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In Sickness and in Health: Analyzing the Ethical Limits of the Marriage between Health Care and the Market in the United States

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To the Graduate Council:

I am submitting herewith a dissertation written by Thomas D Harter entitled "In Sickness and in Health: Analyzing the Ethical Limits of the Marriage between Health Care and the Market in the United States." I have examined the final electronic 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.

Denis G. Arnold, Major Professor

We have read this dissertation and recommend its acceptance:

John Hardwig, David A. Reidy, Alfred Beasly

Accepted for the Council:
Dixie L. Thompson

Vice Provost and Dean of the Graduate School

(Original signatures are on file with official student records.)

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In Sickness and in Health:

Analyzing the Ethical Limits of the Marriage between Health Care and the Market in the United States

A Dissertation
Presented for the
Doctor of Philosophy Degree
The University of Tennessee, Knoxville

Thomas D. Harter
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Dedication

This dissertation is dedicated to all of my undergraduate and graduate Philosophy professors, Susan Williams, Ann Beardsley, Dr. Kevin M. Bond, Todd M. Johnson, my wife Lisa, my children Gwenyth and Owen, my parents Ron and Janet Harter, and my grandmothers Rheba Mote and Wilhelmine Saint. Mentors, friends, and family, without whose patience, care, and insight this would not be possible.

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I perhaps owe the most to my family, friends, and colleagues. My parents have

expressed more faith and patience toward me than I thought possible. We have a mutual respect for one another that allows me to always speak openly with them, even when we disagree with what each other says. My wife and children constantly inspire me to be better. They have provided me with many unique perspectives about my life that I would not have otherwise. Although all of my friends and colleagues have contributed to my philosophical thinking, it is Kevin and Todd with whom I have shared the majority of my ideas and who, in return, have added depth and clarity to my thinking. Both are exemplars of Aristotelian friendship. To Mr. Ed Gamble, my high-school guidance counselor: thank you for our talk that has since motivated me to continuously get back up whenever I get knocked down.

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Abstract

This dissertation aims to determine what should be the appropriate base ethical limits of health care markets in the United States. I argue that because we do not value health care goods and services as commodities, treating them as commodities available for market sale can only be ethical when health care markets accord with at least the principles of honesty, respect for autonomy, and increased access to essential health care goods and services.

I begin by establishing the theoretical foundation of my argument by expositing three theories of commodification and ethical markets that critically examine the relationship of goods to the market. Each theory shows how commodification often fails to account for the non-market value(s) we attribute to many goods. I then apply these theories to health care goods and services to show how they are not properly valued merely as commodities, and to lay the foundation of my argument regarding the ethical limits of health care markets. I then argue why honesty, respect for autonomy, and increased access to essential health care goods and services should be considered the base ethical limits of health care markets by examining how each ideally applies to both health care and the market.

Lastly, I apply my argument to two health care markets: the pharmaceutical industry and a possible legal organ market. For the former, I show how many of the practices of the pharmaceutical industry violate what I argue should be the base ethical limits of health care markets. For the latter, I show the extent to which a legal organ market in the United States could or would violate these limits.

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Introduction

The currently existing marriage between health care and the market in the United States is contentious. Markets – generally understood as a collective group of buyers and sellers who engage in monetary transactions of commodified goods and services – typically create competition among providers and are thusly considered an efficient and effective means of generating a wide range of goods and services at various prices. Theoretically, health care markets can provide individuals a greater number of choices about which medical professionals they visit, what medicines they buy, and even which medical procedures they wish to undergo.

Yet there are many who question the ethical validity of this marriage. Critics of health care markets tend to argue that the ends of health care are incommensurable with the ends of the market, and that market influences have an overall negative impact on the delivery of health care goods and services. By most accounts, health care has intrinsic value as a basic human need requiring intimate, fiduciary relationships between medical professionals and patients. Within the market, however, goods and services merely have instrument value, and are bought and sold to whomever is able and willing to pay for them, while those who cannot afford goods and services must often forgo their purchase. In a recent article of *The Journal of the American Medical Association*, Drs. Robert Berenson and Christine Cassel argue, for example, that patients and health care professionals ought to be cautious before fully embracing market-based competition among health care providers because of the potential for lapses in professional ethical

behavior that can result as a consequence.[1] Norman Daniels, who has written extensively on issues concerning just health care, has recently argued that market-friendly strategies for promoting just health care have either failed or are currently failing.[2] Edmund Pellegrino stakes out an even stronger position against health care markets by arguing that it is ethically wrong to ever treat health care as a commodity. According to Pellegrino, "health and medical care are not, cannot be, and should not be commodities; the ethical consequences of commodification are ethically unsustainable and deleterious to patients, physicians, and society . . . health care is a universal human need and a common good that a good society should provide in some measure to its citizens."[3]

While I am sympathetic to the ethical concerns raised by critics of health care markets, the current realities of the marriage between health care and the market in the United States suggest that a divorce between the two is neither imminent nor practical. The focus of this project is not, therefore, to argue for or against having health care markets. Instead, this project aims to determine the appropriate ethical limits regarding the market sale of health care goods and services in the United States. Specifically I argue that because health care goods and services are not properly valued merely as commodities, treating them as commodities that are bought and sold via health care markets should be limited according to at least the principles of honesty, respect for autonomy, and increaseed access to essential health care goods and services.

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[1] Berenson and Cassel, "Consumer-Driven Health Care May Not Be What Patients Need – Caveat Emptor," 321-323.
[2] Daniels, "Broken Promises."
[3] Pellegrino, "The Commodification of Medical and Health Care," 244.

In making this argument I do not presume that these are the only possible ethical limits of health care markets *or* that by adhering to these limits, the commodification of a health care good or service is necessarily ethical. For example, there could be other concerns regarding medical appropriateness that might ethically prevent the sale of a health care good or service even if the transaction did not violate the limits for which I argue.

Also in making this argument, I do not intend or try to justify the continued use of the current market-based heath care system in the United States. This is because it is questionable whether or not this system is the best way for persons in the United States to meet their health care needs, as it is seemingly failing to achieve the mass level of access and distribution for which markets are typically valued. For example, empirical data shows that the United States has both the highest *per capita* spending and the highest cost as a percentage of gross domestic product for health care goods and services than any other economically advanced nation.[4] Yet there are approximately 50 million uninsured United States citizens who are required to pay out-of-pocket for most or all of their health care expenditures.[5] As a result of these factors, there are now many social, political, and

[4] According to the Organization for Economic Co-Operation and Development (OECD), health care spending in the United States for 2009 was $7,290 *per captia* (adjusted purchasing power parity) and accounted for 16% of its gross domestic product (GDP). By comparison, this *per captia* spending is $2,527 more than second ranked Norway, $2,873 more than third ranked Switzerland, and almost two and half times more than the OECD average of $2,964. The United States GDP for health care spending in 2009 is 5% higher than second ranked France, 5.2% higher than third ranked Switzerland, 5.6% higher than fourth ranked Germany, and more than 7.1% higher the OECD average of 8.9%. See; Organization for Economic Co-Operation and Development. "OECD Health Data 2009: How Does the United States Compare," http://www.oecd.org/dataoecd/46/2/38980580.pdf. (accessed July 29, 2009).

[5] National Coalition on Health Care, "Facts on Health Care Costs," Health Insurance Costs, http://www.nchc.org/facts/cost.shtml. (accessed July 29, 2009).

ethical debates both challenging and urging reform to the United States' current health care system.[6]

Restricting my argument in this way is advantageous for at least two reasons. First, I do not have to try to refute arguments that call into question the efficacy or fairness of health care markets based on the practical problems with the United States' current health care system. Second, my argument regarding the ethical limits of health care markets can still be applicable even if there is a shift the United States away from a predominately market-based health care system.

The rest of this chapter serves two purposes. First, I clarify some concepts I frequently use throughout my argument such as health care goods and services, commodity(-ies) and commodification, and health care markets. I then detail the scope of the project by briefly outlining each of the following chapters.

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[6] Daniels, for example, has recently written a well-argued critique of the current market-based approach to health care in the United States with respect to the demands of justice. Specifically, Daniels argues that current business friendly strategies for managing health care markets in the United States, frustrate rather than promote the goals of justice in meeting health care needs, particularly with the financing and delivery of health care goods and services. The general promises of the market to foster competition among health care providers, thereby theoretically lowering health care costs while increasing access to various health care goods and services is, as Daniels carefully shows, a broken set of promises. This is mostly because of how current business friendly strategies for managing health care markets in the United States have failed to account for the unequal power that favors the supply side of health care markets (i.e. health care providers) over the demand side (i.e. purchasers of health care goods and services). As Daniels argues, the reasons why this unequal power between the supply side and the demand side of health care markets is unfair is because it has resulted in health care costs increasing instead of decreasing, while primarily placing the burden of paying for those increases on those who need health care goods and services the most, but who are also least likely able to afford them because of the correlations between having higher health care needs with a lower or decreasing socio-economic status. In particular, there are five broken promises that Daniels addresses. These are: 1) increased health care competition will result in lower unit prices of health care goods and services, 2) competition among health care plans will lower the rate of increase of health care costs, 3) high deductible health care plans will result in wiser health care purchases and lower health care costs, 4) competition among drug plans outlined in the new Medicare drug benefit will slow increasing costs and increase access to drugs for the elderly, and 5) the introduction of user fees and growth in private sector health care will increase resources for under-funded health care systems in developing countries. See; Daniels, "Broken Promises."

1. **Clarifying the Basic Concepts of the Argument**

This section sketches out what can be considered reasonable, generally agreed upon understandings of the concepts I frequently refer to in my argument. My argument focuses on imposing ethical constraints on the sale of health care goods and services. The term "health care goods and services" should therefore not only be consistent with how health care is regarded throughout typical medical literature, but also broad enough to encompass the possible varieties of health care markets such as, for example, markets in human transplant organs – in which would-be organ sellers are not likely to medically benefit from the transaction. Attempting to meet both criteria, I broadly define "health care goods and services" as goods and services that individuals use to help meet their medical needs in preventing or combating disease, illness, or injury. Transplantation, for example, is a service that combats a disease, such as kidney or heart disease, in the recipient even if it does not medically benefit the donor.

To remain consistent with the market theories I exposit in chapter 1, "commodity" or "commodities" refer to a good(s) or service(s) that has or could have an established economic value. The process of establishing an economic value for a good(s) or service(s) I refer to as "commodification." When referring to health care goods and services as commodities, I am thusly referring to the actual or potential economic value of those goods and services.

Lastly, the term "health care markets" broadly refers to markets in which individuals buy and sell commodified health care goods and services. Though by limiting the scope of my argument to the United States, I also consider these to be free markets

that are regulated but not controlled by the government. In market rhetoric these transactions occur between buyers and sellers. However health care transactions are not said to occur between buyers and sellers, but typically between patients and health care providers such as physicians or institutions like hospitals, health insurance companies, or the pharmaceutical industry at-large. This highlights an aspect of the problem of incommensurability between health care and the market, and is one reason that I specifically do not argue for health care markets. Arguing for health care markets requires reconciling and ethically justifying thinking of and treating patients and health care providers respectively as buyers and sellers of commodified health care goods and services. Additionally, this understanding of health care markets may involve transactions between buyers and sellers who are not traditionally thought of as patients or health care providers. Take those who are wiling to sell their organs for profit for example. These individuals lack the standard medical and professional qualities we attribute to most health care providers, even though they directly provide the organs for sale, and so are "sellers" of a health care good.

2. **Chapter Outline**

Although I present my argument as a single work, it is possible to view this dissertation in two parts. Chapters 1-3 develop my argument that health care goods and services are not properly valued merely as commodities, and that ethically treating them as commodities requires imposing ethical limits on their market sale. Chapters 4 and 5 then apply my argument to two health care markets that have both recently garnered substantial academic and public interest: the pharmaceutical industry, and a hypothetical

legal organ market.

A. *Chapter 1: Examining the Relationship of Goods to the Market*

Chapter 1 critically examines the relationship of goods to the market by expositing three theories of commodification and ethical markets. According to the first theory, we can value goods in a number of ways, and that some goods are incomparably valued higher than other goods. The second theory provides a pragmatic analysis that shows how various goods are properly valued in terms of incomplete commodification – in which persons characterize the sale of those goods both in terms of commodification and noncommodification. The third theory argues that the commodification of goods for market sale is unethical when this results in negative consequences that undermine the values characteristic of liberal democracies. Together these theories help explain why health care goods and services are not properly valued merely as commodities, and provide the conceptual space needed to argue for imposing ethical limits on the market sale of health care goods and services.

B. *Chapter 2: Arguing for the Principle of Increased Access to Essential Health Care Goods and Services*

Chapter 2 sets forth my argument in detail. Building on the view established in chapter 1, this chapter aims to show why there ought to be increased access to essential health care goods and services, and what it means for this normative principle to be an ethical limit of health care markets. I begin by establishing three approaches that each help justify the principle of increased access to essential health care goods and services. Then I attempt to clarify some of the qualities that should define essential health care goods and services. As we shall see, how we come to characterize “essential health care

goods and services" will need to accord with the goal of this principle to balance wealth creation and limited health care resources against the just distribution of those resources. I conclude the chapter by drawing some conclusions about how this principle is an ethical limit of health care markets. Although I detail the three approaches I use to justify this principle in chapter 2, some preliminary remarks about each are helpful here.

The first is a market-based approach in which I argue that increased access to essential health care goods and services is a matter of wealth creation. This argument intends to show how increased access to essential health care goods and services is an ideal of the market, even though free markets are not concerned with fairness or equity regarding essential goods or services. The major drawback of this approach, though, is that it is ultimately insufficient to sustain the normative claim that there ought to be increased access to essential health care goods and services if it were not profitable to do so.

To address this deficiency of the first approach, the next two approaches aim to provide a moral basis for why there ought to be increased access to essential health care goods and services. The first of these argues that there ought to be increased access to essential health care goods and services grounded in a right to health care. The third approach establishes an alternative view that even if persons are not entitled to essential health care goods and services, we ought to still increase access to them because of how we can understand health care as common to all persons within our society. In making this argument I first consider how health care is common based on its development and distribution, and then based on how it is a part of our shared human nature. To be clear,

my intent is not to defend any one of these three approaches as better than another, but to merely use these approaches to legitimize the principle of increased access to essential health care goods and services as an ethical limit of health care markets.

C. *Chapter 3: Arguing for the Principles of Honesty and Respect for Autonomy*

In chapter 3, I move beyond the question of access to argue for why we ought to also limit the market sale of health care goods and services according to the principles of honesty and respect for autonomy. For each of these two principles I begin by providing a theoretical framework, then argue for how each principle applies to both health care relationships between medical professionals and patients, *and* to business transactions between buyers and sellers. I conclude each discussion by addressing what it means for both principles to be an ethical limit of health care markets. Some preliminary remarks about both of these principles are helpful here.

There may be some who look at the principle of honesty and think that the need for honesty in both health care and market transactions is so obvious that it deserves no particular attention in theoretical discussions about health care markets. However, there are many cases involving health care and the market where questions about honesty are at the heart of an ethical dilemma – a physician working in a poor neighborhood debating whether or not to recommend that patients purchase expensive drugs from foreign countries at a cheaper cost; medical professionals debating, because of a patient's ability to pay, whether or not to recommend certain expensive treatments, even if those treatments are more efficacious than cheaper alternatives; persons debating whether or not to lie on insurance forms about known pre-existing conditions that can effect their

scope and cost of coverage. Yet as I argue, even though the value of honesty in health care and market transactions is not a foregone conclusion, to ethically treat health care goods and services as commodities, establishing the principle of honesty is necessary; otherwise health care is left vulnerable to the market notion of *caveat emptor*, which seems unacceptable because of the seriousness of negative consequences that can result from shifting the burden of responsibility for particular health care choices from medical professionals and patients to patients alone.

The reason I argue that respect for autonomy should be considered an ethical limit of health care markets is because of the particular role this principle plays in the success of markets and in helping establish stronger relationships between patients and health care professionals. As standard supply-and-demand economic theory goes, a successful market is one that is able to generate high demand for particular goods and services by providing for the widest range possible of consumer wants and needs. So it seems fair to claim that markets can only be successful by respecting consumer autonomy because, without consumers being able to freely choose what sorts of goods and services they are willing to purchase, markets are unable to respond to consumers' wants and needs accordingly.[7]

[7] Note, however, that "widest range possible" can still be limited with respect to providing for consumer wants and needs. Successful markets require a balance between having a wide variety of goods and services to choose from and having too many choices of goods and services – that is, while consumers prefer having free access to a variety of goods and services, too many options can sometimes have the opposite effect of causing consumers to become indecisive and simply choose to forgo purchasing a good or service at all. However, I am not sure how this idea of a balance between just enough market choices versus too many market choices effects my position because health care is not the standard sort of market product. Yet my intuition is that the possible backlash from having too many choices with respect to health care is not necessarily relevant because (a) health care typically constitutes a need (versus just a want), and (b) most people, assuming it is a need for them and they can afford health care goods and services, will not simply forgo purchasing it because they are faced with too many choices.

In health care, the principle of respect for autonomy is important for two reasons. First, respect for autonomy helps health care professionals and patients be more honest with each other regarding things like their expectations of success for certain treatments, or the satisfaction each party has with the quality of care either given or received. Second, respect for autonomy helps prevent relationships between patients and health care professionals from becoming overly paternalistic. While some paternalism in medical practice is expected (and even appreciated), overly paternalistic relationships, where health care professionals treat patients according only to what they [health care professionals] believe is best, can actually hinder how well patients respond to certain treatments. This is because health care professionals and patients sometimes differ about what treatments qualify as "best." When patients feel as though health care professionals pushing certain treatments compromise their values and choices for how they live their lives, the ability of patients to positively respond to those treatments diminishes. Respect for autonomy helps correct this problem by giving patients the ability to work with health care professionals to help determine what treatments are acceptable in accord with those patients' values and lifestyles.

D. *Chapter 4: Is the Current Pharmaceutical Drug Market in the United States Ethical?*

Chapter 4 applies my argument regarding the base ethical limits of health care markets to the prescription drug market in the United States. As I show throughout chapter 4, the general lack of interference by the United States government toward the market sale of prescription drugs has helped the pharmaceutical industry become one of the nation's most profitable. For example, in 2008 the pharmaceutical industry was the

most profitable of all American health care industries, and the third most profitable industry overall, generating 19.3% profit from revenue.[8] Still, regardless of the industry's profitability, pharmaceutical companies are often criticized for abusing their relationships with those whom they most frequently interact, namely health care professionals and patients. Chapter 4 analyzes five industry practices and shows how and why the current pharmaceutical drug market in the United States is unethical because of how these practices violate the principles of honesty, respect for autonomy, or increased access to essential health care goods and services. I then conclude chapter 4 with six suggestions for how the pharmaceutical industry could reform itself regarding how it violates these limits.

a. Industry Interactions with Physicians

The first three practices I address in chapter 4 all deal with how pharmaceutical companies typically interact with physicians. Physicians, as the ones responsible for prescribing drugs to patients, are the cornerstones of prescription drug sales. Pharmaceutical companies therefore have a vested interest in trying to convince physicians to prescribe their drugs over those of their competitors. One standard industry practice of pharmaceutical companies is to use representatives to market prescription drugs to physicians under the guise of "medical education." However, pharmaceutical representatives are in many ways like traveling salespersons whose presentations are intended to help boost product sales and company profits, and not necessarily to educate physicians. Often pharmaceutical representatives provide objectively questionable

[8] Fortune Magazine, "Our Annual Ranking of America's Largest Corporations: 2009 Top Industries, Most Profitable."

information or slant their presentations in favor of the drug being pitched. As I shall show, biased drug presentations violate both the principles of honesty and respect for autonomy.

The second practice I discuss is the use of industry-sponsored research to market prescription drugs to physicians. Industry-sponsored research often involves pharmaceutical companies paying large sums of money to researchers and physicians to publish and present research that favors a particular drug, while those companies conceal themselves as the sources of funding. Like my argument regarding the use of pharmaceutical representatives to give slanted drug presentations, I will show how the use of industry-sponsored research violates both the principles of honesty and respect for autonomy.

The third practice I address is gift giving from pharmaceutical companies to physicians. Until recently, the pharmaceutical industry endorsed gift giving as a way influence physicians' prescribing practices – although the industry maintains the actual purpose of gift giving is to offset physicians' time listening to drug presentations. I show that, because gift giving from pharmaceutical companies to physicians does not intend to benefit patients or physicians (as the gift recipients), this practice also violates the principles of honesty and respect for autonomy.

b. Direct-to-Consumer Advertising

One way for businesses to help increase their profits is by advertising what goods or services are available for sale. So it makes sense for pharmaceutical companies in the United States to advertise prescription drugs directly to consumers. The fourth industry

practice I address is the direct-to-consumer advertising (DTCA) of prescription drugs. DTCA of prescription drugs has two basic forms: branded and non-branded. Non-branded DTCA does not attempt to market any particular brand-name drug. Branded DTCA, however, explicitly markets a particular drug by its brand name. While the former is not typically regarded as ethically contentious, the latter is. My examination of DTCA therefore focuses exclusively on branded forms of DTCA. Chapter 4 addresses two primary concerns of DTCA: the questionable content of DTCA, and the lack of effective regulation by the Food and Drug Administration (FDA). Based on these two concerns, I further argue in chapter 4 that there are several ways in which DTCA advertising violates both the principles of honesty and respect for autonomy.

c. Industry Pricing of Pharmaceutical Drugs

The final practice I address in chapter 4 is the industry pricing of pharmaceutical drugs. What I show in chapter 4 is that the free market for pharmaceutical drugs in the United States has resulted in higher spending on pharmaceutical drugs throughout the United States than any other industrialized nation. A standard argument given by the industry for why the United States pays a higher amount on pharmaceutical drugs is that the willingness of American consumers to pay top dollar for pharmaceutical drugs is necessary to ensure the industry's ability to pay for future research and development of new drugs. This is an argument that I show is false, while further arguing that the industry pricing of pharmaceutical drugs violates the principles of honesty, respect for autonomy, and the increased access to essential health care goods and services.

E. *Chapter 5: Is an Ethical Organ Market Possible?*

Chapter 5 applies my argument for ethically treating health care goods and services as commodities to a potential legal organ market. In the United States, the number of persons needing organ transplants consistently exceeds the number of organ donations. Of the various solutions for how best deal with this problem, the creation of a legal organ market is one of the more contentious views currently being argued. Not only is organ selling illegal in the United States (for both living and cadaver organs), but it is also a practice that many consider *prima facie* immoral because of the perception that it degrades the intrinsic value of organs as an essential feature of personhood.

Without arguing about the morality of organ selling, chapter 5 analyzes five practical concerns that would likely accompany the establishment of a legal organ market to show the extent to which a legal organ market may violate what I argue are the base ethical limits of health care markets. To avoid any possible confusion, I assume that a basic characteristic of all transplant organs is that they are necessary for anyone who qualifies for an organ transplant. "Would-be sellers" refers to those who are or may be willing to sell their organs for profit, and "would-be buyers" refers to those who are or may be willing to purchase transplant organs.

a. Lying to Secure an Organ Sale

The first concern I address in chapter 5 is that the promise of profit could tempt some would-be organ sellers who are of questionable health to lie about their health status to avoid jeopardizing the sale. Although the current standards of organ donation in the United States require carefully testing the health-quality of organs prior to

transplanting them, we do not know if or how these standards might change in an organ market. Moreover, even with organ testing, some unhealthy organs can go undetected. I then argue how this concern could result in a legal organ market violating both the principles of respect for autonomy and honesty. I further argue that lying to secure an organ sale may or may not violate the principle of increased access essential to health care goods and services.

b. A Legal Organ Market Poses a Health-risk to Would-be Sellers

A legal organ market presumably will be regulated to try to minimize the known health-risks to both would-be organ sellers *and* buyers. Moreover, the health-risks of organ transplantation in a regulated market are likely to be comparable to that of organ donation. My focus regarding this concern is not the degree of health-risk to would-be organ sellers, but what the existence of these health-risks may mean for a legal organ market to function with respect to what I argue are the base ethical limits of health care markets.

There are two cases I consider with respect to this concern. First is the case of would-be organ sellers who are not given information about the known health-risks of organ transplantation. In this case I argue that a legal organ market would violate both the principles of honesty and respect for autonomy. I also consider how, if failing to provide would-be sellers information about the known risks of organ transplantation caused an overall decline in the numbers of organs sold via the market, this case could violate the principle of increased access to essential health care goods and services.

I next consider the case of would-be organ sellers who are informed of the risks of organ transplantation, but who are not provided additional means to help them understand that information. Here I show how merely informing would-be sellers of the risks of organ transplantation is sufficient to meet the principle of honesty. However, I also show how this case would violate the principle of respect for autonomy because of the inability for would-be organ sellers to fully incorporate this information into their decision-making process, thereby undercutting their ability to act autonomously.

c. Economic Desperation as the Motive to Sell

Another concern I address regarding the creation of a legal organ market is that economically desperate sellers, all things considered, genuinely oppose selling their organs. However these persons are willing to sell their organs anyway to try to assuage the bad effects of their economic desperation. Morally, the circumstance of being motivated to sell an organ because of economic desperation is considered equivalent to coercion. As I show in chapter 5, data coming from the Iranian model of paid organ donation suggests that a legal organ market in the United States *would* likely attract a substantially large number of sellers who are economically poor. I then argue how this concern would violate the principle of respect for autonomy. Moreover, I address how this concern appears to render a legal organ market *prima facie* unethical, because even in a regulated market there may be cases in which would-be organ sellers are strictly motivated by their economic desperation while not really wanting to sell their organs.

d. Failure to Receive a Fair Price for Organs

A forth concern about the establishment of a legal organ market is that economically desperate sellers may not receive a fair price for their organs. One reason for this is that economic desperation creates an imbalance of power in the organ sale that unfairly favors would-be buyers. Toward the end of chapter 1, we will see the underlying justification for this point when I discuss how one characteristic of noxious markets is that they create unequal power between market participants. A second reason for this concern is that economically desperate sellers may be willing to accept a lower commodified value for their organs because even a small amount of money would be advantageous for them. I then give several reasons for how this concern could result in a legal organ market violating both the principles of honesty and respect for autonomy. Furthermore I address how the notion of a "fair" price is not necessarily equal to the potential maximal commodified value of transplant organs.

e. A Decrease in Donation Rates

The last concern I address regarding the establishment of a legal organ market in the United States is that it would decrease organ donation rates. Those who oppose organ selling generally find it repugnant partly because it is thought to *de*value the cultural and social significance of organ donation as a form of altruism. By placing a commodified value on organs, there seemingly will be fewer opportunities for individuals to donate their organs, while possibly causing some other individuals to no longer be willing to donate their organs. There is some empirical evidence that appears to justify this concern; namely that once a commodified value is placed on transfusable blood, those who are

altruistically motivated to donate transfusable blood are less likely to donate. I then argue how a decrease in organ donation rates could result in a legal organ market violating both the principles of increased access to essential health care goods and services and respect for autonomy. I conclude this section with a discussion about how, even if a legal organ market resulted in decreased donation rates, it may still be able to sufficiently meet the overall demand for transplant organs.

F. *Conclusion*

This final chapter of the dissertation serves three purposes. First, I summarize my argument that treating health care goods and services as commodities via health care markets can only be ethical when their sale accords with at least the principles of honesty, respect for autonomy, and increased access to essential health care goods and services. Second, I briefly address a residual question with my argument: what might be an appropriate response for when treating health care goods or services as commodities violates the ethical limits of health care markets for which I argue. Third, I broach several possibilities for future research on this topic. These include: further addressing what the appropriate responses might be for when the sale of health care goods and services violate the ethical limits of health care markets; addressing whether or not there are any health care goods or services that should never be for sale; what might be the appropriate ethical limit(s) of a right to health care; the effects my argument might have on other types of non-medical markets; and how my argument might apply to the international production and delivery of health care goods and services.

Chapter One: Examining the Relationship of Goods to the Market

In this chapter I critically examine the relationship of goods to the market. When goods are commodified, their price attempts to represent their value based on what individuals are willing to pay for them. But, as we shall see in this chapter, it is debatable that certain goods can be appropriately valued merely as commodities.

My goal in this chapter is not to argue against the market as a means by which we can appropriately value some commodified goods. Instead, my goal is to show that health care goods and services are not properly valued merely as commodities. To accomplish this goal, I exposit thee theories of commodification and ethical markets that show how and why the value of certain is goods is not properly captured in their commodification. Together, these three theories provide me the conceptual space needed to argue that health care goods and services are not properly valued merely as commodities. However, each of these three theories say very little about the particular issue at-hand regarding the commodification of health care goods and services, leaving ample room for me to fully develop my view in the following chapters that treating health care goods and services as commodities requires imposing ethical limits on their sale. The three theories I exposit in this chapter are those of Anderson in *Value in Ethics and Economics*, Radin in *Contested Commodities*, and Satz in "Noxious Markets: Why Should Some Things Not be for Sale?"

1. **Anderson and the Plurality of Values**

Anderson questions the degree to which markets, as mechanisms for satisfying people's wants, should influence how we value goods. For Anderson, a good widely

refers to a multiplicity of things that individuals can value in some way including physical objects, services, or ideas. Markets may be able to determine the quantitative value(s) of a good, such as how much one is willing to pay for that good, but they cannot determine the qualitative value(s) of a good, such as the love or caring individuals (ought to) feel from receiving a good as a gift.[9] According to Anderson, goods are pluralistic in that, "they differ not only in *how much* we should value them, but in *how* we should value them."[10] Anderson then argues that there are some goods we should value in ways that cannot be expressed via market valuation, and that to properly value those goods, their production, distribution, and use should occur in non-market, social spheres.[11]

In developing her theory, Anderson examines three ways in which people relate to goods: in terms of experiencing values, by how we value or care about goods, and by forming and justifying value judgments. Experiencing values is, for Anderson, to value something as good or bad *with respect to the particular response(s) it elicits from us*. For example, I may laugh at a joke while others do not. This is not because the joke itself necessitates a particular response, but because I find the joke funny while others do not. However this is not the only way individuals relate to goods because it is possible to value goods without directly encountering or experiencing them. No one, for example, needs to directly encounter or experience extreme poverty to know that extreme poverty is, for the most part, an unfavorable condition for humans to live in.[12]

[9] Anderson, *Value and Ethics in Economics*, xi-xii.
[10] Ibid., xiii.
[11] Ibid.
[12] Ibid., 1-2.

To relate to goods by valuing or caring about them is to, "have a complex of positive attitudes towards it, governed by distinct standards of perception, emotion, deliberation, desire, and conduct."[13] This is different than our evaluative experiences of a good because this notion is based on how we value the good itself, not the response the good elicits from us. For example, an adult may deeply care about or value a painting by a young child because the adult is happy that the child is being expressively creative, regardless of whether the adult considers the actual painting good or not.

Lastly, we can relate to goods by way of value judgments. This is different than relating to goods either by our evaluative experiences, or by valuing or caring about them. For example, I can value a Rembrandt painting for the exquisite effort put into creating it, and for the particular emotive feeling I get by viewing a Rembrandt painting, but I can also judge that it is proper to appreciate a Rembrandt painting as an aesthetic contribution to the world of art. Relating to goods via value judgments is to therefore judge the value of a good based on criteria that is independent of our personal experiences or attitudes about those goods. As Anderson puts it, "to judge that something is good is to judge that it is properly valued. And to judge that it is bad is to judge that it is properly disvalued," such that for the proposition, ""x is F," where F is a respect in which something is judged to be genuinely valuable, entails that x meets a particular standard F, and that x merits valuation in virtue of meeting F."[14] This is to say, for instance, that because we think of aesthetic works of art as having inherent value, a Rembrandt painting is valuable by virtue of the fact that it is an aesthetic work of art.

[13] Ibid., 2.
[14] Ibid.

From these three ways in which individuals relate to goods, Anderson argues that there are two ways in which goods are plural. First, given the ways in which we relate to goods, goods are plural in that we can sensibly value them in multiple ways. Second, goods are plural in that the normative standards by which we judge their value(s) are diverse. Anderson further notes that the first sense in which goods are plural is more basic than the second because,

> [The first] explains why the second is true: we need a plurality of standards to make sense of the plurality of emotional responses and attitudes we have to things. The things that sensibly elicit delight are not generally the same things that merit respect and admiration. Our capacity for articulating our attitudes depend upon our understandings of our attitudes, which are informed by norms for valuation.[15]

What Anderson appears to mean by this is that, to sensibly value goods in multiple ways there must be multiple normative standards by which individuals judge the value(s) of those goods. Without normative standards by which individuals judge the value(s) of goods, individuals could not develop, express, or justify their reasons for how and why they subjectively value goods in the ways they do. Because individuals judge the value(s) of goods according to normative standards, Anderson claims that an essential quality of normative standards is that they are fundamentally social in that they are recognized and endorsed by others.[16]

Anderson then discusses how, because goods can be properly valued in different ways, goods differ in kind. One way goods differ in kind is by the modes of valuation used to judge them. For example, we can value goods by how we use, appreciate, or admire them. We can also appropriately value goods by how we personally relate to

[15] Ibid., 5.
[16] Ibid., 3, 12, and 141.

them; individuals can treasure gifts, show gratitude toward teachers, love family members, and express loyalty to friends.[17]

Goods also differ in kind by the social, normative standards individuals use to judge their value(s). To explain this point Anderson gives the example of a classical music concert. Properly valuing such concerts involves obeying particular customs and norms – men and women are expected to "dress-up" for the occasion, the audience is to withhold their applause until a movement is finished, and criticism during the performance is strictly forbidden.[18] By contrast, properly valuing a rock music concert means following a different (perhaps even opposite) set of social customs and norms – audiences are expected to show appreciation for the music by constant, loud cheering, and generally engaging in rowdy behavior for the duration of the show.

With this pluralistic notion of goods in mind, Anderson then argues how some goods are incomparably valued higher than others. Claiming that some goods are incomparably valued higher than others means, for Anderson, that the worth of those goods, "are not candidates for the same mode of valuation."[19] As Anderson further explains, goods can be valued higher than others, "if the things concerning it [i.e. the higher valued goods] make deeper, qualitatively more significant demands on the attitudes, deliberations, and actions of the valuer."[20]

Consider, for example, the difference between the experiences of seeing a concert in person versus hearing a recording of that concert. On Anderson's view, these two

[17] Ibid., 8-11.
[18] Ibid., 12.
[19] Ibid., 70.
[20] Ibid.

experiences cannot be judged by the same set of normative standards because the former is properly valued in multiple and diverse ways that the latter is not. The former experience involves making value judgments that are based on one's aural and visual assessment of the live concert, and via the interactions that audiences members have between each other, and the interactions that occur between the performers and audience. One, however, cannot make such value judgments just by hearing a recording of the concert – that is, the mode of valuation for the latter experience is based solely on one's aural assessment of the quality of the recording. Moreover, since the former experience is properly valued in ways that the latter cannot be valued, it is justifiable to claim on Anderson's view that the experience of seeing a concert in person has an incomparable higher value than the experience of hearing a recording of that concert.

At this point, we can begin to connect Anderson's theory of value to health care goods and services. Although Anderson does not specifically apply her theory to health care goods and services we can still see how, on her view, they ought to be considered as having higher value than many other kinds of commodified goods. Individuals can value goods like furniture, clothing, or electronics for things such as their aesthetic qualities, for their functionality, or their cost. Yet there are few ways that individuals can value these kinds of goods that have the same sort of deeply personal impact on one's attitudes, emotional responses, and judgments as health care goods and services. That is, the modes of valuation for health care goods and services often require individuals to consider aspects of those goods and services that are not expected or necessary to properly value many other kinds of commodities. Properly valuing a pharmaceutical drug, for example,

involves considerations like: the ability of the drug to address an underlying medical condition; whether or not, and to what degree, the drug may interact with other medications in ways that can affect one's health; the potential side effects of taking the drug; or the possible consequences to one's health by not taking the drug. However one can properly value goods like furniture, clothing, or electronics without ever needing to consider something like how purchasing or not purchasing those goods could negatively affect one's health.

While Anderson's theory of commodification helps us see why health care goods and services ought to be valued higher than many other kinds of commodities, it does not clearly address my concern about the ethical limits of health care markets. I now explain how Anderson's view, while indicating that the values we attribute health care goods and services are not properly accounted for in their commodification, is insufficient to deal with how we should regard their commodification for market sale.

A. *A Problem Applying Anderson's Theory to Health Care Markets*

We have already seen how Anderson argues that people are able to value different goods in different ways. It is because people are able to value different goods in different ways that Anderson further argues for a, "robust system of social sphere differentiation that requires sharper limits on the scope of the market."[21] The reason why Anderson argues that sphere differentiation requires market limits is that, without market limits people would be unable to properly value certain goods according to the normative

[21] Ibid., 141.

standards embodied and governed by non-market social spheres. Here Anderson points out that her use of sphere differentiation is similar to Walzer's.[22]

Walzer, being primarily concerned with the relationship of goods to distributive justice, notes that goods concerned with distributive justice are social goods and, as such, are valued in different ways.[23] He further notes that it is the intrinsic social meaning(s) of goods, and not the value of the good-in-itself, that determine the criteria by which goods ought to be distributed. That is, "If we understand what it is [i.e. the good in question], what it means to those for whom it is a good, we understand how, by whom, and for what reasons it ought to be distributed."[24] For example, it is considered *prima facie* unethical to buy political votes in liberal democracies because there is a general social commitment to chose political leaders for their abilities to meet the demands of the offices for which they running, and not simply because they are wealthy. This is similar to simony, prostitution, and bribery, things Walzer notes, "describe the sale and purchase of goods that, given certain understandings of their meanings, ought never to be sold or purchased."[25]

So for Walzer, it is the social meanings of goods that determine the appropriate spheres by which those goods are distributed. The market is the inappropriate sphere for distributing political votes. Likewise, goods rightly distributed via markets should not be

[22] Ibid., 143.
[23] Walzer, *Spheres of Justice*, 7.
[24] Ibid., 9.
[25] Ibid.

sold on the basis of one's political affiliation – as markets, commonly understood, is "open to all comers."[26]

Anderson agrees with Walzer that shared social meanings help justify the plurality of goods. However Anderson differs from Walzer in that, for Walzer, shared social meanings of goods is the only means of justification he discusses for understanding the plurality of goods, whereas for Anderson, justifying the plurality of goods expands beyond just shared social meanings to include individuals' conceptions of value (assuming they are rational).[27]

Given the idea that some goods are properly valued in non-market spheres, Anderson argues that it is proper to value goods as commodities only when their production and exchange accord with market norms. When the production and exchange of goods do not accord with market norms – that is, when the normative standards by which individuals properly value goods are embodied in non-market spheres – Anderson then claims, "we shouldn't treat [those goods] as commodities but rather locate them in non-market spheres."[28] Furthermore, Anderson argues that when market norms governing the production and exchange of goods undermine important ideals necessary for individuals to properly value goods, such as freedom or autonomy, the state may legitimately remove the production and exchange of those goods from the market.[29]

According to Anderson, market norms have five standard features: they are impersonal, egoistic, exclusive, want-regarding, and orientated toward "exit" rather than

[26] Ibid., 10.
[27] Anderson, *Value and Ethics in Economics*, 143.
[28] Ibid., 143.
[29] Ibid., 143-144.

"voice."[30] Markets are impersonal and egoistic in that each party to a market transaction views the other as a mere means to satisfy one's own ends (which are usually developed and defined independently of the relationship), while leaving each party free to pursue their individual interests without having to consider or care for the interests of the other party(-ies). Markets are exclusive in that the benefits of a good are wholly transferred from sellers to buyers, and that the ability for individuals to benefit from a good are generally limited by the buyer's ability to pay for it. Markets are want-regarding in that it is standard for markets to respond to demand for goods without care or concern for the reasons individuals have for wanting them. Markets are orientated toward "exit" rather than "voice" in that often, "The customer has no voice, no right to directly participate in the design of the product or to determine how it is marketed," and that "voice" for goods or services embodied in sellers may be alienated from them (such as when workers lack due process rights to get explanations for managerial decisions that affect their employment).[31]

However, as we shall see in greater detail in chapters 2 and 3, how individuals typically value health care goods and services are not only different from these five features of market norms, but are in many ways opposed to them. Health care relationships are often valued for being intimate and fiduciary, not impersonal or egoistic. Many argue that health care is not exclusive, but a right of all persons, and that access to health care goods and services should not be limited based on one's ability to pay. The delivery of health care goods and services is also not want-regarding because it is

[30] Ibid., 144-145.
[31] Ibid., 145-146.

typically based on need, not just want – for example, health care professionals are not obligated to provide health care goods and services to patients if they believe doing so would be medically inappropriate. Health care relationships also aim to uphold "voice" over "exit" – ideally, health care professionals and patients are expected discuss treatment options that both parties find acceptable and that best accord with patients' values and lifestyles.

On one hand, Anderson's view of market limits seems to justify removing the production and exchange of health care goods and services from the market altogether. This is for two reasons. First, because individuals tend to value health care goods and services in ways that appear opposite of the standard features of market norms, her view advocates that we should not, therefore, treat health care goods and services as commodities. Second, the ability for individuals to properly value health care goods and services is, in some sense, undermined when their production and exchange is governed by market norms. The reason for this is because, again, the ways individuals tend to value health care goods and services appear opposite to what Anderson argues are standard features of market norms.

On the other hand, Anderson's view of market limits also seemingly justifies continuing to allow the production and exchange of health care goods and services to occur within market spheres. As she points out, her view regarding market limits calls for sphere differentiation, not complete sphere segregation.[32] In order to respect the conditions of freedom and autonomy – conditions that are *prima facie* necessary for

[32] Ibid., 147.

individuals to properly value goods – individuals must be free to commodify goods or services either that they own or that are embodied in their persons.

For example, Anderson argues that achieving excellence in a profession is a full time activity. So while doctors and other professionals are valued in accord with how well they meet the standards of their chosen professions, they must be paid for their work, otherwise only those who are independently wealthy could afford to practice a profession. When professionals sell their services to the general public via the market, they can enhance their freedom and autonomy by setting the terms of sale for their services that buyers are then free to either accept or decline.[33]

Herein lies a problem with applying Anderson's theory of value specifically to the commodification of health care goods and services. On her view, in order to respect the freedom and autonomy of patients and health care professionals as willing buyers and sellers of health care goods and services, it is necessary and *appropriate* to allow patients and health care professionals to treat health care goods and services as commodities. At the same time, however, Anderson's view also suggests that because health care goods and services are not valued merely as commodities, and are not properly valued within the market sphere, it is *inappropriate* to treat health care goods and services as commodities, and that their production and exchange ought to occur in non-market spheres.

Some may try to counter-argue that Anderson is able to rectify this problem when she claims that sphere differentiation is sustainable, "only if market norms do not wholly

[33] Ibid., 147-148.

govern exchanges of money for professional products or services."[34] However an attempt to rectify the problem in this way is insufficient. This is because the problem I have highlighted with applying her view to the market sale of health care goods and services is not the degree to which we ought to treat health care goods and services as commodities governed by market norms, but that according to Anderson's theory we get two opposing views that show how we can and cannot justify treating health care goods and services as commodities.

Anderson's theory shows us that we ought to value health care goods and services as a higher kind of good than many other commodities; implying that, at the very least, they are improperly valued merely as commodities. However, her theory does not provide a good basis for arguing what the ethical limits of health care markets ought to be because her theory justifies two opposing views regarding the commodification of health care goods and services.

I now turn to show how, on Radin's view, the commodification of health care goods and services can be thought of in terms of incomplete commodification *and* how health care goods and services have noncommodifiable value(s).

2. **Radin and Incomplete Commodification**

Unlike Anderson, who provides a theoretical analysis for how and why some goods are inappropriately valued within market spheres, Radin takes a pragmatic approach for analyzing the social meanings of various market transactions as they relate to one's personhood. In particular, she focuses on market transactions involving "contested commodities" – goods that could be commodified, yet are typically valued in

[34] Ibid., 148.

noncommodifiable ways. Specifically Radin argues that when market transactions involving contested commodities occur, it is possible to understand how the commodified aspects of those transactions coexist with the noncommodifiable ways individuals typically value the goods being sold by thinking of the transaction in terms of incomplete commodification. "Incomplete commodification" is, for Radin, the concept by which individuals perceive market transactions of contested commodities both in terms of commodification and noncommodification.[35]

Radin argues for incomplete commodification because she does not see how standard theories regarding market limits – namely (Becker's and Posner's) universal commodification (in which everything desired or valued is theoretically subject to commodification and market transfer), (Marx's) universal noncommodification (in which markets should be abolished altogether), and (Walzer's) compartmentalization (in which goods are partitioned into social spheres) – are sufficient to address how individuals actually perceive transaction(s) involving contested commodities.[36] These theories regarding market limits see goods as either commodifiable or noncommodifiable. Radin argues this is problematic because it oversimplifies and overlooks the complexities of trying to commodify goods, "that we have previously valued in a noneconomic way[s]."[37] By discussing Radin's argument for incomplete commodification and how she relates the concept to work and social justice, we are able to see how her view justifies thinking about the commodification of health care goods and services in terms of incomplete

[35] Radin, *Contest Commodities*, xi-xiii, and 102-104.
[36] Radin, *Contested Commodities*, xii-xiii, 2, 79-80, and 103-104; and Radin, "Market Inalienability," 1853-1870.
[37] Radin, *Contested Commodities*, xiii.

commodification, and how, under her view, health care goods and services have noncommodifiable value(s).

A. *Applying Incomplete Commodification to Health Care Goods and Services*

Radin's argument for incomplete commodification addresses how commodified and noncommodified understandings can coexist in market transactions involving contested commodities. For Radin there are at least two states of affairs that explain how viewing a market transaction in terms of incomplete commodification is possible. The first state of affairs is what Radin calls "contested concepts." Contested concepts are concepts that often generate conflicting understandings when they are externally applied to various things. For example, "personhood" is a contested concept when we attempt to apply it to fetuses, as some argue that fetuses can be regarded as persons while others argue they cannot.[38] Given that concepts generally do not apply in the same way to all things, it seems possible that this description would allow us to claim that all concepts are "contested concepts" in some regard. However Radin's use of "contested concepts" is narrowed only to describe concepts that can create conflicting understandings once they are applied to market transactions. So for Radin, understanding incomplete commodification via contested concepts occurs, "when a commodified understanding (for some people) coexists with a noncommodified understanding (for others)."[39]

The second state of affairs Radin discusses for how individuals can view market transactions in terms of incomplete commodification is that of internally conflicted (or

[38] Ibid., 102.
[39] Ibid.

plural) meanings.[40] This is similar to Anderson's view that persons can value goods in multiple and diverse ways. When incomplete commodification occurs via internally conflicted meanings, persons characterize the market transaction of a good in seemingly opposing or conflicting ways that prevent them from understanding the transaction fully in terms of either commodification or noncommodification. An example of this would be when individuals value a good like an artwork or family heirloom as priceless, yet have that good appraised to determine its monetary value for insurance purposes.[41]

Either one of these two states of affairs can apply to the commodification of health care goods and services. As I discuss at the beginning of the Introduction, there are those who caution against health care markets because they see the ends of health care as incommensurable with the ends of the market. Under the first state of affairs, the commodification of health care goods and services can be understood in terms of incomplete commodification because there are some who disagree with the idea that it is ethically possible to treat health care goods and services as commodities.

We have also seen how Anderson's theory of value implies that health care goods and services ought to be valued higher than many other kinds of commodities, because the former involves a deeper, more reflective set of considerations on the part of the valuer. Regarding the second state of affairs, the commodification of health care goods and services can be understood in terms of incomplete commodification because of how their commodification can generate an internal conflict of meaning with respect to the noncommodifiable ways individuals typically value them.

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[40] Ibid.
[41] Ibid., 103

I now turn to discuss how Radin relates incomplete commodification to work and social justice. Although she too does not specifically discuss health care goods and services, her arguments can be used to show how, under her view, health care goods and services have noncommodifiable value(s).

B. *Arguing for the Noncommodifiable Value(s) of Health Care Goods and Services under Radin's View*

a. *Relating Incomplete Commodification to Work*

Radin notes that the work people do often requires some form of human interaction between workers who provide goods and services to others, and buyers or recipients of those goods and services. Yet the levels and degrees of these interactions between workers and recipients vary. When the interactions are less personal, it is easier to perceive them more in terms of commodification as simple pay-for-service exchanges. However, as the relationships between workers and recipients becomes more personal, and workers take greater care in meeting the needs of recipients, the interactions between them are also perceived in various noncommodifiable ways.[42] According to Radin, when the interactions between workers and recipients can be perceived in noncommodifiable ways, their relationship can be understood in terms of incomplete commodification. She further explains this latter point by stating,

> Incomplete commodification can describe a situation in which things are sold but the interaction between the participants in the transaction cannot be fully or perspicuously described as the sale of things. If many kinds

[42] Ibid., 104-106. Here Radin distinguishes between work and labor. "Work" in an ideal, noncommodified and nonmarket aspect, is that which individuals would continue to do if all their necessities were monetarily accounted for by other means, whereas "labor" is work that is stripped bare of its noncommodified human-element and is thought of purely in terms of commodification. Under this distinction, workers conceive of their work as a part of themselves, whereas laborers typically disassociate their lives from their work.

> sales retain a personal aspect even though money changes hands, those interactions are not fully described as the sale of commodities. They exhibit internally plural meanings. There is an irreducibly non-market or nonmonetized aspect of the human interaction going on between seller and recipient, even though a sale is taking place at the same time.[43]

This view of how incomplete commodification relates to work can apply to health care goods and services in how they are exchanged via the relationships between health care professionals and patients. The proverbial health care relationship is often perceived as a special kind of relationship that typically involves more than mere pay-for-service exchanges between health care professionals and patients. Relationships between health care professionals and patients are often characterized as being personal, intimate, and fiduciary. Even when these relationships are contrived and seemingly impersonal – say when they are the result of health insurance plans that limit patients' options for choosing which health care professionals they visit – these relationships still require basic elements like trust and honesty if they are to succeed in providing patients with the various health care goods and services they need. As such, there are noncommodifiable ways in which can we perceive the interactions between health care professionals and patients that prevent us from thinking of the sale of health care goods and services completely in terms of commodification.

b. *Relating Incomplete Commodification to Social Justice*

Radin criticizes various community based and individual based social justice theories that rely on market ideals to describe fair patterns of just distribution for goods. According to Radin,

[43] Ibid., 106-107.

> Whether we are theorizing about justice for the community or for individuals, the still-prevalent liberal metaphor of social contract seems itself to perpetuate market rhetoric. Modern contractualists do not always mean the language of contract to imply monetary exchange or implicit monetizability of all individual and social value. *Yet contract is the linchpin* of the commodified conceptual scheme, and in the liberal tradition the contract metaphor *must draw* its power from the normative power of promises to exchange commodities.[44]

Radin considers social justice theories that rely on market ideals to conceive of the relationships between people and other people, and between people and things, just as a matter of need fulfillment via some understanding of commodification. She claims that under such theories, goods are considered fungible items that merely have instrumental worth, while people are seen as self-contained individuals striving to meet their own ends.[45] The reason Radin considers social justice theories that rely on market ideals problematic is that they to fail to account for the noncommodifiable ways that people both socially connect to one another, and relate or connect various goods to their own personhood. For example, Radin discusses how housing is culturally significant for proper self-development, and not just to protect or provide individuals with security or welfare.

She further argues that social justice is also about recognizing how human interaction with others is valuable in-itself, and that satisfying one's own ends requires communal interdependence and solidarity.[46] When social justice is conceived of in this way, Radin claims it reflects the concept of incomplete commodification because it takes the commodified understanding(s) of need fulfillment as being coupled with the

[44] Radin, *Contested Commodities*, 111. Emphasis added.
[45] Ibid., 112-113.
[46] Ibid.

noncommodifiable ways that persons value their relationships to others and view goods as aspects of their personhood.

By how Radin relates incomplete commodification to social justice there are at least two ways in which health care goods and services can be regarded as having noncommodifiable value. The first is with respect to the personal meanings individuals can attach to various health care goods and services. Certainly health care goods and services have some sort of instrumental value for those who acquire and use them. However, there are many instances in which individuals do not simply value health care goods and services for their instrumental worth. For example, organ transplantation does not just help organ recipients regain their health, it also helps them regain aspects of their personhood that may have been compromised prior to the transplant such as, perhaps, the ability to perform certain activities or functions relating to their work or hobbies. Under Radin's view of how incomplete commodification relates to social justice, we can see that health care goods services have noncommodifiable value with respect to the personal meanings and significance individuals can attribute to them, and because of how they are often valued in connection with human flourishing (which Radin understands as a component of social justice[47]).

Second, how individuals acquire some health care goods and services is reflective of Radin's point regarding the integral interconnectivity of persons. Organ donation, for example, is both literally and metaphorically a type of gift exchange, and represents a situation in which the organ recipient's health is closely tied to the willing generosity of the donor to provide a transplant organ. These types of situations in which one's health is

[47] Ibid., 113.

closely tied to the work or generosity of others cannot be viewed as a mere instrumental exchange of goods or services for sake of meeting one's medical needs. To view these kinds of exchanges strictly in those terms would devalue how each party may view their relationship to the other or the nonmarket significance each party may attach to the transaction (like when the transaction is the result of an altruistic motive).

C. *Concluding Remarks on Radin Regarding the Commodification of Health Care Goods and Service for Market Sale*

Ultimately Radin's view shows us two things regarding the commodification of health care goods and services. First, because of the different non-market, noncommodifiable ways individuals can think about and value health care goods and services, their commodification is not properly understood in terms of *universal* commodification (in which all aspects of health care transactions would be open to commodification and market transfer), but instead in terms of *incomplete* commodification (in which only some aspects of health care transactions can be ethically open to commodification and market transfer). Second, we can see how, under Radin's view, health care goods and services have noncommodifiable value with respect to work and social justice – particularly for how individuals can relate the acquisition and use of health care goods and services to their relationships with others and to their own personhood.

Note however that Radin does not, nor attempts to, argue that goods that are incompletely commodified ought to be removed from the market. This, again, is because Radin is offering a pragmatic analysis regarding the sale of contested commodities, not a theoretical argument for what should or should or should not be for sale. So while

Radin's view shows that we do not simply value health care goods and services merely for their instrumental worth, her view also does not clearly indicate what sorts of ethical limits might be needed for the sale of health care goods and services to respect the noncommodifiable ways individuals can value them.

Next I analyze Satz's argument for democratic egalitarianism to show the conditions under which markets are noxious, and why noxious markets in certain goods ought to be regulated.

3. **Satz and Democratic Egalitarianism**

Satz aims to analyze the relationship between the market sale of commodified goods that historically have not been commodified, such as genetic material or organs, and the values closely connected with democratic institutions.[48] Satz develops what she calls the "democratic egalitarian approach" as a way to understand this relationship. For Satz, the democratic egalitarian approach both draws from and is an alternative to four contemporary approaches regarding commodification that all address, to some degree, questions regarding the appropriate limits of the market. These four approaches are:

- the economic approach: in which regulation of transactions should only occur when and where markets fail to be efficient. This approach allows for nonregulated, voluntary contracts "between two agents that does not have negative externalities on uninvolved outsiders."

- the 'distributive equality' approach: that accepts the legitimacy of relying on markets as a primary means of distribution except for those goods involving our basic rights or liberties. Here markets are used only to achieve an egalitarian distribution.

[48] Satz, "Noxious Markets," 11-13.

- the social meanings approach: in which the appropriateness of treating goods as commodities available for market sale depends on the socially shared meaning or value of those goods.

- the perfectionist approach: in which treating certain goods as commodities available for market sale can, "undermine the conditions for our best flourishing as human beings" in the sense that, "we thrive when certain goods closely connected to our 'personhood' cannot be bought or sold on the market."[49]

The reason Satz does not fully endorse any one of these approaches is that she considers them to be either too narrowly focused on just the values of efficiency and equitable distribution, or "are too controversial and too *a priori* to be the basis of a theory of market regulation."[50] Satz's democratic egalitarian approach concurs with and utilizes the ideas of both the social meanings and perfectionist approaches that a plurality of values helps guide our understanding of market regulation. Yet she claims the values reflected in the democratic egalitarian approach are more closely associated with the economic and 'distributive equality' approaches; values she claims are characteristic of democratic institutions.[51] In particular, the values Satz takes as central to the democratic egalitarian approach are liberty, the equal standing of citizens, and accountability.[52]

Satz acknowledges that democratic egalitarian values may sometimes conflict with one another, and that this will sometimes require making tradeoffs with respect to those values. However, for Satz, resolving these conflicts and determining which tradeoffs are ethically appropriate is not a matter of philosophical determinism, but a matter of democratic politics – that is, the democratic egalitarian approach, "stresses the

[49] Ibid., 12.
[50] Ibid., 13.
[51] Ibid., 13 and 23.
[52] Ibid., 13.

need to consider institutional alternatives to the market and to make comparative judgments—[as] there is a limit to what purely philosophical approaches can tell us to do in abstraction from the context and the facts."[53] This is not to say that democratic reasoning cannot be philosophically informed, only that a pure philosophical analysis of commodification cannot account for all contextual factors regarding the appropriate limits of the market. This aspect of Satz's argument highlights a deficiency in the four contemporary approaches she builds her view on – none of the other approaches by themselves, "has very much to say about the role of politics in allowing people to formulate, voice, deliberate, and decide about how to order conflicting values in the context of setting the limits to the market."[54]

When the commodification of goods for market sale violates one or more democratic egalitarian values, Satz claims that those markets are noxious.[55] According to Satz, there are three ways to characterize noxious markets. Markets can be considered noxious either when they result in extreme outcomes, "that depress people below the level of what they need to function as citizens (or even as human beings);" when they allow for some participants to exercise unequal and unaccountable power over others; or when they undermine values and procedures necessary to support liberal democracies.[56] I now turn to elaborate what Satz means by each of these features of noxious markets and to show how her discussion of noxious markets relates to the commodification of health care goods and services.

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[53] Ibid.
[54] Ibid.
[55] Ibid.
[56] Ibid., 23-24.

A. *Relating Noxious Markets to the Commodification and Market Sale of Health Care Goods and Services*

The first characteristic of noxious markets is that they can lead to extreme, negative outcomes. Satz's understanding of extreme outcomes is primarily based on Ravi Kanbur's from his article, "On Obnoxious Markets." According to Kanbur, the threshold of extreme outcomes for markets is a matter of degree with respect to the context. For example, if a billionaire and a middle-class worker who earns a hundred thousand dollars a year both lose a hundred thousand dollars in the stock market, the negative impact on the billionaire is not likely to be viewed as an extreme outcome, whereas the negative impact on the middle class worker may be devastating to the degree that it can be thought of as an extreme outcome. And while Kanbur acknowledges this is an "untidy" way to think about extreme outcomes, he further claims that, "a good starting point is that if the outcome renders a family or an individual destitute, below some context-specific poverty line, say, that is an extreme outcome."[57] Satz slightly differs from Kanbur regarding this last point. For her, understanding when an outcome is "extreme" is not a question of whether or not the outcome causes a family or individual to be destitute, but whether or not the outcome violates democratic egalitarian values.[58]

Satz claims that noxious markets that cause extreme outcomes can be especially bad, "when the goods that these markets are distributing are ones that people urgently need, as in the case of life-saving drugs or healthcare."[59] She further claims that the reason for this is because, "People whose basic needs have not been met – people who

[57] Kanbur, "On Obnoxious Markets," 44.
[58] Satz, "Noxious Markets," 24.
[59] Ibid.

lack adequate food, education, or medical care – cannot participate in political life or civil society on a footing of equality with others."[60] This is an ambiguous claim and one that Satz does not attempt to argue for or explain. In particular, it is unclear what it means to meet one's basic needs, and how meeting one's basic needs correlates to one's equal political or social participation with others. Moreover, with respect to healthcare, if a large number of people lack the same basic access to healthcare or medical care – such as the nearly 50 million uninsured United States citizens – wouldn't those individuals be on equal, not different, footing in their ability to participate in political life or civil society? However despite Satz's ambiguity here, the underlying force of her point appears to be that noxious markets that produce extreme outcomes are particularly troublesome for goods that *prima facie* appear necessary for individuals to ideally function as members of democratic institutions.

Satz then argues that when the market sale of goods people urgently need cause extreme outcomes, the appropriate response is not necessarily to ban their sale. This is because banning the sale of these types of goods can also have bad effects like the creation of black markets, or an inefficient provision of a needed good.[61] Instead Satz claims the appropriate response is to partially decommodify the market sale of needed goods. Under the idea of partial decommodification, a needed good could still be commodified for market sale, but a minimal level of provision would be guaranteed to all

[60] Ibid.

[61] Ibid. We have already begun to see the effect of market bans to some extent with human transplant organs: because there is such a high unfulfilled demand for transplant organs in the United States, the current ban on organ sales has driven some to purchase transplant organs either from countries where organ sales are legal, or from areas of the world where there exist black markets in transplant organs. See; Taylor, *Stakes and Kidneys*.

(although Satz does not specify what that minimum level would be, or how it would be determined). The reason Satz argues for partial decommodification is not just because it is a way to ensure access of needed goods to all, but also because it expresses the importance a society places on these goods. As Satz claims regarding this point,

> A decent society will not only protect its members from poverty, but also from some specific forms of disenfranchisement: ensuring access to medical care and legal assistance, education, and nutrition… [So] In refusing to completely commodify goods like healthcare or life-saving drugs, a society expresses its recognition of the importance of these goods.[62]

The second way Satz argues markets can be noxious is when some participants are able to exercise unequal and unaccountable power over others. Satz claims this is possible because among other socially influential aspects of markets, "they can also structure the exercise of power and limit the scope of democratic accountability."[63] Satz further claims this is particularly true in cases when markets are not perfectly competitive and there are already socio-economic inequalities between the participants.[64]

To illustrate this point, Satz gives the example the grain market in Bangladesh, in which a recent famine increased the cost of rice beyond what the poor could pay to purchase it. The rich landowners however were not affected by this cost increase, partly because they were often given rice as payment by their tenets for use of their land. The

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[62] Satz, "Noxious Markets," 24. Also in this section regarding the extreme outcomes of noxious markets, Satz criticizes both Radin and Walzer for claiming that some healthcare goods and services should not be treated as commodities. Although Walzer says in *Spheres of Justice* that healthcare falls under the sphere of security and welfare, and so is not (and cannot be) appropriately distributed via the market (Walzer, *Spheres of Justice*, 86-91), Satz criticism of Radin is seemingly unjustified. Although it is possible that Radin makes "ought" claims elsewhere regarding the noncommodification of healthcare, she does not in *Contested Commodities* – again, the most Radin claims is that market transactions involving goods like healthcare are best understood in terms of incomplete commodification.

[63] Ibid., 26.

[64] Ibid.

poor were not only made more vulnerable to extreme outcomes by the increased cost for rice, but also became much more dependent on rich landowners. Although Satz does not explain what she means by "more vulnerable to extreme outcomes," it seems as though, given that Satz takes "extreme outcomes" to be outcomes that violate democratic egalitarian values, she is referring to the unlikelihood in this case that the poor were able to engage in a market relationship with the rich landowners that expressed respect for democratic egalitarian values. She thusly concludes that the grain market at that time in Bangladesh was noxious because of its effect on the power stratification between the rich and poor.[65]

Similar to when markets can result in extreme outcomes, Satz does necessarily think the appropriate response is to ban markets that allow some persons to exercise unequal power over others. According to Satz, this is because banning such markets will not address what are often the underlying inequalities that exist between the market participants. She states, "For example, if the problem with selling kidneys is (as some claim) the 'desperateness' of the exchange, banning the sale will by itself do nothing to relieve the desperate conditions that prompt it."[66] This also is not to say, nor suggest, that regulating these kinds of noxious markets is sufficient to overcome what are often the underlying inequalities between the participants. Regulation of organ markets would not, using Satz's example, be able to address what many see as a moral problem that sellers are more likely be economically disadvantaged than buyers, and that this underlying inequality is tantamount to the poor being exploited for their organs for the sole benefit of

[65] Ibid.
[66] Ibid., 26-27. Quote on 27.

the wealthy. However, given the limit of Satz's argument to the scope of the market, regulating these kinds of noxious markets as opposed to banning them could at least prevent potential abuses of power within those markets as a way to try to mitigate the severity of any underlying inequality between the participants.

The last way Satz argues markets can be noxious is when they undermine the crucial values and procedures of liberal democracies. The reason Satz considers this aspect of noxious markets a problem is because, "The regulative idea of democracy is that citizens are equals engaged in a common cooperative project of governing themselves together."[67] As such, all citizens of a liberal democracy ought to have equal standing in deciding the governing laws and procedures of that particular democratic institution.[68] Although there seems room here to criticize how well this ideal can be implemented within different democratic institutions, Satz's point is only that the freedom granted to citizens in liberal democracies is meaningless if they are without the goods necessary, "to participate effectively in the project of self-government."[69]

To ensure access to goods that individuals need to participate in liberal democracies, Satz argues that a case can be made for regulating or banning markets in those goods. According to Satz, these goods fit into three categories: (i) political goods like voting rights, (ii) goods, like education, that are required for effective participation in liberal democracies, and (iii) goods that, "foster the development of people likely to support democratic institutions and function effectively in a democratic environment."[70]

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[67] Ibid., 28.
[68] Ibid.
[69] Ibid.
[70] Ibid.

We have already seen with respect to noxious markets and extreme outcomes that Satz considers healthcare, like education, a basic need for individuals to ideally function as members of democratic institutions. So on her view healthcare would be considered a good within the second category. As Satz notes when discussing how markets in these kinds of goods can lead to extreme outcomes, a total ban on markets in these goods could have worse effects than if they were regulated. Her concern here, though, is not just that unregulated markets in these kinds of goods can cause those markets to be noxious by leading to extreme outcomes, but that they could also be noxious by limiting access to these goods just to those with the resources to afford them. Satz provides further explanation of this latter point when she applies her view to unregulated organ markets. According to Satz, the problem with unregulated organ markets undermining the values of liberal democracies is that,

> Unregulated organ markets would conflict with widely held ideas about fairness, to the extent that they allowed the rich to purchase the gift of life while others without resources could not. As a social practice, they would confer privileges to the wealthy that send the message that their urgent needs are more important than those of others.[71]

There are two particular points we can draw out of what Satz says regarding noxious markets and how they relate to the commodification of health care goods and services. First, Satz considers healthcare a need that should be provided to all persons in at least some basic form. So whatever health care goods and services would qualify for what she considers "healthcare," they are not valued under her view merely as commodities, but as necessities for people to effectively participate in democratic institutions. Second, Satz is characterizing the features markets exhibit when they either

[71] Ibid., 35.

exceed the threshold of democratic egalitarian values, or exacerbate underlying inequalities between market participants. However, she also acknowledges that the features of different markets raise different moral concerns relative to the kinds of relationships that exist within those markets.[72] So while Satz explains why it is necessary to regulate markets, her view also leaves room to argue what the specific limits of different kinds of markets should be.

4. **Conclusion**

So far I have discussed how the views of Anderson, Radin, and Satz justify the idea that health care goods and services are not properly valued merely as commodities. However, I have also shown that none of these views gives a clear indication of what it means to ethically treat health care goods and services as commodities that are bought and sold via health care markets. Anderson's view is the only one under which we might consider it unethical to treat health care goods and services as commodities because they are not properly valued according to market norms. The problem, though, is that this point contradicts another aspect of her view justifying the idea that respecting the conditions of freedom and autonomy – conditions necessary to properly value goods – would require allowing individuals to willingly treat health care goods and services as commodities. Radin's view shows that health care goods and services can be thought of in terms of incomplete commodification, but she does not specify what ethical limits should be placed on the market sale of incompletely commodified goods. On Satz's view we see that she regards healthcare as a necessary good that persons need to fully participate in democratic institutions, but that banning markets in this kind of good would

[72] Ibid., 37.

likely cause more harmful effects than if such markets were regulated. Yet Satz does not further argue why "healthcare" is required to participate in liberal democracies, what sorts of goods and services she thinks would fall within the bounds of "healthcare," or how we ought to regulate "healthcare" markets.

This analysis about how health care goods and services are not properly valued merely as commodities clears the way and establishes the need for developing a theoretical account of how it may be possible to ethically treat health care goods and services as commodities. Over the next two chapters I attempt to develop such an account. In the next chapter I build on the view that health care is a special kind of good that cannot be valued merely as a commodity to argue for why there ought to be increased access to essential health care goods and services and how this principle is an ethical limit of health care markets. In detailing this aspect of my argument, I attempt to specify the goal of increasing access to essential health care goods and services by articulating what is and is not included under this principle.

Chapter Two: Arguing for the Principle of Increased Access to Essential Health Care Good and Services

None of the theories of ethical markets used to show how health care goods and services are improperly valued as commodities consequently shows that they should also be removed from the market. Anderson argues that goods should not be treated as commodities when their production and distribution fall outside market norms. However I have also shown why this argument is insufficient for removing the production and delivery of health care goods and services from the market, since it contradicts an important aspect of her view regarding the ability of individuals to properly value goods. I now turn to explore how it may be possible to ethically treat health care goods and services as commodities.

There are two main reasons why I argue for the principles of honesty, respect for autonomy, and increased access to essential health care goods and services as the base ethical limits of health care markets. First, each of these appear to reflect some of the ways individuals can value health care goods and services, or the transactions by which those goods and services are exchanged, beyond their mere commodification. Second, as we shall in greater detail over the next two chapters, each of these principles play an important role in governing what we can think of as the ideal for both interactions between health care professionals and patients, *and* market transactions between buyers and sellers.

This chapter attempts to bridge the view established in chapter 1 to my argument regarding the base ethical limits of health care markets. Specifically I aim to show why there ought to be increased access to essential health care goods and services, and what it

means for this normative principle to be an ethical limit of health care markets. In making this argument I examine three approaches that, together, help justify the principle of increased access to essential health care goods and services. The first of these is a market-based approach, in which increased access can be thought of in terms of wealth creation. Then, after noting a problem with this view to ensure access to essential health care goods and services, I provide two moral-based approaches that argue for increased access on the basis of a possible right to health care, *and* on the basis that health care is common to all persons within our society. I then attempt to clarify some of the qualities that should define essential health care goods and services. I conclude by discussing what it means for the principle of increased access to essential health care goods and services to be an ethical limit of health care markets.

1. A Market Approach for Increased Access

At first glance, attempting to develop a market-based argument for increased access to essential health care goods and services may seem odd. This is because, on one hand, most arguments regarding access to essential health care goods and services center on the idea that health care is a basic human need that all persons are entitled to in some fashion as a matter of justice or fairness. On the other hand, markets, historically, have not been used to generate fair or just access to goods or services. Markets typically require persons to forgo purchasing commodities they cannot afford, even if the commodity is also socially recognized as a need, such as health care. This section attempts to reconcile these two opposing views to show that even though markets are not

concerned with fair access, the value of health care goods and services as commodities justifies increasing access to them.

One type of market system that seems naturally inclined toward increasing access to essential health care goods and services is social welfare capitalism. Under this system, the focus of the market shifts away from the traditional goals of wealth creation and the attainment of private property, toward protecting and improving the welfare of all participants within the market. Theoretically, it is possible to accomplish this shift in market ideology by having the government fulfill its duty to citizens by increasing its role from merely stabilizing and correcting potential market failures via regulation to actually controlling the market.[73] The benefit of using social welfare capitalism to argue for increased access to essential health care goods and services is that it recognizes and emphasizes meeting the needs of market participants to enhance their overall well being as tied to economic growth. Despite its promise, though, I reject using social welfare capitalism in this project as a basis to justify a market approach for increasing access to essential health care goods and services.

As Cooley notes, a transition to social welfare capitalism would be a paradigm shift that replaces current market ideology.[74] Using social welfare capitalism to ground a market approach to justify the principle access to essential health care goods and services would therefore be impractical for my overall argument. This is because my theoretical

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[73] See for example; Cooley, "Understanding Social Welfare Capitalism, Private Property, and the Government's Duty to Create a Sustainable Environment."

I am thankful to Dennis Cooley for his comments, and subsequent e-mail conversation, about my project in connection with social welfare capitalism during a paper I gave on the ethical limits of health care markets at the Nineteenth Annual Meeting of the Association for Practical and Professional Ethics.

[74] Ibid.

discussion of the market up to this point and hereafter focuses on a free market system that the government regulates, not a market system that the government controls. Moreover my goal in this project has never been to argue for what kind of market system is best to ethically manage the production and delivery of health care goods and services. A second reason why I reject using social welfare capitalism here is that this is not the kind of market system discussed by Anderson, Radin, or Satz (although Satz theory of Democratic Egalitarianism appears similar), and is not the kind of market system that current health care markets, like the pharmaceutical industry, operate under. So while social welfare capitalism may be useful for analyzing the ethical limits of *future* health care markets, it is not necessarily helpful for analyzing the ethical limits of *current* health care markets. However, it is possible to ground a market approach for increasing access to essential health care goods and services using the current free market system.

A standard feature of free markets is to generate as much monetary value as possible for shareholders. So even though questions about the fair access and distribution of health care goods and services typically fall outside market concerns, free markets ought to still focus on increasing access to essential health care goods and services as a matter of wealth creation. The reason for this is grounded in basic economic theory of supply and demand. According to this theory, markets function best when the amount of a good supplied equals the demand for that good, whereas the ability of markets to maximize wealth creation is not optimal when either the supply or demand for a good outweighs the other. When goods or services have continuous or increasing demand markets in those goods or services will therefore function to try to meet that demand.

Health care, we know, is one institution that has seen steady increases in demand for goods and services since at least the 1960s when public sector financing of health care was introduced with Medicaid and Medicare. Using America's Gross Domestic Product (GDP) as an indictor of consumer demand, the demand for health care has increased its share of America's GDP from 5% in 1960 to 12% in 1990. Additionally, increasing demand led to an annual average of 11% economic growth in health care from 1960 to 1990 (3 percent above the average growth of the United States' economy during that time). Even as the demand for health care steadily dropped throughout the 1990s – due mostly to an increase in managed care systems that saw consumers having to pay higher premiums and deductibles for both private and employer-sponsored health insurance – annual growth in health care still increased at a rate of approximately 5.5%.[75]

The recent economic recession has also slowed the growth in demand for health care goods and services – particularly for those paid out-of-pocket. However, according to the 2008 summary of health care spending by the Centers for Medicare and Medicaid Services, health care spending was still projected to increase by 2.1% between 2008 and 2009, and increase to 4.8% between 2009 and 2010. The report also highlighted several projected spending increases between 2008 and 2009 correlating with increased demand for particular health care goods and services. For example, prescription drug spending was projected to increase from 3.2% in 2008 to 5.2% in 2009, largely due to an increased use of anti-viral drugs associated with H1N1 virus. Also, hospital *and* physician and clinical services spending growth was expected to increase, respectively, from 4.5% and

[75] Institute for the Future, *Health and Health Care 2010*, 25-30.

5% in 2008 to 5.9% and 6.3% in 2009, driven largely by increased demand for services to treat H1N1 virus.[76]

We need to be clear, though, what we mean here by "demand." When talking about the demand for essential goods and services, "demand" refers to the *effective* demand – i.e., the want of a good or service coupled with the ability to pay for it. If goods or services cost too much for persons to afford, the demand for them can decrease, which can then negatively impact profits stemming from the sale of those goods and services. So built into this market approach for justifying increased access to essential health care goods and services is the necessity of the marketplace to keep costs for essential health care goods and services affordable to the degree that their cost does not negatively affect the ability of the market in those goods and services to remain profitable. This is a point that I will return to in the chapter on the pharmaceutical industry when I analyze and refute the claim that high pharmaceutical drug prices in the United States ultimately improve access to prescription drugs.

There is, however, a concern with this approach being able to fully ground the normative principle that there ought to be increased access to essential health care goods and services. As long as markets in essential health care goods and services remain profitable, basing the principle of increased access on the concept of wealth creation works. Hypothetically, though, if markets in essential health care goods and services were not profitable, there would no longer be a reason to increase access to them as a matter of wealth creation. The specific problem with this approach is that it only

[76] United States Department of Health and Human Services and Centers for Medicare and Medicaid Services, *National Health Expenditure Projections 2009-2019*. As of May 2010, I have been unable to find any empirical data that allow us to draw any conclusions about the accuracy of these projections.

recognizes the commodifiable value of essential health care goods and services, while failing to account for how they are necessary for meeting persons' health care needs. To help overcome this problem with the market-based approach, I next argue for two moral-based approaches in which increased access to essential health care goods and services can be grounded either in terms a right to health care *or* the idea that health care is common to all persons within our society.

2. **A Right-to-Health Care Approach for Increased Access**

One way to defend increased access to essential health care goods and services beyond the profitability of health care markets is via a right to health care. This is because a primary function (if not *the* primary function) of arguments for a right to health care is to justify some form of universal access to health care. However, the intent of this section is not to argue for a right to health care *per se*. Instead the focus of this section is to show how there ought to be increased access to essential health care goods and services based on the plausibility of a right to health care. There are two accounts of a right to health care that I use to ground this approach: Daniels' argument for a right to health care on the basis of equal opportunity, and Buchanan's pluralistic account for a right to a decent minimum of health care.[77] Before addressing these two views, though, it will be helpful to first briefly sketch what we mean by a "right" to health care.

[77] For fuller range of arguments for a right to health care, also see; Daniels, "Health-Care Needs and Distributive Justice;" Daniels, "Equity of Access to Health Care: Some Conceptual and Ethical Issues;" Davis, "Inequality and Access to Health Care;" Emanuel, "Justice and Managed Care;" Galarneau, "Health Care as a Community Good;" Harvard Law Review, "Universal Access to Health Care;" and Pellegrino, "The Commodification of Medical and Health Care."

A. *Clarifying the Concept of a Right to Health Care*

Buchanan notes four basic features of valid rights claims. First, "To say that a person A has a right to something X, is . . . to say that A is entitled to X, that X is due to him or her."[78] Furthermore, claiming that person A has a right to X is stricter than claiming that X is either morally good or desired by person A. Second, rights warrant enforceability via sanctions or even coercion by some governing body, *and* that the failure of one's rights to be enforced is itself an injustice. Third, rights trump utility maximization in the sense that, "[I]f A has a right to X, then the mere fact that infringing A's right would maximize overall utility or even A's utility is not itself a sufficient reason for infringing it."[79] Fourth, universal rights, such as a right to health care, apply to all persons.

The third feature requires an important clarification. Utility maximization may not be *sufficient* to infringe upon or override one's rights, but this is not to say that rights are therefore unlimited or that utility maximization cannot be a reason for limiting certain rights. The fulfillment of any right is limited according to the resources available to meet or enforce it. For example, having a right to health care does not thusly entitle all persons to an open-ended array of health care benefits. This is because, as Dougherty explains,

> Such an unbound obligation would conflict with other obligations individuals have, including obligations to themselves, and would lead to a view of persons as merely resources for satisfying others' needs with no space left for personal self-determination . . . Moreover, such an open-ended health care obligation would mean the inability to fund other important public resources.[80]

[78] Buchanan, "The Right of a Decent Minimum of Health Care," 56.
[79] Ibid.
[80] Dougherty, *Back to Reform*, 44.

Although Dougherty does not further specify what he means by an unbound obligation to provide health care conflicting with other obligations to oneself and others, his wording here suggests a Kantian line of thinking. Specifically, Dougherty seems to be implying that an unbound obligation to provide health care would violate Kant's famously argued view that all persons have an obligation to treat themselves and others as ends and never merely as a means to an end.[81] However since Dougherty does not argue for this point it is unclear that this is his intention, and it is unclear how exactly an unbound obligation to provide health care would actually lead to viewing "persons as merely resources for satisfying others' needs . . ." Still, the idea that a right to health care must be limited according to available resources is one consideration I address later in the chapter when I attempt to clarify some of the qualities of essential health care goods and services.

Rights are also often classified as positive or negative. Negative rights are those that, apart from enforcement, require others to abstain or refrain from action against the right's possessor. A negative right to health care therefore refers to the requirement of others not to impede on one's ability to attain health care. Positive rights are those that, beyond enforcement, may require others *to act* on behalf of the right's possessor in order for that person fully attain what is due to him or her. A positive right to health care therefore refers to the obligation others to help individuals attain whatever form of health care is due to him or her. Health care is generally considered to be a positive right, since one's ability to attain health care typically requires more than just the noninterference of

[81] See; Kant, *Groundwork for the Metaphysics of Morals*, 4:428-4:429; and Kant, *The Metaphysics of Morals*, 6:385 and 6:395. Pagination for all references to these two works is from the Academy editions volume 4 for the *Groundwork* and volume 6 for the *Metaphysics of Morals*.

others. To remain consistent with Daniels and Buchanan, I also treat the right to health care as a positive right.

B. *Establishing a Right to Health Care*

Daniels states that attempts to justify a right to health care extend beyond legal positivism – which claims that rights only exist when embodied by laws – toward a moral right.[82] This is because, as he further claims with respect to a right to health care, "Legal entitlements, most people believe, should reflect what society is morally obliged to provide by way of medical services."[83] According to Daniels, it is possible to base a right to health care on the concept of equal opportunity. He argues that disease and disability restrict the normal range of opportunities available to persons within a given society to construct reasonable "life-plans" for themselves, and so, because health care helps people function as close to normal as possible (given their talents and skills), persons are entitled to a fair allocation of health care resources to preserve the range opportunities closed off to them as a result of disease or disability.[84] There are, however, some concerns regarding Daniels' argument.

One concern is that Daniels' notion of a normal opportunity range makes it hard to asses what sorts of essential health care goods services ought to be included under the principle of increased access. On one hand, Daniels claims that a "normal opportunity range" is that which allows persons to pursue reasonable life-plans. However there are a number of reasonable life plans available to persons within our society that, if we provided the health care resources necessary for all persons to pursue them as part of a

[82] Daniels, "Is There a Right to Health Care and, If So, What Does It Encompass?," 316.
[83] Ibid.
[84] Ibid., 319-320. Also see, Daniels, "Health-Care Needs and Distributive Justice."

normal opportunity range, would theoretically lead to a massive depletion of those resources.[85] Basing a right to health care on a right to a normal opportunity range also runs the risk of being circular. While the goal of health care under Daniels' argument is to ensure a normal opportunity range, what constitutes a normal opportunity range within society is partly determined by the quality of health care available within that society. This is problematic is because, as Buchanan notes,

> [A] principle which requires only that resources be allocated so as to assure that everyone attains the normal opportunity range would be inadequate in situations in which the normal opportunity range was unacceptably narrow due to a failure to allocate sufficient resources for health care.[86]

Buchanan then claims that Daniels' argument must be supplemented with a principle requiring the maximization of the normal opportunity range.[87] So, on the other hand, this latter point regarding Daniels' notion of the normal opportunity range could consequently result in having to be too narrow or strict about the kinds of health care goods and services included under the principle of increased access.

Another concern about Daniels' view is that its scope is objectionable. Preserving one's ability to attain a normal opportunity range is undoubtedly a good reason why there ought to be increased access to essential health care goods and services. However, as we shall see in the next section, there are other, more primary reasons why we should be concerned about the attainment of health care. That is, the attainment of health care is

[85] This objection to Daniels is originally given by Buchanan, in which he criticizes Daniels' claim of a "normal opportunity range" being too ambiguous. See; Buchanan, "The Right to a Decent Minimum of Health Care," 63.
[86] Buchanan, "The Right to a Decent Minimum of Health Care," 64.
[87] Ibid.

good even when it does not necessarily preserve or increase one's range of opportunities.[88]

Partly in response to the general concerns of Daniels' view, Buchanan develops an alternative argument that does not look to justify a *prima facie* universal right to health care, but, instead, aims to show how a pluralistic strategy is enough to do the work of supposed a universal right to health care. For the sake of space, I only briefly summarize the main points of Buchanan's argument. Also, the full purpose of Buchanan's argument is to develop an obligation of state enforced beneficence regarding the right to a decent minimum of health care. He does this primarily to counter-argue the libertarian view that persons are not entitled to health care because such a right would be tantamount to an *unjust* distribution of resources. However I abstain from discussing this aspect of Buchanan's argument because merely establishing the plausibility of a right to a decent minimum of health care does not also require showing how enforcing that right is fair or just.

First Buchanan argues that, at the least, there three ways we can defend a *specialized* right to health care – i.e., a right that only applies to certain individuals or groups. These ways are: 1) arguing that groups like Native Americans or African Americans are due core health care benefits to rectify past injustices that either directly or indirectly resulted in health detriments within those groups; 2) by arguing that those who, through some form of employment, have been either unjustly harmed or unjustly exposed to health risks, are entitled to core health care benefits as a matter of just compensation; and 3) by arguing that core health care benefits are due to those whose exceptional

[88] Ibid., 63.

sacrifices for society have resulted in adverse health, such as when military personnel are wounded during combat.[89] Second, Buchanan argues that our society already accepts expending public resources to attain public health measures such as sanitation and immunization from potentially harmful, communicable diseases, and that because of this, there is an extended moral obligation, "to achieve some standard of *equal protection* from the harms these measures are designed to prevent."[90] Third, Buchanan argues that a right to health care can also be defended via non-moral, prudential reasoning. For example, basic health care measures not only help protect persons from various health related harms, but they also *improve* the health of some persons, thereby potentially improving the overall quality of society, such as by helping to create a stronger workforce.[91]

Buchanan's argument for a right to health care is more practical than theoretical. This helps him avoid the same kinds of ambiguities that can arise from using concepts like "normal opportunity range." The point, however, is not to debate the strength of Buchanan's and Daniels' arguments compared to each other. Whether or not Buchanan's argument or Daniels' argument is ultimately more justifiable than the other, both provide seemingly plausible ways for understanding how there can be a right to health care. Furthermore, the combined weight of these arguments for a right to health care is enough to lay the groundwork for why, apart from wealth creation, there ought to be increased access to essential health care goods and services.

The underlying force of Daniels' argument for a right to health care is the preservation of normal species functioning to ensure a normal opportunity range. Based

[89] Ibid., 66-67.
[90] Ibid., 67-68. Quote on 68.
[91] Ibid., 68.

on this, there ought to be increased access to essential health care goods and services whenever a lack of access to these things inhibits persons' functioning in a way that threatens or jeopardizes their ability to be within the normal opportunity range. However, even if we reject this conclusion because of the ambiguity of the normal opportunity range, Buchanan's understanding of a right to health care gives us other reasons why there should still be increased access to essential health care goods and services. Buchanan's argument for a right to health care focuses on the attainment of basic health care either as some form of restitution to particular groups or individuals, *or* as something that serves the overall benefit of the general public. So based on this view, there are at least two reasons why there ought to be increased access to essential health care goods and services. First, increasing access to essential health care goods and services would be necessary whenever a lack of access resulted in a failure to provide particular groups or individuals some basic form of health care due to them as a matter of just compensation. Second, there ought to be increased access to essential health care goods and services when a lack of access fails to protect particular groups or individuals from health detriments that our society already expends resources to prevent among the general public.

This approach toward justifying the principle of increased access to essential health care goods and services works so long as we accept the validity of arguments for a right to health care. Yet there are some who may reject such arguments on the grounds that fulfilling a universal right to health care would involve the collection and redistribution of resources that is intuitively unfair either to those who are better off and

can afford paying for private health care measures, or for those who are relatively healthy and who may contribute much more to fund basic public health care measures than they will realistically use. So it is likely that those who reject arguments for a right to health care will remain unconvinced that this approach is able to legitimately ground the principle of increased access to essential health care goods and services. As I argue next, though, it is possible to justify the principle of increased access to essential health care goods and services even if there is no right to health care.

3. **A Common-View Approach for Increased Access**

I argue in chapter 1 that health care goods and services are not properly valued merely as commodities. In making this argument, there is an unstated presumption that health care should be used for the betterment of society because it is common to all persons within society. This is particularly evident on Satz's view when I merely take as given her claim that healthcare is a need of citizens to effectively participate in democratic institutions. But I have yet to address what it means, or may mean, for health care to be a common good of all persons within society. That is my goal in this section. Specifically, I aim to provide two possible explanations for how health care is common to all persons within our society, and why this helps justify increased access to essential health care goods and services as a result.

A. *Health Care as Common based on its Development and Distribution*

One way that health care can be understood as common to all persons within our society is that its development and distribution is fundamentally social. As Pellegrino argues, medical knowledge develops and is transmitted via the participation and sanction

of the general public, making it a good to which the members of society have a substantial claim. First, medical knowledge has developed over centuries of clinical observations and controlled experiments that often respond to previous medical research, is widely accessible to health care professionals and the public, and has frequently relied on the participation of the general public as human research subjects. Moreover, medical knowledge that comes from research and experimentation is largely paid for via public agencies and institutions *or* private philanthropies to which most of the general public contributes either by paying taxes or donating funds.[92]

Second, the acquisition and transmission of medical knowledge "is ethically possible only with society's sanction."[93] Often the kinds of activities that are legally permitted within medical communities are punishable crimes outside of them. Such activities are permitted within medical communities, however, because they intend to provide a broad social benefit. There are several examples of this. Our society has laws governing the treatment of deceased bodies, and maintains a standard that we ought to revere and show respect for deceased persons. Yet our society also allows for medical practioners to perform autopsies, dissections, and other kinds of experiments on cadavers to help advance medical knowledge of human bodies. We also have laws that aim to protect individuals' privacy and private information. However, for the sake of providing students advanced "hands-on" medical training, medical teaching hospitals grant students the right to ask patients and their families private and often personal questions about patients' health. Students in these settings are also given a wide range of open access to

[92] Pellegrino, "The Commodification of Medical and Health Care," 250.
[93] Ibid.

patients' medical records. Our society also has laws that prevent the production and distribution of various kinds of drugs; yet we permit pharmaceutical companies to conduct controlled experiments in which human subjects are given various doses of drugs that, at that stage, still present a high level of known and unknown risk to them.

Furthermore, most persons – even those with medical knowledge and training – are incapable of meeting their medical needs without the assistance of others. As Galarneau explains, the attainment of health care has many complex interpersonal and institutional dimensions. Care giving typically involves some sort of face-to-face interaction between medical professionals and patients. These interactions often occur in community based clinics, offices, or hospitals, each with unique procedures or protocols. They can be shaped or influenced by the personal relationships (or lackthereof) between medical professionals and patients, or be subject to institutional influences stemming from organizations such as pharmaceutical companies, insurance companies, or local community groups. The interactions between medical professionals and patients are also governed by professional and legal standards, and may also require according with specific local community practices.[94]

However there is a problem regarding this latter point for showing how health care is common to all persons within our society. Although the distribution of health care *is* fundamentally social, involving multiple, dynamic relationships between individuals, communities, and institutions, this particular line of reasoning falls short of showing how health care is common to all persons within our society because the argument fails to

[94] Galarneau, "Health as a Community Good," 36.

establish how health care generally constitutes a need of all persons. However, as I show next, essential forms of health care can be seen as needs of all persons.

B. *Health Care as Common based on Shared Human Nature*

Another way to understand health care as common to all persons is that it is thought to be an integral part of our shared human nature both practically *and* symbolically or emotionally. In a symbolic or emotional sense, there are particular life-events involving health care that all persons experience and that have deep social significance both on individual and community levels. As noted in the 1983 report of the President's Commission on Bioethics,

> Beyond its practical importance, the involvement of health care with the most significant and awesome events of life – birth, illness, and death – adds a symbolic aspect to health care: it is special because it signifies not only mutual empathy and caring but the mysterious aspects of curing and healing.[95]

In a practical sense, humans are finite, relatively fragile, and susceptible to disease, illness, and injury. Regardless of the numerous ways that individuals can be distinct from one another, such as in educational or socioeconomic status, all persons will eventually suffer the effects of poor or declining health, directly and also indirectly when ill health affects our loved ones.[96] Particularly for individuals and families, ill health is a disruptive force that inhibits flourishing. According to Pellegrino, for example,

> Chronic illness, pain, discomfort, or disability can constrain the most determined and best-adjusted person. For most people, it is difficult or impossible to do the things they want to do or enjoy when they are affected by illness. Health is a fundamental requirement for the fulfillment of the human potential and freedom to act and direct one's life. To lack

[95] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Securing Access to Health Care*, 11.

[96] See for example; The Hastings Center Report, "The Goals of Medicine," S6

> health and to need treatment is to be in a diminished state of human existence – a state quite unlike other deprivations [that] can be borne if one is healthy.[97]

This is not to say either that a diminished state of health (brought about by conditions such as chronic pain, illness, or disability) prevents human flourishing, or that health care is the only good necessary for human flourishing. We can imagine how some persons may reassess their life goals in light of ill health to set and accomplish new life goals they may not have otherwise considered or tried to accomplish. For example, some persons who are terminally ill will use their illness as a reason to travel, write their memoirs, participate in community health projects, or work to amend or deepen their personal relationships with others. There are also other goods besides health that are closely tied with being human such as happiness, wealth, friendship, or work. Pellegrino's point, though, is that ill health makes the fulfillment of one's goals more difficult to achieve, and either compromises or makes impossible one's ability to attain other goods also associated with human flourishing.[98]

C. *How the Common-View Approach Further Justifies Increased Access to Essential Health Care Goods and Services*

Based on these two ways for how health care is common to all persons, there are at least three moral reasons why there ought to be increased access to essential health care goods and services. First, we ought increase access to essential health care goods and services as a matter of respect for persons. Within a Kantian framework, for example, persons ought to be respected because they have dignity stemming from their capacity to

[97] Pellegrino, "The Commodification of Medical and Health Care," 248.
[98] Ibid., 248 and 259.

rationally govern their actions.[99] Yet it is reasonable to think that when one's basic needs are not met, one's ability to self-govern is not only more difficult but can also be compromised – a point that will become more evident in the next chapter when I examine the principle of respect for autonomy as an ethical limit of health care markets. In a Kantian sense, then, showing proper respect for persons requires working to make sure that individuals' basic needs are met. Again, health care constitutes a basic need of persons both in that all persons are susceptible to the effects of ill health, and also because a lack of health care can impede the attainment of others goods we consider necessary for human flourishing. So at a minimum, respect for persons also justifies increased access to essential health care goods and services for persons who lack access to basic health care needs.

Second, we ought to also increase access to health care goods and services as a matter of fairness. Since all persons within society can claim to have a stake in the development and distribution of health care, it would be unfair to prevent any person within our society access to essential health care goods and services. Although this reason is not without exception, because health constitutes a need of all persons any counter arguments to this point would seemingly have to demonstrate how *prima facie* unfair or unjust distributions of essential health care goods and services – in which some persons are guaranteed access while others are required to forgo access – would be ethically permissible.

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[99] See for example; Guyer, *The Cambridge Companion to Kant and Modern Philosophy*; Hill, *Dignity and Practical Reason in Kant's Moral Theory*; Hill, "Humanity as an End in Itself;" Kant, *Groundwork of the Metaphysics of Morals*; Kant, *The Metaphysics of Morals*, Kerstein, *Kant's Search for the Supreme Principle of Morality*; Koresgaard, *Creating the Kingdom of Ends*; Louden, *Kant's Impure Ethics*; O'Neill, *Acting on Principle*; Wood, *Kant's Ethics Thought*; and Wood, "What is Kantian Ethics?"

Third, we ought to increase access to essential health care goods and services as a matter of utility. All the members of society contribute to and benefit from the advances in medical knowledge. By increasing access to essential health care goods and services we can expand on the intended benefits of medical knowledge by helping society's individual members better meet their health care needs and presumably improve their overall health. Furthermore, increasing access to health care goods and services can provide additional benefits to society as a whole. For example, increasing access to essential health care goods and services will likely require developing new or expanding currently existing health care institutions that, as Galarneau explains,

> [A]re integral to the institutional fabric of local community life and thus have the potential to improve community infrastructure by providing employment, training, and leadership opportunities. They also support other social institutions by helping to keep individual community members healthy and capable of participating in them as workers, students, and political citizens.[100]

Lastly, beyond these moral reasons, there is a practical reason to justify increased access to essential health care goods and services. Health care is part of many basic human life events. Our society in particular has grown accustom to associating the provision(s) of health care with events at the beginning and end of life, and also for a wide array of injuries and illnesses. I take as uncontroversial the idea health care goods and services are the primary means by which individuals meet their health care needs during these events. In this sense, then, there ought to be increased access to essential health care goods and services to ensure that persons experiencing these kinds of basic life events are able to meet their health care needs.

[100] Galarneau, "Health as a Community Good," 37.

Up to this point, I have examined three approaches for why there ought to be increased access to essential health care goods and services. I now turn to clarify what qualities should define essential health care goods and services.

4. **Clarifying "Essential Health Care Goods and Services"**

In this section I do not attempt to argue for what *specific* health care goods or services are, or should be, included under this principle of increased access. There are two reasons for this. First, attempting to specify which particular goods and services we should increase access to is not something we can infer simply by showing why there ought to be increased access to essential health care goods and services. Second, attempting to argue for which specific health care goods and services fall under this principle would be too laborious for this work. What I attempt instead is to clarify some of the qualities of essential health care goods and services. To do this, we first need to solidify our understanding of what these three approaches tell us about the goal for the principle of increased access to essential health care goods and services.

A. *Solidifying the Goal of Increased Access*

From the three approaches I discuss, the goal for the principle of increased access to essential health care goods and services becomes clearer: to balance (although not necessarily equally) wealth creation and limited health care resources against the just distribution of those resources. Wealth creation can justify enormous increases in access to *any* health care resource so long as there is a demand for it. Furthermore wealth creation, or at least the promise of profit, can spur medical breakthroughs or improvements to currently existing health care goods and services. However, if wealth

creation were to be the primary motive for increasing access to essential health care goods and services, we could then claim that when applied as an ethical limit of health care markets, any health care market that increases its profits is functioning ethically even if it does not actually increase access to essential health care goods and services. An example of this that I discuss more thoroughly in the chapter on pharmaceutical drugs is Azidothymidine (AZT). When the Food and Drug Administration approved AZT for market distribution, it was the first and only anti-HIV drug. This allowed the drug's developer, Burroughs Wellcome, to corner the market in anti-HIV drugs even though many people who needed AZT were denied access to it because they could not afford its high price. So a problem with focusing too much on wealth creation is the counter-intuitive nature that this might not actually ensure access to essential health care goods and services. We also have reasons why we should increase access to essential health care goods and services apart from wealth creation.

Understanding health care as common to all persons within our society as well as arguments for a right to health care also justify increasing access to essential health care goods and services. Furthermore, based on these reasons, we see that we should increase access to essential health care goods and services when persons lack access to these things. These reasons thusly appear able to counter-balance the potential problem of wealth creation such that when this principle of increased access is applied to health care markets, we can claim that these markets function ethically when they increase profits *and* do not prevent or inhibit persons from access to needed health care goods or services.

However we must also be careful regarding these other reasons for justifying this principle of increased access. If we give too much weight to these other reasons without further qualifying "essential health care goods and services," we run the risk of potentially overextending this principle when applied to health care markets. For example, someone could take a strong interpretation of this principle to say that it justifies increasing access to all health care goods or services that are capable of meeting persons' health care needs. Not only is it widely understood that we have limited health care resources that would make fulfilling such a strong interpretation of this principle impractical, but it would also be unjust to use our limited public funds to try to increase access to this degree, since this would result in diverting those funds from other important public resources like education or our transportation infrastructure.

So keeping in mind that the goal of increased access to essential health care goods and services is to balance wealth creation and limited resources against the just distribution of those resources, we can now begin to see some of the qualities that should define our understanding of essential health care goods and services.

B. *Characteristics of Essential Health Care Goods and Services*

Based on the three approaches I have used to show why there ought to be increased access to essential health care goods and services, there are at least three qualities that should characterize these goods and services. First and foremost, we should consider essential health care goods and services to be goods and services that help individuals address their medical needs. Admittedly this is somewhat redundant given that from the onset I narrowed my understand of health care goods and services as those

things that help individuals meet their medical needs in preventing or combating disease, illness, or injury. From Daniels' argument for a right to health care, we can also understand medical need as something that prohibits us from a normal state of functioning relative to social standards.

While this quality for understanding essential health care goods and services is fairly uncontroversial this does not mean, however, that health care goods and services that do not help address a medical need should necessarily be inaccessible for persons who want them. For example, cosmetic plastic surgery (as opposed to reconstructive plastic surgery) does not typically provide a medical benefit to patients. So in general it should not be considered *essential* health care that falls within the purview of this principle for increased access. However, as long as providing a non-essential health care good or services does not create an overall inability for persons to attain health care goods and services that are primarily used to meet persons' medical needs, those goods and services should also remain available. If we were to try further justifying this latter point, we could either argue for the legitimate interests of businesses – which in this case would include the providers of these non-essential goods and services – to meet the demand for these goods and services as a matter of wealth creation, *or* by arguing that as a matter of self-determination, health care providers should be free to provide non-essential health care goods and services to willing patients so long as this neither resulted in gross negligence on the part of the health care provider, nor any foreseeable long-term harm to patients.

A second quality of essential health care goods and services is that they should be cost-effective. Specifically, from the aspect of balancing wealth creation against just distribution of health care resources, cost-effectiveness is the ability of markets in the essential health care goods and services to remain profitable, while working to ensure that persons who need those goods and services can afford access to them. Determining how best to establish the cost-effectiveness of essential health care goods and services falls outside the scope of this work. However there are some strategies currently employed within our society – usually with high, but still varying degrees of success – to maintain both the profitability of and access to essential health care goods and services, such as both public and privately funded health insurance programs, or manufacturer discounts (particularly for pharmaceutical drugs).

Third, because we are talking about goods and services that we should increase access to and that ought to meet a medical need, what we consider to be essential health care goods and services should also be system relative. The idea of system relativity is frequently used in discussions about health care rights, with Daniels using this particular term to delimit entitlements under a right to health care.[101] However the term generally refers to our ability to help individuals meet their medical needs in connection with the availability of resources within our current health care system. System relativity therefore has a wider range of applicability than just health care entitlements.

Since the principle of increased access to essential health care goods and services must account for limited health care resources, it is reasonable to assume that the goods and services in question should be as efficacious as possible. So when medical needs are

[101] Daniels, "Is There a Right to Health Care and, If So, What Does It Encompass?," 320.

fairly common and have widely-used, standardized treatments, what qualifies as "essential" in those cases will not include experimental or unproven treatments whose efficacious nature is questionable. If, however, the medical need is relatively uncommon, the scope of what is considered "essential" for treating that need might have to be wider and possibly include treatments with questionable effectiveness. Understanding what qualifies as essential health care goods and services under the notion of system relativity should also consider the consequences of non-treatment for a medical need. It may be the case, for example, that initially disqualifying non-standard, highly costly health care goods or services from being considered "essential" could result in a greater, long-term drain on health care resources such that we may want to consider them "essential" nonetheless. For instance, gastric bypass surgery is more effective for helping morbidly obese persons lose weight than either drug therapy or life style changes in one's diet and exercise.[102] But it is also an expensive treatment that raises some safety concerns, and that a number of insurance companies do not cover.[103] However, given the increasing rates of obesity in the United States[104] and the annual health care expenditures for

[102] Mitka, "Surgery Useful for Morbid Obesity, but Safety and Efficacy Questions Linger," 1575.

[103] Ibid., 1576. The average cost for gastric bypass surgery is $25,000, not including any pre-operative consultation costs or post-operative costs associated with long-term care.

[104] Although obesity rates among men in the United States for age groups 20-59 dropped slightly from 2005-2006 to 2007-2008, the overall obesity rates from 1999-2000 to 2007-2008 increased for the 20 and under age group from 27.5% to 32.3%, and from 23.7% to 27.5% for the 20-39 age group, and from 28.8% to 34.3% for the 40-59 age group. Obesity rates among United States woman saw similar trends, except for the 20-39 age group, which has seen a steady increase in obesity rates from 1999-2000 to 2007-2008. The obesity rates for United States women from 1999-2000 to 2007-2008 increased for the 20 and under age group from 33.4% to 35.5%, 28.4% to 34% for the 20-39 age group, and 37.8% to 38.2% for the 40-59 age group.
See; Flegal, Carroll, Ogden, and Curtin, "Prevalence and Trends in Obesity Among US Adults, 1999-2008," 238-239.

medical costs associated with treating obese persons[105], it might be that we will eventually want to consider increasing access to gastric bypass surgery as an essential health care good for helping reduce obesity in the United States.

5. **Conclusion**

Throughout this chapter we have seen why there ought to be increased access to essential health care goods and services, as well as some of the qualities necessary for this principle to be effective in practice. At this point we can begin to see what it means, or may mean, for this principle to be an ethical limit of health care markets. Claiming that the principle of increased access to essential health care goods and services is an ethical limit of health care markets refers to the requirement of these markets to provide fairly distributed, cost-effective access to essential health care goods and services. Health care markets are within this limit when they function in ways that do not prevent persons from accessing health care goods and services necessary to effectively treat their medical needs. They violate this limit when some sort of unfair distribution of essential health care goods or services prevents persons from being able to effectively treat their medical needs.

It is important to note, though, that the principle of increased access to essential health care goods and services would not apply to all health care markets. The force of this limit largely stems from how we understand essential health care goods and services as those things that are effective in treating a medical need. So for markets in health care

[105] According to data collected from 2000-2005, it is estimated that the annual health care expenditures related to obesity for children and youth ages 6-18 is $11 to $14 billion, and $73 to $93 billion for adults ages 19-85.
See; Bell, Zimmerman, Arterburn, and Maciejewski, "Health-Care Expenditures of Overweight and Obese Males and Females in the Medical Expenditures Panel Survey by Age Cohort."

goods or services that do not aim to treat an underlying medical need, such as with cosmetic plastic surgery, concerns about increasing access to these goods or services in fair or cost-effective ways would not apply. Furthermore, it is also possible that the approaches used to justify this principle could be modified to apply to other markets in essential goods, like food.

Lastly, based on the notion of system relativity, what we consider to be essential health care goods and services will fluctuate according to multiple, variable factors. For example, new epidemics and other natural events will change our individual and community health care needs; new medical technologies or improvements to currently existing medical technologies will change the standards for how we treat our medical needs; changes in our social and political spectrum will affect the production and distribution of whatever we consider to be essential health care goods and services. As these factors become known, they will have a foreseeable effect on how this principle limits health care markets.

Next, I move beyond showing why there ought to be increased access to essential health care goods and services to argue for why health care markets should also be limited according to the principles of honesty and respect for autonomy.

Chapter Three: Arguing for the Principles of Honesty and Respect for Autonomy

While I have shown why there should be increased access to essential health care goods and services, ethically treating health care goods and services as commodities requires more than just this. One of the underlying reasons addressed in chapter 1 for why health care goods and services are not properly valued merely as commodities is that their distribution occurs via health care relationships that are not strictly governed by market norms. Even though the principle of increased access is partly justified on the basis of the relationships between health care providers and patients, this principle does not tell us anything about the character of those relationships. Since the relationships matter in how we value health care goods and services, we should, in order to ethically treat them as commodities, account for the relationships by which they are primarily exchanged, namely the relationships between health care professionals and patients.

My aim in this chapter is to establish additional ethical limits for health care markets that accord with the market distribution of commodities and are based on the relationships between health care professionals and patients. Specifically I argue that health care markets should be limited according to the principles of honesty and respect for autonomy. As I show in this chapter, these two principles ideally govern both the market transactions between buyers and sellers, *and* the interactions between health care professionals and patients. For each principle, I first provide a theoretical framework and then argue for how each applies to the relationships between health care professionals and patients *and* market transactions between buyers and sellers. I then conclude my

discussion of each principle by addressing what it means for these principles to be ethical limits of health care markets.

1. **Honesty**

Initially it is somewhat difficult to see why honesty should be considered an ethical limit of health care markets. There are at least two reasons for this. First, although honesty is now considered an important aspect of the relationship between health care professionals, patients, and a patient's family or surrogate(s), it is not always clear how far this principle extends within these relationships. For example, do physicians violate the principle of honesty if they do not disclose to patients how often they entertain pharmaceutical representatives who often provide physicians with biased information about new drugs on the market? Second, deception within business is fairly common as a means of securing an economic advantage over competitors, thereby making my claim that honesty is an important principle for governing market transactions appear oxymoronic, or worse, simply false. Furthermore, deception can sometimes be considered morally permissible within business, such as when replying to certain questions during a negotiation.

An example of business related deception in health care is the marketing of the well-known antihistamine, Claritin. In *Hooked*, Brody notes how Claritin is, "the most profitable antihistamine of all time, with annual sales of more than two billion dollars"[106] (p. 18). Part of what makes Claritin so popular is that direct-to-consumer advertisements for the drug claim it is a non-sedating medication – something many other antihistamines cannot claim. But according to Brody, 30-40% of those taking prescription Claritin fail to

[106] Brody, *Hooked*, 108.

receive any benefit from the drug. This is troubling considering that, in addition to this relatively high percentage, the cost of prescription Claritin (in 2001) was about eighty to eighty-five dollars a month (compared to less than ten dollars a month for the generic form, Chlor-Trimeton).[107]

The initial data on Claritin submitted to the FDA in 1987 shows that in small, 10-milligram doses, Claritin *is* non-sedating. Yet this data also shows that the reported effectiveness for test subjects taking the 10-milligram doses of Claritin is only about 10% higher then the reported effectiveness for test subjects taking just placebos. However in other data sets where larger doses of Claritin were taken by test subjects, Claritin is shown to be highly effective but also much more likely to cause drowsiness.[108]

Hoping to get Claritin approved as a "non-sedating" drug, the company that produces Claritin, Schering-Plough, made sure no data was submitted to the FDA for amounts more than 10 milligrams – meaning that prescription Claritin could not actually be sold in the higher, more effective doses. But in its direct-to-consumer advertisements for Claritin, Schering-Plough has used both data sets to justify the dual claims that Claritin is non-sedating *and* highly effective, and that, because of this unique combination, Claritin is a special antihistamine.[109]

To argue for honesty as an ethical limit of health care markets, I thusly need to provide a thorough yet succinct defense of the principle of honesty.

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[107] Ibid., 18.
[108] Ibid., 19.
[109] Ibid.

A. *A Theoretical Account of Honesty*

I begin with the basic and widely accepted assumption that honesty involves telling the truth while avoiding intentional lying, deceiving, or promise breaking in our communications with others. Note that this is an unqualified assumption that has not been molded or shaped to fit any particular view of honesty. As I will argue shortly, how we understand the ethical nature of honesty should require us to consider the context of the situation in which questions of honesty arise. Later I will argue that even within health care relationships, there are some kinds of information disclosures that health care professionals and patients do not need to be fully honest about with each other. At this point, though, I merely wish to briefly address the question: why should we be honest, especially in light of examples like Claritin in which dishonesty can be quite profitable and goes unpunished?

Kant, whose views on lying are regularly interpreted as being quite rigid, gives us two primary reasons why we should not lie. First, he argues that we are obligated to act in ways that could apply universally, and that we are obligated not to act in ways that cannot apply universally. For Kant, persons cannot be morally obligated to lie because if lying were universally permitted, our abilities to effectively engage in meaningful communication with others would cease since we would have no reason to trust one another.[110] Second, Kant also argues that we should always treat all persons as ends and never merely as means to an end, and that the reason for this is because all persons have inherent moral worth. According to this argument, we can never be morally obligated to

[110] Kant, *Groundwork for the Metaphysics of Morals*, 4:402-4:403, and 4:421-4:423; and Kant, *The Metaphysics of Morals*, 6:221-6:227.

lie because if we were, this would permit us to use others solely for our benefit in a way that fails to appreciate their dignity as moral beings. Kant extends this point further by also arguing that even if it intends to benefit another person, an intentional lie would still be immoral because the person committing the lie knows the truth, and so uses himself or herself merely as a means bring about some discretionary end.[111]

However even if we reject the moral foundation of these arguments, there is an underlying practicality to Kant's view that remains for why we should be honest. On Kant's view, we should be honest lest we run the risk of not being able to trust one another. While Kant uses to this notion to argue that acting morally involves developing maxims for action that apply universally, the idea that we should be honest as means of fostering trust between persons is also a prudential reason, since a lack of trust would render communication between persons worthless. This reasoning holds true even for the egoist who may believe that acts of lying, deception, or promise breaking are morally permissible in order to advance one's self-interests, as acting in one's self-interest also requires being able to consistently trust others.

Still arguing for why we should be honest does not seem to get us very far. Most persons *prima facie* accept that we should be honest. But arguing that we should be honest does not necessarily tell us what it means to be honest. So before turning to address how the principle of honesty specifically applies to both health care and business, more should be said about the context in which questions of honesty arise.

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[111] Kant, *Groundwork for the Metaphysics of Morals*, 4:429-4:431; and Kant, *The Metaphysics of Morals*, 6:386-6:388, 6:393-6:394, and 6:429-6:431. Since Kant uses lying as a primary example in developing his moral theory, there is also a large catalogue of secondary literature that discuss specific details regarding these two arguments.

a. *Limits of Honesty*

Part of the reason that I focus on Kant's arguments against lying is because they establish what is often considered an inflexible moral requirement. For Kant, lying is never moral. Some of Kant's statements about the wrongness of lying seem so strict and excessive that, according to noted Kant scholar Alan Wood, "most Kantians who have dealt with the topic have tried to distance themselves from them, usually claiming that they do not (or need not) follow from Kant's own principles."[112]

If the prohibition against lying is as strict as Kant presumably argues it is, this might not only mean we are morally obligated to always tell the truth without any further qualifications, but this would also seemingly conflict with other widely-held morals of the medical profession such as the moral and legal obligation to maintain patient privacy. Under standard interpretations of Kant's views on lying, a doctor, for example, would be morally obligated to honestly disclose a patient's medical information to anybody who asked for it – a clear violation of the Health Insurance Portability and Accountability Act of 1996. These kinds of examples are perhaps why many Kantians presumably distance themselves from Kant's views on lying – on the face of it his stance against lying seems too strict to be practical.

However Wood argues that such interpretations of Kant's views on lying are wrong. According to Wood, Kant recognizes at least two distinguishable limits for when making intentionally false statements is not immoral. First, Wood argues, the duty not to lie only extends to falsifications that would undermine the rights of others when applied universally. But if a falsification does not undermine the rights of others when applied

[112] Wood, *Kantian Ethics*, 240.

universally, then the falsification does not violate Kant's duty not to lie (here the term "right" refers to *duties of right*, which is Kant's notion of obligations we have toward others).[113] Second, in dealing with the view that lying is also immoral because it violates a duty to oneself (by treating oneself as a mere means), Wood argues that for Kant, the purpose of duties to oneself is to maintain self-respect. Making a falsification that aims to protect one's self-respect does not, Wood therefore argues, violate the intent of duties to oneself (even though, Wood also notes, making falsifications *prima facie* violates what Kant explicitly says about why we should not lie in regard to the obligation to treat ourselves as ends).[114]

Presuming Wood is correct, his analysis of Kant's views on lying shows that even for Kant honesty is not absolute; false statements can be permitted under certain conditions. Alan Strudler makes similar points in his recent analysis of the relationship

[113] Ibid., 240-251. Wood's argument for this point relies on a detailed examination of numerous statements Kant makes in multiple works about lying, as well as his written replies to others, namely French writer Benjamin Constant (who Wood credits with challenging Kant's views on lying with the famously difficult and paradigmatic example of the "murdered at the door" (i.e. a murderer comes to your door and asks where your friend is so that he may kill him; which is meant to show the impracticality of Kant's views on lying, since it is presumed on Kant's view that you would be morally required to honestly disclose the location of your friend)). Also in making this argument, Wood argues that much of the inaccuracy regarding the standard interpretations of Kant's views against lying stem from a common misunderstanding regarding a analytical aspect of Kant's terminology. For Kant, the term "lie" is a technical term meaning, "an intentionally untruthful statement *that is contrary to duty*, especially contrary to a duty of *right*," where as a falsification is an untruth that does not necessarily violate a duty of right (p. 240).

[114] Ibid., 251-258. In making this argument, Wood reiterates the technical difference Kant makes between a falsification and a lie. He also argues that Kant states his argument against lying so strictly regarding duties to ourselves because, "Kant thinks people tend to make exceptions to rules in their own interests when they should not, and this often makes the speech act of asserting the unexceptionableness of moral rules morally justified even when it is an error theoretically" (p. 253-254). Also, Wood notes, Kant recognizes something special in moral issues involved with truthfulness, further justifying his [Kant's] exaggeration of the immorality of lying; he considers deception and duplicity a vice of human nature for engaging civilly with others (p. 254). As we have already seen, if lying were morally permissible, it would inhibit our abilities to engage in civil discourse.

between deception, manipulation, and trust. For Strudler, there are times when making false or deceptive statements can be considered moral.

Strudler argues for two basic kinds of deception: deception that does and does not result in breeches of trust. In making this argument, he carefully shows that all that is needed to deceive or manipulate someone is for the deceiver to establish credibility that the persons being deceived then appeal to in their decision to believe the deceiver. There is no necessary connection between creditability and trust; we can distrust persons and still believe the information they tell us is credible because they either have external evidence to substantiate their claims, or we rationalize that if they are lying to us they will suffer negative consequences.[115] Deception that results in breeches of trust occurs when the deceiver solicits the trust of the person(s) being deceived and uses that trust to manipulate them. This is because, Strudler further argues, soliciting one's trust conveys,

> [T]hat you can rely on my goodwill, that is, my intention to act for your sake and not simply for my advantage. I manipulate you, because in ways that I willfully hide from you, I cause you to have a false belief about whether I have goodwill toward you, and then exploit that belief in order to get you to behave as I wish.[116]

For Strudler, simple deception – i.e., deception not resulting in breeches of trust – can be morally permissible if the person being deceived has no discernable right to the information he or she is being deceived about. What determines if deception in such cases is morally permissible is whether or not it is a matter of self-defense, that is, when the deception is the only means to prevent an otherwise unavoidable harm to the

[115] Strudler, "Deception Unraveled," 459-461. Since this aspect of Strudler's argument is only to deconstruct the notion that deception and breeches of trust are inextricably tied, I abstain from further detailing it here.
[116] Ibid., 460.

deceiver. Strudler illustrates this point using a standard negotiation process in which being fully honest would undermine the deceiver's ability to remain competitive in the negotiation, thereby compromising the underlying fairness of the process and constituting an economic harm for the deceiver. However Strudler also notes that if the perceived harm is avoidable, the self-defense argument does not hold.[117] The self-defense argument also would not work in cases of deception involving breeches of trust. I could not, for example, solicit your trust with the intent of manipulating you while also maintaining that the deception is necessary to prevent a perceived harm to myself (on Strudler's account this would amount to engaging in an avoidable preemptive attack rather than unavoidable self-defense).

Strudler then argues deception that involves breeches of trust is always wrong when used for any kind of economic gain. This is because of how a solicitation of trust invites persons to rely on the truth of the information they receive. There is, however, an exception to this in which deception that involves a breech of trust can be morally permissible. Deception that involves a breech of trust can be moral if and only if it is used against a substantial wrong.[118] However while it is possible for cases like this to occur in a medical setting, this particular exception to honesty in which breeches of trust are morally justified to prevent some other moral wrong is not presumably applicable to establishing honesty as an ethical limit of health care markets.

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[117] Ibid., 462-465.

[118] Ibid., 465-470. Imagine, for example, a police officer posing as a member of a criminal organization to gain their trust so that the police officer may expose the organization's criminal activities and ultimately bring them to justice. In this case, the police officer deceives the criminal organization with the intent to both gain and manipulate their trust. Yet, because this is done to stop the organization's criminal activities, this, presumably, would not be an immoral breech of trust.

From both the arguments of Wood and Strudler, it is reasonable to conclude that we should amend our initial assumption about honesty. Originally I claimed that honesty involves telling the truth while avoiding intentional lying, deception, or promise breaking. This is still true for most kinds of communication between persons. However, there are times when it is necessary, or at least when it is permissible, for us not to be fully honest. We do not have to be fully honest when persons' rights are not violated, or when telling the truth would leave us susceptible to some sort of unavoidable harm. This is an important qualification that will become more apparent particularly in the next section regarding honesty in health care relationships. As I argue next, patients have a legitimate expectation they will be told the truth about information pertinent to their medical care, but not to information that is irrelevant to their care.

B. *Honesty in Health Care Relationships*

One reason that we should consider honesty an ethical limit of health care markets nnnmnnm ,,jj,,j,ujpatients. O'Neill, for example, discusses how honesty is necessary for establishing trustworthiness in health care relationships, while the lack of honesty (which she also discusses primarily in terms of deception) creates an aura of untrustworthiness.[119] Beauchamp and Childress also view honesty as an important aspect of health care relationships. While they do not consider honesty to be one of the four main principles of biomedical ethics, they treat it as an essential rule for professional-patient relationships to act in accord with those moral principles.[120] For them honesty

[119] O'Neill, *Autonomy and Trust in Bioethics*, 118-140.

[120] Beauchamp and Childress, *Principles of Biomedical Ethics*, 288. As Beauchamp and Childress famously argue, the four main principles of biomedical ethics are respect for autonomy, nonmalficence, beneficence, and justice.

within health care, "refers to comprehensive, accurate, and objective transmission of information, as well as to the way the professional fosters the patient's or subject's understanding."[121] Furthermore, the arguments they give in support of honesty as a principle of health care relationships mirror the arguments I noted in the previous section for why we should be honest. Specifically, they argue,

> [O]bligations of veracity are based on respect owed to others. Even if consent is not at issue, the obligation to respect others' autonomy supports obligations of veracity in many contexts. Second, obligations of veracity are connected to obligations of fidelity, promise-keeping, and contract. When we communicate with others, we implicitly promise that we will speak truthfully and that we will not deceive listeners . . . Third, relationships between health professionals and patients and subjects depends on trust, and adherence to rules of veracity is essential to foster trust.[122]

These two views of honesty help us gain a better idea of its importance within health care relationships. Honesty is necessary for health care professionals and patients to establish and maintain fiduciary relationships with one another. However, even if we were to reject the idea health care relationships require trust between health care professionals and patients we can still claim that because of the nature of their relationship they should, at the very least, be truthful with one another as a matter of mutual respect. Yet even though honesty plays an essential role in health care relationships, there is still an open question about what kinds of information health care professionals and patients should be honest about and to what degree?

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[121] Ibid., 289. Beauchamp and Childress actually use the term "veracity" instead of "honesty." Literally the term refers to the truthfulness or accuracy of facts. Although there are nuanced distinctions we could tease-out between "honesty" and "veracity," I regard them as synonymous since both involve providing truthful disclosures about medical information used in the treatment decision-making process.

[122] Ibid.

When patients and health care professionals enter into a relationship with one another it is usually because patients have a medical need they want health care professionals to help treat. Generally the reason for this is that health care professionals have medical knowledge and training the patient presumably does not. By entering into this relationship patients therefore rely on health care professionals to use their medical expertise in caring for the patient(s). Because of the nature of the relationship between health care professionals and patients, in which the health care professional is charged with caring for the well being of the patient and the patient relies on the medical expertise of the health care professional, they owe it to each other to provide truthful disclosures regarding medical information about the patient's treatment. Furthermore, when patients receive treatment from medical professionals, this does not typically occur via a standard negotiation process: physicians do not try to discern what patients are willing to pay for treatment and then offer their services based on that amount, and patients do not try to find what medical goods or services physicians are willing to offer for a particular price and then try use that knowledge to try to gain a certain level of medical care. So it is not the case that health care professionals and patients could morally deceive one another about medical information relevant to patient care on the basis of either Wood's interpretation of when Kant believes making false statements is permissible under duties or right, or Strudler's notion of simple deception that is permissible with regard to self-defense. However, even though patients and health care professionals should be honest with each other about information relevant to the patients' care, and are not permitted to deceive one another about this information, this does not mean that patients and health

care professionals are therefore morally obligated to be honest and not deceive each other about all informational disclosures.

Nothing about the relationship between health care professionals and patients implies that either one is entitled to honest disclosures about information that is *ir*relevant to patient treatment. Although what specifically qualifies as relevant versus irrelevant information regarding patient treatment is context dependent – needing to account for patients' medical needs, what the standard treatments are for addressing those needs, and the availability of those treatments – Beauchamp and Childress give us an idea of the general sorts of information relevant to patient treatment. For them, relevant information is information about a patient's diagnosis, prognosis, and available treatment options.[123] Reasonably, then, we can imagine that irrelevant information is information that does not knowingly impact the quality of patient care, such as personal information unrelated to the patients' underlying medical condition or treatment options. Since disclosures of irrelevant information fall outside the range health care relationships, there is no reason to think that patients or health care professionals have a right to know that information, and so it would be permissible for them not to be fully honest about information that is irrelevant to the medical care of the patient.

Admittedly, there are still tough cases regarding honesty in health care relationships that may eventually need to be settled. However I am unsure at this point what effect these cases might have on honesty as an ethical limit of health care markets. For instance, nothing here accounts for the role of families in health care relationships. Yet they are often an important aspect of patient treatment. Are they "owed" anything

[123] Ibid.

regarding honest disclosures by either health care professionals or patients? We may be tempted to say 'yes,' but if so, are there differences in degree, that is, are there things we expect health care professionals and patients to be fully honest about with each other, but perhaps less honest about, maybe even slightly deceptive, with families? There seems to be at least one case in this concern might occur. Imagine a person who has been noticeably ill. After completing several medical tests, a physician tells the person that he or she has an inoperable and untreatable illness. Soon after receiving this information, one of the person's family members ask what the doctors think is wrong. Surely the person could tell the family member he or she has an inoperable and untreatable illness; we might even wish to argue the person is morally obligated to tell the family the truth based on the account of honesty I have given here. Yet, I can also image the person wanting to deflect the family member's question or simply lie about the seriousness of the illness. Here an appeal to the family member's right to know the truth as someone vested in the care of the sick person might not suffice since this seems to conflict with the sick person's right to privacy. This case might even be further complicated if we know the family is paying for the person's medical care, since they presumably have a right to know the truth about what they are paying. However debating about the degree to which honesty should occur within health care relationships does not usurp my argument honesty helps buttress successful health care relationships and that honesty should thusly be considered an ethical limit of health care markets.

Here we have seen how honesty is an important aspect of health care relationships. Yet I have also tried to show that, while health care professionals and

patients should be honest with one another about medically relevant information *and* should not deceive each other about that information, they are not required to be honest about all kinds of information disclosures – particularly regarding information that is medically irrelevant. As I argue next, we should also consider honesty an ethical limit of health care markets based on it role within business.

C. *Honesty in Business*

As I noted at the beginning of my analysis on honesty, Schering-Plough's use of conflicting test data to advertise Claritin helped the drug become the most profitable antihistamines on the market. This and other similar examples in which intentional acts of lying or deception are used to maximize profits seem to debunk my attempt to show how honesty is a governing principle of ideal market transactions and why honesty should therefore be an ethical limit of health care markets. The idea that business ought to primarily be concerned with maximizing profits is perhaps best epitomized in the writings of economist Milton Friedman. According to Friedman, the only [social] responsibility of a business is to use its resources to maximize profits so long as the business acts "within the rules of the game."[124] This seems to imply that if the overall culture of business accepts violating ethical principles for the sake of maximizing profits, then such acts are permissible.

However there are good reasons to reject the idea that honesty, and ethical principles in general, fall outside the realm of business. First, while Friedman claims businesses must operate "within the rules of the game," he further stipulates that this

[124] Friedman, *Capitalism and Freedom*, 133. See also; Friedman, "The Social Responsibility of Business Is to Increase Its Profits."

means business must engage, "in open and free competition, without deception or fraud"[125] So even if Friedman is correct that the only obligation of business is to maximize profits, there is an understanding that this obligation still requires adhering to the principle of honesty because it is via this principle that those engaged in market transactions are able to consistently trust one another. This point is similar to that of Donaldson and Dunfee who, in laying the foundations of Integrative Social Contracts Theory, state that,

> Rational contractors will understand that successful economic communities and systems require a foundation of ethical behavior. *At a minimum*, business done efficiently often requires a certain level of trustworthiness… in order for capital markets to operate efficiently, many transactions must be done on the basis of oral promises buttressed by fundamental honesty.[126]

Note that Donaldson and Dunfee claim the *minimum standard* for successful economies is trust established through honesty.

Yet, like with honesty in health care relationships, we do not need to accept the link between trust and honesty to argue for why there should be honesty within business. Bowie, for example, argues that there should be honesty in business based on Kant's notion of treating others as ends and never merely as means. Bowie considers trust an essential for business relationships if a business is to achieve its various ends.[127] Still, Bowie argues, businesses should be honest with each other not simply to develop trust, but also because this what is morally required of businesses to show respect for the

[125] Friedman, *Capitalism and Freedom*, 133.
[126] Donaldson and Dunfee, *Ties That Bind*, 33. Emphasis added.
[127] Bowie, *Business Ethics: A Kantian Perspective*, 30-37.

dignity of their stakeholders, namely their employees.[128] This point about showing respect for stakeholders segues into my next reason for why we ought to reject the idea that business operates outside the realm of ethics, a reason that applies not just to honesty, but ethical principles in general.

In his recent work on Stakeholder theory, Freeman describes how the Dominate model of business – in which business is a hierarchy that works toward creating as much monetary value as possible for shareholders – is ethically problematic because of how it appears to authorize any action that benefits shareholders whether that action is ethical or not. The Dominate model, Freeman argues, relies on the Separation fallacy that claims business decisions have no ethical content while ethical considerations are inapplicable to business. After giving several open ended questions that illustrate how business decisions are tied to ethical considerations, Freeman then argues that a better business model is one that centers on the Integration thesis, which is the idea that most business decisions involve some ethical considerations, and that most ethical considerations are applicable to business in some way (this is consistent with my view that other ethical principles could also possibly limit health care markets).[129] Ultimately Freeman's point is that because a business relies on multiple individuals and groups that affect and can be affected by the business (i.e. stakeholders), the ability and the right of a business to create monetary value is not something that can occur in ignorance or isolation of ethical principles or guidelines.

[128] Ibid., 41-60.
[129] Freeman, "Managing for Stakeholders," 56-60.

Stakeholder theory, and particularly Freeman's point about business decisions being integrally tied to ethical considerations, represents a shift in thinking about ethics and business that has not traditionally existed. When discussing the principle of honesty with respect to health care, I argued that honesty is considered a necessary component for fostering fiduciary health care relationships. Traditionally, though, the reason for honesty in business has not been to establish or maintain fiduciary relationships in market transactions, but to try to overcome the essence of *dis*trust that often exists between market transactors to help sustain efficient, successful economies. That is, honesty in business has primarily been used as a practical and convenient tool to conduct successful market transactions, and not as a normative basis for how people and businesses ought to interact with one another. Yet assuming the ethical justifications for Stakeholder theory show how this shift in thinking about the relationship between ethics and business is *bona fide*[130], honesty in business should not be seen as merely serving a practical or utilitarian function, but also as a guiding principle for ideal market transactions.

There is, however, an apparent problem with tying the principle of honesty to business. On one hand I am arguing that honesty, although not to any specified degree, is a necessary component of business. On the other hand we have seen in the example of Schering-Plough and Claritin how acting dishonestly in business can be very profitable. Furthermore, Schering-Plough has yet to be held accountable for their deceptive marketing of Claritin.

[130] Freeman, for example, shows how Stakeholder theory can be ethically justified according to Utilitarianism, rights theories, virtue ethics, and Pragmatism. See; Freeman, "Managing for Stakeholders," 65-67.

Donaldson and Dunfee offer one reply to this problem. Accord to them, those who fail to be honest and trustworthy will, over time, likely be identified, exposed, and with respect to market transactions, "thus lose out on attractive opportunities."[131] Despite that this reply makes those who engage in dishonest business practices appear naïve to the wrongness of their actions, examples such as Enron executives being charged with fraud and the company filing for bankruptcy, Martha Stewart being accused and found guilty of insider trading and, most recently, Bernard Madoff pleading guilty to and receiving a 150-year prison sentence for orchestrating an elaborate, multi-billion dollar Ponzi scheme all illustrate Donaldson's and Dunfee's point. So the problem seemingly becomes less paradoxical if we recognize and accept the idea that dishonesty in business could end up costing companies like Schering-Plough billions of dollars – much in the same way that in December, 2004, after minimizing potential cardiovascular risks in its marketing of Vioxx (an anti-arthritis, Cox-2 inhibitor drug), Merck lost $33 billion (33% of the company's total market capitalization) and had a 60% drop in the value of its shares following its recall of Vioxx for increasing the incidence of heart attack in those taking the drug.[132]

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[131] Donaldson and Dunfee, *Ties That Bind*, 154.

[132] Beauchamp, Bowie, and Arnold, *Ethical Theory and Business*, 345-349. While it is difficult to determine the exact number of people who suffered adverse cardiac reactions from taking Vioxx, especially the number of those who may not have needed the drug but took it anyway after getting prescriptions for it, Merck was found culpable in May, 2008, of deceptive advertising leading to increased incidence of heart attack by Martha Coakley, Attorney General of Massachusetts. In the $58 million settlement between Merck and 29 other states Coakley claims, "Merck's aggressive advertising of Vioxx drove hundreds of thousands of consumers to seek prescriptions before Vioxx's risks were fully understood." Moreover, Coakley further states, "Merck heavily promoted Vioxx in [direct-to-consumer] television and print ads from the time of the drug's launch. Merck eventually acknowledged the significant risk of heart attacks associated with Vioxx, a fact not disclosed in Merck's promotions." See, Coakley, "Attorney General Martha Coakley Files Judgment against Merck Pharmaceutical for the Company's Deceptive Marketing of Vioxx."

Still, it is unlikely that any reply can sufficiently resolve this problem in its entirety. This is because there is no way to guarantee that deceptive or fraudulent business practices will ever be exposed or punished in a way that is either significant or will dissuade those who are willing to commit such acts.[133] Yet while we may not be able to fully resolve this paradoxical problem, how we culturally respond to dishonesty in business by publicly vilifying such acts, by trying to protect whistle-blowers who expose corporate dishonesty from unfair retaliation, and by creating and enforcing laws or regulations against dishonest business practices shows that, even though dishonesty occurs in business and acting dishonestly can be quite profitable, culturally we continue repudiate dishonesty in business as unethical.

D. *Honesty as an Ethical Limit of Health Care Markets*

We can now begin to tease out what it means for honesty to be an ethical limit of health care markets. Based on the foregoing arguments for why we should be honest, the limits of honesty, and for how honesty is an essential feature of both health care and business relationships, honesty should be regarded as an ethical limit on actors in health care markets in at least two ways. First, honesty should be an ethical limit of health care markets with respect to either establishing and maintaining fiduciary health care relationships between health care professionals and patients or, at the least, being able to provide honest disclosures about medically relevant information necessary to provide

[133] Regarding this latter point, consider for example that when Martha Stewart was found guilty of insider trading she received a relatively paltry sentence of 5 months in prison and a $30,000 fine, and that according to Forbes her net worth, although falling as a result of her conviction, was still $85 million. Moreover, when she was released from prison she used her experience to further promote her company and new television show (which she hosted). Her net worth has since rebounded, and is now rumored to be approximately $680 million.

patients appropriate care in treating their medical needs. Second, honesty should be considered an ethical limit of health care markets because it is a necessary component for establishing efficient and effective markets in commodified health care goods or services. From the arguments I made in this section, it appears that for health care markets to operate within this limit there must be an expectation (likely backed by enforceable guidelines) for all participants to provide honest disclosures about pertinent medical information that could impact the care provided to patients, or could have a potential negative effect on the ability of those markets to efficaciously or efficiently provide health care goods or services to patients. Concomitantly, health care markets can be thought of as violating this limit if participants are pervasively permitted to engage in intentionally dishonest or deceptive behavior regarding medically relevant information that is either not meant to serve patients' best interests or could potentially cause harm to patients by providing them with inappropriate or unnecessary health care goods or services – either because those markets have no regulations against intentionally dishonest or deceptive behavior, or that regulations within those markets against such behavior are, for whatever reason, un-enforced.

2. **Respect for Autonomy**[134]

Like with the principle of honesty, arguing for why the principle of respect for autonomy should be considered an ethical limit of health care markets first requires giving an account of autonomy as a framework. There are two accounts of autonomy that I provide here. The first is Dworkin's in *Theory and Practice of Autonomy*. I provide

[134] Parts of this section, namely Dworkin's account of autonomy, derive primarily from my work on autonomy with respect mandatory organ conscription. See; Harter, "Overcoming the Organ Shortage: Failing Means and Radical Reform," 157-158.

Dworkin's account of autonomy because it is widely used in ethical debates regarding the ability and right of individuals to govern their actions. Taylor, for example, uses Dworkin's account of autonomy to justify his arguments for a legal organ market – which I reference throughout chapter 5. However, because of their criticism against Dworkin's view, as well as how they apply their view to health care relationships, the account of autonomy I use when defending respect for autonomy as an ethical limit of health care markets is that of Beauchamp and Childress in *Principles of Biomedical Ethics*.

In philosophical and moral discussions, the concept of autonomy generally denotes a type of self-governing or –rule free from authoritative influences. However, Dworkin argues that there is a problem with understanding and using the concept of autonomy in this way. For Dworkin, understanding autonomy only as a type of self-governing or –rule free from authoritative influences tends to wrongly depict autonomy as being equivalent to the concept of liberty, while at the same time failing to clarify that autonomy seemingly requires more than just acting in accord with one's wishes or desires.[135]

Dworkin argues that for individuals to be autonomous, they must be able to develop and act upon preferences *for how they want to identify* themselves in relation to their wishes or desires. This means that in addition to being free of another's control, acting autonomously requires, "a second-order capacity to reflect critically upon one's first-order preferences and desires, and the ability either to identify with these or to change them in light of higher-order preferences and values."[136] In other words, acting

[135] Dworkin, *The Theory and Practice of Autonomy*, 14-15 and 105-106.
[136] Ibid., 108.

autonomously is not just the ability for individuals to freely choose the things they want and desire (i.e. first-order preferences), but to also freely choose how they identify with those wants and desires (i.e. second-order preferences).[137] Moreover, Dworkin is clear that limiting choices is still compatible with an individual's ability to exercise his or her autonomy.[138]

Beauchamp and Childress give a two-headed critique of this view. First, they argue that simply identifying and acting in accord with a second-order preference does not necessarily make the act autonomous.[139] This is because there is no clear understanding for how second-order preferences are unique from first-order preferences – that is, this account of autonomy does not clarify how second-order preferences either develop independently of, or are not influenced by, the same sorts of things that affect our first-order preferences such as one's addictions, beliefs, or values. As Beauchamp and Childress further explain, "If second-order desires (decisions, violations, etc.) are generated by prior desires or commitments, then the process of identifying with one desire rather than another does not distinguish autonomy from nonautonomy. The second-order desires would not significantly differ from first-order desires."[140]

Second, Beauchamp and Childress argue that this account of autonomy is too idealistic to be practical because it takes reflective deliberation as the benchmark by

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[137] In her article "A Coherence Theory of Autonomy," Ekstrom adds to this discussion by further addressing the technical distinction between preference and desire. According to Ekstrom, autonomously developing a higher (or second) order preference about a desire means developing an authoritative preference about a desire such that the desire leads one to act in coherence with one's character system. For a detailed explanation of this view see, Ekstrom, "A Coherence Theory of Autonomy."

[138] Dworkin, *The Theory and Practice of Autonomy*, 65-81.

[139] Beauchamp and Childress, *Principles of Biomedical Ethics*, 100.

[140] Ibid., 101.

which our choices are autonomous or not. In this regard, the problem Beauchamp and Childress see is that this account of autonomy needs, but does not have,

> [A] way for ordinary persons to qualify as deserving respect for their autonomy even when they have not reflected on their preferences at a higher level. Few choosers and few choices would be autonomous if held to the standards of higher order reflection in this theory, which presents an aspirational ideal of autonomy . . . No theory of autonomy is acceptable if it presents an ideal beyond the reach of normal agents and choosers.[141]

As an alternative to this view, Beauchamp and Childress provide an account of autonomy that focuses on the nonideal conditions that, as we shall see, fit with they consider are the moral requirements of "respect for autonomy." According to Beauchamp and Childress, individuals are autonomous if they: 1) act intentionally, 2) act of their own free accord, and 3) act with understanding (which they claim is having pertinent information that allows individuals to form relevant beliefs about the nature and consequences of their choices[142]).[143] They note that while the first condition is not a matter of degree (acts are either intentional or not), to act with understanding and without undue constraints *are* matters of degree. Consequently, it is not only possible that individuals may be more or less autonomous at different times, but also that at any one time, a particular choice could be more or less autonomous than another depending on one's understanding and the influence others have on that choice.

Beauchamp and Childress then argue that for an action to be autonomous on this account, "it needs only a substantial degree of understanding and freedom from

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[141] Ibid.
[142] Ibid., 127.
[143] Ibid., 101

constraint, not a full understanding or a complete absence of influence."[144] This is because to require a complete understanding or total freedom from influence would set the bar so high for acting autonomously that no person could reasonably or practically meet it. To assert that individuals could even have complete understanding or total freedom from influence is, Beauchamp and Childress claim, a mythical ideal.[145]

This understanding of autonomy makes the concept appear somewhat arbitrary because it places the ability to act autonomously on a continuously sliding scale that involves varying degrees of understanding and influence. Beauchamp and Childress acknowledge this. However, they further contend that even though the ability act autonomously depends on one's understanding and freedom from undue constraint, it is possible to have standards that help determine the degree to which a choice or action is autonomous. As they claim, "thresholds marking substantially autonomous decisions can be carefully fixed in light of specific objectives such as meaningful decision making . . . The appropriate criteria for substantial autonomy are best addressed in a particular context."[146]

Next I show how respect for autonomy is a guiding principle of both the interactions between health care professionals and patients and of market transactions, and argue for why, therefore, is should be considered an ethical limit of health care markets.

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[144] Ibid.
[145] Ibid., 102.
[146] Ibid.

A. *Respect for Autonomy as a Principle of Health Care Relationships*

Within health care, respect for autonomy has been increasingly emphasized over approximately the last fifty years. Traditionally, health care relationships have been characterized in terms of medical paternalism – that is, patients being given little or no opportunity to provide input regarding their treatment and overall medical care, while trusting health care professionals to know and act in patients' best interests. Now, however, the nature of health care relationships have shifted to allow patients more freedom to choose medical practices and treatments that better accord with their values and lifestyles.[147] For example, patients can now refuse what are otherwise considered standard medical treatments, such as a Jehovah's Witness refusing non-artificial blood products because he or she believes using these products violates important religious doctrines of the Jehovah's Witness faith.

From this it appears as though respect for autonomy in health care relationships is really a principle of noninterference toward patients' treatment decisions. While noninterference regarding (many) patient choices is certainly an aspect of showing proper respect for autonomy, understanding respect for autonomy as a principle of health care relationships requires more than just noninterference. Respect for autonomy as a principle of health care relationships also involves acting in ways to empower persons to make choices that best accord with their values and lifestyles. As Beauchamp and Childress note, respect for autonomy includes,

[147] See for example; Buchanan, "Medical Paternalism;" Beauchamp and Childress, *Principles of Biomedical Ethics*, 102-111; Husak, "Paternalism and Autonomy;" Clark, Sorenson, and Hare, "Ethical Problems in Clinical Practice;" and O'Neill, *Autonomy and Trust in Bioethics*, 34-37.

> building up or maintaining others' capacities for autonomous choice while helping to ally fears and other conditions that destroy or disrupt autonomous action. Respect, in this account, involves acknowledging the value and decision-making rights of persons and enabling them to act autonomously, whereas disrespect for autonomy involves attitudes and actions that ignore, insult, demean, or are inattentive to others' rights of autonomous action.[148]

Often discussions of respect for autonomy in health care relationships focus on *patient* autonomy. This is likely because patients' needs leave them particularly vulnerable to having their autonomy usurped throughout the course of treatment, as they are the ones who, in most cases, must rely on health care professionals to help them make treatment decisions that best accord with their values and lifestyles. But what Beauchamp and Childress are implying here is that the principle of respect for autonomy requires mutual respect in both attitude and action for the meaningful contributions of *both* patients and health care professionals in the treatment decision-making process. It would be contradictory to this principle if either party in a health care relationship was unduly pressured by the other to provide or accept treatment decisions that did not accord with their values or lifestyles; although in order to meet this principle it may still be necessary in certain cases for health care professionals to at least inform patients of various treatment options, even if they are unwilling to directly provide them. Regarding this latter point, for example, obstetricians opposed to abortion have the right not to provide them in non-emergency situations, but are also required as a matter of respect for autonomy not to impede the right of patients to get accurate information about the procedure or take steps to prevent patients from having the procedure done elsewhere.

[148] Beauchamp and Childress, *Principles of Biomedical Ethics*, 103.

Furthermore, like with the principle of honesty in health care relationships, the principle of respect for autonomy is not absolute. As Beauchamp and Childress also note, "Respect for autonomy has only *prima facie* standing, and competing moral considerations sometimes can override this principle."[149] For example, basic tenets of the medical profession would disallow health care professionals from honoring a patient's request to sell his or her heart to a transplant patient, even if the request appears autonomous. However, clarifying which moral considerations could override this principle, and whether or not such moral considerations should be permitted to override this principle in all instances are concerns beyond the scope of this particular project.

B. *Respect for Autonomy in Business*

In business, respect for autonomy is the core of economic life. As both Freeman and Donaldson and Dunfee discuss, respect for autonomy is necessary for individuals to freely enter into, fulfill, and exit from contracts with one another.[150] Yet, while it is generally recognized that there should be respect for autonomy in most aspects of business, there is a debate over whether or not the commonly accepted practice of direct-to-consumer advertising violates respect for autonomy.

Direct-to-consumer advertising tells consumers of different products on the market. On one hand, this form of advertising could therefore be autonomy enhancing by possibly helping consumers become more aware of the set of product choices available to them. At the very least, direct-to-consumer advertising does not violate autonomy *per se*

[149] Ibid., 105.

[150] Donaldson and Dunfee, *Ties That Bind*, 25-26 and 35-38; R. Edward Freeman, "A Stakeholder Theory of the Modern Corporation." For additional information about how respect for autonomy plays a specific role with respect to the interaction between individuals within an organization also see; Hartman, *Organizational Ethics and the Good Life* , 121-142.

because it cannot force individuals to purchase products against their wills. However many direct-to-consumer advertisements either fail to clearly present product information or use misinformation in ways that potentially create misunderstanding for consumers about the advertised products. So on the other hand, much direct-to-consumer advertising seems to hinder autonomous action by frustrating the ability of consumers to make informed product choices.

With respect to health care, this debate is most frequently associated with the direct-to-consumer advertising of pharmaceutical drugs. While this is an issue I thoroughly address in the next chapter, we already see with the example of Claritin how direct-to-consumer advertising of pharmaceutical drugs can deceive patients into believing they are better informed about a drug than they really are. As I argue in the next chapter, direct-to-consumer advertising of pharmaceutical drugs actually weakens patient autonomy in ways that violate this principle.

C. *Respect for Autonomy as an Ethical Limit of Health Care Markets*

From what I have shown here about how respect for autonomy applies to both health care relationships and business, there are at least two ways that this principle should be considered an ethical limit of health care markets. First, respect for autonomy should be considered an ethical limit of health care markets in that persons must have access to whatever information they need in order to make autonomous choices regarding the sale or purchase of health care goods or services. In the sense that Beauchamp and Childress discuss respect for autonomy, this requirement can be thought of as including an obligation for health care professionals or institutions (such as hospitals or insurance

companies) not only to provide to the best of their abilities the information patients need to properly exercise their autonomy, but to also provide means to help patients understand that information (even if those health care professionals or institutions are unwilling or unable to directly provide the goods or services patients may want). This obligation on the part of health care professionals or institutions is perhaps especially strong when health care relationships are contrived due to things like insurance or health care policy restrictions – restrictions that in some ways pose barriers to respect for autonomy in health care relationships because the relationships that result from such restrictions may not have a solid enough foundation of communication or trust to generate the kind of understanding expected for patients to autonomously engage in the treatment-decision making process.

Second, respect for autonomy should be considered an ethical limit of health care markets in that persons must be free of undue influence to make autonomous choices regarding the sale or purchase of health care goods or services. This does not mean, though, that making autonomous choices regarding the sale or purchase of health care goods or services requires total freedom from influence. Not only is it impractical to try to maintain that autonomous health care or market-based choices can be free from influence, but, particularly with respect to health care markets, there could also be times when not trying to influence patients' choices seemingly contradicts the principle of respect for autonomy. For example, many patients rely on the advice of health care professionals about certain health care goods or services to make better-informed choices. Respect for autonomy also seems to require influencing patients' health care choices

when they have not fully considered the consequences of those choice(s), such as, for example, if insured patients are unaware that the health care goods or services they want are not covered by their insurance – in such cases, appropriately expressing respect for autonomy would, at the very least, involve informing patients of what goods and services could meet their needs that are also covered by their insurance. The difference between when influence adheres to the principle of respect for autonomy and when influence violates this principle is that the former attempts to enable persons to make better informed decisions, while the latter constrains or pressures persons in ways that intentionally prevent or hinder their abilities to make autonomous decisions.

These two ways for how respect for autonomy shold be considered an ethical limit of health care markets also indicate at least two ways that health care markets could violate this limit. First, health care markets could violate this limit by not having provisions to provide participants the information they need to make well-informed treatment decisions. Second, health care markets could violate this limit by failing to have regulations that aim to prevent participants from making decisions about the sale or purchase of health care goods or services that result from undue constraint or influence.

3. **Conclusion**

Properly valuing health care goods and services requires properly valuing the primary relationships by which they are acquired. This is why ethically treating health care goods and services as commodities cannot rest just upon the principle of increased access. Throughout this chapter I have argued that ethically treating health care goods

and services as commodities also requires limiting health care markets according to at least the principles of honesty and respect for autonomy.

Over the next two chapters I apply my argument for the ethical limits of health care markets to both the pharmaceutical industry and a hypothetical legal organ market in the United States. The general reason why I focus on these two markets is because of the public and academic interest both have recently garnered: the pharmaceutical industry because of its high profitability and the ethically contentious ways it generates those profits; a potential legal organ market because it represents an alternative means of organ procurement that could help lessen the growing gap between the numbers of needed transplant organs and organ donors, *and* because organ selling is currently illegal in the United States. As we shall see next, the current *modus operandi* of the pharmaceutical industry in the United States violates each of the ethical limits of health care markets for which I have argued.

Chapter Four: Analyzing the Ethical Limits of the Pharmaceutical Industry

This chapter applies my argument for ethically treating health care goods and services as commodities to the pharmaceutical industry in the United States. I focus on the pharmaceutical industry for two primary reasons. First, as Callahan and Wasunna note, the pharmaceutical industry plays a crucial role in health care and so warrants serious moral and ethical scrutiny.[151] Second, unlike most other industrialized nations, the United States government takes a laissez-faire approach to drug pricing. One result of this is that approximately half of the industry's global sales of pharmaceutical drugs come from the United States alone.[152]

My aim in this chapter is to analyze five industry practices according to what I argue should be considered the base ethical limits of health care markets. In my analysis I show how each practice violates one or more of these limits. With respect to how pharmaceutical companies interact with physicians, I analyze: the use of pharmaceutical representatives to promote "medical education," the use of industry-sponsored research to market to physicians, and gift giving from pharmaceutical companies to physicians. Next I analyze the practice of direct-to-consumer advertising of pharmaceutical drugs. Lastly, I analyze the industry pricing of pharmaceutical drugs in the United States. I conclude by providing several suggestions for how the pharmaceutical industry can reform itself in order to ethically treat pharmaceutical drugs as commodities.

[151] Callahan and Wasunna, *Medicine and the Market*, 164.
[152] Organization for Economic Co-operation and Development, "Pharmaceutical Pricing Policy Project."

1. **Analyzing the Industry's Interaction with Physicians**

Physicians play a key role in prescription drug sales. Convince them that a prescription drug is valuable to patients, and they are more likely to prescribe that drug. Fail to convince them that a prescription drug is valuable to patients, and a pharmaceutical company may not only lose out on profits from lost prescription drug sales, but also runs the risk of a physician prescribing a competitor's drug. Pharmaceutical companies know this, and do what they can to convince physicians to prescribe their drugs over those of their competitors.

It is not inherently unethical for pharmaceutical companies to try and convince physicians that their drugs are better than those of their competitors. For example, if there is supporting data that shows how a particular prescription drug is more effective at treating a certain condition than another drug, and the pharmaceutical company attempts to present this data in a clear, unbiased way, then it is difficult to see how this type of action is unethical. Assuming that a particular prescription drug is more effective at treating a certain condition than another drug, than it may actually be unethical *not to* try to convince physicians that this drug should be the one they prescribe to patients. What makes the interactions between pharmaceutical companies and physicians ethically problematic, though, is not that pharmaceutical companies try to convince physicians their drugs are better than their competitors, but *how* pharmaceutical companies attempt to influence the prescribing practices of physicians.

The Pharmaceutical Research and Manufactures of America (PhRMA), who represent the leading pharmaceutical research and biotechnology companies in the United

States, claim that a critical part of their mission is having ethical relationships with healthcare professionals.[153] However, the primary practices used by pharmaceutical companies when interacting with physicians do not appear to exemplify attempts at having ethical relationships with them. These practices are: A) using pharmaceutical representatives to promote "medical education," B) the use of industry-sponsored research to market to physicians, and C) gift giving from pharmaceutical companies to physicians. In what follows, I first provide and description of each practice, then after each description I address how that practice violates the principles of honesty and respect for autonomy.

A. *Pharmaceutical Representatives and "medical education"*

As Brody discusses in *Hooked*, drug wholesalers began employing drug salesmen as early as the 1850s. Between 1900 and 1945, the role of drug salesmen expanded to include "detailing" – drug salesmen were no longer expected just to pitch the drugs they were selling, but to also provide all the details of a medication for physicians who wrote prescriptions instead of directly making drug purchases. Then in the years between 1945 and 1955, there were three events that resulted in the special role that pharmaceutical representatives now play within health care: "[1] The explosion in new drugs. [2] The failure of medical education to address the drug explosion. [3] The retreat of the [American Medical Association] from objective drug assessment."[154] These events,

[153] Pharmaceutical Research and Manufactures of America, *Code on Interactions With Healthcare Professionals*, 2. See Appendix 1.

[154] Brody, *Hooked*, 141-143. When speaking of the American Medical Association's (AMA) retreat from objective drug assessment, Brody is referring to how, prior to the 1950s, advertising a drug in the Journal of the American Medical Association (JAMA) would require drug manufacturers to obtain the AMA's "Seal of Acceptance." As the pharmaceutical industry's profits increased, they found they no longer needed to advertise in JAMA. So once the advertising revenues from JAMA started declining,

Brody shows, established the platform for using pharmaceutical representatives to market prescription drugs to physicians in terms of "medical education."[155]

The problem with characterizing drug presentations by pharmaceutical representatives as "medical education" is that they are not. The term "education" typically denotes a form of systematic instruction that many believe should be unbiased and objective. However, pharmaceutical representatives often give presentations that are mixed with varying degrees of fact and bias, and that are one-sided in favor of the drug being pitched.[156] As Carl Elliott discusses, the distinction between pharmaceutical medical education and pharmaceutical public relations is now so slender that pharmaceutical representatives even have trouble distinguishing between the two. Citing Neil Kendle, chief executive officer of Lowe Fusion Healthcare, Elliott writes, "[T]he broad distinction between healthcare PR and medical education is becoming obsolete . . . Sometimes I describe Lowe Fusion as a 'PR consultancy', sometimes as a 'healthcare communications agency', sometimes I just cop out and list the things we do."[157]

Evidence suggests a pervasive use of pharmaceutical representatives providing drug presentations to physicians. As Blumenthal notes, in 2001, the number of pharmaceutical representative employed by the industry topped 90,000 in the United States – approximately 1 representative for every 5 office-based physicians.[158] Moreover, according to a 1995 survey conducted by the Department of Medicine at the University of

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the AMA gave up the objective testing requirements needed to get the "Seal of Acceptance." As a result, Brody notes, the advertising revenues now represent more than half the entire income of the AMA. Ibid., 145.

[155] Ibid., 145-149.

[156] Bardes, "Ethics and Prescribing," 148; and Hubbard, "The Dangers of Detailing," 140-141.

[157] Elliott, "Pharma Goes to the Laundry," 18.

[158] Blumenthal, "Doctors and Drug Companies," 1886.

California at San Diego School of Medicine, from 106 drug statements made during 13 presentations by pharmaceutical representatives to physicians, only 12 (11%) were inaccurate or false. Yet all 12 statements favored the drugs being pitched, while no statement made during the presentations favored competitors drugs. What is perhaps also troubling about these findings is that of the 27 physicians who attended these presentations, only 7 of them (26%) recognized the false statements, while 10 of the physicians (37%) said the information provided influenced their prescribing practices.[159] However, given that latter survey is relatively small, and the lack of results regarding what sort of relevance these misleading statements had on the physicians' prescribing practices, it is difficult to draw any solid conclusions about the overall effects of drug presentations to physicians.

a. How Pharmaceutical Drug Presentations Violate the Principle of Honesty

As I discuss in chapter 3, the principle of honesty is violated when health care markets permit market participants to engage in dishonest or deceptive behavior not intended to serve patients' best interests, or that could potentially harm patients. This practice of using pharmaceutical representatives to give drug presentations under the guise of "medical education" seemingly fails to be forthright and truthful because they include some inaccurate or false information. However, giving drug presentations that include some inaccurate or false information does not necessarily mean that this practice violates the principle of honesty. It may be possible that the inaccurate or false information is somehow derived accidentally in a way that neither a pharmaceutical company nor a representative recognizes as inaccurate or false. If this is the case, then

[159] Ziegler, "The Accuracy of Drug Information from Pharmaceutical Sales Representatives."

even though pharmaceutical representatives are presenting some bad information to physicians, this practice may not violate the principle of honesty because neither a pharmaceutical company nor a representative could be charged with intentionally trying to deceive physicians in a way that would be unethical regarding the patient-physician relationship. Yet, as Elliott tells us, pharmaceutical representatives understanding that the goal of drug presentations is to generate good public relations as much as it is to "educate" physicians. So there is good reason to think that, because drug presentations are intentionally slanted, the possibility of deriving some bad drug information by accident is likely false.

This leads us to two possible conclusions regarding how this practice relates to the principle of honesty. First, at the least, this practice may violate the principle of honesty because some of the drug information may accidentally be inaccurate or false, while still being presented with the intent of favoring the drug being pitched. Second, at the worst, this practice explicitly violates the principle of honesty because the presentations use inaccurate or false information to bias physicians prescribing practices in ways not necessarily intended to serve patients' best interests *and* that could potentially harm patients.

b. How Pharmaceutical Drug Presentations Violate Respect for Autonomy

In chapter 3 I argue that respect for autonomy as an ethical limit of health care markets requires providing patients with information that helps them make treatment choices that best accord with their values and lifestyles. I also note how respect for autonomy is violated when a lack of information hinders the ability of patients to exercise

their autonomy in the treatment decision-making process. When pharmaceutical companies have representatives give drug presentations to physicians that include some inaccurate or false information, they violate the principle of respect for autonomy by impeding the accurate transfer of information between physicians and patients, thereby limiting the ability of patients to work with physicians to make well-informed treatment decisions. There are two reasons how this is the case. First, as we have already seen, pharmaceutical representatives can influence the prescribing practices of some physicians despite presenting them with some inaccurate or false drug information. When this occurs, pharmaceutical representatives effectively manipulate the ability of physicians to provide information patients may need to make well-informed treatment decisions. Second, as Hubbard argues, patients lack the proper medical training and knowledge to make treatment decisions on their own, and so rely on the expertise of physicians to help them make treatment decisions that are in their best interests.[160] When pharmaceutical representatives present inaccurate or false drug information to physicians, they also effectively constrain the ability of patients to have access to information in a way seemingly hinders their abilities to more freely participate in the treatment decision-making process.

B. *Industry-Sponsored Research*

Pharmaceutical companies will also use industry-sponsored research to market prescription drugs to physicians. Similar to how we typically understand the term "education," the term "research" denotes information that we typically assume has been obtained and presented in an objectively unbiased way. Yet there are numerous reasons to

[160] Hubbard, "The Dangers of Detailing," 139.

question the objectivity and bias of industry-sponsored research. Brody, for example, discusses how some industry-sponsored research papers will use the abstract, contrary to its intended purpose as a brief summary of key research findings, to highlight only the positives of a study while leaving out any undesirable findings. In particularly egregious examples, some of these research papers will even use the abstract to audaciously suggest that physicians prescribe the researched drug as their first-choice. Pharmaceutical companies do this because they know many physicians will read just the abstract instead of the entire study.[161]

Physicians, however, are getting better at recognizing the one-sidedness of industry-sponsored research. As Brody states,

> Many physicians are starting to get the message that research conducted by drug firms may be biased in favor of the company's drugs. Numerous reviews have shown that the likelihood of an industry-sponsored study showing the superiority of the drug in question is substantially greater than in studies paid for by neutral sources.[162]

Brody further suggests that pharmaceutical companies therefore attempt to conceal themselves as research sponsors by simultaneously conducting multiple drug trials at different universities and medical institutions, and by using several intermediaries to administer the studies.[163] This works to hide which studies are funded by pharmaceutical companies while still allowing them to control the flow of information being presented to physicians.

Pharmaceutical companies will also attempt to influence physicians by paying their colleagues to take part in presenting industry-sponsored research. Brody and Elliott

[161] Brody, *Hooked*, 127.
[162] Ibid., 128.
[163] Ibid.

give several examples in which pharmaceutical companies will pay physicians large sums of money, anywhere from $1,500 to $300,000, to attach their names to ghostwritten research papers, give prewritten lectures to colleagues at medical conferences that tout the virtues of a particular drug over others, or even write textbooks about diseases for which the sponsoring company has just created a drug treatment.[164]

a. How Industry-Sponsored Research Violates the Principle of Honesty

Each of these examples shows how using industry-sponsored research to market to physicians violates the principle of honesty by being intentionally deceitful. These examples show that pharmaceutical companies attempt to influence the prescribing practices of physicians by either presenting only favorable research data for the drug in question, by hiding themselves as the sources of research funding knowing that some physicians are aware that the data may be biased, or by paying physicians to market industry-sponsored research to other physicians in ways that seemingly violate the collegial trust that typically exists between members of a profession. While some kinds of deceit can be ethically permissible, this is not the case here. Attempting to manipulate research data so that physicians favor particular prescription drugs over others is a self-serving act that could consequently prevent physicians from being able to honestly disclose information to patients that patients presumably have a right to know given its relevancy to their medical care. Using industry-sponsored research to market to physicians can also be considered to violate the principle of honesty because of how attempts to suppress unfavorable research data may otherwise cause physicians *not* to

[164] Brody, *Hooked*, 130-135 and 202-211; Elliott, "Pharma Goes to the Laundry," 19-20.

prescribe the drug in question, especially if the missing research data shows that the drug in question is potentially harmful to patients.

One example of this is GlaxoSmithKline's suppression of research data regarding the use of the anti-depressant drug, Paxil, in children and adolescents. Studies on Paxil and other similar anti-depressant drugs show how using those drugs to treat childhood depression can have serious adverse effects on children and adolescents, including worsening their depression, increasing their hostility and aggressiveness, and increasing thoughts or attempts of suicide.[165] The evidence from these studies is strong enough that on June 10th, 2003, Gordon Duff, chairman of the Committee on Safety in Medicines in Great Britain, ruled that Paxil should not be used to treat childhood depression because cases of suicide were more frequent in patients under 18, *and that* on October 27th, 2003, the United States Food and Drug Administration made a similar recommendation.[166] However, as Brody notes, GlaxoSmithKline quickly published and has given considerable publicity to a research study that apparently shows how Paxil *is* effective in treating childhood depression, while doing its best to conceal the contrary data from the medical community.[167] These actions not only appear to be unethically deceptive and fraudulent, but have also prompted legal ramifications. In June 2004, then-Attorney General of the State of New York, Eliot Spitzer, filed legal charges of fraud against GlaxoSmithKline for, "withholding negative information and misrepresenting data on prescribing its antidepressant Paxil to children . . . [and that] an internal 1999 Glaxo

[165] Varley, "Psychopharmacological Treatment of Major Depressive Disorder in Children and Adolescents," 1092.
[166] Brody, *Hooked*, 2; Varley, "Psychopharmacological Treatment of Major Depressive Disorder in Children and Adolescents," 1092.
[167] Brody, *Hooked*, 2.

document showed that the company intended to "manage the dissemination of data in order to minimize any potential negative commercial impact.""[168]

b. How Industry-Sponsored Research Violates Respect for Autonomy

These examples regarding the use and promotion of industry-sponsored research also show how this practice violates the principle of respect for autonomy. Similar to pharmaceutical representatives giving drug presentations under the guise of "medical education," the current use and promotion of industry-sponsored research disrupts the medical decision making process between patients and physicians and effectively manipulates the ability of physicians to fully act in their patients' best interests. This is for two reasons. First, physicians who accept money to be voiceboxes for industry-sponsored research may fail to act fully autonomously because they may feel pressured to make treatment assessments and decisions that concur with the research findings they have been paid to promote. Second, pharmaceutical companies that promote only favorable research data while suppressing unfavorable research data, can be considered an undue influence that constrains the abilities of patients and physicians from being aware of information that might otherwise cause them to make different treatment decisions.

C. *Gift Giving*

Another way pharmaceutical companies try influence the prescribing practices of physicians is to provide them and their staffs with gifts. Standard gifts include branded office items like pens and notepads that are inscribed with the company's logo, free

[168] Associated Press, "Spitzer sues GlaxoSmithKline over Paxil." As of this writing the New York State Supreme Court has yet to make any formal documents related to this case public.

lunches for physicians and staffs, and drug samples. The latter is particularly convenient for physicians and patients, as patients get to try brand name drugs that they may not otherwise be able to afford, and without physicians having to write prescriptions that patients must then spend extra time getting filled.

Pharmaceutical companies also give physicians what can be deemed "entertainment gifts." These include items such as free dinners, bottles of alcohol, cigars, or golf outings (and perhaps for a particularly good client, a new set of golf clubs). While $100 is typically the upper limit for a gift, the type of gift and the actual amount spent is often times arbitrarily left to discretion of a pharmaceutical representative. As Brody notes, so long as sales in a particular territory are good, money is not an issue.[169]

Gift giving is often a way of expressing one's valued appreciation for another, and so is not typically considered unethical. Furthermore, many medical professionals – namely medical residents and physicians – do not consider accepting pharmaceutical gifts to be very ethically problematic. For example a survey conducted in 2003 by Drs. Allen Brett, Wayne Burr, and Jamaluddin Moloo of the Department of Medicine at the University of South Carolina School of Medicine, asked 37 of 42 faculty physicians (73%) and 39 of 42 medical residents (93%) with at least three years of training to judge the ethical appropriateness of 18 different pharmaceutical gifts. On a scale of 0-3 – in which 0 indicates "not problematic," 1 is "mildly problematic," 2 is "moderately problematic," and 3 is "very problematic" – no gift was rated at 2 or higher.[170] Gift giving

[169] Bardes, "Ethics and Prescribing," 148; Brody, *Hooked*, 169-172.

[170] Brett, Burr, and Moloo, "Are Gifts From Pharmaceutical Companies Ethically Problematic?," 2214-2215. Gifts within the 0-1 range, or "not problematic," for both faculty and residents include: pencils and notepads, $40 textbooks, free drug samples, free lunch for a resident conference with a formal

from pharmaceutical companies to physicians, though, does violate the principles of honesty and respect for autonomy.

a. How Gift Giving Violates the Principle of Honesty

Initially one might try to argue that gift giving from pharmaceutical companies to physicians violates the principle of honesty either because patients are unaware of the practice, or because patients are unaware of the influence pharmaceutical gifts can have on physicians' prescribing practices. In both cases, the influence of gift giving on the prescribing practices of physicians could be seen as undermining the essence of trust that, as I argue in chapter 3, ought to exist between patients and physicians. There is some justification for this argument. According to a 1994 survey conducted by Dr. Robert Blake and Elizabeth Early of the University of Missouri at Columbia, patient awareness of certain kinds of gifts from pharmaceutical companies to physicians is low. For example, of the 486 participants, just 22.4% and 13.8% respectively were aware that gifts to physicians include free dinners and coffee makers. Moreover, nearly half of the participants did not approve of these gifts (48.4% and 40.7% respectively).[171]

However this argument ultimately fails for two reasons. First, the study by Blake and Early also shows that 87% and 55.3% of participants respectively were aware that physicians receive free drug samples and office supplies from pharmaceutical companies. Moreover, 82.1% of participants approved of physicians receiving drug samples, while

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drug presentation, free lunch for a resident conference with an informal discussion with a pharmaceutical representative, and a $1000 unrestricted gift to the department. Gifts within the 1-2 range, or "mildly problematic," for both faculty and residents include: $40 golf balls, a dinner speaker with a product mentioned favorably, a grand rounds speaker with a product mentioned favorably, and a trip to a resort.

[171] Blake and Early, "Patient's Attitudes about Gifts to Physicians from Pharmaceutical Companies."

67.3% approved of physicians and their staffs receiving office supplies. Second, 70% of participants in this study believe that pharmaceutical gifts to physicians sometimes or frequently influence a physician's prescribing practices.[172] So, on one hand, it is true that a majority of patients are unaware of the full range of gifts pharmaceutical companies give to physicians. But, on the other hand, it is not the case that a majority of patients are completely unaware that physicians receive gifts from pharmaceutical companies, or that they unaware about the influence of these gifts have on physicians' prescribing practices.

Still it is possible to show that gift giving from pharmaceutical companies to physicians violates the principle of honesty because, in this case, it is a deceitful practice that intends to unethically influence physicians' prescribing practices. Part of our general understanding of gift giving is that the gift is intended to benefit the recipient in some way. Certainly many pharmaceutical gifts like notepads, pens, and free drug samples, can benefit physicians, their staffs, and patients. One can even argue that gifts like free lunches with an accompanying drug presentation, trips to a resort for a drug conference, or paid-for golf outings with pharmaceutical representatives, professionally benefit physicians by providing them with a relaxing break in their daily routines while still getting drug information in the process. Yet we have good reason to believe that the intent of pharmaceutical gifts is not necessarily to benefit physicians, their staffs, or patients, but to solely help pharmaceutical companies boost their profits by successfully market their products to physicians.

In 1955, a group calling itself the Pharmaceutical Advertising Club sponsored and published a study conducted by the Institute of Motivational Research titled, *A Research*

[172] Ibid.

Study on Pharmaceutical Advertising. Also known as the "Dichter study," after head researcher Ernest Dichter, the study examined the influence of pharmaceutical advertising on physicians. As Brody notes,

> The Dichter study broke new ground by identifying how important the process of *rationalization* was in successful pharmaceutical marketing. The company had to treat the physician in one way yet be perceived as if they were treating him in a very different way . . . For example, a visit from the rep might *really* be a break in a busy afternoon of seeing patients, a chance to talk with an old buddy about a hobby, or an exchange of gossip about other physicians in town. But just enough scientific information had to be exchanged – even a brochure that would never be read – so that the physician could rationalize the visit as "education."[173]

The Dichter study indicates why gift giving from pharmaceutical companies to physicians is deceiving in a way that seemingly violates the principle of honesty. Pharmaceutical gifts are primarily used as tools by the industry to get physicians to rationalize their exposure to pharmaceutical marketing as something that personally or professionally benefits them instead of as something that is really designed just to benefit a company's drug sales. The problem is that by giving these gifts, pharmaceutical companies are inviting physicians to trust that they have the physicians' best interests in mind while using that trust to manipulate physicians' prescribing practices for the sake of economic gain (something, again, that Strudler argues is an unethical use of deception).

b. How Gift Giving Violates the Principle of Respect for Autonomy

Before examining how gift giving from pharmaceutical companies to physicians *prima facie* violates the principle of respect for autonomy, it is interesting to note another

[173] Brody, *Hooked*, 146-147. I have conducted an extensive search to procure a copy of this study, going so far as to write Brody to see if I could borrow his. Unfortunately Brody only has an electronic copy that is currently on a computer locked in a building damaged by hurricane Rita in September 2008. The only other copy I have tracked down is in the Libraries of Congress. However I have been denied access to this copy because it is only available via inter-library loan to contracting institutions.

finding of the Dichter study. According to the study, physicians will attempt to portray themselves as independent thinkers who are not influenced by pharmaceutical marketing.[174] This still seems to be the case today. In the study by Brett, Burr, and Moloo, for example, the average response by faculty physicians about how influential free drug samples are on their prescribing practices was 1.54, or "mildly influential." This again is on a scale of 0-3, in which 0 indicates "not influential," and 3 indicates "very influential."[175] The reason this is interesting is because it indicates how well the process of rationalization has worked in pharmaceutical marketing. If physicians were to believe that pharmaceutical gifts were largely influential on their prescribing practices, they may be unwilling to accept them. But because physicians often believe that they are not and cannot be influenced by these gifts, they willingly accept them without much ethical concern. The problem with rationalizing pharmaceutical gifts in this way, and the reason for why this practice violates the principle of respect for autonomy, is that gift giving is psychologically tied to the rule for reciprocation.

According to Robert Cialdini, a psychologist at Arizona State University and author of *Influence: The Psychology of Persuasion*, humans are conditioned to react to receiving gifts with a sense of obligation because of the rule for reciprocation.[176] The rule says that, "we should try to repay, in kind, what another person has provided us."[177] As Cialdini further notes, the rule for reciprocation and the sense of obligation associated

[174] Ibid., 147.
[175] Brett, Burr, and Moloo, "Are Gifts From Pharmaceutical Companies Ethically Problematic?," 2216. Medical residents, however, had an average response to this question of 2.04, or "moderately influential," with 31 of 39 scoring this question in the 2-3 range, or "moderately" to "very" influential.
[176] Cialdini, *Influence*, 17-18.
[177] Ibid., 17.

with it is so pervasive that, "[A]fter intensive study, sociologists such as Alvin Gouldner can report that there is *no human society* that does not subscribe to the rule. And within each society it seems pervasive also; it permeates exchanges *of every kind*."[178] A common explanation for why this rule is so pervasive, and why it is psychologically tied to gift giving, is that a fundamental component of social survival for individuals and societies is the ability to share resources in a cooperative manner. As Brody further explains, it is important to the social system that, "the person who initiates a gift exchange can be confident that his cooperative gesture will be replied to with a similarly cooperative gesture."[179]

The rule for reciprocation tells us that the act of receiving a gift is itself influential, and explains why gift giving from pharmaceutical companies to physicians unethically violates the principle of respect for autonomy. This is because gift giving from pharmaceutical companies to physicians creates a potential undue influence on the ability of physicians to act on their patients' behalf. Even if pharmaceutical gifts are not intended to influence the prescribing practices of physicians, we can, in this case, view the psychological response for reciprocation to receiving a gift as a manipulative force that leaves physicians vulnerable to making biased prescription choices that may not be the best or most appropriate way to help patients meet their medical needs.

2. **Analyzing the Industry's use of Direct-to-Consumer-Advertising**

Although physicians play a key role in prescription drug sales, it is the continuous needs and wants of patients for prescription drugs that sustain the pharmaceutical

[178] Ibid., 18. Emphasis added.
[179] Brody, *Hooked*, 174.

industry's profits. It makes sense, then, for pharmaceutical companies to also want to market prescription drugs directly to consumers. Often pharmaceutical direct-to-consumer advertising (DTCA) takes the form of television commercials, Internet advertisements, printed advertisements, and general public advertisements such as billboards and flyers.[180]

Pharmaceutical DTCA can be separated into two kinds: branded and non-branded. Branded DTCA market particular pharmaceutical drugs by naming them in the advertisement. Non-branded DTCA does not attempt to market particular pharmaceuticals drugs and do not mention specific drugs by name.[181] As Arnold notes, distinguishing between branded and non-branded DTCA is necessary because the arguments for and against pharmaceutical DTCA do not apply equally to both kinds.[182] Branded DTCA, because it aims to market specific drugs to consumers, is typically considered more ethically controversial than non-branded. For example, Arnold argues that the branded DTCA is unethical, while non-branded DTCA is not. Since this chapter addresses how the pharmaceutical industry violates the ethical limits of health care markets in the United States, this section focuses exclusively on branded DTCA.

The pharmaceutical industry promotes the practice of DTCA as a valuable service to consumers. In 2005, PhRMA's Chief Medical Officer, Paul Antony, submitted a written testimony to Congress about the industry's use of DTCA. According to Antony's testimony,

[180] Abrams, "The Regulation of Prescription Drug Promotion," 159.
[181] Arnold, "The Ethics of Direct to Consumer Pharmaceutical Advertising," 174.
[182] Ibid.

> DTC advertising has been proven beneficial to American patients. And, continuing regulatory oversight by the FDA helps ensure that the content of DTC advertising informs and educates consumers about medical conditions and treatment options . . . DTC advertising can be a powerful tool in educating millions of people and improving health. Because of DTC advertising, large numbers of Americans are prompted to discuss illness with their doctors for the first time. Because of DTC advertising, patients become more involved in their own health care decisions, and are proactive in their patient – doctor dialogue. Because of DTC advertising, patients are more likely to take their prescribed medications.[183]

Although DTCA may have this effect on American patients, Antony's testimony provides no empirical data justifying these claims. Moreover, the degree to which the United States Food and Drug Administration (FDA) actually provides effective regulatory oversight of DTCA is questionable. As Donohue, Cevasco, and Rosenthal show, from 1996 to 2005 the industry's expenditures on DTCA have increased 330%, from $985 million to $4.2 billion. This increase also represents an increase in the percentage of total promotional spending used on DTCA during that time, from approximately 9% to 14%. However from 1997 to 2006, while the number of noted problems of DTCA complying with FDA regulations increased from 15.5% to 33.3%, the number of letters sent by the FDA to pharmaceutical companies informing them they had violated DTCA regulations went from 142 in 1997 to approximately 160 in 1998, but steadily decreased each year since to a low of 21 in 2006.[184] This data shows that pharmaceutical companies are increasing their use of DTCA, that pharmaceutical companies are increasingly violating the FDA's regulations for DTCA, and that the FDA is effectively failing to communicate those violations back to the offending

[183] Pharmaceutical Research and Manufactures of America, "PhRMA Chief Medical Officer Testifies on DTC Advertising."

[184] Donohue, Cevasco, and Rosenthal, "A Decade of Direct-to-Consumer Advertising of Prescription Drugs," 673-679.

pharmaceutical company(-ies). Yet it is the ways DTCA violates FDA regulations that highlight how DTCA also violates the base ethical principles of health care markets for which I argue. As Donohue, Cevasco, and Rosenthal also note, from 1997 to 2006, 84% of DTCA that violated FDA regulations was, "for either minimizing risks (e.g., minimizing or omitting information on side effects), exaggerating effectiveness (e.g., portraying the indication too broadly or making unsubstantiated claims of superiority over other drugs), or both."[185]

A. *How DTCA Violates the Principle of Honesty*

There are three ways I show that DTCA violates the principle of honesty: 1) in how DTCA is promoted by PhRMA, 2) in how broadcasted pharmaceutical advertisements have been deregulated by the FDA, and 3) with respect to the perceived accuracy of the information in DTCA. The underlying concern with each of these ways is that the transmission of false, inaccurate, or incomplete information may cause some persons to seek drug prescriptions that may be medically inappropriate for them, or that they simply do not need. I do not, however, attempt to argue that DTCA is unethical based on the idea that, similar to other kinds of non-pharmaceutical direct-to-consumer advertisements, it may contain clearly false images. Clearly false images are those that show an advertised product doing impossible things, like a vehicle vertically scaling a building unassisted. The reason I do not argue this point is that it is difficult to show how using false images in advertisements violates the principle of honesty, as most rational persons do not accept clearly false images as being true in the first place.

[185] Ibid., 677.

One way that DTCA violates the principle of honesty is because of how PhRMA promotes the practice as a service that helps inform and educate consumers. We know from the example of Schering-Plough using dual claims to dubiously market Claritin to consumers as an effective, non-drowsy antihistamine, that PhRMA's claim about DTCA informing and educating consumers is not true in all cases. Moreover, as John Abramson perceptively notes in *Overdosed America*, assuming the purpose of DTCA is to inform and educate consumers, it is disingenuous to use ad agencies instead of health educators to create pharmaceutical advertisements that heavily rely on emotional appeals instead of clearly stated facts.[186]

Another way DTCA is unethically deceptive is because, despite PhRMA's claim that DTCA aims to inform consumers, broadcasted pharmaceutical advertisements, namely television commercials, are not required to disclose detailed risk information. Detailed risk information, however, is something most persons consider medically relevant information to know prior to taking a prescription drug. Prior to 1997, the FDA required all broadcasted pharmaceutical advertisements to have a brief summary of risk information that included the drug's effectiveness, side effects, major risks, and contraindications.[187] According to Rosenthal and Donohue, "These rules served as a *de facto* barrier to broadcast advertisements . . . because it was costly to air the entire brief summary on television."[188]

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[186] Abramson, *Overdosed America*, 155.
[187] Rosenthal and Donohue, "Direct-to-Consumer Advertising of Prescription Drugs," 171; Brody, *Hooked*, 231.
[188] Rosenthal and Donohue, "Direct-to-Consumer Advertising of Prescription Drugs," 171.

In August 1997, the FDA clarified and subsequently loosened its restrictions on DTCA. The FDA's new requirements allow broadcasted pharmaceutical advertisements to simply include information referrals for risk disclosure. That is, instead of being required to summarize risk information in the advertisement itself, pharmaceutical companies could now adequately fulfill their obligation of risk disclosure by providing consumers with a toll-free number, a Website address, or by suggesting that individuals speak with a physician if they have questions about the advertised drug.[189] However the force behind this objection is not just that pharmaceutical companies no longer have to disclose risk information in their broadcasted advertisements, but also that since the FDA's policy change, television commercials have gone from not playing a major role in DTCA to becoming the primary source it.

As Rosenthal and Donohue show, pharmaceutical companies spent almost no money on television commercials in 1994 and 1995, while industry expenditures on DTCA for television commercials in 1996 and 1997 was approximately $250 million (about 25% of total DTCA expenditures). In 1998, just after the FDA's deregulation of broadcasted DTCA, industry expenditures on DTCA for television commercials rose to approximately $600 million (about 50% of total DTCA expenditures). In 2001, just four years after the FDA's policy change, industry expenditures on DTCA for television commercials jumped to approximately $1.75 billion (about 64% of total DTCA expenditures).[190]

[189] Ibid., 170-171.
[190] Ibid., 170.

DTCA can also be considered to violate the principle of honesty because of how the information presented in DTCA often causes patients to misperceive the accuracy of the advertisements, while largely believing they are educational and informative. In April 2008, the Kaiser Family Foundation published a report on public and physician perceptions of DTCA. According to this report, 91% of the sample population from the general public claimed to have seen a drug advertisement in 2008, with 67% believing that DTCA is educational, and 52% claiming to at least somewhat rely on DTCA for information about prescription drugs.[191]

However, according to a 2002 FDA sponsored survey, the accuracy of the information patients receive from DTCA is questionable. The survey asked 500 physicians – 250 general practioners, and 250 specialists – to evaluate the effects of DTCA on patient-physician relationships. According to the results, 65% of physicians surveyed believe that DTCA either somewhat or greatly confuses patients about the risks and benefits of the advertised drug. Moreover, 75% of physicians somewhat or greatly believe that DTCA causes patients to overestimate the benefits of the advertised drug.[192]

B. *How DTCA Violates the Principle of Respect for Autonomy*

On one hand, DTCA appears to promote patient autonomy. There are two primary reasons for this. First, despite its accuracy, DTCA informs consumers of various prescription drugs for particular medical conditions that they might not have known about otherwise. Second, DTCA encourages patients to actively participate in treatment discussions with physicians; thus seemingly help curb paternalistic prescribing

[191] Kaiser Family Foundation, "Kaiser Public Opinion Spotlight: Public and Physician Views of Direct-to-Consumer Prescription Drug Advertising," 7.
[192] Aikin, "Direct-to-Consumer Advertising of Prescription Drugs: Physician Survey Preliminary Results."

practices.[193] Moreover, as Rosenthal and Donohue also show, consumer surveys suggest DTCA makes patients more compliant with medication therapy, while physician surveys suggest that, "DTCA encourages patients to follow the treatments recommended by their physicians."[194] Assuming this latter point is correct, DTCA also appears to help promote patient autonomy by encouraging patients to be more responsible in adhering to their drug treatments.

On the other hand, despite how it may appear to potentially promote patient autonomy, DTCA violates the principle of respect for autonomy in at least two ways. First, DTCA manipulates the ability of physicians to act autonomously in their treatment of patients. Second, because it gives insufficient information about the risk-benefit ratio of the advertised drugs, DTCA actually *weakens* patient autonomy by causing patients to believe they are better informed about advertised drugs than they actually are, *and* by potentially increasing medical paternalism.[195]

Regarding the first reason, Rosenthal and Donohue state that in a 2002 survey on DTCA and consumer drug choices, 32% of consumers who saw a drug advertisement asked their physicians about it. Of those consumers, 27% asked for a prescription.[196] However nothing in my argument about the principle of respect for autonomy shows how creating or expressing a want or desire for a product violates one's autonomy. The

[193] In depth analysis of the arguments supporting these two reasons can also be found in Abrams, "The Regulation of Prescription Drug Promotion;" Calfee, Winston, and Stempski, "Direct-to-Consumer Advertising and the Demand for Cholesterol-Reducing Drugs;" Holmer, "Direct-to-Consumer Advertising;" and Hurwitz and Caves, "Persuasion or Information?"

[194] Rosenthal and Donohue, "Direct-to-Consumer Advertising of Prescription Drugs," 177.

[195] In depth analysis of the arguments supporting these three reasons can also be found in Donohue, Cevasco, and Rosenthal, "A Decade of Direct-to-Consumer Advertising of Prescription Drugs;" Harder, "Dangerous Practices;" Harder "Pushing Drugs;" and Mello, Rosenthal, and Neumann, "Direct-to-Consumer Advertising and Shared Liability for Pharmaceutical Manufacturers."

[196] Rosenthal and Donohue, "Direct-to-Consumer Advertising of Prescription Drugs," 174.

problem, though, is that many physicians feel pressured to comply with patients' requests for advertised drugs they do not need. As Rosenthal and Donohue further note, "four out of five physicians think DTCA encourages patients to seek treatments they do not need," *and* that approximately 70% of patient requests for advertised drugs are honored.[197] This influence of DTCA over physicians' prescribing practices is unethical in light of the principle of respect for autonomy because of how it manipulates their prescribing practices in ways they recognize are not necessarily in the best interests of their patients.

I already discussed how the quality of the information in DTCA violates the principle of honesty. Again this is because of how DTCA does not require risk disclosures in the ads, while presenting information to patients that can be confusing and cause them to overestimate the benefit of the advertised drugs. These points also show how DTCA violates the principle of respect for autonomy by weakening patient autonomy.

The quality of information in DTCA weakens patient autonomy in two ways. First, DTCA may cause patients to believe they are better informed about the advertised drugs then they really are. When consumers request and press for advertised drugs based on this information, they not only fail act autonomously because they are acting based on misinformation, but they also devalue their physicians' professional abilities to make knowledgeable treatment decisions. Second, the lack of forthright and truthful information in DTCA about the risks and benefits of the advertised drugs seems to have the opposite effect of their original intent. Instead of promoting patient autonomy, DTCA appears to cause retrogression toward medical paternalism. This is because when patients

[197] Ibid., 175-176, quote on 175.

request and press for advertised drugs based on the information in DTCA, physicians may feel obligated to deny these requests, as directed by their professional obligation to act in their patients' best interests, which may again lead consumers and patients to believe these physicians are acting overly and unjustly paternalistic.

Before turning to analyze the ethics the industry's pricing of life-saving pharmaceutical drugs, I first briefly explain why I do not argue that the use of DTCA violates the desire to increase access to essential goods and services.

C. *Why DTCA does not appear to Violate the Principle of Increased Access to Essential Health Goods and Services*

There is a general concern that DTCA raises the costs of pharmaceutical drugs within the United States, and thus raises the overall costs of health care. This might appear to be the case given that from 1996 to 2005, total expenditures on pharmaceutical marketing to physicians and consumers increased from approximately $11.5 billion to nearly $30 billion. This represents a 4% increase in the percentage of annual pharmaceutical sales used on marketing (from 14.2% to 18.2%).[198] At the same time, the average price of pharmaceutical drugs in the United States is approximately one-third to a half more than other countries with national health care systems.[199]

However, in order to show how DTCA violates the principle of increased access to essential health care goods and services, there would need to be clear evidence showing how this practice actually prevents people from receiving needed pharmaceutical drugs. While high drug prices prevent some people from accessing

[198] Donohue, Cevasco, and Rosenthal, "A Decade of Direct-to-Consumer Advertising of Prescription Drugs," 676.
[199] Brody, *Hooked*, 55.

needed drugs – a point I discuss more in the next section – there is no substantial evidence that these high prices result directly from DTCA. As PhRMA representative Alan Holmer claims, "Direct-to-consumer advertising does not affect the prices of drugs: price increases of drugs are the least important factor contributing to the increase in pharmaceutical spending."[200] Being a representative of the pharmaceutical industry, Holmer's statement is likely biased. However Donohue, Cevasco, and Rosenthal echo this view in their analysis of the data on DTCA expenditures. They claim:

> Driven by increases in direct-to-consumer advertising, total promotion as a percentage of sales has increased substantially . . . leading some observers to worry that consumers must bear these increased costs in the form of higher prices. Economic theory and evidence suggest that changes in marketing costs are unlikely to have a direct effect on pharmaceutical prices.[201]

At most any evidence linking DTCA expenditures to prohibitive increases in drug costs are mixed.[202] Brody also acknowledges the lack of evidence linking DTCA expenditures to higher drug costs. According to Brody, "The fact is that we do not know very much about the impact of DTC ads, for good or ill. The question of whether DTC ads lead to increased costs of drugs as more consumers demand a high-priced product, or as consumers seek drug therapy for a condition they previously willing to live with, is very difficult to determine."[203]

It may be that DTCA violates the principle of increased access to essential health care goods and services because it prompts individuals without genuine medical needs to

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[200] Holmer, "Direct-To-Consumer Advertising: Strengthening our Health Care System," 528.
[201] Donohue, Cevasco, and Rosenthal, "A Decade of Direct-to-Consumer Advertising of Prescription Drugs," 677-678.
[202] Ibid., 678.
[203] Brody, *Hooked*, 232.

seek medical consultations, thereby possibly delaying access to essential health care goods and services for those with genuine medical needs. In addition to the findings of Rosenthal and Donohue, a national survey conducted by Weissman, *et. al*., found that of the 643 physicians who responded, 78.6% either somewhat agree or strongly agree that DTCA encourages patients to seek unneeded treatments.[204] However, even though DTCA could be responsible for causing delays in treatment for persons with genuine medical needs, there is no quantifying data that allows us to claim with any certainty that DTCA actually prevents persons with genuine medical needs from gaining access to essential treatment.

3. **Analyzing the Industry's Pricing of Pharmaceutical Drugs**

The Organization for Economic Co-operation and Development (OECD) recently concluded a study of pharmaceutical pricing policies among member nations.[205] The study aimed to create a framework for comparing international drug pricing policies, and analyze the impacts of differing drug prices on OECD nations and on pharmaceutical research and development.[206] Two results of this project with respect to pharmaceutical drug pricing in the United States are clear. First, the United States has the highest *per capita* spending on pharmaceutical drugs than any other OECD nation. In 2005, the *per capita* spending on pharmaceutical drugs in the United States was $792. This is $203 more than second ranked Canada, and $388 more than the OECD average.[207] Second, of

[204] Weissman, et. al., "Physicians Report on Patient Encounters Involving Direct-to-Consumer Advertising," W4.224.
[205] Organization for Economic Co-Operation and Development, "Pharmaceutical Pricing Policy Project."
[206] Ibid.
[207] Organization for Economic Co-Operation and Development, "Figure 1.2. Per Capita Spending on Pharmaceuticals, 2005."

OECD member nations, the United States accounts for 45% of global pharmaceutical drug sales.[208] These two statistics imply that the United States both pays a higher price for and purchases a higher quantity of pharmaceutical drugs than any other OECD nation.

There are two general explanations for why the United States annually spends so much on pharmaceutical drugs: research and development, and the free market. First, the pharmaceutical industry often claims that drug spending in the United States is justified because it fuels future research and development. As Brody further explains,

> Most other nations have a national health system and negotiate discounted drug prices, paying usually half or two-thirds what American's typically pay. According to spokespersons for the industry, Americans' willingness to pay top dollar for drugs is subsidizing the rest of the world's pharmaceutical research. If the United States . . . [ever brought] the cost of drugs down to the average level in other developed countries, the bottom would fall out of research on new pharmaceuticals.[209]

Whether or not the industry is correct to link drug spending in the United States to funding for research and development is a debatable point that I return to momentarily.

Second, pharmaceutical drug spending in the United States is also the result of the free market. One conclusion of the OECD's pharmaceutical pricing project is that drug prices are often defined by a willingness to pay for a particular drug and not based on the medicinal value of the drug.[210] Free market systems that allow pharmaceutical companies to set the prices of drugs based on the willingness to pay is particularly effective in the United States for three reasons. First, the United States employs a patent system that is meant to generate innovation by protecting proprietary knowledge. Consequently this system allows pharmaceutical companies to earn exclusive profits on the drugs (and the

[208] Organization for Economic Co-Operation and Development, "Pharmaceutical Pricing Policy Project."
[209] Brody, *Hooked*, 54-55.
[210] Organization for Economic Co-Operation and Development, "Pharmaceutical Pricing Policy Project."

composite chemical combinations of those drugs) for 17 years after the initial patent approval.[211] Second, United States law prohibits drug reseal. This prevents individuals from buying and re-importing drugs that were produced in the United States from foreign countries where those drugs may be available at a cheaper cost.[212] Lastly, as discussed in the previous section, the pervasive use of DTCA has increased the number of people in the United States seeking and receiving pharmaceutical drug prescriptions.

A. *How Pharmaceutical Drug Pricing in the United States Violates the Principle of Honesty*

There are two ways that pharmaceutical drug pricing in the United States violates the principle of honesty: by pharmaceutical companies deceptively masking how drug prices are set, and by pharmaceutical companies making a false connection between drug prices and the funding of future research and development. Regarding the first point, consider the example of world's first anti-HIV drug, Azidothymidine (AZT). In the late 1980s the FDA approved AZT, which at the time was also the only available anti-HIV drug. Although the company that produced the drug, Burroughs Wellcome, had substantial support from government funding and university scientists, they retained the rights to sell AZT. Using various market mechanisms, Burroughs Wellcome priced AZT at $10,000 for a year's treatment (approximately $833 per month). While many argued this price was too expensive for many persons infected with HIV, Burroughs Wellcome

[211] For an a detailed account of how the United States patent system works in connection with pharmaceutical innovation and profits see; Barton and Emanuel, "The Patents-Based Pharmaceutical Development Process: Rationale, Problems, and Potential Reforms;" Brody, *Hooked*, 69-85; Caves, Whinston, Hurwitz, Pakes, and Temin, "Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry;" Statman, "The Effect of Patent Expiration on the Market Position of Drugs;" Statman and Tyebjee, "Trademarks, Patents, and Innovation in the Ethical Drug Industry;" and Werhane and Gorman, "Intellectual Property Rights, Access to Life-Enhancing Drugs, and Corporate Moral Responsibilities."

[212] Brody, *Hooked*, 57.

attempted to justify their pricing of AZT by claiming that they had invested about $86 million into the drug's development and, as Brody notes, "feared either that the epidemic would wane or that competing drugs would soon eat into their market share."[213] As Brody further notes, Burroughs Wellcome "made one hundred million dollars on the drug in its first year of sales . . . [and] recouped their investment many times over within a few years."[214]

The case of Burroughs Wellcome's and AZT exemplifies a standard criticism of pharmaceutical drug pricing. Specifically, pharmaceutical companies are criticized for failing to detail or disclose how they determine drug prices, keeping the process closed from external evaluation. Like Burroughs Wellcome, many pharmaceutical companies claim that a drug's price reflects, or should reflect, the monies spent developing the drug. In his detailed examination of the relationship between AIDS activism and the pharmaceutical industry, Martin Delaney discusses how this claim is dubious. According to Delaney,

> The actual cost [of drug development] is difficult, if not impossible, to calculate because there is no agreed-upon standard of accounting for the determining cost . . . At the very least, the manufacturers believe that the cost of every successful drug must also reflect a portion of the costs of all the drugs that failed during development. Just how much was spent on failed drugs is impossible to calculate without complete access to a company's books and a complex auditing process . . . The real cost of drug development largely remains a "black box" of indeterminate proportions . . .[215]

Whether or not pharmaceutical companies correctly assess the cost of drug development as reflected in the drug's price is not at issue. It is possible that

[213] Ibid., 261.
[214] Ibid.
[215] Delaney, "AIDS Activism and the Pharmaceutical Industry," 311.

pharmaceutical companies determine drug prices in ways that are both accurate and fair. My particular criticism with respect to how drug pricing violates the principle of honesty is that, by being unwilling to openly justify drug prices with empirical support, pharmaceutical companies act deceptively in a way that does seemingly intend to serve patients' best interests.

One could try to refute this criticism by noting that within free market systems, there seems to be no reason for companies to disclose how they determine product prices. This is because, as I discussed toward the beginning of chapter 2, the ideal goal of the market is for supply and demand to exist in equilibrium. Product prices will therefore partly adjust in accord with demand for that product. So for example, if the cost of a drug prevents patients from purchasing it, thereby causing a drop in demand, the price of the drug will come down to try to increase sales, thereby helping to reestablish demand. Whether or not this is a fair way to determine drug prices is not a question of honesty, but rather a question of whether or not this accords with the principle of increased access to essential health care goods and services.

This refutation may work for some non-heath care commodities, but fails with respect to pharmaceutical drugs. To claim that it is unnecessary for pharmaceutical companies to show how they set drug prices because drug prices will adjust according to market demand is to claim that they *can be valued merely* as commodities. However, despite the fact that some patients seek and receive prescriptions for drugs they do not need, pharmaceutical drugs are often necessary for people to combat or prevent disease or illness. As such, based on my arguments for why health care goods and services are not

properly valued merely as commodities, this refutation fails because it attempts to characterize the value of pharmaceutical drugs as properly being subject to market forces.

Pharmaceutical companies in the United States will also attempt to set drug prices based on the argument that pharmaceutical profits are necessary to fund future drug research and development.[216] Yet this argument falsely equates revenue with profit. We can think of the difference between revenue and profit as a difference in total income versus excess monetary or financial gain after paying for all other operating costs. Revenue is necessary to fund future research and development. Excess financial gain, however, is not. Brody helps clarify this point by comparing the 2002 financial data of the top-ten performing pharmaceutical companies to that of the average *Fortune 500* company. Although all pharmaceutical companies in the *Fortune 500* for that year reported profit increases that were higher than the average for all *Fortune 500* companies, the top-ten performers earned profits that, on the most conservative scale, were 2.7 times higher than this average (equaling a total profit of $35.9 billion). What Brody shows is that if the top-ten pharmaceutical performers for 2002 were to maintain the same revenue but allocate 26% of their profits to research and development, they would still have been twice as profitable as the average *Fortune 500* company *and* would have been able to increase their research and development funding by 32% - from $30.7 billion to $40.3 billion.[217]

[216] As Brody notes, this is a common argument given by pharmaceutical companies to justify drug prices. See Brody, *Hooked*, 86.

[217] Ibid., 86-87. Brody further notes that this increase to research and development would occur without decreasing any funds allocated to operating costs or marketing.

This argument does not necessarily justify decreasing pharmaceutical prices. It is possible that decreasing drug prices could result in lost revenue that would prevent a pharmaceutical company from meeting its operating costs while still being profitable and able to fund research and development. What this argument shows, however, is that it is pharmaceutical companies trying to justify high pharmaceutical prices on the grounds that future research and development exclusively relies on the industry's profitability is deceptive in a way that appears to violate the principle of honesty. By keeping the process for how drug prices are determined secretive, the pharmaceutical industry has authorized itself as the primary source of information we have about how they set drug prices. This is tantamount to a solicitation of trust that is therefore breeched when pharmaceutical companies provide consumers false information about drug pricing for the purpose of ensuring their continue financial gains.

B. *How Pharmaceutical Drug Pricing in the United States Violates the Principle of Respect for Autonomy*

When pharmaceutical drugs are first introduced to the market, they provide patients a new treatment option that did not previously exist. So even when pharmaceutical drugs are too expensive for patients to afford, simply introducing them to the market seems to accord with respect for autonomy by adding to the overall number of available treatment options. Although this seems to be a plausible conclusion, it is incorrect for two reasons. First, when pharmaceutical drugs are too expensive for patients to afford, they cannot be considered *bona fide* treatment options because their purchase is impractical. Second, as I discuss in chapter 3, it is not the range of choices available that make a choice autonomous or not, and so it is false to claim that simply bringing a drug

to the market accords with respect for autonomy by increasing treatment options for those who can afford them.

However, it is possible that pharmaceutical drug pricing can violate the principle of respect for autonomy. Pharmaceutical drug pricing violates this principle when the costs of pharmaceutical drugs manipulates or influences patients' treatment choices in ways that do not adequately meet their health care needs. For example, when AZT was first introduced to the market, many HIV infected persons had to choose between either paying the high cost of AZT or forgo treatment. The former choice was impractical for many HIV infected persons because they could not afford AZT, while the latter choice was, perhaps except for cases in which HIV infected persons accepted the consequences of forgoing treatment, contrary to the aims of health care.

C. *How Pharmaceutical Drug Pricing in the United States Violates the Principle of Increased Access to Essential Health Care Goods and Services*

It is not enough to claim that because the United States has the highest *per capita* spending on pharmaceutical drugs than any other OECD nation, and that because the United States accounts for nearly half of global pharmaceutical sales, that drug pricing in the United States therefore violates the principle of increased access to essential health care goods and services. This is because, as I argue in chapter 2, violations of this principle occur in health care markets when individuals are prevented from attaining access to health care goods or services necessary to effectively treat their medical needs. Assuming patients in the United States are able and willing to pay the out-of-pocket expenses for needed pharmaceutical drugs, no violation of this principle seems to occur. When, however, the cost of needed pharmaceutical drugs is more than what patients can

afford out-of-pocket, and they are thusly forced to forgo drug treatment as a result, we can conclude that in those particular cases drug pricing has violated the principle of increased access to essential health care goods and services. For example, when AZT was first introduced to the market, it was the only drug available to help treat HIV, but cost too much for many HIV infected persons to afford. In this case the pricing of AZT violated the principle of increased access because, while some HIV infected persons were likely able and willing to pay for the drug, the cost prevented many others from having access to the drug. There are, though, two possible refutations to this argument.

One refutation is that the pharmaceutical industry relies on the willingness of the United States to pay top dollar for pharmaceutical drugs to maintain funding for research and development of new drugs. The inference is that as the industry develops more market-ready drugs for particular conditions, the cost of drugs for those conditions will drop as a matter of competition, thereby helping to increase rather than prohibit affordable access to drug treatment. Moreover, as Burroughs Wellcome claimed regarding the initial market price of AZT, a drug's price partly aims to recover the company's investment costs before generic versions of that drug cut into the market share. Regarding this latter point, even if the costs of an essential drug initially prevent some persons from having access to it, presumably cheaper versions of that drug will soon be available, thereby ultimately increasing access to needed drug treatment.

A second possible refutation is that because the United States allows pharmaceutical companies to operate under its free market system, drug prices are set via market mechanisms. As a result, the price of pharmaceutical drugs in the United States

should account for the demand for those drugs. This idea reflects the other reason given for the cost of AZT. In addition to their concern about generic versions of AZT cutting into their profits, Burroughs Wellcome was also concerned that new AIDS and HIV drug research would soon make AZT obsolete, cutting demand for the drug. Further justifying this point is the fact that the price of AZT has dropped since it was first introduced to the market. Data from the World Bank shows that less than decade after AZT was introduced to the market, the yearly cost of AZT fell to $2,738 (approximately $288 per month).[218] So drug pricing in the United States should never actually prevent access to needed drugs as their prices are partly determined by demand, and should reflect what patients are willing to pay for those drugs. Still, while these two refutations seem to debunk the notion that pharmaceutical drug pricing in the United States sometimes violates the principle of increased access to essential health care goods and services, there are several reasons why we ought to reject them.

First, as we have already seen, there is no necessary connection between the industry's profitability and the funding for research and development of new drugs. So it is possible that decreasing costs for needed drugs as a means of increasing access to them for those who cannot afford their costs could result in lost profits, but not necessarily resulting in cuts to funding for future research and development.

Second, the concern that companies must set drug prices to help them recover their investment costs before other "me-too" drugs cut into the market share is unsubstantiated. This is for two reasons. First, as I already noted from Delaney, there is

[218] Floyd, and Gilks, "Costs and Financing Aspects of Providing Anti-Retroviral Therapy: A Background Paper," Table 1.

no clearly agreed to way for determining a company's actual investment costs for introducing a new drug to the market. Second, there is no way to determine the actual effect of "me-too" drugs on the market. For example, in the three and half years from March, 1987 – when the FDA first approved AZT for market sale – until December 1990, there were only two other anti-HIV drugs approved by the FDA: Dideoxyinosine and Retrovir. Dideoxyinosine is a milder form of AZT and is for patients who cannot tolerate the latter, while Retrovir is a syrup form of AZT. Both were approved on the same day, September 28th, 1989, and were developed by Burroughs Wellcome. So not only was Burroughs Wellcome wrong about the "me-too" drug effect on their profits from AZT, through the production of Dideoxyinosine and Retrovir they were able to increase their market share of anti-HIV drug treatments.[219]

Third, as we see with both the current patent system and the government regulations banning drug re-sale, the United States protects the financial interests of pharmaceutical companies. This has two major effects on drug pricing in the United States. Again it allows pharmaceutical companies to earn exclusive profits on patented materials for a substantial period of time. Second, it slows the process of cheaper, generic drugs from being introduced to the market. Both points seemingly counter the idea that pharmaceutical companies must set higher drug prices to reflect potential market overcrowding.

Fourth, setting and adjusting drug prices according to market mechanisms can be inappropriate for patients needing drug treatment. This is for two reasons. Again, this

[219] United States Department of Health and Human Services, and the United States Food and Drug Administration, "HIV/AIDS Historical Timeline 1981-1990."

practice inaccurately assumes that pharmaceutical drugs can be properly valued merely as commodities, while failing to account for the non-commodifiable value(s) drug treatment has in helping persons regain or sustain their health. Second, setting and adjusting pharmaceutical drug prices according to market mechanisms can be too slow for patients needing those drugs. This is because the process requires gathering market data and analyzing the correlations between prices, demand, and profits. So even if a drug's price affects demand for that drug, adjusting the price accordingly will only occur after a pharmaceutical company knows the effect this has on its profits. The problem is that this can be a timely process that does account for patients who may initially be denied access to a drug treatment because of its cost.

4. **Conclusion and Suggestions for Reforming the Pharmaceutical Industry in the United States**

Throughout this chapter I have shown many ways that the pharmaceutical industry in the United States violates what I argue are the base ethical limits of health care markets. From these arguments, it appears that in order to ethically treat pharmaceutical drugs as commodities, the pharmaceutical industry in the United States requires reform. I conclude this chapter by offering six suggestions that the pharmaceutical industry should adopt to help resolve the ways it violates these limits regarding its interactions with physicians, its use of DTCA, and drug pricing.

Suggesting reforms that the pharmaceutical industry ought to adopt is not the only means to help the industry comply with these ethical limits of health care markets. Arguing for government enforced regulatory reforms is also a fairly common strategy for those who criticize the current *status quo* of the pharmaceutical industry in the United

States. The primary reason I employ the former over the latter strategy is because I wish to place the onus of responsibility and accountability on the pharmaceutical industry for its own actions in violating these ethical limits of health care markets.

- *Suggestion #1*: Ban all industry-sponsored gift giving and financial support to health care professionals and medical institutions.

Effective as of January 1st, 2009, PhRMA's updated *Code on Interactions with Health Care Professionals* is a semi-detailed guide that attempts to address the frequent criticisms directed at the industry's interactions with physicians. It appears to be a step in the right direction by banning what PhRMA sees as either extravagant or non-essential forms of compensation to all health care professionals or medical institutions. Still, the *Code* permits pharmaceutical companies to provide physicians and medical students with gifts that they consider educational for either patients or health care professionals, such as medical textbooks or subscriptions to scientific journals.[220] The *Code* also allows pharmaceutical companies to help fund educational events so long as they do not direct how those funds are used and do not promote the events for their own financial gain.[221]

However even this level of industry-sponsored gift giving and financial support for health care professionals and medical institutions can be ethically problematic. This is because any gift or financial support from a pharmaceutical company, regardless of whether or not the industry considers it modest or fair, still leaves open the possibility that health care professionals or medical institutions, via the rule for reciprocation, may feel obliged to speak or act favorably on behalf of that company in ways that do not serve

[220] Pharmaceutical Research and Manufacturers of America, *Code on Interactions with Health Care Professionals*, 19.
[221] Ibid., 28.

the best interests of patients. A total ban on industry-sponsored gift giving or financial support to physicians or medical institutions may therefore be necessary to avoid the potential ways this can violate the principles of honesty and respect for autonomy.

- *Suggestion #2*: Ensure the promotion of all industry-sponsored research complies with professional standards.

The main problem with industry-sponsored research comes from the intentional bias that is often present in the promotion of that research. Paying physicians to publish articles or textbooks that advertise or unfairly favor particular drugs over others, suppressing contradictory research data, or disguising the source of funding for a research program are all ways that industry-sponsored research violates the principles of honesty and respect for autonomy. To avoid this, pharmaceutical companies ought to comply with professional standards for promoting research. For example: authors should not be paid simply to attach their names to ghostwritten articles, all research data that can affect a health care professional's understanding of the effectiveness and side-effects of a drug ought to be completely and clearly presented, and all published research ought to fully and clearly disclose the primary sources of financial funding for a research program.

- *Suggestion #3*: Discontinue employing pharmaceutical representatives to provide drug presentations.

Whether or not we should consider pharmaceutical representatives "educators" or public relation officers, they can unduly influence a physician's prescribing practices in ways that violate the principles of honesty and respect for autonomy. Yet the industry maintains that pharmaceutical representatives help inform health care professionals about new pharmaceutical products. However it is possible to educate and promote new

pharmaceutical products to health care professionals without using pharmaceutical representatives. A pharmaceutical company could, for example, create and send a promotional video and supplemental information sheet to medical offices and hospitals that health care professionals could watch during their lunch breaks. This would result in at least two foreseeable benefits. First, physicians could still avoid having to spend time researching new pharmaceutical products while still getting the same type of information they could get from a pharmaceutical representative. Second, a promotional video would presumably be checked for accuracy prior to mass distribution, and so could help minimize possibly communicating any inaccurate or false information.

There is at least one problem with this suggestion. The industry uses pharmaceutical representatives because they are successful at helping increase pharmaceutical sales. Using some other means, like videos, to educate health care professionals may not be as successful. So discontinuing the use of pharmaceutical representatives could decrease pharmaceutical sales, while potentially driving up the cost of pharmaceutical drugs. However, there really is no way to know for certain how pharmaceutical sales would be affected by discontinuing the use of pharmaceutical representatives. For example, we know that physicians often feel inclined to write prescriptions for drugs that patients' request while believing the prescription is unnecessary. So it is possible that, because of consumer demand, pharmaceutical sales would not diminish at all. Yet even if pharmaceutical sales were to diminish as a result of discontinuing the use of pharmaceutical representatives, this would not necessarily drive up the costs of pharmaceutical drugs. A decline in pharmaceutical sales would result in

lost profits. But, as we have seen, the concern over lost profits does not by itself justify increasing drug costs.

- *Suggestion #4*: Require all DTCA to provide sources of objective information about the advertised diseases or conditions, the risks and benefits of the advertised drugs, proven alternate therapies to advertised diseases or conditions, *while refraining from directing individuals seek this information from health care professionals*.

Effective as of March 2nd, 2009, the updated *PhRMA Guiding Principles: Direct to Consumer Advertisements About Prescription Medicines* outlines the information pharmaceutical companies ought to include in DTCA.[222] The *Guiding Principles* maintain the industry's stance that DTCA aids public health by providing accurate and balanced information about diseases and different therapeutic options.[223] Furthermore, the *Guiding Principles* urge pharmaceutical companies to work with the FDA, health care professionals, and patients to obtain feedback about the content of a DTCA and, when changes need to be made to a specific piece of DTCA, either alter or discontinue it. Assuming pharmaceutical companies follow these recommendations, it seems likely that DTCA could avoid some of the problems that cause it to be unethically deceitful, while helping patients and health care professionals make better informed, and thus more autonomous, treatment decisions.

However, despite the information the *Guiding Principles* state DTCA ought to include, they actually exacerbate one of the more serious ethical problems with DTCA. A common theme in all pharmaceutical DTCA – and one that is encouraged in the *Guiding Principles* – is that individuals wanting information about the advertised drug should

[222] Pharmaceutical Research and Manufacturers of America, *PhRMA Guiding Principles: Direct to Consumer Advertisements About Prescription Medicines*. See Appendix 2.
[223] Ibid., 3-4.

consult with health care professionals (namely physicians). Yet, as we have seen, when individuals seek information about advertised drugs from physicians, this can increase medical paternalism, thereby weakening patient autonomy in ways that can violate the principle of respect for autonomy.

One may counter that in addition to health care professionals, the *Guiding Principles* also encourage DTCA to include the website and toll-free phone number for the FDA's MedWatch, *and* for DTCA to direct individuals to print advertisements and websites where they can find additional risk-benefit information about the specific drug in question. The problem with FDA's MedWatch is that it is only for obtaining safety information and medical reporting of safety concerns. It does not provide individuals with detailed information about pharmaceutical drugs.

Directing individuals to print advertisements and drug websites are also problematic. Print advertisements are often placed in specialized magazines that require subscriptions and whose audience tends to be affluent (e.g., *Golf Digest*). So directing individuals to print advertisements limits who will see that information to those who pharmaceutical companies believe will likely purchase the advertised drug. Drug websites are typically created by the drug manufacturer and so frequently conceal factual claims amid biased marketing messages. Moreover, both print advertisements and drug websites will claim that persons wanting more information should consult with health care professionals.

Those who want an advertised drug as a result of DTCA will still have to consult a physician prior to getting a prescription for it. Physicians, having a professional

obligation to act in patients' best interests, should help determine the appropriateness of patient requests for advertised drugs. So the purpose of this suggestion is not to remove health care professionals from being a source of information for patients who request advertised drugs. Instead the purpose of this suggestion to prevent health care professionals from being the one's who are primarily responsible for providing drug information to patients, and place that responsibility directly on drug manufactures.

- *Suggestion 5:* Create an agreed upon, empirically based industry standard for determining drug prices that is easily open to public scrutiny.

Pharmaceutical companies operating in the United States should retain some right to price drugs in accord with free market principles. However, as we have seen, the argument that drug prices must reflect the costs of development is deceiving because there is no way to account for all such costs. Creating an agreed to industry standard for determining drug prices that is empirically based and open to public scrutiny would remove questions about how drug prices are set with respect to the development costs for those drugs, while still allowing pharmaceutical companies to price drugs according to what patients are willing to pay.

- *Suggestion 6:* Assume responsibility for when free market pricing limits or prevents access to needed drug treatment, and work toward developing industry-orientated solutions for increasing access to needed drug treatment.

Using the market to set drug prices can limit or prevent patients from accessing needed drug treatment in ways that violate the principles of respect for autonomy and increased access to essential health care goods and services. However, because the industry believes that drug prices are justified to recoup drug development costs and help

fund new drugs, the industry-wide attitude is that improving access to drug treatment requires improving access to affordable health care coverage, and not to lower the cost of pharmaceutical drugs *per se*. PhRMA, for example, has issued a platform urging health care coverage for all United States citizens through private insurers.[224] PhRMA has also founded the Partnership for Prescription Assistance – a cooperative between PhRMA, health care providers, and patient advocacy and community organizations that helps low-income patients search for public and private programs to subsidize some or all of their drug treatment costs.

Not many people will deny that trying to improve access to affordable health care coverage is a good thing. Still it is frustrating that the industry presses for affordable health care coverage as the solution to some patients being prohibited from access to needed drug treatment because of its cost. This is for two reasons. First, the industry's drug pricing policies is a primary reason why some patients in the United States lack affordable access to needed drug treatment. Second, this solution shifts the focus of responsibility for providing affordable access to drug treatment from the pharmaceutical industry to patients and policy-makers. What this suggestion implies, therefore, is that because the industry is the primary party responsible for producing and pricing pharmaceutical drugs, it ought to adjust its own pricing policies to ensure that all persons can have appropriate access to needed drug treatment.

Next I apply my argument to a hypothetical legal organ market in the United States. Since the United States currently does not have a legal organ market, this analysis faces the challenge of being without the kind of empirical data I examined in this chapter.

[224] Pharmaceutical Research and Manufacturers of America, *For A Healthy America*.

Chapter Five: Is An Ethical Organ Market Possible?

In this chapter I apply my argument for ethically treating health care goods and services as commodities to a hypothetical legal organ market in the United States. There are two primary reasons why I address this market. First, as I discuss in "Overcoming the Organ Shortage," organ donation has been consistently failing to meet the demand for transplant organs in the United States.[225] This continues to be the case. Recent data from the Organ Procurement and Transplantation Network (OPTN) shows that the current number of people in the United States on organ transplant waiting lists is approximately 105,000, while the total number of transplants performed from January to November 2009 is 26,082; 20,139 from deceased donors, 5,943 from living donors.[226] Furthermore, from 1995-2009, 97,235 persons died while waiting for transplant organs (6,344 in 2009).[227] A legal organ market would theoretically assuage this problem by providing those needing transplant organs with an additional means to procure them.

Second, the practice of organ selling is morally controversial and is illegal in the United States.[228] On one hand, some, like James Taylor, argue that respect for personal

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[225] Harter, "Overcoming the Organ Shortage," 155-156.

[226] OPTN Transplants by Donor Type Database, http://www.optn.transplants.hrsa.gov/lastestData/ (accessed February 15, 2010). The reason I estimate the current number of people on transplant waiting lists is because OPTN constantly updates their transplant data information.

[227] OPTN Waitlist Removals: Removal Year by Removal Reason Database, http://optn.transplant.hrsa.gov/latestData/rptData.asp (accessed February 15, 2010). It is perhaps also important to note that this particular statistic only includes those who were medically suitable and well enough to receive an organ transplant, *and* who had not refused to receive an organ transplant. Although OPTN does not record the cause of death for these persons, it is implied that these persons died as a result of not receiving a transplant organ.

[228] Specifically, Title III, section 301(a), of the National Organ Transplant Act of 1984 prohibits acts affecting interstate commerce involving the acquisition or transfer of human organs for "valuable consideration" for transplantation, and is punishable by up to 5 years in prison and a $50,000 fine. Title III, section 301(a) further claims that "interstate commerce" has the same meaning as in section 201(b) of the Federal Food, Drug and Cosmetic Act, in which "interstate commerce" is commerce that occurs between any state or territory. Using the term "interstate commerce" in this context is interesting for

autonomy and concern for human well-being support the view that organ selling is moral and should be legal.[229] On the other hand there appears to be, as Cherry notes, a global consensus regarding public policies that transplant organs should be treated as gifts, not commodities, *and* that they ought to be viewed as public-interest resources, not as goods for private profit or gain.[230]

My aim in this chapter is to analyze five practical concerns that would likely accompany the establishment of a legal organ market to see the extent to which this kind of market may violate what I argue should be the base ethical limits of health care markets. However, as I previously noted, I do not intend to argue about the morality of a hypothetical legal organ market. This is because we can still imagine a legal organ market existing even if it is immoral – much in the same way that there continues to be a substantial market in pornography despite a variety of arguments for why it is immoral. Moreover, my arguments in this chapter only focus on a legal organ market in which "would-be sellers" are living persons, and in which the organs removed could be taken without killing the seller. My reason for this is so that I can narrow the arguments in this chapter to would-be sellers who are the decision makers regarding their willingness to sell an organ, and who are the primary beneficiaries of the sale, without having to also consider the role of surrogates or alternative beneficiaries (such as family members). The

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two reasons. First, the wording implies that the intent of prohibiting organ sales is to prevent the creation of large-scale organ markets. Second, organ sales that do not affect interstate commerce are presumably permitted. However as Taylor notes regarding this second point, "interstate commerce" has, "very broad construal after the United States Supreme Court ruling in the 1942 case *Wickard v. Filburn* (317 U.S. 111, 63 S. Ct. 82) that a farmer growing wheat on his own land for use by his own family was affecting interstate commerce" (Taylor, *States and Kidneys*, 26, n.45).

See; United States Congress, *National Organ Transplant Act*, 98th Congress, 1st session, October 19, 1984 42 USC 274e, http://history.nih.gov/research/downloads/PL98-507.pdf (accessed October 24, 2009).

[229] Taylor, *Stakes and Kidneys*, 201.

[230] Cherry, *Kidney for Sale by Owner*, 4.

five concerns I analyze in this chapter are: 1) that would-be sellers may lie about their health status to avoid jeopardizing an organ sale, 2) that a legal organ market would pose a health-risk to sellers, 3) that economically desperate sellers are only willing to sell their organs *because of* their economic desperation, 4) that economically desperate sellers may not receive a fair price for their organs, and 5) that a legal organ market would decrease organ donation rates. I conclude that while the occurrence of these concerns would make a legal organ market unethical, it is questionable whether or not the United States should continue to ban organ sales.

I now turn to analyze each of these concerns to assess the ethics of a legal organ market in the United States.

1. **Lying to Secure an Organ Sale**

One concern of a legal organ market is that the promise of profit could tempt some would-be sellers whose organs are of questionable health, to lie about their health status to avoid jeopardizing the sale. This concern is based on a point by Titmuss in *The Gift Relationship*, in which he argues that voluntary donation is superior to markets for procuring transfusable blood.[231] As Titmuss notes, tainted or diseased transfusable blood can be lethal to the recipient and so requires those giving blood to provide truthful health and social histories. He further argues that markets for procuring transfusable blood have much higher rates than voluntary donation systems of persons with potentially tainted or

[231] Although Titmuss focuses his arguments on the transfusable blood, he clearly sees a link between the commodification of transfusable blood and the commodification of transplant organs. According to Titmuss, "If blood [as a living tissue] is considered in theory, in law and is treated in practice as a trading commodity, then ultimately human hearts, kidneys, eyes, and other organs of the body may also come to be treated as commodities to be bought and sold in the marketplace." See; Titmuss, *The Gift Relationship*, 219.

diseased blood attempting to deceptively mask their poor health. Titmuss concludes that markets in transfusable blood are less desirable than voluntary blood donation because the former fails to maximize the conditions that encourage persons to be honest about their health and social histories.[232]

Tainted or diseased transplant organs can severely damage the health of the recipient. It is also possible that tainted or diseased transplant organs may go undetected by those who assess the quality of the organ(s) or those who perform the transplant operation(s). For example, a recent article in *The Journal of the American Medical Association* detailed how Viral Encephalitis – a disease causing inflammation of the brain – was transmitted from a single, deceased donor to four transplant patients, eventually causing their deaths. The diseased organs were the result of the donor being bitten by a rabid bat (which was later determined to have caused the donor's death, but was initially misdiagnosed).[233] What this shows is that despite the apparent health of transplant organs, tainted or diseased organs can go undetected, and so it is crucial to the health of would-be organ buyers that would-be sellers be as honest as possible about their health.

Another aspect of this concern – one that I discuss in more detail later in the chapter – is the presumption that individuals willing to sell their organs are likely to be economically impoverished. Within the United States, empirical data demonstrates a correlation between one's economic status and one's health. According to a recent report by the United States Department of Health and Human Services, in conjunction with the Centers for Disease Control and Prevention *and* the National Center for Health Statistics,

[232] Titmuss, *The Gift Relationship*, 200-214.
[233] Burton, et. al., "Viral Encephalitis Transmitted From Donor to Organ Recipient."

those who are economically impoverished suffer worse physical health compared to those who are not economically impoverished.[234] For example, those who live in poverty are more limited in their physical activity as a result of chronic health conditions, and less often engage in leisurely physical activity (the latter being a factor typically considered to promote good physical health).[235] Those who live in poverty also suffer from hypertension and elevated blood levels more often than those who do not live in poverty.[236] Young children between the ages of 19-35 months who live in impoverished homes are also not vaccinated from standard diseases as often as young children who do not live in impoverished homes, making the former more susceptible to conditions that can negatively impact their health as they age.[237]

A. *How Might lying to secure an Organ Sale Violate the Ethical Limits of Health Care Markets?*

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[234] As noted in the report, "poverty" is not an absolute term. "Poverty" refers to household income thresholds that are annually updated by the United States Census Bureau to reflect the current Consumer Price Index for urban consumers, in relation to the size and composition of the household. "For example, the average poverty threshold for a family of four was $20,614 in 2006, $17,603 in 2000, and $13,359 in 1990." See; United States Department of Health and Human Services, Centers for Disease Control and Prevention, and the National Center for Health Statistics, *Health, United States, 2008*, 562-563. Quote on 562.

[235] United States Department of Health and Human Services, Centers for Disease Control and Prevention, and the National Center for Health Statistics, "Table 58: Limitation of activity caused by chronic conditions, by selected characteristics: United States, selected years 1997-2006;" and United States Department of Health and Human Services, Centers for Disease Control and Prevention, and the National Center for Health Statistics, "Table 74: Leisure-time physical activity among adults 18 years of age and over, by selected characteristics: United States, 1998, 2005, and 2006."

[236] United States Department of Health and Human Services, Centers for Disease Control and Prevention, and the National Center for Health Statistics, "Table 71: Hypertension and elevated blood pressure among persons 20 years of age and over by selected characteristics: United States, 1988-1994, 1999-2002, and 2003-2006;" and United States Department of Health and Human Services, Centers for Disease Control and Prevention, and the National Center for Health Statistics, "Table 72: Serum total cholesterol levels among persons 20 years of age and over, by sex, race, and Hispanic origin, and poverty level: United States, selected years 1960-1962 through 2003-2006."

[237] United States Department of Health and Human Services, Centers for Disease Control and Prevention, and the National Center for Health Statistics, "Table 85: Vaccination coverage among children 19-35 months of age for selected diseases, by race, Hispanic origin, poverty level, and location of residence in metropolitan statistical area (MSA): United States, selected years 1995-2006."

There are two ways in which would-be organ sellers lying about their health status to secure an organ sale could result in a legal organ market violating what I argue should be the base ethical limits of health care markets. First, lying to secure an organ sale may violate the principle of respect for autonomy, particularly toward would-be organ buyers. This is because the ability of would-be organ buyers to autonomously choose whether or not to engage in an organ sale would partly depend on the extent, and their understanding, of the information they have about the health of the organ(s) they receive. So, if we assume that would-be organ buyers had to solely rely on the truthfulness of would-be sellers who lie about their health status, would-be buyers would therefore be prevented from having access to information that would have a foreseeable impact on their choice to continue with the sale.

Second, lying to secure an organ sale may also violate the principle of honesty. There are two ways in which this violation might occur based on my argument for why the principle of honesty should be considered an ethical limit of health care markets. First, would-be organ sellers who lie about their health status to secure an organ sale pass along false information that could result in would-be buyers making decisions about the organ sale, and subsequent transplant operation, that either fail to be in their best interest (presuming they are trying to procure the best quality organ possible), or could potentially increase the risk of harm to them in ways they did not initially understand or agree to. Presumably, because the health of would-be buyers relies on the information they get from would-be sellers, they have a right to expect would-be sellers provide honest disclosures about their health status.

Another way that would-be organ sellers lying to secure an organ sale could violate the principle of honesty is by having a foreseeable negative impact on the functionality of the organ market. As I argue in chapter 3, honesty is a necessary component for markets to function efficaciously and efficiently. When organ sellers try to lie about their health status, the organ market, which is already considered to be morally contentious, becomes more susceptible to a tarnished reputation for involving dishonesty and deception. This idea, coupled with the health risks to persons who receive unhealthy transplant organs, could ultimately cause potential would-be buyers to forgo using an organ market as a means to procure transplant organs.

Whether or not would-be organ sellers lying about their health status to secure an organ sale would violate the principle of increased access to essential health care goods and services depends on both the effect lying about one's health status may have on market demand for transplant organs, and the market response to a potential change in demand. If, on one hand, lying to secure an organ sale resulted in fewer persons willing to purchase transplant organs, and the market failed to respond, thereby ultimately decreasing the profitability of the market, then lying to secure an organ sale could be thought of as violating the principle of increased access, since this would presumably decrease access rather than be a viable means of helping increase access to transplant organs. On the other hand, if the market were to avoid any potential loss in demand resulting from would-be sellers lying about their health status due to a drop in the cost of transplant organs (which may also have the effect of helping to increase demand), then, so long as the market were able to maintain profitability, lying to secure an organ sale

would not violate this principle, since the market would still be effectively functioning to increase access to transplant organs.

Despite these potential ways in which would-be sellers lying about their health status to secure an organ sale could violate the principles I have argued for, I am skeptical about the degree to which this would be a concern of legal organ markets. This concern seems more applicable to *black markets* in transplant organs, in which there are no laws or regulations to either help ensure the quality of transplant organs or to prevent lying about one's health from becoming a pervasive problem. Yet the essence of a *legal* organ market is the idea that the market would be regulated to try to prevent concerns such as lying to secure an organ sale from becoming a pervasive problem, and to prevent would-be buyers from purchasing unhealthy transplant organs. This is not to say that lying to secure an organ sale would never occur within a legal organ market. However, as I discussed in chapter 3, even though lying occurs in regulated markets, the overall culture of markets – at least those within the United States – remain committed to the view that lying is generally unethical and ought to be repudiated.

2. **A Legal Organ Market Poses a Health-risk to Would-be Organ Sellers**

Another concern of a legal organ market is that it would pose a health-risk to organ sellers. This concern primarily stems from the debate over whether or not kidney sales constitute an immoral form of dangerous employment. In *Stakes and Kidneys*, Taylor, who argues for the moral permissibility of regulated markets in human organs, extensively addresses both the anti-market and pro-market sides of this debate. On one hand, some argue that kidney sales exhibit unique characteristics that make them morally

distinct (and thus immoral) from other kinds of (morally permissible) dangerous employment, like firefighting or military service. On the other hand, some argue that kidney sales are not morally distinct from other kinds of dangerous employment, and that a commitment to respect for autonomy justifies allowing persons to sell their kidneys in a *regulated* kidney market (some take this view even farther by arguing that a commitment to respect for autonomy also justifies *un*regulated kidney sales). Since I do not aim to discuss the morality of a legal organ market, further elaborating on the particular points of this debate is unnecessary. It is important to note, though, that Taylor does not attempt to defend regulated kidney sales by trying to refute claims that they are dangerous to the health would-be sellers. Instead, Taylor tries to show how kidney sales are of comparable danger to other kinds of morally permissible dangerous employment.[238]

Presuming a legal organ market would be regulated to try to minimize known health-risks to both sellers *and* buyers, a legal organ market would pose a similar level of health-risk to sellers as organ donation does to living donors. Particularly with respect to kidneys, there does not appear to be any correlating long-term health risks for persons with one functioning kidney compared to persons with two functioning kidneys. For example, Taylor argues that there is no difference in long-term mortality rates as a result of having one functioning kidney as opposed to having two functioning kidneys.[239] Moreover, while kidney functioning typically declines with age, this age-related decline is consistent between persons with one functioning kidney and those with two functioning kidneys (although a small population of kidney donors (56 of more than

[238] Taylor, "Kidney Sales and Dangerous Employment," in *Stakes and Kidneys*, 117-143.
[239] Ibid., 126.

50,000) ultimately require transplants themselves).[240] However, there are several short-term health risks to living organ donors of all types. These include: a morality rate of approximately .03 percent (similar to most operations involving general anesthesia); bleeding during or after the operation; and potential for post-operative infection.[241] Although these potential health-risks of organ transplantation are similar to the risks that accompany other kinds of medical operations, my concern is not a question of the degree of severity these risk pose for would-be organ sellers, but what the existence of these kinds of health-risks may mean for a legal organ market to operate with respect to what I argue should be the base ethical limits of health care markets.

A. *Would the Health-risks to Would-be Organ Sellers Violate the Ethical Limits of Health Care Markets?*

Whether or not the health-risks to would-be organ sellers would violate the principles I have argued for depends on the information given to would-be sellers about those risks, and how well they understand that information. There are two cases I consider here: a) would-be organ sellers who are not given information about the known health-risks of organ transplantation, and b) would-be organ sellers who are informed of the known health-risks of organ transplantation but are not provided the means to help them understand this information.[242]

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[240] Ingelfinger, "Risks and Benefits to the Living Donor," 448.

[241] Ibid. Taylor further shows how the .03 mortality rate associated with organ donation is actually *less than* other kinds of morally permissible dangerous employment such as: being a commercial fisherman or merchant seaman (.103 and .05 respectively), *or* scaffolding, steel erecting, and roofing (.02, .04, and .02 respectively) (The latter category, Taylor claims, is work that is considered undesirable, and so in that respect is analogous to selling one's kidney). See; Taylor, *Stakes and Kidneys*, 126-127.

[242] There is a potential third case we may need to consider in future analysis of this topic: would-be organ sellers who are informed about and understand the health-risks of organ transplantation. In this case, because would-be sellers are informed of and understand the health-risks of organ transplantation, there is no apparent violation of what I argue are the base ethical limits of health care markets. What is

a. Failure to Inform Would-be Sellers of Known Health-risks of Organ Transplantation

If would-be sellers within a legal organ market were not informed of the known risks associated with organ transplantation, then the market would violate both the principles of honesty and respect for autonomy. Failure to inform would-be sellers of the known health-risks associated with organ transplantation would violate the principle of honesty for two reasons. First, failure to provide information to those undergoing a medical operation about the known risks of that operation deprives them of information they have a legitimate right to know as the individuals being operated on by those whom they have entrusted to perform the operation. Second, from how I argue for honesty as an ethical limit of health care markets, the failure to provide would-be sellers information about the health-risks associated with organ transplantation may also violate the principle of honesty because of the potential harm that could befall would-sellers if those risks were to occur. This is because even though they are the seller of a health care good, they are also patients during the operation who entrust those performing the operation with their well being.

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unique about this case, and why I say it is one that we may need to consider further, is that *not* having a legal organ market seemingly violates the principle of respect for autonomy because would-be sellers who know of and understand the risks of organ transplantation would therefore paternalistically be prevented from selling their organs. The reason I do not fully discuss this case here is because it is still unclear to me whether or not the absence of a legal organ market that has provisions to inform and help persons understand the health-risks of organ transplantation *would* violate the principle of respect for autonomy. Simply having and understanding the health-risks of organ transplantation does not by itself guarantee persons who sell their organs are therefore acting autonomously. For example, I may fully understand the risks of organ transplantation, but am otherwise coerced to sell my organs. In such a case, my understanding of the health-risks of organ transplantation is not sufficient to claim I am thusly acting autonomously because I am selling my organs against my will. However, if would-be sellers are un-coerced, informed of the health-risks of organ transplantation, and have the means available to help them understand that information, yet are still prevented from being allowed to sell their organs via a legal organ market, then the absence of a legal organ market would likely constitute a violation of respect for autonomy.

Failing to provide would-be sellers information about the known health-risks of organ transplantation would also violate the principle of respect for autonomy. In chapter 3 I argue how respect for autonomy requires persons to have appropriate access and understanding of information regarding the purchase of health care goods and services. Although I discuss this limit with respect to the *purchase* and not the *sale* of health care goods or services because, in the case of a legal organ market, sellers are also undergoing a medical procedure (and are thus also under the care of those performing the transplant), it is appropriate to include would-be sellers under the scope of this limit. If would-be organ sellers are not given information about the health-risks associated with organ transplantation, then the sale does not accord with the principle of respect for autonomy because would-be organ sellers would be missing information that could significantly impact their willingness to continue with the organ sale.

It is also possible that failing to inform would-be sellers about the known health-risks associated with organ transplantation could violate the principles of increased access to essential health care goods and services. This would be the case if, as a result of consistently failing to inform would-be sellers about the known health-risks of organ transplantation, fewer persons were willing to sell their organs, which then led to an overall decline in the numbers of organs being sold. However, if persons were to still willing to sell their organs despite not being fully informed about the health-risks of organ transplantation, and the market was able to meet the demand for transplant organs, then a legal organ market would not seem to violate this principle.

b. Informed but Lack Aid for Understanding

From how I argue that honesty is an ethical limit of health care markets, merely providing honest information to would-be organ sellers about the potential health-risks of organ transplantation is sufficient to meet this principle. This does not mean, though, that by informing would-be sellers of the risks of organ transplantation, a legal organ market therefore absolutely avoids violating the principle of honesty. It is certainly possible that, even though a legal organ market may be within the limit of honesty regarding the information provided to would-be sellers about the health-risks of organ transplantation, a legal organ market could still violate the limit of honesty because of some other feature present in the market such as not having provisions to help curb the potential for would-be sellers to lie about their health status, that ultimately would allow would-be buyers or sellers to deceive one another about information relevant to the sale of the transplant organ.

If, however, would-be organ sellers were informed of the known health-risks of organ transplantation but were not provided additional means to help them understand this information, a legal organ market would violate the principle of respect for autonomy. As I noted in chapter 3, one's ability to properly exercise his or her autonomy does not just depend the information one has about the choice-at-hand, but also on one's ability to understand and incorporate that information into one's decision-making process. A legal organ market that did not provide the means to help would-be organ sellers understand the health-risks of organ transplantation, or one that allowed persons to

sell their organs when they have not considered this information, would fail to actualize this necessary element for would-be sellers to act autonomously.

3. **Economic Desperation as the Motive for Selling an Organ**

A third concern about the creation of a legal organ market is that economically desperate sellers would only be willing to sell their organs *because of* their economic desperation. This concern stems from the moral debate over whether or not economic desperation coerces persons to sell their organs. It is typically agreed that coercion is immoral in most cases because of how it is considered to unfairly usurp one's autonomy. On one hand, those opposed to organ selling commonly argue that, all things considered, organ sellers who are economically desperate are willing to sell their organs *only because* they are trying to assuage the bad effects of their economic desperation, but otherwise *genuinely oppose* selling their organs. Often they conclude that because would-be organ sellers do not really want to sell their organs, economic desperation is therefore coercive as the primary motivator of the sale.[243] Taylor, on the hand, argues in *Stakes and Kidneys* that economic desperation cannot coerce individuals to sell their organs because it is not an intentionally acting agent capable of controlling the actions of others. He concludes that because economic desperation is not coercive, those who are motivated to sell their organs because of their economic desperation still act autonomously.[244]

Since my analysis is on a hypothetical organ market, there is no empirical data within the United States showing how far reaching this concern might be. Yet we can

[243] See for example; Cherry, *Kidney for Sale by Owner*, 5-6 and 92; DeJong, et. al., "Options for Increasing Organ Donation," 468; Duxbury, "Do Markets Degrade?," 345; Harter, *Overcoming the Organ Shortage*, 160; Taylor, *Stakes and Kidneys*, 33 and 51-52; and Titmuss, *The Gift Relationship*, 307-308.

[244] Taylor, *Stakes and Kidneys*, 58-61. Also see; Harter, "Overcoming the Organ Shortage," 161.

glimpse the probable socioeconomic breakdown of would-be organ sellers by examining statistical data from Iran. In 1988, Iran developed a government-funded, government–regulated, and government–compensated program for paying living unrelated organ donors (LUDs). A recent study of this program shows that of 500 randomly chosen LUDs, 84% were poor, 16% were middle class, and none were wealthy. According to the study, those who could afford only average housing, food, and college training for their children were included in the "middle class." Those who could afford less or more than those things were respectively classified "poor" and "wealthy."[245] Although we do not know how these numbers might vary for a legal organ market in the United States, the overwhelming percentage of paid LUDs in Iran who are poor versus those who are middle class and wealthy gives us a reason to assume that the majority of organ sellers within the United States would also be economically poor.

A. *How Would Selling an Organ from Economic Desperation Violate the Ethical Limits of Health Care Markets?*

This concern is farther reaching than just a legal organ market. Since the basis of this concern is that economic desperation may force some persons to sell their organs, and not that a legal organ market would force them to sell, it applies to any type of organ sale. However, presuming the motive of economic desperation violates any of the ethical limits I argue for, a legal organ market would be culpable for cases in which persons motivated by their economic desperation were to sell an organ within that market.

[245] Ghods, Ossareh, and Khosravani, "Comparison of Some Socioeconomic Characteristics of Donors and Recipients in a Controlled Living Unrelated Donor Renal Transplant Program," 2626; and Ghods, and Savaj, "Iranian Model of Paid and Regulated Living-Unrelated Kidney Donation," 1140.

If economic desperation were the only reason why some persons may be willing to sell their organs in a legal organ market, this would violate the principle of respect for autonomy. Furthermore, presuming this concern is true, it would violate this principle even if Taylor is correct and we reject the view that economic desperation is coercive. This is because of how I argue in chapter 3 that the principle of respect for autonomy is violated when market participants are subjected to undue influence or constraint in the purchase or sale of health care goods or services. So if it is correct that economic desperation would motivate some persons to sell their organs while, at the same time, they genuinely oppose selling their organs, "economic desperation" can be considered to be an undue influence because of how it appears to manipulate the choice of would-be organ sellers in a way that they do not fully endorse.

Prima facie this concern shows that a legal organ market is unethical on my view. This is because even in a regulated organ market, there can be cases in which would-be organ sellers are strictly motivated by their economic desperation while otherwise being genuinely opposed to selling their organs. However, a legal organ market could successfully address this concern if were to implement a vetting procedure capable of consistently differentiating between would-be organ sellers who are strictly motivated by their economic desperation but who otherwise oppose selling their organs, and those who, regardless of their motive, are not genuinely opposed to selling their organs.

4. **Economically Desperate Sellers may not receive a Fair Price for their Organs**

A fourth concern of a legal organ market is that economically desperate sellers may fail to receive a fair price for their organs. Again, while we do not know how many

would-be sellers in the United States may be affected by this concern, we have reason to assume from statistics of the Iranian model of paid organ donation that most would-be sellers are likely to be economically poor. There are two primary bases of this concern. First is the idea that the economic desperation of organ sellers creates an underlying imbalance of power in the organ sale that disproportionately favors would-be buyers.[246] Second, as Cherry notes, economically desperate sellers may be willing to sell their organs for a relatively small amount of money because even a small amount of money would be relatively advantageous for them.[247]

A. *How Would Failing to Receive a Fair Price for One's Organs Violate the Ethical Limits of Health Care Markets*?

There are two ways in which economically desperate sellers failing to receive a fair price for their organs could violate what I argue should be the base ethical limits of health care markets. First, failing to receive a fair price for one's organs could violate the principle of honesty. This would happen if would-be organ sellers were *intentionally* kept from receiving a fair value for their organs by whoever was paying for them.[248] This is because violations of the principle of honest occur when participants in health care markets are permitted to engage in intentional deception or lying in ways not meant to serve patients' best interests. All would-be organ sellers, like would-be buyers, can rightly be thought of as patients during the process of the organ sale because, as I

[246] See for example; Cherry, *Kidney for Sale by Owner*, 88-89 and 90-95; Delmonico, et. al., "Ethical Incentives – Not Payment – For Organ Donation;" Mahoney, "The Market for Human Tissue," 212; and Morelli, "Commerce in Organs." Also see my discussion of Satz and noxious markets in chapter 1 (specifically, the section describing Satz second condition of noxious markets being that they create unequal and unaccountable power between market participants).

[247] Cherry, *Kidney for Sale by Owner*, 90.

[248] Presumably, because this would be a market relationship, the "payer" would be the organ buyer(s), regardless of the actual institutional make-up of the market.

mentioned earlier, they are also undergoing a medical procedure that places them under the care of those performing the transplant. By intentionally failing to provide would-be sellers a fair price for their organs, their interests are not only treated as secondary to those of the buyer(s), but the would-be sellers' interests are also not served to the same degree that they would be if were to receive a fair price for their organs. While this reasoning applies to all would-be organ sellers, this is a particularly crucial point for economically desperate sellers who are thought to be more vulnerable because of their economic desperation.

Second, failing to provide economically desperate sellers a fair price for their organs could violate the principle of respect for autonomy. There are two ways this would seemingly occur. First, a violation of the principle of respect for autonomy would occur if the market were to determine organ prices via negotiation. Economically desperate sellers, because of their economic desperation, would seemingly lack bargaining power in this negotiation process. Moreover, while it makes sense that organ buyers would not want to jeopardize the organ sale by offering too low a price for the organ they wish to purchase, a negotiation process provides would-be buyers the leeway to offer just enough money to secure an organ sale irrespective of whether or not this price is "fair." Specifically, a negotiation process over the price of organs would violate the principle of respect for autonomy for economically desperate sellers because of how their economic desperation and presumed lack of bargaining power could unfairly manipulate their decision-making process.

It is possible that a violation of the principle of respect for autonomy could also occur in a market in which organs prices are not negotiated. This would occur if would-be organ sellers did not have access to and were not provided information about what constitutes a "fair" price for their organs. In this case, the lack of information provided to would-be organ sellers would be a direct violation of the principle of respect for autonomy because of the foreseeable impact this would have on organ sellers, particularly those who are economically desperate, to make a well-informed decision about whether or not to continue with the organ sale.

However it is also important to recognize that a "fair" price for transplant organs is not necessarily the same thing as a price equal to the maximal commodified value of those organs. While it would be appropriate to provide would-be sellers a price for their organs that shows sensitivity to their economic needs and circumstances, it would be also be unfair if, conversely, the price of transplant organs was so high that would-be buyers relying on the market could not practically afford them. In this latter case, organ buyers would be exploited on the basis of their medical needs. Moreover, such exploitation in a legal organ market could result in a violation of the principle of increased access to essential health care goods and services if buyers relying on the organ market were unable to sufficiently meet their medical needs in some other way. What it would mean to determine a "fair" price for transplant organs, however, is beyond the scope of this project. Yet what constitutes a "fair" price for transplant organs will presumably minimize the potential exploitation of both sellers and buyers on the basis of economic desperation or medical need.

5. **A Legal Organ Market Would Decrease Organ Donation Rates**

The last concern I address in this chapter is that a legal organ market would decrease organ donation rates. Part of the value of organ donation is its cultural and social significance as one of the highest forms of individual altruistic expression. Often, organ donation is metaphorically described as a "gift of life" to organ recipients. This concern is primarily based on the moral argument against organ selling that, by placing a commodified value on organs, the purely altruistic motive to donate will be supplanted in some cases by a monetary motive, thereby limiting the number of opportunities individuals have to donate their organs, *and* causing some individuals who were willing to donate their organs to no longer be willing to donate.[249]

There is some justification for this concern. One study, cited by Taylor, examines how a small monetary incentive alters the willingness of individuals to donate blood. Blood donors were broken up into two groups: A) those who regularly donate blood, and B) those who occasionally donate blood. Both groups were then offered $10 to donate a pint of blood. The $10 incentive substantially decreased the donation rate of A while slightly increasing the donation rate of B. According to Taylor, this result, "seems to bear out the anti-market view that commercial incentives will crowd out altruistic motives."[250] In *The Gift Relationship*, Titmuss also provides a variety of statistical data from within the United States that, although now outdated, show when there are monetary incentives

[249] See for example; Abouna, Sabawi, Kumar, and Samhan, "The Negative Impact of Paid Organ Donation;" Cherry, *Kidney for Sale by Owner*, 4-7, 14, 76, and 99-102; Taylor, *Stakes and Kidneys*, 173; Titmuss, *The Gift Relationship*, 279-290 and 314.

[250] Taylor, *Stakes and Kidneys*, 174. Taylor also notes that it is fallacious to thusly conclude that even though payment for blood or kidneys appears to decrease altruistic donations the overall numbers of available blood or kidneys would also decrease.

the numbers paid blood donors far exceed the numbers of non-paid, altruistic blood donors.[251]

A. *How Might a Decrease in Organ Donation Rates Violate the Ethical Limits of Health Care Markets?*

For wealthy patients who would be willing use a legal organ market to buy transplant organs, this is not a very relevant concern. It is mostly applicable to patients who either could not, or who are morally opposed, to purchasing transplant organs. There are two ways, then, this concern could result in a legal organ market violating what I argue should be the base ethical limits of health care markets. First, this concern could result in a legal organ market violating the principle of increased access to essential health care goods and services. This would be the case if a legal organ market decreased donation rates, and persons who were either unable or morally opposed to purchasing transplant organs were consequently prevented from getting them via some form of voluntary donation. The reason why this case would result in a legal organ market violating this principle is because, again, this limit is violated when patients are prevented or denied access to needed health care goods or services.

Second, this same scenario for a legal organ market could also result in a violation of the principle of respect for autonomy. I argue that meeting the principle of respect for autonomy within health care markets requires treatment decisions neither be forced nor the result of undue influence or constraint. So by causing a decrease in donation rates, a legal organ market could reasonably be thought of as unduly constraining the abilities of some patients to best meet their medical needs if those patients were morally opposed to

[251] Titmuss, *The Gift Relationship*, 146-153.

purchasing transplant organs on the market and were also unable to procure a transplant organ via donation.

However, even if a legal organ market resulted in diminishing donation rates, we cannot conclude that it would thusly fail to meet organ demands. Conversely, it may be possible that even with diminishing donation rates, a legal organ market could sufficiently meet the demand for transplant organs. While there is no evidence to support the former claim, there is some to support the latter. One of the successes of the Iranian model of paid organ donation is that within 11 years, from 1988 to 1999, Iran was able to completely eliminate their national renal transplant waiting list.[252] Moreover, the study of the Iranian model shows that of 500 randomly chosen organ recipients, 50.4% were poor (using the same socioeconomic criteria as for LUDs).[253]

We must be careful, though, how we regard these results from the Iranian model. The Iranian model is a government-run and government-funded program that is not based on free market principles. However my argument about the ethical limits of health care markets has consistently regarded health care markets as well-regulated *free* markets. So there is still plenty of room to remain skeptical about whether or not a legal organ market in the United States could sufficiently address this concern about diminishing organ donation rates, especially since recent health care reform debates in the United States have shown how divided its citizens are regarding government involvement with health care. Yet, what we can still see from these results of the Iranian model is that it is possible to meet the demand for transplant organs even when organ recipients cannot

[252] Ghods, and Savaj, "Iranian Model of Paid and Regulated Living-Unrelated Kidney Donation," 1137.
[253] Ibid., 1140.

afford to pay for them and without the need for altruistic donation. A legal organ market in the United States could theoretically accomplish similar success if it were to employ various market tools such as coupons, government-funded vouchers, government-enforced price controls, addendums to current health insurance coverages, or special medical loans. Ultimately, though, if a legal organ market is to successfully address this concern while being within the limit of increased access, it will need to be regulated such that whatever supply an organ market could generate to meet organ demands, the distribution of those organs will need to be fair.

6. **Conclusion**

In this chapter I have analyzed five concerns with respect to my argument for the base ethical limits of health care markets to a hypothetical legal organ market in the United States. I have shown how each concern could or would violate one or more of those limits. Although it may be possible for a legal organ market to address each concern to prevent it from violating the limits I argue for, a legal organ market that allowed any one of these concerns to come to fruition would be unethical. It would be odd, for example, to claim that a legal organ market is ethical when measures have not been taken to either minimize the possibility of would-be sellers lying about their health status, or to minimize the potential health-risks to would-be sellers *and* buyers, or to try to prevent would-be sellers and buyers from being coerced or exploited, or to try to prevent a potential decrease in organ donation rates from limiting access to transplant organs for those in need.

At this point, though, the moral concerns about organ selling continue to block the

establishment of a legal organ market. Some, however, have chosen not to accept the illegality of organ selling as a deterrent to purchasing transplant organs. Recent news stories show that persons within the United States are engaging in publicly veiled organ sales.[254] Coupled with the current organ shortage in the United States, whether the willingness of some United States citizens to engage in unregulated organ sales justifies the partial decommodification of organs, as Radin and Satz would likely say it does, or whether this means we should continue to work within the paradigm of organ donation while remaining committed to a ban on organ sales is still a question for further debate.

[254] See for example; Associated Press, "Man says he sold kidney in U.S. for $20k;" and Associated Press, "44 arrested in N.J. corruption probe."

Conclusion

Throughout this dissertation, I have argued that we ought to impose ethical limits on health care markets. When applying the views of Anderson, Radin, and Satz to health care goods and services we see that, because of how health care goods and services can affect an individual's overall well being in ways that most other commodities do not, properly valuing health care goods and services requires a wider set of qualifications and considerations beyond their mere commodification. While it is improper to value health care goods and services merely as commodities, we also see, with particular respect to Satz, why banning the sale of health care goods and services might also be inappropriate, because of how bans on needed goods can lead to worse outcomes, like the creation of black markets in those goods. I then argued that in order to ethically treat health care goods and services as commodities, their sale should be limited according to the principles of honesty, respect for autonomy, and increased access to essential health care goods and services. I argued for these three limits because of how each appears to respect the noncommodified ways persons can value health care goods and services and because of the role each plays in ideal interactions between health care professionals and patients *and* market transactions between buyers and sellers. I then applied this argument to two health care markets: the pharmaceutical industry and a hypothetical legal organ market. For the former, I showed how many of the practices of the pharmaceutical industry violate what I argue should be the base ethical limits of health care markets. For the latter, I showed the extent to which a legal organ market in the United States could or would violate these limits.

There is, however, a further question about my view that I have yet to address. What might be an appropriate response when the sale of health care goods or services violates one or more of the limits for which I argue? The rest of this chapter briefly discusses three possible answers to this question, and lays the foundation for future research on this topic.

1. **Three Responses for Dealing with Violations to the Ethical Limits of Health Care Markets**

I have argued that when health care markets violate one of more of the limits for which I argue, they should be considered unethical. But it would be both foolish and inaccurate to think that all health care markets that violate one or more of these limits can or should be regarded in the same way. One possible response to when the sale of health care goods or services violates one or more of the limits for which I argue is that the goods or services in question should be decommodified – that is, removed from market sale. Anderson's view might justify this response because of how, when applied to health care goods and services, her view shows that the noncommodifiable value(s) of health care goods and services is undermined when the production of those goods and services is controlled by market norms. Yet it is doubtful that Anderson's view could be used to totally justify this response, because her view also justifies the continued use of health care markets based on the idea that persons must be free to commodify goods they either own or that are embodied in their persons. We have also seen how neither the views of Radin nor Satz would justify this response. Furthermore, based on the suggestions I discuss for how the pharmaceutical industry might reform itself to comply with the limits for which I argue, my view also implies that violations of these limits should not result in

market bans of those goods and services. Not only might Satz be correct that market bans on needed goods could lead to the creation of black markets in those goods, but market bans on the sale of health care goods and services in the United States would be impractical because of both the wide use of the free market in the production and distribution of health care goods and services, *and* the foreseeable likelihood that a large number of United States citizens would be opposed to removing health care goods and services from the free market (as is perhaps evident by the discursive reaction to the recent attempts by the United States government to reform the distribution of health care goods and services).

Another possible response to when the sale of health care goods and services would violate the limits for which I argue is to *partially* decommodify the health care goods or services in question. This is the suggestion Satz gives when markets in needed goods are noxious. Given how Radin argues that commodified goods that traditionally have not been commodified can be characterized in terms of incomplete commodification, she too may endorse this response (although Satz claims that Radin actually endorses removing health care goods and services from the market altogether, which I believe is an incorrect interpretation of Radin's view).[255]

Yet I am not sure about the degree to which partial decommodification is an appropriate response. As Satz employs the concept, "partial decommodification" involves regulating a good a means to provide minimum provisions of that good to all. If, however, we broaden the scope of the term "health care goods or services" from my original limit of things persons use to meet their health care needs, to include goods or

[255] Satz, "Noxoius Markets," 25; and chapter 1, note 62.

services that do not meet a medical need but are still considered to fall within the realm of health care, then the use of partial decommodification to deal with violations of the limits for which I argue would be too narrow. Consider, for example, the market in cosmetic plastic surgery. Cosmetic plastic surgery is a procedure provided by medically trained surgeons to patients who do not often times have an underlying medical need for it. If the cosmetic plastic surgery market were to violate any of the ethical limits of health care markets for which I argue (although, again, the principle of increased access to essential health care goods and services would not likely be applicable to this market, except for cases in which we are dealing with reconstructive plastic surgery as opposed to cosmetic plastic surgery), partial decommodification seems to be inappropriate in this case since it is unlikely the goal would be to ensure some minimal access of cosmetic plastic surgery to all.

These two responses are also seemingly inadequate for another reason. Assume, for example, that the pharmaceutical industry at-large were to reform itself so that it no longer pervasively violates the ethical limits for which I argue, but it was still the case either that a small number of pharmaceutical companies continued to consistently violate one or more of these limits, *or* that a pharmaceutical company might have (perhaps unintentionally) violated these limits on one or some occasions, but otherwise has complied with them. For pharmaceutical drugs, or other health care goods and services in which the market is subject to similar circumstances, decommodification or partial decommodification seems inefficient so long as the overall culture of the health care market does not violate the limits for which I argue. The problem with these two

responses is that both only work toward addressing how to deal with these violations at the macro-level of health care markets, but are not particularly helpful for addressing violations that occur at the micro-level of individual health care providers.

A third response for when the sale of health care goods or services would violate one or more of the limits for which I argue is to implement a system of warnings, fines, and sanctions against the entities culpable for the violation(s). There are three apparent advantages of this response, with the latter two showing how it is seemingly preferable to either total or partial decommodification of the health care goods or services in question. First, although it does not suggest any sort of decommodification of health care goods and services, this response recognizes and is sensitive to the idea that health care goods and services are not properly valued merely as commodities, and that in treating them as commodities the focus remains on ethically meeting patients' medical needs. Second, by allowing for the health care goods or services in question to continue being treated as commodities, this response helps avoid any possibly disruptions in their (efficient) production or distribution that might occur as a result of removing them, either totally or partially, from the free market. Third, the use of warnings, fines, and sanctions is more flexible than either total or partial decommodification in that they can be applied at both the macro-level of heath care markets and the micro-level of individual health care providers. For this response to work in practice, though, it would be necessary to ensure that whatever warnings, fines, and sanctions were implemented, that they be severe enough to sufficiently dissuade actions within health care markets that would clearly or intentionally violate what I argue should be the base ethical limits of health care markets.

2. **Possibilities for Future Research on this Topic**

There are several possibilities for future research on this topic stemming from the arguments I have made throughout this dissertation. First, from what I have said here in the conclusion, more work needs to be done regarding what the appropriate response(s) should be for when the sale of health care goods or services would violate the ethical limits of health care markets for which I argue. For example, while I argue that partial decommodification would be too narrow – applying only to health care markets in which goods or services are necessary to meet medical needs – this does not necessarily disqualify partial decommodification from being an appropriate response for health care markets in goods and services that *are* necessary for individuals to meet their medical needs. Also, there remain questions with respect to the third suggestion such as: what sort of warning, fines, or sanctions would produce the desired outcome of consistently getting the sale of health care goods and services to conform to the ethical limits for which I argue; and how would these warnings, fines, and sanctions be enforced – by some regulatory agency like Food and Drug Administration, by the industries responsible for producing the goods or services, or by some other means like a collaboration between regulatory agencies and associations such as the Food and Drug Administration, the American Medical Association, and the Securities Exchange Commission?

Second, stemming from the initial concern about the ends of health care being incommensurable with the ends of the market, there is a question about whether or not there are some health care goods or services that should never be for sale. Addressing this question appears to require at least two foci. One focus would need to address the idea

that there may be some health care goods or services that are valued to such a degree that it would impossible to ethically commodify them. In the previous chapter I abstained from arguing about the morality of organ selling. Still, the debate continues about whether or not organ commodification should be considered moral or legal. Another focus of this question may need to address current markets in health care goods or services that are legal but that are also ethically contentious. I noted in the last section how cosmetic plastic surgery falls within the realm of health care, but often does not medically benefit patients. The pharmaceutical industry is also criticized for sometimes producing and marketing drugs that have questionable medicinal value, such as drugs like Viagra for erectile dysfunction (a condition that does not necessarily impede a man's ability to live a healthy life). Here, instead of arguing that the good or service in question is too valuable to commodify, the concern is that the good or service in question should not be commodified because its application does not actually serve to meet a *bona fide* medical need.

In chapter 2 I argue that the principle of increased access to essential health care goods and services is based, in part, on a right to health care. Ethicists, like Daniels, who write extensively on questions concerning a right to health care, have tried to show why such a right exists, and what sorts of health care goods or services qualify as something that persons have a right to. However there still appears to be room within this large body of work to address nuanced questions regarding a right to health care and what constitutes "fair" or "equitable" access to health care goods or services. One such question is: what might be the appropriate ethical limit(s) of a right to health care? Addressing this

particular question will likely require categorizing health care goods and services according to things such as their cost(s) *and* the range and degree of medical necessity they serve. Then, once we have a clearer idea of the different kinds of ways to categorize health care goods and services, we can then begin to argue for specific limits to right to health care that help us discern which health care goods and services ought to be included under this right, and to what degree.

Also in chapter 2, I briefly mentioned how the principle of increased access could possibly apply to markets in needed goods other than health care. Whether or not this means that my view regarding the base ethical limits of health care markets has broader application than just health care is an open question. The ways that I have argued for honesty, respect for autonomy, and the principle of increased access to essential health care goods and services have focused exclusively on their application to health care markets. Another possible topic for future research, then, is trying to see if, how, and what changes to my arguments might be necessary to apply my view of the base ethical limits of health care markets to other kinds of markets in non-medical needed goods.

The last possibility for future research that I discuss here is the applicability of my view to the international production or delivery of health care goods and services. From the onset, I narrowed the scope of my research and arguments to the United States. But economic, cultural, and governmental differences make it unclear what sort of impact these arguments might, or could, have on an international scale. There are some places in which the principles of honesty, respect for autonomy, and increased access to essential health care goods and services might not translate well as ethical limits of health care

markets. For example, while medical paternalism is not nearly as present in Italian health care relationships as it once was, Italian-trained doctors traditionally have placed a greater importance on protecting patients from "frightening" information than on providing them detailed information about their health (as the latter is believed to impede patient-treatment by causing patients to feel overwhelmed and isolated).[256] In other places, economic underdevelopment seems to cause the opposite effect of what health care markets intend by preventing the efficient and efficacious provision of health care goods and services to persons in need.[257] My intuition is that applying my view to the international production or delivery of health care goods and services will be most successful in economically developed nations, *but* that regardless of where the international focus would be, substantial alterations to my arguments will be necessary to account for whatever differences may exist between health care relationships in the United States and elsewhere.

[256] Surbone, "Letter From Italy," 1661.
[257] See for example; Callahan and Wasunna, *Medicine and the Market*, 117-161.

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Appendices

Appendix 1: PhRMA's *Code on Interactions with Health Care Professionals*

1. Basis of Interactions

Our relationships with healthcare professionals are regulated by multiple entities and are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical education.

Promotional materials provided to healthcare professionals by or on behalf of a company should: (a) be accurate and not misleading; (b) make claims about a product only when properly substantiated; (c) reflect the balance between risks and benefits; and (d) be consistent with all other Food and Drug Administration (FDA) requirements governing such communications.

2. Informational Presentations by Pharmaceutical Company Representatives and Accompanying Meals

Informational presentations and discussions by industry representatives and others speaking on behalf of a company provide healthcare providers with valuable scientific and clinical information about medicines that may lead to improved patient care.

In order to provide important scientific information and to respect healthcare professionals' abilities to manage their schedules and provide patient care, company representatives may take the opportunity to present information during healthcare professionals' working day, including mealtimes. In connection with such presentations or discussions, it is appropriate for occasional meals to be offered as a business courtesy to the healthcare professionals as well as members of their staff attending presentations, so long as the presentations provide scientific or educational value and the meals (a) are modest as judged by local standards; (b) are not part of an entertainment or recreational event; and (c) are provided in a manner conducive to informational communication.

Any such meals offered in connection with informational presentations made by field sales representatives or their immediate managers should also be limited to in-office or in-hospital settings.

Inclusion of a healthcare professional's spouse or other guest in a meal accompanying an informational presentation made by or on behalf of a company is not appropriate. Offering "take-out" meals or meals to be eaten without a company representative being present (such as "dine & dash" programs) is not appropriate.

3. Prohibition on Entertainment and Recreation

Company interactions with healthcare professionals are professional in nature and are

intended to facilitate the exchange of medical or scientific information that will benefit patient care. To ensure the appropriate focus on education and informational exchange and to avoid the appearance of impropriety, companies should not provide any entertainment or recreational items, such as tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips, to any healthcare professional who is not a salaried employee of the company. Such entertainment or recreational benefits should not be offered, regardless of (1) the value of the tems; (2) whether the company engages the healthcare professional as a speaker or consultant, or (3) whether the entertainment or recreation is secondary to an educational purpose.

Modest, occasional meals are permitted as long as they are offered in the appropriate circumstances and venues as described in relevant sections of this Code.

4. Pharmaceutical Company Support for Continuing Medical Education

Continuing medical education (CME), also known as independent medical education (IME), helps physicians and other medical professionals to obtain information and insights that can contribute to the improvement of patient care, and therefore, financial support from companies is appropriate. Such financial support for CME is intended to support education on a full range of treatment options and not to promote a particular medicine. Accordingly, a company should separate its CME grant-making functions from its sales and marketing departments. In addition, a company should develop objective criteria for making CME grant decisions to ensure that the program funded by the company is a bona fide educational program and that the financial support Is not an inducement to prescribe or recommend a particular medicine or course of treatment.

Since the giving of any subsidy directly to a healthcare professional by a company may be viewed as an inappropriate cash gift, any financial support should be given to the CME provider, which, in turn, can use the money to reduce the overall CME registration fee for all participants. The company should respect the independent judgment of the CME provider and should follow standards for commercial support established by the Accreditation Council for Continuing Medical Education (ACCME) or other entity that may accredit the CME. When companies underwrite CME, responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conferences or meetings in accordance with their guidelines. The company should not provide any advice or guidance to the CME provider, even if asked by the provider, regarding the content or faculty for a particular CME program funded by the company.

Financial support should not be offered for the costs of travel, lodging, or other personal expenses of non-faculty healthcare professionals attending CME, either directly to the individuals participating in the event or indirectly to the event’s sponsor (except as set out in Section 9 below). Similarly, funding should not be offered to compensate for the time spent by healthcare professionals participating in the CME event.

A company should not provide meals directly at CME events, except that a CME provider at its own discretion may apply the financial support provided by a company for a CME event to provide meals for all participants.

5. Pharmaceutical Company Support for Third-Party Educational or Professional Meetings

Third-party scientific and educational conferences or professional meetings can contribute to the improvement of patient care, and therefore, financial support from companies is appropriate. A conference or meeting is any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented.

Since the giving of any subsidy directly to a healthcare professional by a company may be viewed is an inappropriate cash gift, any financial support should be given to the conference's sponsor, which, in turn, can use the money to reduce the overall conference registration fee for all attendees. When companies underwrite medical conferences or meetings other than their own, responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conferences or meetings in accordance with their guidelines.

Financial support should not be offered for the costs of travel, lodging, or other personal expenses of non-faculty healthcare professionals attending third-party scientific or educational conferences or professional meetings, either directly to the individuals attending the conference or indirectly to the conference's sponsor (except as set out in Section 9 below). Similarly, funding should not be offered to compensate for the time spent by healthcare professionals attending the conference or meeting.

6. Consultants

Consulting arrangements with healthcare professionals allow companies to obtain information or advice from medical experts on such topics as the marketplace, products, therapeutic areas and the needs of patients. Companies use this advice to inform their efforts to ensure that the medicines they produce and market are meeting the needs of patients. Decisions regarding the selection or retention of healthcare professionals as consultants should be made based on defined criteria such as general medical expertise and reputation, or knowledge and experience regarding a particular therapeutic area. Companies should continue to ensure that consultant arrangements are neither inducements nor rewards for prescribing or recommending a particular medicine or course of treatment.

It is appropriate for consultants who provide advisory services to be offered reasonable compensation for those services and reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services. Any compensation or reimbursement made in conjunction with a consulting arrangement should be reasonable and based on fair market value.

Token consulting or advisory arrangements should not be used to justify compensating healthcare professionals for their time or their travel, lodging, and other out-of-pocket expenses. The following factors support the existence of a bona fide consulting arrangement (not all factors may be relevant to any particular arrangement):

- a written contract specifies the nature of the consulting services to be provided and the basis for payment of those services;
- a legitimate need for the consulting services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;
- the criteria for selecting consultants are directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular health- care professionals meet those criteria;
- the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose;
- the retaining company maintains records concerning and makes appropriate use of the services provided by consultants;
- the venue and circumstances of any meeting with consultants are conducive to the consulting services and activities related to the services are the primary focus of the meeting; specifically, resorts are not appropriate venues.

While modest meals or receptions may be appropriate during company-sponsored meetings with healthcare professional commercial consultants, companies should not provide recreational or entertainment events in conjunction with these meetings.

It is not appropriate to pay honoraria or travel or lodging expenses to non-faculty and non-consultant healthcare professional attendees at company-sponsored meetings, including attendees who participate in interactive sessions.

7. Speaker Programs and Speaker Training Meetings

Healthcare professionals participate in company-sponsored speaker programs in order to help educate and inform other healthcare professionals about the benefits, risks and appropriate uses of company medicines. Any healthcare professional engaged by a company to participate in such external promotional programs on behalf of the company will be deemed a speaker for purposes of this Code, and the requirements of Section 7 apply to company interactions with that healthcare professional in his or her capacity as a

speaker. Company decisions regarding the selection or retention of healthcare professionals as speakers should be made based on defined criteria such as general medical expertise and reputation, knowledge and experience regarding a particular therapeutic area, and communications skills. Companies should continue to ensure that speaking arrangements are neither inducements nor rewards for prescribing a particular medicine or course of treatment.

Speaker training is an essential activity because the FDA holds companies accountable for the presentations of their speakers. It is appropriate for healthcare professionals who participate in programs intended to train speakers for company-sponsored speaker programs to be offered reasonable compensation for their time, considering the value of the type of services provided, and to be offered reimbursement for reasonable travel, lodging, and meal expenses. Such compensation and reimbursement should only be offered when (1) the participants receive extensive training on the company's drug products or other specific topic to be presented and on compliance with FDA regulatory requirements for communications; (2) this training will result in the participants providing a valuable service to the company; and (3) the participants meet the general criteria for bona fide consulting arrangements (as discussed in Section 6 above). Speaker training sessions shoul be held in venues that are appropriate and conducive to informational communication and training about medical information; specifically, resorts are not appropriate venues.

Any compensation or reimbursement made to a healthcare professional in conjunction with a speaking arrangement should be reasonable and based on fair market value. Each company should, individually and independently, cap the total amount of annual compensation it will pay to an individual healthcare professional in connection with all speaking arrangements. Each company also should develop policies addressing the appropriate use of speakers, including utilization of speakers after training and the appropriate number of engagements for any particular speaker over time.

Speaker programs may include modest meals offered to attendees and should occur in a venue and manner conducive to informational communication.

While speaker programs offer important educational opportunities to healthcare professionals, they are distinct from CME programs, and companies and speakers should be clear about this distinction. For example, speakers and their materials should clearly identify the company that is sponsoring the presentation, the fact that the speaker is presenting on behalf of the company, and that the speaker is presenting information that is consistent with FDA guidelines. Beyond providing all speakers with appropriate training, companies should periodically monitor speaker programs for compliance with FDA regulatory requirements for communications on behalf of the company about its medicines.

8. Healthcare Professionals Who Are Members of Committees That Set

Formularies or Develop Clinical Practice Guidelines

Healthcare professionals who are members of committees that set formularies of covered medicines or develop clinical practice guidelines that may influence the prescribing of medicines often have significant experience in their fields. That experience can be of great benefit to companies and ultimately to patients if these individuals choose to serve as speakers or commercial consultants for companies. To avoid even the appearance of impropriety, companies should require any healthcare professional who is a member of a committee that sets formularies or develops clinical guidelines and also serves as a speaker or commercial consultant for the company to disclose to the committee the existence and nature of his or her relationship with the company. This disclosure requirement should extend for at least two years beyond the termination of any speaker or consultant arrangement.

Upon disclosure, healthcare professionals who serve as speakers or consultants for companies should be required to follow the procedures set forth by the committee of which they are a member, which may include recusing themselves from decisions relating to the medicine for which they have provided speaking or consulting services.

9. Scholarships and Educational Funds

Financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other healthcare professionals in training to attend carefully selected educational conferences may be offered so long as the selection of individuals who will receive the funds is made by the academic or training institution. “Carefully selected educational conferences” are generally defined as the major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations.

10. Prohibition of Non-Educational and Practice-Related Items

Providing items for healthcare professionals’ use that do not advance disease or treatment education — even if they are practice-related items of minimal value (such as pens, note pads, mugs and similar “reminder” items with company or product logos) — may foster misperceptions that company interactions with healthcare professionals are not based on informing them about medical and scientific issues. Such non-educational items should not be offered to healthcare professionals or members of their staff, even if they are accompanied by patient or physician educational materials.

Items intended for the personal benefit of healthcare professionals (such as floral arrangements, artwork, music CDs or tickets to a sporting event) likewise should not be offered.

Payments in cash or cash equivalents (such as gift certificates) should not be offered to

healthcare professionals either directly or indirectly, except as compensation for bona fide services (as described in Sections 6 and 7). Cash or equivalent payments of any kind create a potential appearance of impropriety or conflict of interest.

It is appropriate to provide product samples for patient use in accordance with the Prescription Drug Marketing Act.

11. Educational Items

It is appropriate for companies, where permitted by law, to offer items designed primarily for the education of patients or healthcare professionals if the items are not of substantial value ($100 or less) and do not have value to healthcare professionals outside of his or her professional responsibilities. For example, an anatomical model for use in an examination room is intended for the education of the patients and is therefore appropriate, whereas a DVD or CD player may have independent value to a healthcare professional outside of his or her professional responsibilities, even if it could also be used to provide education to patients, and therefore is not appropriate.

Items designed primarily for the education of patients or healthcare professionals should not be offered on more than an occasional basis, even if each individual item is appropriate.

12. Prescriber Data

Companies use non-patient identified prescriber data to facilitate the efficient flow of information to healthcare professionals. Such prescriber data, which does not identify individual patients, may serve many purposes, including enabling companies to: (a) impart important safety and risk information to prescribers of a particular drug; (b) conduct research; (c) comply with FDA mandated risk management plans that require drug companies to identify and interact with physicians who prescribe certain drugs; (d) track adverse events of marketed prescriptions drugs; and (e) focus marketing activities on those healthcare professionals who would most likely benefit from information about a particular drug.

Companies that choose to use non-patient identified prescriber data to facilitate communications with healthcare professionals should use this data responsibly. For example, companies should (a) respect the confidential nature of prescriber data; (b) develop policies regarding the use of the data; (c) educate employees and agents about those policies; (d) maintain an internal contact person to handle inquiries regarding the use of the data; and (e) identify appropriate disciplinary actions for misuse of this data.

In addition, companies should respect and abide by the wishes of any healthcare professional who asks that his or her prescriber data not be made available to company sales representatives. Companies may demonstrate this respect by following the rules of

voluntary programs that facilitate prescribers' ability to make this choice.

13. Independence and Decision Making

No grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's prescribing practices.

14. Training and Conduct of Company Representatives

Pharmaceutical company representatives play an important role in delivering accurate, up-to-date information to healthcare professionals about the approved indications, benefits and risks of pharmaceutical therapies. These representatives often serve as the primary point of contact between the companies who research, develop, manufacture and market life-saving and life-enhancing medicines and the healthcare professionals who prescribe them. As such, the company representatives must act with the highest degree of professionalism and integrity.

Companies should ensure that all representatives who are employed by or acting on behalf of the companies and who visit healthcare professionals receive training about the applicable laws, regulations and industry codes of practice, including this Code, that govern the representatives' interactions with healthcare professionals. In addition, companies should train their representatives to ensure that they have sufficient knowledge of general science and product- specific information to provide accurate, up-to-date information, consistent with FDA requirements.

Companies should provide updated or additional training in all of these areas as needed for their representatives who visit healthcare professionals.

Companies should also assess their representatives periodically to ensure that they comply with relevant company policies and standards of conduct. Companies should take appropriate action when representatives fail to comply.

15. Adherence to Code

All companies that interact with healthcare professionals about pharmaceuticals should adopt procedures to assure adherence to this Code.

Companies that publicly announce their commitment to abide by the Code and who complete an annual certification that they have policies and procedures in place to foster compliance with the Code will be identified by PhRMA on a public web site. The certification must be signed by the company's Chief Executive Officer and Chief

Compliance Officer. The website will identify the companies who commit to abide by the Code; provide contact information for their Chief Compliance Officers; and, at the appropriate time, publish the status of each company's annual certification.

Any comments received by PhRMA relating to a company's observance of the Code or conduct that is addressed by the Code will be referred by PhRMA to the relevant company's Chief Compliance Officer.

In addition, companies are encouraged to seek external verification periodically, meaning at least once every three years, that the company has policies and procedures in place to foster compliance with the Code. PhRMA will prepare general guidance for such external verification and will identify on its web site if a company has sought and obtained verification of its compliance policies and procedures from an external source.

Appendix 2: ***PhRMA Guiding Principles: Direct to Consumer Advertisements About Prescription Medicines***

1. These Principles are premised on the recognition that DTC advertising of prescription medicines can benefit the public health by increasing awareness about diseases, educating patients about treatment options, motivating patients to contact their physicians and engage in a dialogue about heal the concerns, increasing the likelihood that patients will receive appropriate care for conditions that are frequently under-diagnosed and under-treated, and encouraging compliance with prescription drug treatment regimens.

2. In accordance with FDA regulations, all DTC information should be accurate and not misleading, should make claims only when supported by substantial evidence, should reflect balance between risks and benefits, and should be consistent with FDA approved labeling. Accordingly, companies should continue to base promotional claims on FDA approved labeling and not promote medicines for off-label uses, including in DTC advertisements.

3. DTC television and print advertising which is designed to market a prescription drug should also be designed to responsibly educate the consumer about that medicine and, where appropriate, the condition for which it may be prescribed. During the development of new DTC television advertising campaigns, companies should seek and consider feedback from appropriate audiences, such as health care professionals and patients, to gauge the educational impact for patients and consumers.

4. DTC television and print advertising of prescription drugs should clearly indicate that the medicine is a prescription drug to distinguish such advertising from other advertising for non-prescription products.

5. DTC television and print advertising should foster responsible communications between patients and health care professionals to help patients achieve better health and a more complete appreciation of both the health benefits and the known risks associated with the medicine being advertised.

6. In order to foster responsible communication between patients and health care professionals, companies should spend an appropriate amount of time to educate health professionals about a new medicine or a new therapeutic indication and to alert them to the upcoming advertising campaign before commencing the first DTC advertising campaign. In determining what constitutes an appropriate time, companies should take into account the relative importance of informing patients of the availability of a new medicine, the complexity of the risk-benefit profile of that new medicine and health care professionals' knowledge of the condition being treated. Companies are encouraged to consider individually setting specific periods of time, with or without exceptions, to educate health care professionals before launching a branded DTC television or print advertising campaign. Companies should continue to educate health care professionals as

additional valid information about a new medicine is obtained from all reliable sources.

7. Working with the FDA, companies should continue to responsibly alter or discontinue a DTC advertising campaign should new and reliable information indicate a serious previously unknown safety risk.

8. Companies should submit all new DTC television advertisements to the FDA before releasing these advertisements for broadcast.

9. DTC print advertisements for prescription medicines should include FDA's toll-free MedWatch telephone number and website for reporting potential adverse events. DTC television advertisements for prescription medicines should direct patients to a print advertisement containing FDA's toll-free MedWatch telephone number and website, and/or should provide the company's toll-free telephone number.

10. Companies that choose to feature actors in the roles of health care professionals in a DTC television or print advertisement that identifies a particular product should acknowledge in the advertisement that actors are being used. Likewise, if actual health care professionals appear in such advertisements, the advertisement should include an acknowledgement if the health care professional is compensated for the appearance.

11. Where a DTC television or print advertisement features a celebrity endorser, the endorsements should accurately reflect the opinions, findings, beliefs or experience of the endorser. Companies should maintain verification of the basis of any actual or implied endorsements made by the celebrity endorser in the DTC advertisement, including whether the endorser is or has been a user of the product if applicable.

12. DTC television and print advertising should include information about the availability of other options such as diet and lifestyle changes where appropriate for the advertised condition.

13. DTC television advertising that identifies a product by name should clearly state the health conditions for which the medicine is approved and the major risks associated with the medicine being advertised.

14. DTC television and print advertising should be designed to achieve a balanced presentation of both the benefits and the risks associated with the advertised prescription medicine. Specifically, risks and safety information, including the substance of relevant boxed warnings, should be presented with reasonably comparable prominence to the benefit information, in a clear, conspicuous and neutral manner, and without distraction from the content. In addition, DTC television advertisements should support responsible patient education by directing patients to health care professionals as well as to print advertisements and/or websites where additional benefit and risk information is available.

15. All DTC advertising should respect the seriousness of the health conditions and the medicine being advertised.

16. In terms of content and placement, DTC television and print advertisements should be targeted to avoid audiences that are not age appropriate for the messages involved. In particular, DTC television and print advertisements containing content that may be inappropriate for children should be placed in programs or publications that are reasonably expected to draw an audience of approximately 90 percent adults (18 years or older).

17. Companies are encouraged to promote health and disease awareness as part of their DTC advertising.

18. Companies should include information in all DTC advertising, where appropriate, about help for the uninsured and underinsured.

Vita

Thomas David Harter was born in Longmont, Colorado on December 22, 1978. He was raised in Walkersville, Maryland and graduated from Walkersville High School in 1997. After beginning his study of Philosophy at Western Maryland College (now McDaniel College), he transferred to Radford University where he earned a Bachelor of Arts degree in Philosophy and Religious Studies with a concentration in Philosophy in 2001. After marrying his wife, Lisa, in 2003, Thomas continued his study of Philosophy at the University of Tennessee, Knoxville, focusing his research and teaching in Medical Ethics and Business Ethics. In 2005 he earned a Master of Arts degree in Philosophy, and in 2007 began writing his dissertation under the direction of Denis G. Arnold. Upon completing his Ph.D., Thomas will begin the two-year Cleveland Fellowship in Advanced Bioethics in Cleveland, Ohio, and plans to continue working on ethical issues that arise at the intersection of medicine and business.