160 million in annual interest costs related to the Medco purchase."[161] This demonstrates how the PBM's control of the distribution process can maximize profits for the pharmaceutical manufacturer who owns it, and maximize the conflicts of interest for the hundreds of PBM pharmacists who manage patient drug therapy within the mail service pharmacy. To recall the modification of Leubke's argument regarding the risk assessment that can result when we have an objectively measurable interest creating a moral category conflict of interest, it seems possible that the $160 million annual interest charge that must be paid by Merck, the owner of Medco, to its lender creates a moral category conflict of interest -- a conflict created by the firm's need to make this substantial payment. Consequently, with such a large sum of money hanging in the balance, it appears that the potential risk to Medco's customers, and the patients that Medco pharmacists serve, is extremely high.

To fully appreciate the scope and reality of this problem, consider the following information about Medco, which is the most experienced mail service pharmacy PBM. In July 1996 its parent company, Merck, agreed to adopt new guidelines in New Jersey that govern its marketing practices and to contribute $50,000 toward consumer education. This agreement, which was reached with the State's Department of Consumer Affairs, requires Medco employees to make certain disclosures when contacting doctors to discuss changing a prescription from one brand to another. This action followed Merck's

[161] Burton (1997), p. A6.

recent agreement to pay nearly $2 million to seventeen states to reimburse a year-long investigation into charges that Medco violated consumer laws by promoting Merck drugs over competitive products.[162] Recalling the framework suggested by Brock and Buchanan, the actions described in the above agreements were often performed by pharmacists, and appear to represent cases where pharmacists' behavior was actually affected by adverse interests.

FORMULARY MANAGEMENT

A formulary is a preferred list of drugs that the health plan has approved for its employees or MCO members. Formularies are administered by the PBM in either an open or closed manner. In an open (or voluntary) formulary, the employee or MCO member is encouraged to use formulary drugs, and the physician and pharmacist are encouraged to prescribe and dispense formulary drugs. There is no financial penalty if a formulary drug is not provided to the employee or MCO member. In a closed (or restricted) formulary, the member will pay more for a non-formulary drug than he or she would for a formulary drug. This cost is usually seen as a higher co-payment, although some health plans will not pay for drugs that are not on the formulary. In these cases, the employee or member must pay the full amount for the prescription.

I noted in the first chapter that the integrity of the PBM's formulary management program is at risk for compromise. This is particularly true of the development and

[162] See Silverman (1996). See Kolata (1994) for additional commentary on this subject.

management of the formulary because the revenue and profit derived from the formulary program is so significant. With respect to development, the formulary document is typically developed by PBM pharmacists, often in conjunction with external experts. If the document is developed appropriately, then it should reflect the most cost effective and clinically appropriate drugs available within a therapeutic class. One of the risk points for potential conflicts of interest within the formulary program is when the PBM pharmacist participates in a process that skews this development toward increasing corporate profits, and then tries to articulate to the customer that the products on the formulary list have been evaluated solely on cost and clinical parameters. Consequently, the split between word and deed has occurred, and the pharmacist has destroyed the wholeness of character that typifies a person of integrity. Management of the formulary follows a process much like the physician intervention programs described above, and the resulting adverse interests and conflicts of interest are similar. I will describe these in a moment.

A key question to ask is whether a pharmacist who works for PBM owned by a pharmaceutical manufacturer should be precluded from being the patient's fiduciary? In the development phase of the formulary, if the drug list is developed with an exclusive reliance on internal assessment, then the answer would be yes. Pharmacists who work for a manufacturer-owned PBM should be precluded from the fiduciary role because it would be nearly impossible for them to convince their patients that their decision making process was unbiased. In this case giving the appearance of a conflict would be wrong. However, if the PBM utilizes external physicians and pharmacists to drive the

development process, and the PBM applies their assessment of what drugs to place on the formulary, then the PBM pharmacist's role as fiduciary can be preserved. This would be true only if disclosure and consent from the client were secured.

A limited reliance on internal assessment is viable in the second scenario since decision making was done jointly with external experts. As the reliance on the external experts increases, the risk of harm decreases. For example, if the external experts had final authority over all formulary product selection decisions, then the risk of harm would be minimized, if not eliminated. Guidelines for managing the potential conflict of interest around product selection might include this provision. In addition, these guidelines might suggest that minutes of the product selection meetings be kept, and that these minutes be distributed to current and prospective clients to assure that the opinions of the external experts were incorporated into formulary selection decisions.

With respect to formulary management, it becomes harder to make the case that disclosure and consent eliminate the conflict of interest, since the PBM pharmacist is responsible for managing the educational and direct interventions that target physicians who are not prescribing the preferred formulary drug. If the clinical appropriateness of each formulary drug switch could be demonstrated, then a case could possibly be made that the fiduciary relationship stayed intact. This would be a difficult outcome to demonstrate.

When a pharmaceutical manufacturer has contracted with a PBM to provide a rebate for increasing the market share of its product, or when it owns the PBM so that movement to the parent's brand drug is recognized as direct revenue, then the PBM has

an interest to establish and manage a formulary that facilitates this movement. If the PBM creates a set of incentives or disincentives to motivate their pharmacists to facilitate this movement, an actual conflict of interest situation is created. This is because the incentives may be adverse to the patient's interest since the primary criteria for drug product selection is revenue potential, and safety and clinical efficacy are considered secondary. The PBM pharmacist's interest conflicts with the patient's interest in the following ways. First, if the patient had been receiving drug therapy, and was then required to switch to a different drug because it was the only formulary choice, then the unknown effects of the new drug may place the patient at risk. Second, the patient and the plan may incur additional expense if the formulary has been developed such that the owner's drugs are the preferred products. Third, the patient and the plan may be simply used as a means to an end. More specifically, PBMs may provide the owner's drug product at such a low price that employers or MCOs cannot refuse the arrangement for their employees or members, so the pharmaceutical manufacturers are able to show Wall Street a higher market share, and the investment community creates better returns for the corporate shareholders through increases in stock purchases. In this case, the employer or MCO has gotten a bargain, but at what price and cost?

With respect to formulary development and management, if the PBM's financial interest carries any weight in formulary decisions, an actual conflict of interest is created. In an effort to minimize this influence, PBM pharmacists attempt to keep financial issues out of the clinical discussions regarding efficacy and safety. Ideally, financial considerations are brought into the discussion last, and only have bearing if all other

clinical considerations are equal. The point I am attempting to make is that the ideal situation is compounded by multiple financial considerations, which occur regardless of the ownership status of the PBM.

To validate my concerns, consider that in January 1993, of the eight Merck products that totaled ninety percent of all Merck's brand name product sales to Medco enrollees, only one was on the Medco formulary. In May 1993, Medco announced an agreement with Merck to add the existing seven products to its formulary. Two months later Merck and Medco reached a decision to merge and six months later they closed the merger. Between 1994 and 1995 four of the eight products listed on the formulary faced less competition because non-Merck products were eliminated from the formulary.[163] The results of the Medco formulary management program for Merck drugs between 1993 and 1996 show that in 1993 the total market share of Merck products sold through Medco was ten percent, and by 1996 this percent had grown to fifteen.[164] We cannot conclude that these changes to the Medco formulary mean that the patients' interest have been neglected in pursuit of profit for Merck; however, they do raise questions about the interests that are at play.[165] They also partially indicate why the FTC has decided to continue its oversight of PBM-pharmaceutical manufacturer integration. In fact, as of

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[163] See GAO (1995), p. 14-17.

[164] See Burton (1997), p. A3.

[165] In addition to continued oversight by the FTC, the Government Accounting Office has established an ongoing investigation of Medco and PCS related to the work they are doing for the Federal Employees Health Plan. Other regulatory agencies with an interest in this potential problem include HCFA, the FDA, and a number of state level Attornies General.

June 17, 1996, Senator Ron Wyden asked the FTC to maintain its review of the manufacturer-owned PBM formularies.[166]

Conflicts of interest do occur for the PBM pharmacist. These conflicts occur when PBM policies or procedures create an interest that is adverse, or likely to become adverse, to the clinical decision making process that PBM pharmacists undertake on behalf of their patients. This adverse interest can manifest itself either in an overutilization or underutilization scenario, as well as via preference for a certain product. This interest is objective in the sense that it can be measured in revenue dollars or market share improvements; consequently, we can identify the conflict and assess its risk to the fiduciary relationship. There are a number of possible results from these conflicts: first, the patient's health and finances can be adversely affected; second, the health plan's finances can be adversely affected; and third, the trust placed in the PBM pharmacist, and consequently the entire patient-pharmacist-PBM relationship, is placed at risk. Resolving these conflicts is the subject of Chapter V.

[166] See Anonymous (1996), p. T&G-6.

CHAPTER V

Strategies for Managing Conflicts of Interest

> Nothing more exposes a physician's true ethics than the way he or she balances his or her own interests against those of the patient.
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> Edmund D. Pellegrino, 1987

The PBM pharmacist who is prepared to take a serious look at his or her practice setting will find himself or herself torn between the traditional commitment to the patient's welfare and his or her obligations as employee of a for-profit corporation. Any pharmacist who works for a PBM cannot avoid these conflicts of interest in every case, since he or she is paid to bring clinical knowledge to a discussion that is focused on balancing quality and cost concerns.[167] The challenge in balancing these concerns is made greater by financial incentives to underutilize or overutilize drug products, or perhaps steer prescribing or dispensing toward a preferred drug. Simply by practicing in a managed care setting, the PBM pharmacist must wrestle with the tension that exists between maintaining quality and managing costs. This is because one of the PBM's primary business objectives is to control rising costs. Consequently, the PBM pharmacist enters his or her practice environment already involved in a conflict of interest; since the

[167] It should be noted that this discussion is not imposed on patients totally by managed care companies, including PBMs. Public concern over the cost of public and private health care is the source of an ongoing debate. This includes a focus on maintaining the balance between containing costs and delivering quality care.

pharmacist (as fiduciary and PBM employee) has an interest (i.e., the PBM's drive for profit) that is adverse, or likely to become adverse, to the reason for which reliance was placed (i.e., delivering and maintaining quality pharmaceutical care).

Recall Leubke's conclusion that it is not wrong to have, be in, or find oneself in a conflict of interest; however, it is wrong to knowingly enter or knowingly fail to avoid one. This action is wrong because it betrays trust in particular cases and contributes to a general level of distrust. Leubke also recognizes that conflicts of interest are at times unavoidable, and when placed in these situations, we must manage the conflicts by minimizing the threat to the fiduciary relationship through disclosure and consent. The conflicts of interest that are created by PBMs are unavoidable for pharmacists. This is because the conflicts created by the PBM result from the shift to managed care, and are identical in many ways to the conflicts created for any contemporary health care practitioner. In general terms, these are the conflicts to underutilize services, and they can be contrasted with the era of indemnity care that was marked by conflicts to overutilize services. If pharmacy benefit programs are not managed through PBMs, then some other organization will be created to manage prescription drugs. To argue that PBMs should be abandoned misses the larger point that managed pharmacy is here to stay. Just as managed care has replaced indemnity care with its unavoidable conflicts of interest, managed pharmacy has replaced fee-for-service pharmacy with its unavoidable conflicts. To reject managed pharmacy, which in its current form means PBMs, is to show preference for the fee-for-service model which is morally unacceptable because it

shows little concern for the cost-quality balance that is essential to managing the health care budget in the 1990's and beyond.

In either case, health care practitioners have always faced conflicts of interest. In the traditional fee-for-service model, conflicts were generated by the incentive to overutilize services. In the managed care model, the common concern is that services will be underutilized in an effort to save money. In either model, there is always a potential conflict, and in some cases these have become actual conflicts and patient interests have suffered. Consequently, the PBM pharmacist must become aware of the potential conflicts of interest inherent in his or her practice setting, and learn how to act when he or she is involved in one. The profession of pharmacy in general must also become aware of these conflicts, realize that the trust between the patient and the pharmacist is at stake in this practice setting, and adopt strategies to help protect the integrity of the patient-pharmacist relationship. PBM pharmacists will have the opportunity to maintain the trust placed in them by patients and the PBM's customers only when a framework for accomplishing this task is developed and used consistently.

A review of the literature highlights a variety of strategies for managing conflicts of interest. These range from a reliance on personal integrity or a code of ethics to legislative and regulatory controls. Over the next few pages I will review these strategies, and then offer my own. Haavi Morreim, in a general discussion of health care corporations, suggested that prospective employees research the incentive structures of the institution they are considering joining, and refuse to accept an offer of employment if

the institution links financial consequences and individual patient care decisions.[168] This kind of personal commitment to the patient's welfare can support actions that are described in a profession's code of ethics, which is another strategy described in the literature. The American Medical Association reaffirmed the physician's role of patient advocate in the managed care setting, and outlined guidelines for managed care physicians to follow.[169] Developing this kind of standard, which was put forth by the AMA Council on Ethical and Judicial Affairs, is similar to the conclusion drawn by Ronald Green. In writing about the conflicts of interest faced by physicians who act as entrepreneurs, Green concludes that "Codes should include a provision forbidding physicians from holding substantial investments in services or facilities to which they refer patients."[170] The pharmaceutical analogue to this would be forbidding PBM pharmacists who play a role in formulary product selection or intervention program management from holding stock in a pharmaceutical company whose product use they may be recommending or discouraging.

Efforts to encourage ethically appropriate behavior through a code of ethics have also been seen in pharmacy. The American Pharmaceutical Association released its Guidelines for Acceptable Medication Incentive Programs in May 1995.[171] These

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[168] See Morreim (1995), p. 463.

[169] See Council on Ethical and Judicial Affairs, American Medical Association (1995), pp. 334-35. Also see Anonymous (1994). See Appendix I for the full text of the AMA Guidelines.

[170] Green (1990), p. 296.

[171] See American Pharmaceutical Association (1995). Also see Anonymous (1995), p. 26. See Appendix II for the full text of the APhA Guidelines.

guidelines were developed to help pharmacists determine the ethical appropriateness of medication incentive programs. Incentive programs, which are sponsored by pharmaceutical manufacturers, PBMs, or other third party administrators, use a variety of methods to encourage the use of one drug over another. The Guidelines stress that the patient's health and safety should be of primary concern, and that incentive programs must not compromise the availability of a pharmacist to provide pharmaceutical care. In addition, the Guidelines highlight the need for disclosure and consent, that confidential information must be protected, and that fair remuneration to pharmacists for providing pharmaceutical care is appropriate.

I believe that a significant level of integrity, displayed individually and collectively by a profession, is the cornerstone of a management strategy designed to handle conflicts of interest. This is because the loss of integrity, which threatens the trusting fiduciary relationship, is the key moral concern in analyzing conflicts of interest. Recalling May, integrity would tell the pharmacist not to give in to the pressure to make decisions that sacrifice the patient's best interest for corporate interests.[172] Furthermore, it tells the pharmacist to maintain the connection between word and deed, which Benjamin and Curtis describe as the "principled continuity of conduct" and Mitchell described as "pureness."[173, 174] These aspects of personal integrity are captured by the evaluative process that Morreim suggests for prospective employees of a health care

[172] See May (1980), pp. 408-10. May was discussed in Chapter I, page 12.

[173] Benjamin and Curtis (1986), p. 17.

[174] See Mitchell (1982), pp. 64-71.

corporation. Besides cultivating integrity among professionals and the profession, tolerance of behaviors that do not merit trust should be frowned upon. This is because trust is essential to the fiduciary relationship between patient and pharmacist.

But even though reliance upon personal integrity or a code of ethics is necessary for managing conflicts of interest, it is not sufficient for handling them effectively. As Mark Rodwin points out, "In medicine, as in government, business, and law, evidences of abuses and the inadequacy of self-regulation justifies public intervention."[175] Rodwin argues for public policy as a method to eliminate financial conflicts of interest in medicine. I will describe his argument shortly; however, there are other possibilities, including disclosure and other forms of legislation, which I will discuss before returning to Rodwin's position.

Charles Dougherty suggests that physicians be "insulated against the pressures of cost cutting [even though this might] entail limiting the range of their professional choices."[176] Physicians' choices would be limited in some cases by moving these decisions from the individual to the administrative level. He reconciles the limiting of choices by viewing it as the lesser of two evils. Dougherty suggested this approach as a way to keep physicians from inappropriately coding with diagnostic related codes, which is a practice known as "DRG Creep."[177] Inappropriate coding can lead to higher reimbursement for a lesser level of service. With this approach he theorized that

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[175] Rodwin (1993), p. 245.

[176] Dougherty (1989), p. 10.

[177] See Dougherty (1989), p. 8.

physicians could retain their traditional role as patient advocates while operating within the institutional constraints. Dougherty's suggestion might eliminate some of the concerns relating to bedside rationing decisions, because it would move allocation decisions to a higher policy making level. This is particularly true for primary care providers acting as gate keepers in a managed care setting. This idea that the physician separate himself or herself from certain aspects of the decision making process in which the conflict resides has been advocated by others.

Ezekiel Emanuel and Daniel Steiner wrote on conflicts of interest that occur in the institutional setting, particularly as they apply to medical research.[178] They tried to argue that a combination of disclosure and internal and external monitoring provided a safeguard against the harms that could result from institutional conflicts of interest. They concluded that "Such an external monitoring committee, whose purpose would be analogous to that of peer review of articles submitted for publication and grant applications, would seem to provide the best safeguard [against the potential harm due to institutional conflict of interest.]"[179, 180]

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[178] See Emanuel and Steiner (1995), pp. 265-67.

[179] Emanuel and Steiner (1995), p. 266.

[180] In a related discussion, debate regarding the role that pharmaceutical manufacturers should play in marketing and information exchange in light of the growth of managed care is ongoing at the FDA. The FDA is asking whether it should have oversight of information that is delivered through manufacturer owned managed care divisions, which would include PBMs. Alan Hillman, director of the center for health policy at the University of Pennsylvania, suggested that the FDA create an advisory panel that would draw up guidelines regarding the dissemination of

Katherine Swartz and Troyen Brennan propose the use of oversight committees for integrated delivery systems as a way to protect patient welfare and not retard the growth of managed care.[181] These committees would be one of a number of strategies designed to meet this goal. These include broadened oversight of managed care by states, public disclosure, regulation of capitation through controls managed by each state insurance commissioner, and avoidance of radical reform. Swartz and Brennan conclude with a theme that echoes the words of Rodwin:

> We do not believe that professional ethics alone can cure the moral conflicts that threaten quality of care in an integrated health care market. Judicious use of regulation that blunts some of the incentives in capitated financing; that gives consumers information; and that allows physician, nurse, and patient oversight of care protocols is appropriate. The need to develop these regulatory mechanisms is urgent, because the integration of health care is proceeding quickly, and the good of the patient is not always the central concern in today's health care market.[182]

A number of the authors also call for disclosure, which was one of the solutions that Leubke defended, as part of the solution for managing unavoidable conflicts of interest. Disclosure of a conflict of interest is probably the most commonly discussed resolution strategy for conflicts.[183] The American Medical Association developed

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this information. What is relevant is that this is another suggestion to create an external body to help manage potential conflicts of interest. See Anonymous (1995a), p. 7.

[181] See Swartz and Brennan (1996), pp. 446-47.

[182] Swartz and Brennan (1996), p. 447. Any capitated arrangement incentive creates the possibility of a conflict of interest. However, studies of MCOs utilizing different financial incentives have not shown deficiencies in quality. Caution should be used in interpreting the results because the study of quality has been rudimentary. Swartz and Brennan (1996), p. 444.

[183] See Thompson (1993), p. 576.

conflict of interest guidelines in 1986 that encouraged physicians to disclose investments in facilities to which thay are making referrals. Douglas Levinson, in writing about the financial incentives and disincentives affecting physicians practicing in HMOs, argued in 1987 for clear disclosure of these incentives to potential subscribers.[184] He contends that consumer rights to choose health plans should fuel formal disclosure practices by HMOs. In 1994, Bernard Hirsh argued that federal guidelines to protect Medicare beneficiaries from being under served by HMOs should be written into the health care reform legislation that was pending at the time. He wrote, "The AMA's policies regarding disclosure of financial incentives and disincentives to prospective enrollees should be included as statutory requirements in any legislation that may be enacted to reform the health care system."[185] The guidelines released on medication incentive programs in 1995 by the American Pharmaceutical Association also put a disclosure requirement in place.[186]

Disclosure between provider and patient is intended to promote open communication and facilitate a trusting relationship. However, evidence suggests that full disclosure does not occur frequently in the area of medical informed consent, and that what is accomplished does not meet the expectations described in the law.[187] Rodwin argues that disclosure is problematic because it alone is insufficient to protect patients.

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[184] See Levinson (1987), p. 1729.

[185] Hirsh (1994), p. 12.

[186] See American Pharmaceutical Association (1995). See Appendix II for the full text of the APhA Guidelines.

[187] See Rodwin (1989), p. 1405.

He views disclosure as part of the solution to the problems associated with conflict of interest, but believes that an external organization of some sort must be available to assess the disclosed information and provide independent advice. Dennis Thompson sees the limits of disclosure extending from the fact that information may be hard to interpret, and that patient anxiety may increase in the absence of alternatives. This might lead to a general suspicion of the physician, and may destroy the patient's trust in the physician. As Thompson points out, "Disclosing a conflict only reveals a problem, without providing any guidance for resolving it."[188] I agree with Thompson on this point, and pointed out Leubke's shortfalling on this issue in Chapter II. A similar conclusion was reached by Robert Veatch in his discussion of the "double agent problem," in which the professional is simultaneously an agent for the organization and for an individual client.[189] He concludes, "It is unlikely, however, that full disclosure alone will solve the double agent problem. As the practice of medicine in a for profit enterprise evolves, a study of additional safeguards and guidelines to minimize conflict of interest must be developed."[190, 191]

Another strategy for managing conflicts of interest focuses on more formal regulations. Bernard Hirsh points out that physicians have been successfully sued in malpractice litigation for failing to provide medically necessary care to patients denied

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[188] Thompson (1993), p. 575.

[189] See Veatch (1983), pp. 143-44.

[190] Veatch (1983), p. 144.

[191] For additional background on disclosure, see Anonymous (1994).

coverage by HMOs. Hirsh speculates that as managed care grows, and efforts to conserve health care resources increase, the use of financial incentives could result in a decline in the quality of care delivered and a rise in malpractice litigation unless resource conservation is controlled by law.[192] Morreim has suggested that the legal doctrine "bad faith breach of contract" could serve as a basis on which "patients and payers could hold physicians liable for abusive self-referral."[193] The doctrine recognizes that although every contract has a covenant of good faith, some contracts require more. In contracts where there is not an equal bargaining position, special penalties may occur for failure to act in good faith. Although no court has laid out the criteria for bad faith suits, the common elements include the following: (1) one of the parties is in a superior bargaining position; (2) the purpose of the weaker party in entering the agreement is to protect himself or herself, as by gaining financial security or peace of mind; (3) the weaker party reasonably places trust and confidence in the stronger party, thus creating a relationship of fiduciary or quasi-fiduciary character; and (4) the stronger party acts to deprive the weaker party of the benefits of the bargain. The doctrine of bad faith has been successfully applied in the insurance industry in cases where benefits were inappropriately and deliberately deprived; however, it has not been applied to medicine and the obligations of physicians. Although placement of this prohibition might be a sufficient moral safeguard, other moral safeguards are still necessary to protect the patient in his or her dealings with the PBM pharmacist. These safeguards are rooted in the

[192] See Hirsh (1994), p. 14.

[193] Morreim (1990), pp. 438-40.

covenantal obligations between patient and pharmacist, and stem from the gift of trust given by the patient.

On the legislative front, the California Nurses Association, in alliance with health consumer groups and labor unions, placed an initiative on the November 1996 ballot entitled the Patient Protection Act.[194] Although this initiative did not pass, it would have forbidden managed care companies from ordering their doctors, nurses, and other health care professionals to withhold from patients cost information relevant to their health care. The action described above is part of a general movement against "gag clauses" put in place by managed care organizations. The American Medical Association has spoken out against them. Several states have passed laws against them, and federal legislation to ban these clauses has been introduced. This kind of legislative action is also occurring in pharmacy. At present, the National Association of Chain Drug Stores is asking the FTC to reopen its approval of the Lilly-PCS merger and strengthen the consent decree to require disclosure of all financial incentives to all physicians involved in brand switches by PCS for the use of Lilly drugs, and to eliminate all financial incentives to PCS and its employees to use Lilly products in PCS formularies.[195] Other modifications sought included the development of an oversight body to monitor the formulary decision making process, development of new criteria for formulary product selection, and measures relating to generic drug product selection and drug pricing. In another example of a policy approach, Marcia Angell has suggested that the effort to maintain patient

[194] See Hentoff (1996), p. A21.

[195] See Zolkos (1996).

commitment at a time when a more efficient health care system is needed requires a national health care system.[196] This system would be designed with a global cap on spending and a single payer.

While state regulation of managed care is generally intended to put protections in place for patients by providing them with information and ensuring the fiscal integrity of managed care organizations, there is wide variance in the approaches that states have taken.[197] Maryland has enacted legislation that encourages MCOs to provide high quality care by requiring them to provide the following services: (1) 24-hour access to a physician, (2) physician evaluation of all medical problems, (3) the opportunity for clients to select a primary care provider, and (4) the provision of preventive health services. California has taken this approach to another level by requiring on-site surveys to evaluate performance. Texas has taken a tougher approach with MCOs, and has enacted any-willing-provider legislation to ensure access into managed care networks for health care providers. Twenty-seven other states have enacted similar legislation.

Kevin Shulman et al. recommend that policies be put in place to monitor the quality of pharmaceutical benefits managers, which will provide a positive incentive for PBMs to improve their services.[198] The authors recognize that the PBM has the potential to improve patient outcomes, but they also realize that there are multiple points in the

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[196] See Angell (1993), p. 286.

[197] See Swartz and Brennan (1996), pp. 444-45.

[198] See Schulman (1996), p. 912.

benefit management process where the patient can be adversely affected. Consequently, they call for PBMs to:

1) Maintain a formulary development process that is open to external review;
2) Establish a system of external physician review that will aid employers in their understanding of the PBM's formulary and policies;
3) Regularly use a request-for-proposal process that seeks information [from objective sources] on formulary criteria and clinical provisions;
4) Maintain stability in the formulary so physicians can use it more effectively;
5) Closely track drug interaction rates, adverse drug reaction rates, and patient compliance;
6) Monitor the effects of physician intervention programs on prescribing behavior and patient outcomes;
7) Report this data quarterly to employers; and
8) Establish a system that instructs pharmacists to inquire about a patient's health status when prescriptions are refilled.[199]

This article is valuable because the authors have focused the conversation on the PBM industry, bringing to bear many of the standard elements for managing conflicts of interest, including external review and disclosure. Shulman et al. did not take their discussion the next step, which is to the PBM pharmacist, and how he or she manages personal conflicts of interest.

This brief review of the literature demonstrates the range of approaches available for managing conflicts of interest. The authors who have provided the most comprehensive and recent looks at the issue of physicians' financial conflicts of interest are Rodwin[200] and Morreim.[201] As noted earlier, Rodwin believes that disclosure by itself is insufficient to address conflicts of interest. He argues for a mix of prohibiting

[199] Schulman (1996), p. 911.

[200] See Rodwin (1993).

[201] See Morreim (1991a).

certain kinds of activities, monitoring and regulating conduct, and providing penalties for improper conduct. The combination would depend on the market situation, and prohibitions would focus on broad classes of conduct since this is simpler and more effective than focusing on individual behavior.[202] In addition, Rodwin argues that courts should establish fiduciary standards that could be used to hold physicians accountable for deviation from conflict of interest standards. Existing institutions would be utilized, and perhaps new ones established, to enforce, supervise, monitor, and modify the rules and policies designed to manage conflict of interest situations.[203] Rodwin believes significant lessons can be learned from the changes in medical practice that resulted from development of the doctrine of informed consent. Informed consent was once seen as a private issue between patient and physician, and by bringing it into the public domain patients benefited by having standards created that held physicians accountable to public norms. He recognizes the critics who claim that legalizing ethical issues diminish their ethical component; however, Rodwin is quick to point out how the process of legalization has actually reinforced the ethical component of some key issues.[204] He cites the changes in attitudes, and the research that blossomed, following the development of federal regulations regarding biomedical research on human subjects by the National Institutes of Health. Rodwin also articulates a role for the medical profession, which is to complement conflict of interest policies through educational efforts that are linked to

[202] See Rodwin (1993), p. 225.

[203] See Rodwin (1993), pp. 236-37.

[204] See Rodwin (1993), p. 246.

public policies.[205] Finally, patients and the public are to be empowered to hold the government and its providers accountable, if they perform their roles inadequately.[206]

Rodwin's strategy for addressing physicians' conflicts of interest offers us one position from which we can consider how PBM pharmacists should manage their conflicts of interest. If we extend Rodwin's conclusions to PBMs, which in part I do, then we must assume that the lessons learned from medicine, namely that conflicts cannot be resolved by physicians alone, apply to the PBM pharmacists as well. If this was attempted, we should expect that as time passes patient interests will be overridden by the ever-increasing incentives driven by for-profit PBMs. Without accountability for maintaining fiduciary relationships, pharmacists may tend toward self-interested behavior, thus the patient's best interest, and consequently the trust placed in the pharmacist, will be sacrificed. In part, the resolution to this problem includes development of public standards that hold PBM pharmacists accountable for their actions. This position, which I take as a fair representation of Rodwin's position, is a partial solution for the PBM pharmacist because it creates accountability. It is incomplete because it does not attend adequately to the morally relevant elements of trust and integrity that are at risk in conflicts of interest. Legal regulations do not adequately address the issues of trust and integrity. A pharmacist who acted in a patient's best interest solely because of the threat of legal action has no more integrity than the pharmacist who harms a patient's best interest by actively pursuing financial gain. To

[205] See Rodwin (1993), p. 247.

[206] See Rodwin (1993), p. 247.

adequately address conflicts of interest, regulation is best positioned as an adjunct to activities that serve to strengthen and build trust and integrity.

Morreim, in considering the changing economics of health care, outlines key patient rights and the implied duties of physicians in the new health care system.[207] She recognizes that since incentives are created by third parties, the first duty of disclosure rests with them. In the PBM industry, this means that the PBM has the duty to disclose to its customer what incentives affect their pharmacists. This is considered the "duty of honesty in contract."[208] In addition to the PBM's duty to disclose, the pharmacist also shoulders certain duties. As Morreim points out, even though the economic agent has created the incentives, in most cases physicians have agreed to participate. She states, "They have agreed to pay a personal price (or enjoy a reward) and, thereby, have agreed that their relationships with their patients will be constrained in certain ways."[209] The analogous situation for the PBM pharmacist is that when switching a patient's drug to a preferred brand, the pharmacist has knowingly entered a situation in which his or her own interests may be conflicting with the patient's. The patient's deficiency of knowledge in this situation suggests that the pharmacist has a fiduciary duty to disclose economic information. This is consistent with the obligations inherent in the fiduciary relationship described in Chapter I, specifically the requirement for disclosure and consent. Leubke also indicates that disclosure and consent are required to minimize the threat to the

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[207] See Morreim (1991a).

[208] See Morreim (1991a), pp. 309-10.

[209] Morreim (1991a), p. 311.

fiduciary relationship once an individual is involved in a conflict of interest. As Morreim suggests, "Given the enormous trust and reliance inherent in, and necessary for, an effective healing relationship, physicians surely are at least as obligated as other fiduciaries to disclose their conflicts of interest."[210] PBM pharmacists rely on the trust given to them by the patient to manage pharmaceutical care, and considering that the patient may be at a knowledge deficit, and may be vulnerable as a result of their disease, the obligation to disclose information and secure consent is present.

The PBM pharmacist owes his or her patient a reasonable level of pharmaceutical care, which should be delivered with competence and compassion.[211] He or she owes the patient assistance in moving through the bureaucracy of the pharmacy benefit, and help in cutting through red tape when resource allocation would occur unfairly. The PBM pharmacist does not owe his or her patient resources to which they are not legally or morally entitled. Resources the patient is legally entitled to include those specified in their health benefit. Resources they are morally entitled to include those in the benefit, as well as drugs that fall into the following category. Consider a drug whose use in the treatment of a particular disease is on the borderline between accepted medical practice and experimental research. If the benefit excludes payment for research uses, there is no entitlement. However, if the current thinking in medicine suggests that the therapy be

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[210] Morreim (1991a), p. 312.

[211] By "reasonable" I am drawing on the reasonable person standard. In this context, "reasonable" is what would reasonably be expected of a pharmacist practicing in a PBM setting when his or her professional objective was to serve their patient's best interest.

considered accepted medical practice, then a moral entitlement is present even if the evidence is thin. The obligation of the pharmacist would include bringing this to the attention of the plan administrator so the plan's parameters could be extended to include coverage for this drug. This obligation would occur regardless of the cost of the drug. This opens up the question of what is the "best" pharmaceutical care? I believe that the best care does not necessarily involve the most expensive drugs. As long as clinical, cost, and humanistic parameters are recognized and evaluated, the best drugs can be selected for the benefit.

The pharmacist is not obligated to sacrifice himself or herself, or his or her professional dignity, in the process. Consider again our experimental drug from the previous example. If the pharmacist believed that the drug therapy should be considered medically necessary, even though a consensus of health care professionals recommended that the use should still be considered experimental, the pharmacist should not certify medical necessity. Consider a case under review that involved a physician who had expert knowledge of the disease, and who fit key research criteria. If the physician pressures the pharmacist to certify the case by citing literature and pressuring them professionally, the pharmacist should not certify the case and sacrifice their dignity. As difficult as it is for the pharmacist to tell a person that they are unable to certify medical necessity, this is their responsibility in each case. The pharmacist is not required to sacrifice his or her professional dignity to push any case through the process, even though it might appear to help. Finally, although the pharmacist is obligated to secure what is

appropriate for his or her patient's best interest, he or she is not obligated to correct the wrongs of the health care system by himself or herself.[212]

The reason I have articulated these rights and duties is so PBM pharmacists can begin to understand their prima facie duties to patients, and their duties to distribute drugs and services fairly as they apply in the PBM setting. These duties, articulated at a general level, are outlined in the current American Pharmaceutical Association's Code of Ethics, which is where I believe the PBM pharmacist's strategy for resolving conflicts of interest must begin. Point Two of the Code identifies the pharmacist's duty to promote the good of every patient in a caring, compassionate, and confidential manner. Point Eight identifies the duty to strive for fair and equitable distribution of health resources. In addition, Point Three of the Code recognizes the autonomy and dignity of each patient. The explanatory note states, "In honoring the autonomy and dignity of patients, the pharmacist promotes the right of self-determination and recognizes their self-worth. The pharmacist encourages patients to participate in decisions regarding their health and communicates in terms that are understandable."[213] This point alone clearly suggests that the PBM pharmacist has a duty to disclose conflicts of interest. Incorporation of these duties by PBM pharmacists into their professional practice, and ongoing reinforcement of them by the profession of pharmacy, should underpin any conflict of interest management strategy.

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[212] See Morreim (1988), p. 24.

[213] See Fink (1994), p. 80. See Appendix III for the full text of the APhA Code of Ethics.

The outcome of these actions is a strong affirmation by PBM pharmacists, and the profession generally, of the advocacy role that the pharmacist should play. In order to maintain (and enhance) the level of trust placed in the PBM pharmacist, it is essential that this fundamental duty to promote the patient's best interest be upheld. In addition, by focusing on the basic tenets of the Code, the PBM pharmacist will recognize his or her obligation to promote full disclosure to patients when restrictions to the pharmacy benefit apply. In addition, he or she will recognize that they must advocate for the patient when pharmaceutical care that falls within the bounds of legal or moral entitlement is being denied. These obligations should be recognized as professional standards of care.

The next component of this strategy should involve the development of guidelines by the profession of pharmacy for PBM pharmacists' actions in conflict of interest situations. These guidelines could be modeled after the work completed by the AMA's Council on Ethical and Legal Affairs regarding managed care, and would serve to promote ethical awareness and provide principles for ethical action. The AMA Guidelines drafted by the Council were approved by the House of Delegates of the American Medical Association on June 14, 1994.[214] Although I was not able to ascertain from the literature any studies that attempted to document the success of these guidelines, conceptually they do not appear to lack any of the key elements for managing conflicts of interest. A brief description of these elements follows.

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[214] See Council on Ethical and Judicial Affairs, American Medical Association (1995), pp. 334-35. See Appendix I for the full text of the AMA guidelines.

The guidelines point out the conflicts that physicians face in managed care when they must balance the interests of their patients with the interests of other patients, and when the needs of patients conflict with the financial interests of the physician.[215] The balancing is accomplished mainly through a change in daily practice that utilizes decision making treatment guidelines which are established at a higher policy making level. These guidelines would be developed with active input from physicians, and would be managed in a context of full disclosure and consent. This eliminates bedside rationing situations. If the recommended therapy falls outside of the guidelines, then the physician's duty to advocate for the patient's rights comes into play. As advocate, the physician is responsible for assuring that an appropriate appeal is conducted for care that is not considered medically necessary. When denials occur as a result of unfair guidelines, the physician's duty is to seek modifications of the guidelines.

In an effort to create a workplace environment in which PBM pharmacists can consistently manage their actions when actually or potentially involved in a conflict of interest, I suggest consideration of the following guidelines for ethical conduct:

1. The pharmacist must recognize their fundamental obligation to act in their patient's best interest first. This obligation stems from the fiduciary relationship between the patient and pharmacist. The obligation requires that the pharmacist advocate for their patient's interest.

[215] See Council on Ethical and Judicial Affairs (1995), p. 331.

2. Decisions made by PBMs regarding drug exclusions, limitations, and drug product selection for the formulary should be made by interdisciplinary teams acting at the policy level. These teams should be comprised of health care professionals and non-professionals. Policies should be translated into protocols for case management decision making. Pharmacists should be actively involved in the policy making process and advocate for patient interests. Well documented and easily accessible appeal mechanisms should be in place for plan members and providers. Pharmacists should actively disclose policies regarding exclusion, limitation, and drug product selection; and should not participate in activities that are substandard and therefore do not promote a patient's best interest. Pharmacists should strive to involve payers in decisions regarding drug exclusions, limitations, and drug product selection for the formulary.

3. Financial incentives should only be offered to PBM pharmacists when they reward cost-effective changes in drug therapy and are not associated with medical necessity determinations. Financial incentives pose a significant risk for conflict of interest, and should be used prudently. Any incentive should be fully disclosed to the PBM client, and when possible, to the patient. Financial incentives should be limited, and when possible, be determined based on the performance of the entire pharmacy department. Incentives should be based on quality measures that include cost effectiveness, rather than strictly on cost reduction. Quality instruments should rely on objective criteria, should take into account the limits of the pharmacist's role in the total health care picture, and should incorporate patient satisfaction survey data.

4. Clients have the responsibility to communicate prescription drug plan parameters to their members (or employees). In this way the autonomy of the patient is respected by providing them with critical information regarding the scope and limitations of their pharmacy benefit so change can be initiated where and when it is appropriate. The pharmacist has an obligation to support clients in this action since it is consistent with respect for patient autonomy. The patient's autonomy does not create or guarantee a right to have any pharmaceutical product dispensed by, or reimbursed through, the PBM. The pharmacist maintains the duty to disclose conflicts of interest, which includes acting as advocate, but the patient does not have an unlimited claim on the pharmacist for pharmaceutical care. Where client's have put limits on drug product selection, the pharmacist has the prima facie obligation to enforce this restriction. This is because the pharmacist is applying his or her professional knowledge within a system designed to create economic savings. However, when the patient's best interest is jeopardized by these restrictions, their duty to advocate for the patient becomes primary.

By creating, promoting, and acting upon guidelines that place the patient's interest first; acting upon disclosure and consent measures regarding drug limitations; appropriately placing and managing financial incentives; and promoting patient autonomy, pharmacists will be in a better position to manage conflict of interest situations than they currently are. Pharmacists will be able to minimize the number of conflicts of interest they might knowingly enter, and through active disclosure and consent parameters, they will be equiped to either resolve the conflict or ethically operate within the conflict. In addition, through active disclosure of plan limitations, pharmacists

will reduce the appearance of conflicts of interest. Finally, by placing certain restrictions on financial incentives for pharmacists, the risk will be reduced that pharmacists will create a conflict of interest that could seriously harm the patient and threaten the patient-pharmacist-PBM relationship.

If PBM pharmacists manage their professional actions according to these guidelines, the risk to the patient in case management programs is significantly reduced for a number of reasons. First, the pharmacist is relying on guidelines developed at the policy level for first level decision making. Second, the pharmacist acting as advocate is clearly working in his or her patient's best interest, and consequently is assuring that the patient receives an appropriate review, and if necessary, an appropriate appeal. In retrospective drug utilization review or physician education programs, the possibility of conflict of interest is reduced because policy choices regarding drug product selection for the formulary have been fully disclosed. With respect to formulary programs, by moving drug product selection up to the policy level, assuring that disclosure and consent procedures are in place, and advocating for patients when appeals are necessary (and requesting them on behalf of patients who are not aware of the option), interests that are potentially adverse to the patient-pharmacist relationship are significantly minimized. The key point implicit in these guidelines is that the pharmacist does not act on issues that have value implications for the patient. This stems from the obligations of the fiduciary relationship, and is demonstrated through the advocacy duty and the disclosure and consent requirements. Remember that it is acceptable to make technical decisions

without client consent, but it is never acceptable to assume client values when managing conflicts of interest.

As attention becomes focused on the challenges associated with conflicts of interest, these guidelines might be welcomed by the senior management staff at the various PBMs, particularly if the PBMs accept their responsibility to inform their customers regarding potential conflicts as Morreim suggests. This element of my strategy is another key for success, and I believe it should include disclosure, but also extend beyond it. The significant limitations of disclosure were discussed earlier. I believe that PBMs, at a corporate level, must come to a broad understanding and acceptance of their role in the delivery of health care. This role is associated with ethical issues, including conflict of interest, confidentiality of information, and informed consent. Consequently, I believe that PBMs should adopt a code of ethical conduct, as hospitals have begun to do.[216] The idea of establishing a set of ethical standards for managed care plans in Minnesota has been suggested by David Strand, the president of Medica Health Plans.[217] Strand argues that the standards "would help make managed care organizations more accountable to the public and ensure that members are informed about decisions that affect their health care." Precedent for collective action by the various PBMs has already occurred in the area of on-line data transmission; so the idea of reaching consensus around the issue of ethical guidelines should not be perceived as

[216] See Joint Commission on the Accreditation of Health Care Organizations (1996).

[217] See Lerner (1996), p. D1.

foreign.[218] As quality initiatives continue to grow within managed care, and as these initiatives continue to incorporate pharmacy, the requirement that PBMs abide by ethical standards should be created.[219]

I envision this code outlining ethically appropriate behavior for PBM employees, including pharmacists. Consequently, PBM pharmacists should play a key role in its development, and they should be sure that the principles and virtues recognized in the APhA Code are reflected in the PBM code. The ideas expressed in this code would serve as a public statement by the PBM of what they see as ethical conduct. This document would play a secondary role for the PBM pharmacist looking for guidance regarding ethical behavior since the APhA Code would still be primary. However, when seeking clarity on PBM specific issues, or when looking for a consensus opinion from colleagues within the PBM industry, this code may be a valuable resource. If a PBM decided not to

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[218] An organization called the National Council for Prescription Drug Data was formed to develop and manage these standards. Representation includes those industries that rely on this data for daily business activity. Attention has been paid to the confidentiality of patient specific information, especially as it is shared among businesses.

[219] Managed care organizations created a self-regulation framework in 1979, which became an independent non-profit organization in 1990. This organization, known as the National Committee for Quality Assurance (NCQA), has established accreditation standards in six areas: preventive health, medical records, utilization management, members' rights and responsibilities, credentialing, and quality improvement. The quality improving aspects of accreditation are based on a list of performance measures known as the Health Plan and Employer Data and Information Set (HEDIS). The use of HEDIS is growing in the public and private sector. HCFA announced on October 18, 1996, that it would require HEDIS reports for all Medicare Managed Care programs. It may turn out that PBMs will come under NCQA review with specific HEDIS requirements.

accept this code, it would still be acceptable for a pharmacist to work for that PBM, assuming that he or she maintained integrity in the workplace and was not required to work in sub-standard conditions. This rejection of the PBM code would suggest a lot more about the moral fiber of the PBM's senior staff than about the pharmacists who work for the PBM. If the code became inadequate or out of date because of some change in technology, it would become the responsibility of the PBM industry leaders, especially pharmacy-leaders, to update the code to reflect appropriate ethical conduct.

If PBMs display a public acceptance of their role in the delivery of health care through the development and acceptance of their own code of ethical conduct, they will formalize their obligation to adhere to informed consent requirements. This will facilitate the disclosure of exclusions, limitations, or drug product selection policies that they have made as a corporate entity or are required to enforce on behalf of their customers, as well as any financial incentives that may apply to the PBM's pharmacists. This code should reinforce the notion that guidelines for restricting or limiting pharmaceutical care be made at a policy level, and not at the level of the individual pharmacist. This would not eliminate the opportunity for a pharmacist to make a conscientious objection to a policy. In addition, PBMs should encourage individual pharmacists (and create the opportunities for them) to participate in policy making decisions that relate to restricting care. This code should also require PBMs to promote appeal mechanisms to patients and physicians in clear terms. These appeal processes should be easy to access, and at their final stage should be conducted by external experts to assure a fair and unbiased review. The PBMs

should also agree to develop quality measures that can be used as criteria for providing incentives to PBM pharmacists.

Finally, the PBM's customers also have the responsibility to watch over the actions of their PBM, and they should be held accountable for communicating critical information about the pharmacy benefit to MCO members and corporate employees. The economics of managed care pharmacy have significantly affected the patient-pharmacist relationship. The comfort of going to a corner drugstore to pick up a prescription, perhaps in a reimbursable cash transaction or through a nominal two or three dollar co-payment, has been replaced by a corporate system designed to promote economic efficiency. As I noted earlier, the PBM pharmacists who act within this system have ethical responsibilities for which they should be held accountable by their profession and by their PBM. But this system cannot be construed as a one-way street. Employees and MCO members must be provided the opportunity to learn as much as possible about their pharmacy benefit, watch over the PBM for inappropriate actions, and be empowered to act individually and collectively to make changes when employer policies or PBM practices are deemed inappropriate. In this way patients can exert their autonomy by actively participating in benefit design and drug coverage determinations.

If the elements of the strategy I have just described can be pulled together -- namely a refocusing on the profession's Code of Ethics, the development of professional guidelines, collective action by the PBMs to create ethical standards, and oversight of managed pharmacy by consumers -- then the conflicts of interest in which the PBM pharmacist finds himself or herself have the best opportunity to be managed effectively

and consistently. Recalling the discussion of role from Chapter II, actualizing these suggestions will maintain the patient's best interest, preserve integrity, and optimize the cost effectiveness of the benefit through clinical management programs. As these actions are coordinated, PBM pharmacists will retain (and merit) the gift of trust their patients place in them. Through this action PBM pharmacists will also stay true to their discipline by focusing on the best interests of their patients first. Managed care pharmacy should pay extremely close attention to the financial costs associated with drug utilization. This activity should consider total drug costs, as well as total medical savings that can result from managed care pharmacy. This is the PBM's core competency and it can drive beneficial effects for employers and MCOs. It is also one of the key reasons why the PBM can turn a profit. Unfortunately, pharmacists currently practicing in the PBM setting do not have an understanding of the relevant ethical issues at risk in conflict of interest situations, nor do they have any formal guidelines from their profession or support from their employers. As I indicated in the first chapter, the profession of pharmacy has not taken a close look at the conflicts of interest in the PBM industry. Consequently, patient interests are being placed at risk on a daily basis.

An important question that I asked at the close of the first chapter was how the PBM pharmacist should appropriately manage conflicts of interest so ethical integrity can be maintained. With respect to the management aspect of this question, I believe the four actions described above are the essential means to manage conflicts of interest. As these actions are coordinated, I believe ethical integrity will be strengthened, and a foundation for building upon it will be created. Recall Benjamin and Curtis and their idea of

"principled continuity of conduct." By refocusing on the profession's Code of Ethics, and deriving from the principles and virtues espoused in the Code guidelines for appropriate action, the PBM pharmacist will have a benchmark for defining principled conduct. With guidelines in place that require disclosure, consent, and respect for patient autonomy, the PBM pharmacist's actions will be marked by the honesty and fairness that Mitchell views as core dimensions of integrity. Through regular application of these actions, the pharmacist will display the wholeness that both Mitchell and May viewed as critical. May viewed wholeness, or completeness of character, as the element that does not permit the split between word and deed. By honestly taking the position of patient advocate from first meeting through the final stages of appeal, the pharmacist will demonstrate the wholeness that marks the person of integrity. If PBMs develop ethical standards, then the PBM pharmacist will have another benchmark for appropriate behavior. Consider the issue of disclosure of financial incentives. Bok pointed out that integrity is often used in relation to truthfulness and fair dealings. If the PBM pharmacist is questioned by a prospective client about financial incentives during a sales presentation, and the PBM's code of ethical conduct encourages the pharmacist to provide honest answers regarding financial incentives, then by answering honestly they have demonstrated their own integrity, as well as the PBMs, by participating in the creation of a fair business relationship. As PBM pharmacists continue to display their integrity through their practice actions, their patients and clients will begin to take notice through their oversight activities. It is through this action that PBM pharmacists have the opportunity to enhance their integrity in the eyes of those they serve.

If the profession of pharmacy is unable to coordinate these actions, then the argument put forth by Rodwin will have to prevail. Public policy and legislative actions will have to drive ethical action. I view this as less desirable because I prefer a health care system in which the patient's best interest and appropriate safeguards are managed primarily by health care professionals in conjunction with their patient. Regulations are often cumbersome to apply, and with health care characterized by contingencies, using public policy as a guide can be difficult. I recognize that policy and legislative action can enhance the autonomy of citizens through democratization, and the example that Rodwin uses of informed consent in biomedical research clearly shows the value that can be derived through policy initiatives. Still, I prefer less government intrusion when possible. In the case of conflict of interest in the pharmacy benefits management industry, my hope is that individual PBM pharmacists, the larger profession of pharmacy, and the PBMs will be able to see their way clear to create the environment in which the patient-pharmacist-PBM relationship can be maintained without having to rely primarily on public policy. This is not to deny a role for public policy, rather it is to place policy and legislative action in a supporting role.

Regardless of the final mix of actions that are eventually put into place to manage conflicts of interest in the pharmacy benefits management industry, it is essential that the profession of pharmacy and society act now to ensure that managed pharmacy techniques are administered in such a way that protects patient interests and the patient-pharmacist relationship.

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APPENDIXES

APPENDIX I

ETHICAL ISSUES IN MANAGED CARE

Council on Ethical and Judicial Affairs, American Medical Association

GUIDELINES[220]

For the reasons described in this report, the Council on Ethical and Judicial Affairs issues the following guidelines:

1. The duty of patient advocacy is a fundamental element of the physician-patient relationship that should not be altered by the system of health care delivery in which physicians practice. Physicians must continue to place the interests of their patients first.

2. When managed care plans pace restrictions on the care that physicians in the plan may provide to their patients, the following principles should be followed:

   (a) Any broad allocation guidelines that restrict care and choices - which go beyond the cost-benefit judgments made by physicians as a part of their normal professional responsibilities - should be established at a policy making level so that individual physicians are not asked to engage in ad hoc bedside rationing.

   (b) Regardless of any allocation guidelines or gatekeeper directives, physicians must advocate for any care they believe will materially benefit their patients.

   (c) Physicians should be given an active role in contributing their expertise to any allocation process and should advocate for guidelines that are sensitive to differences among patients. Managed care plans should create structures similar to hospital medical staffs that allow physicians to have meaningful input into the plan's development of allocations guidelines. Guidelines for allocating health care should be reviewed on a regular basis and updated to reflect advances in medical knowledge and changes in relative costs.

   (d) Adequate appellate mechanisms for both patients and physicians should be in place to address disputes regarding medically necessary care. In some circumstances, physicians have an obligation to initiate appeals on behalf of their patients. Cases may arise in which a health plan has an allocation

[220] Council on Ethical and Judicial Affairs (1995).

guideline that is generally fair but in particular circumstances results in unfair denials of care, i.e., denial of care that, in the physician's judgment, would materially benefit the patient. In such cases, the physician's duty as patient advocate requires that the physician challenge the denial and argue for the provision of treatment in the specific case. Cases may also arise in which a health plan has an allocation guideline that is generally unfair in its operation. In such cases, the physician's duty as patient advocate requires not only a challenge to any denials of treatment from the guidelines but also advocacy at the health plan's policy making level to seek an elimination or modification of the guidelines. Physicians should assist patients who wish to seek additional appropriate care outside the plan when the physician believes the care is in the patient's best interests.

(e) Managed care plans must adhere to the requirement of informed consent that patients be given full disclosure of material information. Full disclosure requires that managed care plans inform potential subscribers of limitations or restrictions on the benefit package when they are considering entering the plan.

(f) Physicians also should continue to promote full disclosure to patents enrolled in managed care organizations. The physician's obligation to disclose treatment alternatives to patients is not altered by any limitations in the coverage provided by the patient's managed care plan. Full disclosure includes informing patients of all their treatment options, even those that may not be covered under the terms of the managed care plan. Patents may then determine whether an appeal is appropriate or whether they wish to seek care outside the plan for treatment alternatives that are not covered.

(g) Physicians should not participate in any plan that encourages or requires care at or below minimum professional standards.

3. When physicians are employed or reimbursed by managed care plans that offer financial incentives to limit care, serious potential conflicts are created between the physicians' personal financial interests and the needs of their patients. Efforts to contain health care costs should not place patient welfare at risk. Thus, financial incentives are permissible only if they promote the cost-effective delivery of health care and not the withholding of medically necessary care.

(a) Any incentives to limit care must be disclosed fully to patients by plan administrators on enrollment and at least annually thereafter.

(b) Limits should be placed on the magnitude of fee withholds, bonuses, and other financial incentives to limit care. Calculating incentive payments according to

the performance of a sizable group of physicians rather than on an individual basis should be encouraged.

(c) Health plans or other groups should develop financial incentives based on quality of care. Such incentives should complement financial incentives based on the quantity of services used.

4. Patients have an individual responsibility to be aware of the benefits and limitations of their health care coverage. Patients should exercise their autonomy by public participation in the formulation of benefits packages and by prudent selection of health care coverage that best suits their needs.

APPENDIX II

Guidelines for Medication Incentive Programs[221]

Preamble

The following guidelines were developed to provide assistance in judging the ethical merits and professional integrity of medication incentive programs. Medication incentive programs may include coupon programs, academic detailing, tele-marketing, compliance and therapeutic switch, that attempt to influence the use of particular medications over alternative medications or therapies. The participants in these programs include:

- *providers*, such as pharmacists and other health care practitioners;
- *sponsors*, such as pharmaceutical manufacturers, mail order companies, pharmacy benefit management firms (PBMs), other third-party administrators such as the state Medicaid programs, hospitals, and insurance companies;
- *employers*, and
- *government regulators*.

The touchstones for these Guidelines are the American Pharmaceutical Association's (APhA) Mission and Purpose statements,[1,2] both the former APhA Code of *Ethics*[3] (1969) and the current Code of *Ethics for Pharmacists*[4] (1994), and policies adopted by the APhA House of Delegates (see Appendix A).[5]

Both the former APhA Code of *Ethics* (1969) and the current Code of *Ethics for Pharmacists* (1994) describe the relationship between the pharmacist and the patient. Although there are many differences between the two documents, they share the common philosophy that the well-being of the patient is at the center of professional pharmacy practice.

Health care professionals face conflicts of interest on a daily basis. The reason for the high regard for professionals and their use of professional judgment by society is that they are trusted to make the right decisions for those patients (consumers) who are under their care. Health care professionals are entrusted to make decisions in the best interest of patients.

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[221] American Pharmaceutical Association (1995).

Guidelines for Acceptable Medication Incentive Programs

I. The Patient's Health and Safety Should Take Precedence.

Positive patient outcomes should be the cornerstone of any medication incentive program, regardless of the sponsor. The inherent program design must not cause any harm to the patient and allow the potential for the patient to receive some benefit, be it therapeutic and/or economic. The program must not in any way compromise the therapeutic benefit to the patient (example: by requiring the pharmacist to dispense a less effective drug).

Medication incentive programs that are therapeutically or economically neutral to the patient, but result in economic savings to the provider or health plan are also acceptable.

Medication incentive programs must remain economically neutral or save patients/purchasers money in the long-term by defraying other health care costs (decreased incidents or hospitalizations, decreased incidents of strokes, etc.), even if they are more expensive in the short-term. Medication incentive programs should acknowledge and consider the contribution of pharmacy services to decreasing the overall cost of health care.

II. Patients are entitled to pharmaceutical care services.

Medication incentive programs must incorporate the concepts of pharmaceutical care into the patients' comprehensive health care plans. The programs must not compromise the availability of pharmacists to provide pharmaceutical care services.

Pharmaceutical care is defined as:

"...the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes are: (1) cure of a disease, (ii) elimination or reduction of a patient's symptomatology; (iii) arresting or slowing of a disease process; or (iv) preventing a disease or symptomatology.

...the pharmacist cooperates with a patient and other [health care] professionals in designing, implementing and monitoring a therapeutic plan that will provide specific therapeutic outcomes for the patient. Monitoring, in turn, involves three functions; identifying, resolving, and preventing drug related problems.

The fundamental goals, processes, and relationships of pharmaceutical care exist regardless of practice setting."[6,7]

III. Patients and their health care professionals are entitled to full disclosure concerning medication incentive programs within the health care system for the use or omission of pharmaceuticals.

Disclosure of all material facts about a medication incentive program must be made to patients and health care professionals in order for them to make fully informed decisions regarding their program participation. Material facts (including any remuneration received by the pharmacist from the program sponsor) are those that would affect a person's conduct or decision on the purchase or selection of goods or services.[8] This disclosure of all material facts about the programs to patients may occur either directly to the patients or through pharmacists and/or prescribers. Medication incentive programs must document that the patient has (1) received all material facts about the program and (2) given his or her consent to participate in the program. In this regard, advance disclosure of the material facts regarding the program, together with the patient's active participation in the program and documentation of these activities, shall constitute a full and informed consent.

IV. Patients' privacy rights must be protected.

Patients have a right to expect that pharmacists will not reveal "...to others [those not involved in the care of the patient] the nature of pharmaceutical services provided...without the [patients'] consent..."[10] Preventing disclosure of patient-specific information to non-health care providers without explicit patient approval is paramount. Patient-specific information includes, but is not limited to, the name of the patient, and if provided together with the patient's name, the date the prescription was filled, the amount of the prescription drug dispensed[10], the diagnosis or medical condition of the patient, and the name of the prescriber.

Pharmacists may reveal patient-specific information to the program sponsors only with the consent of the patients and where allowed by law. Medication incentive programs must document that the patient has (1) received all material facts about the disclosure of the patient-specific information and (2) given his or her consent to the release of the information to the program sponsor. In this regard, advance disclosure of the material facts regarding the disclosure of the patient-specific information, together with the patient's active participation in the program and documentation of these activities, shall constitute a full and informed consent.

V. It is appropriate to provide fair remuneration to pharmacists for providing pharmaceutical care and cognitive services to patients.

Pharmacists are responsible for helping patients achieve optimal therapeutic outcomes through the appropriate use of medications, devices, and services. Pharmacists provide patients cognitive services (i.e., services requiring professional judgment), which may or may not be related to the dispensing or sale of a product. Historically, reimbursement to

pharmacists has been tied to the cost of the medication or device and not on the value of cognitive services provided to patients. APhA supports separate payment systems that distinguish between compensation for the provision of pharmaceutical care and other cognitive services and reimbursement for product distribution.

Medication Incentive Program Administration

Medication incentive programs must cover the costs of administration and/or participation to providers. The programs must recognize and clearly define costs associated with remuneration for all applicable areas of pharmaceutical care and related services, including (1) reimbursement for product selection, preparation, and dispensing, (2) compensation for pharmaceutical care and cognitive services, and (3) programmatic administrative allowances. Compensatable activities need to be clearly defined. Compensation for pharmacist/pharmacy services and products must be based on sound, defensible cost methodology. The programs must encourage innovation of patient-oriented services.

Sponsors should seek to involve both pharmacists and patients or their representatives (e.g., focus groups) early in the program development stages for the purposes of the identification and avoidance of problems during implementation. In cases where medication incentive programs involve drug product selection (i.e., "switch" programs) for provider networks and managed care entities, the program must be reviewed, approved, and monitored by a representation panel of prescribers and pharmacists (e.g., a pharmacy and therapeutics committee or formulary committee).

Programs should be offered by sponsors on an equal availability basis to all qualified pharmacists within a define network or health care system. Patients must be able to participate in the programs utilizing the providers of their choice within the defined network or health care system.

Federal and state laws and regulations must be applied equally to all medication incentive programs, regardless of sponsor (e.g., pharmaceutical manufacturers, pharmacy benefit management firms, mail order companies, other third-party programs such as state Medicaid programs, hospitals, insurance companies, and employers).

APhA does not assume any responsibility for the legality or propriety of any specific medication incentive programs that may be adopted which conform to the precepts of these Guidelines.

Prepared by the APhA Pharmacy/Industry Working Group, approved by the APhA Board of Trustees, May 1995.

Appendix A

(1) The Mission Statement of the American Pharmaceutical Association: To serve its members and the profession, the American Pharmaceutical Association will:

- advocate the interests of pharmacists;
- influence the profession, government, and others in addressing vital pharmaceutical care issues;
- promote the highest professional and ethical standards; and
- foster science and research in support of the practice of pharmacy.

(2) The purpose Statement of the American Pharmaceutical Association:

The American Pharmaceutical Association exists to serve its members, to enhance pharmacists' ability to provide pharmaceutical care, and to further the public's recognition of the profession's value.

(3) Policies adopted by the American Pharmaceutical Association House of Delegates:

- The Mission of Pharmacy Practice: APhA affirms that the missions of pharmacy is to serve society as the profession responsible for the appropriate use of all medications, devices, and services to achieve optimal therapeutic outcomes.

- APhA supports separate payment systems that distinguish between compensation for the provision of pharmaceutical care and reimbursement for product distribution.

- Additional policy on pharmaceutical care, cognitive services, and pharmacy payment system reform adopted by the APhA House of Delegates is found in Attachment B at the end of this document.

(4) Professional

- Webster's Ninth New Collegiate Dictionary[9] defines a professional ass one who is "characterized by or conforming to the technical or ethical standards of a profession."

- Profession is defined as "a calling requiring specialized knowledge and often long and intensive academic preparation." Smith, et al.,[10] defines a profession as "an occupational group identified (1) by its specialized knowledge and (2) its highly trained membership (intellectual training), who, (3) acting with individual judgment, (4) intimately affected the affairs of others. It is usually

characterized by (1) its code of ethics, (2) its spirit of altruism,..." (unselfish regard for or devotion to the welfare of others) "...and (3) its self-organization."

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APPENDIX III

CODE OF ETHICS FOR PHARMACISTS (1994)[222]

PREAMBLE

Pharmacists are health professionals who assist individuals in making the best use of medications. This Code, prepared and supported by pharmacists, is intended to state publicly the principals that form the fundamental basis of our roles and responsibilities. These principles, based on moral obligations and virtues, are established to guide pharmacists in relationships with patients, health professionals, and society.

I. A pharmacist respects the covenant relationship between the patient and pharmacist.

Considering the patient-pharmacists relationship as a covenant means that each pharmacist has moral obligations in response to the gift of trust received from society. In return for this gift, the pharmacist promises to help individuals achieve optimum benefit from their medications, to be committed to their welfare, and to maintain their trust.

II. A pharmacist promotes the good of every patient in a caring, compassionate, and confidential manner.

The pharmacist places concern of the good of the patient at the center of professional practice. In doing so, the pharmacists considers needs stated by the patient ass well as those defined by health science. The pharmacist is dedicated to protecting the dignity of the patient. With a caring attitude and a compassionate spirit, the pharmacist focuses on serving the patient in a private and confidential manner.

III. A pharmacist respects the autonomy and dignity of each patient.

In honoring the autonomy and dignity of patients, the pharmacist promotes their right of self-determination and recognizes their self-worth. The pharmacist encourages patients to participate in decisions regarding their health and communicates in terms that are understandable. In all cases, the pharmacist is aware of personal and cultural differences among patients.

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[222] American Pharmaceutical Association (1994).

IV. A pharmacist acts with honesty and integrity in professional relationships.

Patient's colleagues, and other health professionals have a right to expect the pharmacists to tell the truth. The pharmacists has a duty not to lie or to deceive others and to act with conviction of conscience. A pharmacist does not participate in unfair discriminatory practices. A pharmacist will not practice under or condone personal or employment conditions that impair professional judgment.

V. A pharmacist maintains professional competence.

Mindful of patients' trust place, a pharmacist has a duty to maintain knowledge and abilities as new medications, devices, and technologies become available and as health information advances.

VI. A pharmacist respects the values and abilities of colleagues and other health professionals.

When appropriate, a pharmacists asks for the consultation of colleagues or other health professionals or refers the patient. A pharmacist acknowledges that colleagues and other health professionals may differ in the beliefs and values they apply to the care of the patient.

VII. A pharmacist serves individual, community, and societal needs.

The ethical obligations to which a pharmacist is held primarily accountable include those that concern individual patients. However, these obligations may at times extend beyond the individual to the community and society. In such cases, the pharmacist recognizes the responsibilities that accompany these obligations and acts accordingly.

VIII. A pharmacist strives for fair and equitable distribution.

When involved with decisions regarding the access to and of health resources, the responsibility of the pharmacist is to seek a just distribution of the goods and services.

VITA

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