To the Graduate Council:

I am submitting herewith a thesis written by Jason E. Hubbard entitled "The Dangers of Detailing: How Pharmaceutical Marketing Threatens Health Care." I have examined the final electronic copy of this thesis for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Master of Arts, with a major in Philosophy.

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The Dangers of Detailing:
How Pharmaceutical Marketing Threatens Health Care

A Master's Thesis
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Abstract

This master's thesis examines the issues that surround the practice of Direct to Physician (DTP) marketing by pharmaceutical companies. The thesis begins by looking at the normative foundations that ground objections to DTP marketing. Developments that have recently emerged in contemporary Kantian ethics are utilized in order to defend a Kantian moral framework. The first and second formulations of the categorical imperative are then utilized in order to derive four mid level principles that serve to guide the discussion through the following chapters.

Chapter 3 criticizes DTP marketing as deceptive and manipulative and argues that is strongly correlated to negative affects on prescribing behavior, both harming patient care and undermining the fiduciary duties physicians owe their patients. As such, DTP marketing does not show the proper respect patients and physicians are owed as moral agents.

Chapter 4 considers the economic impact of DTP marketing. Indications suggest that DTP marketing is primarily utilized to create an artificial market for "me-too" drugs. As these drugs are often very expensive and offer little to no therapeutic benefit over existing alternatives they drive up health care spending. When understood within the context of a failing health care system it becomes a self defeating business strategy and harms patients through rising health care costs.

Finally, Chapter 5 concludes with a discussion of the potential for the industry to regulate itself and examines the likely impact regulation of DTP marketing will have on the industry. While a voluntary ban is called for, financial incentives make it unlikely

that self regulation will be sufficient. In which case, it will be the responsibility of state or federal governments to regulate the practices. While regulation of DTP marketing may threaten profitability of the industry it is claimed that the current reliance on "me-too" drugs entails that the primary affect of regulation will be to force pharmaceutical companies to concentrate on truly innovative drugs. As such, contrary to the claims of critics, regulation will likely encourage innovation as opposed to stifling it.

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Chapter 1

Introduction

We owe a great deal to the pharmaceutical industry. Pharmaceutical companies have developed treatments that have not only dramatically improved our quality of life but that save lives. The introduction of antibiotics has led to a reduction in mortality rates from rheumatic fever and rheumatic heart disease of 83%. ACE inhibitors, beta blockers, and nitrates have aided in lowering the mortality rate from atherosclerosis by 74%.[1] Pharmaceuticals are also at least partially responsible for the dramatic rise in life expectancy from 68.2 years in 1950[2] to 77.8 in 2006.[3]

There is even strong evidence that for certain conditions, pharmaceuticals are the most cost effective means for the treatment of disease. Pharmaceuticals can help to minimize hospital stays and physician interactions, both of which are extremely expensive treatment options. Frank Lichtenberg has argued that $1.00 spent on pharmaceutical drugs can be correlated with a $3.65 reduction in health care spending.[4] While there is reason to be concerned that Lichtenberg's analysis is selective and only holds for certain treatments, it is still important to recognize that at least some pharmaceutical therapies do lead to significant reductions in health care expenditures.

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[1] Masia, Neal A. "Pharmaceutical Innovation: Lowering the Price of Good Health," *Economic Realities in Health Care Policy*, 2, no. 2, (2002) http://www.heartland.org/pdf/3264bd.pdf, 8 (accessed 3/22/07).
[2] National Center for Health Statistics, *National Vital Statistics Reports*, 54, no. 19, June 28, 2006, *Infoplease*, "Life Expectancy at Birth by Race and Sex, 1930-2004," http://www.infoplease.com/ipa/A0005148.html (accessed 3/22/07).
[3] U.S. Census Bureau Data, *Infoplease*, "Infant Mortality and Life Expectancy for Selected Countries, 2006," http://www.infoplease.com/ipa/A0004393.html (accessed 3/22/07)
[4] Lichtenberg, Frank R. "The Economic Benefits of New Drugs," *Economic Realities in Health Care Policy*, 2, no. 2, (2001), 14-19.

Yet, despite these incredible successes, the pharmaceutical industry continues to come under sustained criticism for many of its practices. For decades the industry has consistently been one of the most profitable in America. At the same time, health care spending continues to outpace growth of the economy at an alarming rate, steadily consuming ever greater portions of our GDP. This trend raises questions over the appropriateness of such profits. However, the industry defends their substantial profits by arguing that the pharmaceutical industry is inherently risky and substantial profits are necessary to encourage the investment necessary for continued innovation. Thus, if we wish to continue to benefit from the incredible developments that the pharmaceutical industry has brought us, then we must not endanger their ability to sustain profits at their current levels.

One of the primary mechanisms by which the pharmaceutical industry maintains such high profits is through their immense investment in marketing, nearly $20 billion in 2003. While spending on direct to consumer advertising (DTCA) continues to grow dramatically, it remains a relatively small percentage of total advertising spending, only 21.9% in 2003. The remaining 78.1% or roughly $15.6 billion is spent on direct to physician (DTP) marketing.[5] While such huge expenditures within the context of a health care industry struggling to survive should certainly raise eyebrows, it is not in

[5] Lam, Michael D., "A $20 Billion Bill and Plenty of Change," *Pharmaceutical Executive*, Sept., (2004), http://www.imshealth.com/vgn/images/portal/cit_40000873/48/36/70684838PE012204ePlentyofChange.pdf (accessed 3/22/07). It is exceedingly difficult to determine precisely what is spent on marketing by pharmaceutical companies. There is a disturbing lack of transparency in the public documentation of their spending. SEC filings by pharmaceutical companies lump marketing, advertising, and administration into a single group making it difficult in the extreme to determine exactly how much is being spent and on what. These technicalities are what lies behind the significant differences that often exist in attempts to estimate marketing expenditures by the industry and where that money is directed.

itself reason to charge pharmaceutical companies with unethical conduct. They are still a business, and as such, have a right to pursue profit.

However, it is the tactics and methods that the pharmaceutical industry employs in their marketing endeavors that raise the most concern. In particular, interactions with physicians and health care professionals seem most worrisome. Accounts of these interactions abound, and are characterized by the showering of small trinkets, buying of meals, all expense paid trips to conferences on continued medical education (CME) which are themselves sponsored by pharmaceutical companies and serve to highlight their newest and greatest products, enrollment of physicians as drug company-sponsored consultants, advisory board members, and public speakers, and many other debatable practices.[6] While there have been efforts to limit, discourage, and outright ban many of the most worrisome practices by the American Medical Association (AMA), PhARMA

[6] Abrams, Thomas. "The Regulation of Prescription Drug Promotion." In *Ethics and the Pharmaceutical Industry*, eds. Michael A. Santoro and Thomas M. Gorrie; Allman, Richard L., M.D. "The Relationships Between Physicians and the Pharmaceutical Industry: Ethical Problems with the Every-Day Conflict of Interest." *Health care Ethics Committee Forum* 15, no. 2 (2003): 155-70; Angell, Marcia M.D. *The Truth About the Drug Companies: How They Deceive Us and What To Do About It*. New York: Random House, 2004; Dana, Jason, MS; George Lowenstein, PhD. "A Social Science Perspective on Gifts to Physicians From Industry." *JAMA* 290, no. 2 (2003): 252-255; Elliot, Carl. "The Drug Pushers." *The Atlantic Monthly* April (2006): 2-13; Freeman, Jerome W., MD, FACP and Brian Kaatz PharmD. "The Physician and the Pharmaceutical Detail Man: An Ethical Analysis." *The Journal of Medical Humanities and Bioethics* 8, no. 1 (1987): 34-9; Griffith, David. "Reasons for Not Seeing Drug Representatives." *BMJ* 319, no. 10 (1999): 69-70; Human, Delon. "Conflicts of Interest in Science and Medicine: The Physician's Perspective." *Science and Engineering Ethics* 8, no. 3 (2002): 273-276; Katz, Dana, Arthur L. Caplan, and Jon F. Merz. "All Gifts Large and Small: Toward an Understand of the Ethics of Pharmaceutical Industry Gift-Giving." *The American Journal of Bioethics* 3, no. 3 (2003): 39-46; Lexchin, Joel. "Doctors and Detailers: Therapeutic Education or Pharmaceutical Promotion?" *International Journal of Health Services* 19, no. 4 (1989): 663-79; Relman, Arnold S., MD. "Defending Professional Independence: ACCME's Proposed New Guidelines for Commercial Support of CME." *JAMA* 289, no. 18 (2003): 2418-20; Reuter, Lars, PhD. "The Ethics of Advertising Strategies in the Pharmaceutical Industry." *Ethics & Medicine; A Christian Perspective on Issues in Bioethics* 19, no. 3 (2003): 171-5; Rodwin, Marc A. *Medicine, Money, and Morals: Physicians' Conflicts of Interest*. New York: Oxford University Press, 1993; Tsai, Alexander C. "Policies to Regulate Gifts to Physicians From Industry." *JAMA* 290, no. 13 (2003): 1776; Wazana, Ashley, MD. "Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?" *JAMA* 283, no. 3 (2000): 373-380; Ziegler, Michael G., MD; Pauline Lew, PharmD; Brian C. Singer, PharmD. "The Accuracy of Drug Information From Pharmaceutical Sales Representatives." *JAMA* 273, no. 16 (1995), 1296-8.

(the trade group that represents the pharmaceutical industry), and even through government legislation, there is still concern that these practices continue to undermine the practice of medicine.

Critics of DTP marketing argue that the practice damages the patient physician relationship. There is serious concern that the influence of pharmaceutical sales representatives (PSR's) interferes with physicians' ability to make proper prescribing decisions that are in the best interests of their patients. If this concern is well founded then not only does this threaten to harm the patient physician relationship but also puts the health and wellbeing of patients at risk. Even more, there is serious concern that within the context of a struggling health care industry, the practice of DTP marketing needlessly drives up health care spending by encouraging the prescribing of newer, more expensive products that have little or no advantage over existing treatments.

The pharmaceutical industry defends DTP marketing practices by arguing that pharmaceutical detailing serves a valuable educative role. They claim that they provide accurate, unbiased information to physicians that help them to make better prescribing decisions. Further, the practice of buying meals is defended as merely a way to most effectively use the very valuable and limited time physicians have. Physicians must eat, so why not use that time to educate them about a new product and purchase their meal as compensation for the time spent with them? Above all else, the pharmaceutical industry is just that, an industry. Thus, it seems wrong to unnecessarily limit their pursuit of profit through the most effective marketing mechanism at their disposal. Finally, even if we do find solid moral objections to the practices that surround DTP marketing, we must

carefully consider the implications of any reform we wish to enact, less we limit the industry's ability to continue to develop innovative, life saving therapies.

Yet, much of what has been written in objection to the practice of DTP marketing has been authored by physicians. While their firsthand experience and proximity to the practices is invaluable, often the discussion lacks a firm foundation upon which objections may be grounded. What has resulted is a debate in which both sides talk past each other. Physicians argue from the standpoint of patient care while the pharmaceutical companies argue from the standpoint of sustainability and profitability. The problem then becomes one of explaining why patient care should win out over considerations of profitability and sustainability. Without a clearly articulated ethical framework to argue from, this becomes a daunting task in which each side believes their point of view should win out over the opposing side. However, by grounding these objections in a Kantian framework we may begin to see why concerns of patient care and the unhindered practice of medicine should sometimes trump the pursuit of profit.

In this context I will begin in Chapter 2 by defending and utilizing Barbara Herman's distinct interpretation of the first formulation of the Categorical Imperative (CI) combined with Denis Arnold and Norman Bowie's interpretation of respect for persons. I will then utilize these two interpretations of the CI to develop four midrange principles that can be utilized to determine the acceptability of current practices surrounding DTP marketing. In Chapter 3 I will address concerns surrounding whether the practice of DTP marketing is inherently deceptive and manipulative. In the end, I conclude that the practices are in fact deceptive and manipulative. Even more, such practices clearly threaten patient care and the patient physician relationship, violating the

demands of respect for both patients and physicians. Next, in Chapter 4 I will examine the financial impact that DTP marketing has had on the health care industry. I conclude by arguing that DTP marketing has unnecessarily driven up health care spending. As such, DTP marketing both threatens the stability of the health care system and restricts access to care and financially harms patients through increases in drug prices and insurance premiums. Finally, in Chapter 5 I argue for a voluntary ban by both the AMA and PhARMA on all questionable marketing practices surrounding DTP marketing. However, there is strong reason to doubt whether a voluntary ban by these organizations will be sufficient. If voluntary bans are not effective at eliminating the unethical practices then the federal government has a responsibility to institute legislation to effectively halt these practices.

Chapter 2

Kantian Foundations

The pharmaceutical industry continues to come under sustained criticism for many of its questionable practices. One of the most central concerns has been the practices surrounding DTP marketing. While many have attempted to argue that the practice is immoral and needs to be radically altered, if not completely banned, few have grounded these objections in a broader ethical framework. At the same time, much work has been done in contemporary Kantian philosophy which has immensely expanded the scope and salience of Kant's original work. It is my intention to utilize these new approaches to Kant's ethics to ground objections to the practices of DTP marketing. However, before beginning it will be important to address several concerns. Most notably I must explain how we may properly consider corporations as moral agents and why I find it necessary to formulate original principles instead of utilizing the work developed by Principlists such as Tom Beauchamp and James Childress. Further, while I argue that the position articulated by Beauchamp and Childress is unconvincing, I must explain why I find Herman's contemporary account of Kantian ethics a more promising source for the derivation of the guiding principles that will be necessary for the discussion that follows.

1. Corporations as Moral Entities:

Since it is highly contentious as to whether corporations can even be properly considered moral entities, it will be important to say something on this topic before beginning. In 1979 Peter French developed an account of the metaphysical status of corporations in which he argued that corporations can be properly understood as moral agents.[7] As Denis Arnold points out, French argues for three main conclusions. These are, "[f]irst, corporations exhibit intentionality. Second, corporations are capable of exhibiting rationality regarding their intentions. And, third, corporations are capable of altering their intentions and patterns of behavior."[8] However, in response to his critics French later adopted Bratman's planning theory of intentionality.[9]

Under their conception of intentionality, the corporate internal decision structure (CID) articulated by French can be seen as indicative of moral agency. The CID structure, "includes hierarchical lines of organizational responsibility, rules of procedure, and corporate policies."[10] Within this context it is helpful to examine the example that Arnold uses to illustrate how a common interest and the meshing of subplans may emerge in the context of a corporation. Arnold asks us to imagine the implementation of a new environmental management program. The implementation of the new program will require the meshing of subplans between different departments and divisions within the company. Within this, "Human Resources crafts disciplinary procedures for employees who violate the environmental policy. Corporate communications ensures that all

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[7] French, Peter A., "The Corporation as a Moral Person," *American Philosophical Quarterly*, 16 (1979): 207-15.
[8] Arnold, Denis G. "Corporate Moral Agency," *Midwest Studies in Philosophy*, 30 (2006): 279-91, 280.
[9] For a recent review of the literature on this issue see, Arnold, Denis G, "Corporate Moral Agency" in *Encyclopedia of Business Ethics and Society*, ed. Robert W. Kolb, Thousand Oaks: Sage Publishers, 2007.
[10] Ibid, 288.

employees are informed of the environmental policy, together with sanctions for violation, and so on."[11] Each department must be aware of how the subplans, with regards to the running of their department, are to mesh with the shared intention of implementing the new policy. So long as all members within the corporation are sufficiently aware of the new policy and its implications on how their specific function within the corporation is affected, then all members within the corporation effectively share the intention of implementing the new policy. Thus, by sharing a common intention and meshing their subplans to achieve this common goal, a corporation may be properly understood as being an intentional entity and thus a moral agent. As such, the work of French, Bratman, and Arnold gives strong reason to accept corporations as moral agents. However, if one does not accept French's theory of corporate agency, one need only to replace the discussion of corporate moral responsibility with the moral responsibility of managers.[12] I imagine few would argue that corporate managers are persons and as such have moral obligations. Further, since the decisions and actions managers undertake, qua managers, often dictate the policies of the corporation and their effects on other moral agents, it makes sense to say that these managers have moral obligations in the same sense that I argue that corporations themselves do. Therefore, it should be unproblematic for those who do not accept the account developed above to merely substitute the language of corporate moral responsibility with that of responsibility of corporate managers.

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[11] Ibid, 289.

[12] While this is an acceptable alternative, I find the utilization of corporate moral agency particularly helpful in this discussion. The reason for this is the fact that the practices examined in this thesis seem to be indicative of, not only a corporate culture, but of a culture that is industry wide culture. As such, these problems are not limited to the individual actions and policies of a few managers but seem to be pervasive throughout the pharmaceutical industry. Hence, it is beneficial to be able to speak of corporate responsibility across the industry as opposed to the actions of individual managers.

2. The Common Morality:

There should now be sufficient reason to believe that we may effectively speak of corporations as moral agents, however, the question still remains as to why I should bother constructing my own foundation and deriving original principles when so much work has been undertaken in the development of principles, in particular the work done by Beauchamp and Childress.[13] The answer lies in the popularity of the "common morality" as the foundation for the derivation of principles. In recent years the common morality has rapidly gained prominence as several authors have used it as the basis from which their ethical theories may be constructed. Most notable has been the enthusiastic acceptance of the common morality as the starting point for the derivation of their principles by Beauchamp and Childress in the 5th edition of *Principles of Biomedical Ethics*[14] and its central role in the construction of their "descriptivist" ethical theory by Gert, Culver, and Clouser in *Bioethics: A Return to Fundamentals.* [15]

Supporters of the common morality maintain that,

> [A]ll humans – at least all morally serious humans – have a pretheoretical awareness of certain moral norms. The claim is that normal humans intuit or in some other way know that there is something wrong with things like lying or breaking promises or killing people. These purportedly universal shared insights can provide the raw data from which ethical theories can be constructed."[16]

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[13] Beauchamp, Tom L. and James F. Childress, *Principles of Biomedical Ethics*, 2nd -5th eds., New York: Oxford University Press, 1983, 1989, 1994, 2001.
[14] Beauchamp, Tom L. and James F. Childress, *Principles of Biomedical Ethics*, 5th ed, New York: Oxford University Press, 2001.
[15] Gert, Bernard, Charles M. Culver, and Danner K. Clouser, *Bioethics: A Return to Fundamentals*, New York: Oxford University Press, 1997.
[16] Veatch, Robert M., "Is There a Common Morality?," *Kennedy Institute of Ethics Journal*, 13, no. 3 (2003): 189-192.

When one considers that one of the central problems within ethics, and in particular applied ethics, has been how to construct an ethical theory that has universal normative weight, it is easy to see why the common morality has been so attractive. As ethical theory has traditionally developed, theories inevitably carry substantive, normative or metaphysical presuppositions with them. As a result, one needs only to maintain that they do not accept those presuppositions in order to reject the foundations that the theory stands on. When those foundations are rejected, the ethical theory no longer carries any normative weight for those who do not accept the presuppositions the theory is derived from. Therefore, it is often difficult to develop an ethical theory that is universally applicable. In response to these deep seated problems, the prospect of deriving an ethical theory from supposedly universal empirical claims about the ethical nature of humans has been extremely enticing.

The viability of the common morality view lies in the empirical claim that certain general intuitions are universal to all morally serious humans. However, there is strong reason to be skeptical about the universal nature of the common morality. Leigh Turner has argued that, "proponents of a common morality approach to moral reasoning have not made a persuasive argument in support of the claim that there are cross-cultural moral norms supporting a "universal" common morality."[17] He argues that such empirical claims are in fact testable and that until a sufficient body of evidence exists to support such empirical claims the common morality should be questioned. In a reply to several critics, including Turner, Tom Beauchamp recognizes that the empirical claims that form

[17] Turner, Leigh, "Zones of Consensus and Zones of Conflict: Questioning the 'Common Morality' Presumption in Bioethics," *Kennedy Institute of Ethics Journal* 13, no. 3 (2003): 193-218, 196.

the foundation of the common morality need to be examined.[18] Even more, Robert Veatch notes that a group of scholars at the Kennedy Institute along with others around the world have committed themselves to the exploration of the common morality, including the empirical studies that Turner calls for.[19]

However, such studies may present a daunting task and are far from uncontroversial. Beauchamp himself recognizes a central problem involved in testing the empirical claims of the common morality. These problems center around the requirement that all "morally serious" persons would universally agree on the common morality. Defenders of the common morality readily acknowledge that there will be amoral or immoral individuals who do not take morality seriously. Their claim is that all people who do take morality seriously will share basic common moral intuitions. The problem is that, "the question could be begged either by (1) designing the study so that the only persons tested are precisely those who already have the commitments and beliefs the investigator is testing for or (2) designing the study so that all persons are tested regardless of whether they are committed to the objectives of morality."[20] Regardless, as far as the common morality relies on universal empirical claims, the burden of proof is on the defenders of the common morality to provide solid grounds for those claims.

However, problems surrounding the common morality go deeper than merely the lack of studies that support the empirical claims. Jeffrey Brand-Ballard has argued that the differences between the two primary camps who rely on the common morality, the "principlists" such as Beauchamp and Childress and the "descriptivists" such as Gert,

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[18] Beauchamp, Tom L, "A Defense of the Common Morality," *Kennedy Institute of Ethics Journal* 13, no. 3, (2003): 259-74.
[19] Veatch.
[20] Beauchamp (2003), 263.

Culver, and Clouser, lies in a deep seated inconsistency in the common morality.[21] Brand-Ballard argues that the division between the two approaches lies in their understanding of how precisely they should utilize reflective equilibrium (RE) or wide reflective equilibrium (WRE) to bring individual considered moral judgments (CMJ's) into line with the broader principles of principlism or the single moral system of descriptivism. Brand-Ballard contends that both camps should see themselves as differing approaches to the same problem of bringing CMJ's into alignment with the more general norms derived from the common morality.

Brand-Ballard's criticism of the two approaches to the common morality does not necessarily undermine the ability of the common morality to function as the starting point for the derivation of an ethical theory. However, his criticism does pick out a serious concern about ethical theories that rely on the common morality. This concern centers on the fact that even if there is a universal common morality, we have not yet been able to parse out how norms derived from the common morality should relate to the CMJ's of moral agents. There is significant disagreement as to where the epistemic weight lies in ethical theories that rely on the common morality. If the epistemic weight lies in the norms derived from the common morality, then the CMJ's should be brought into line with the more general norms. In fact, this is how Brand-Ballard characterizes what goes on in descriptivist theories. On the other hand, if there is significant epistemic weight given to individual CMJ's, then the norms derived from the common morality should, at least to some degree, be brought into congruence with the CMJ's in reflective equilibrium, as Beauchamp and Childress argue for. Thus, if Brand-Ballard is correct,

[21] Brand-Ballard, Jeffrey, "Consistency, Common Morality, and Reflective Equilibrium," *Kennedy Institute of Ethics Journal* 13, no. 3 (2003): 231-58.

then it is not clear how exactly we are to proceed from the empirical fact of a common morality to an ethical theory based upon it. This very concern seems to have been present when Beauchamp recognizes that, "a full defense of this view would require a justification of all of the elements of my account, in particular, the object of morality, considered judgments, the role of coherence, pragmatic justification, and specification."[22] Thus, an examination of ethical theories based on the common morality serves to illustrate just how early in development such accounts are. As such, there is reason for healthy skepticism about the ability of the common morality to fare any better than earlier attempts at a universal ethical theory. These concerns combined with the great strides that have been made in contemporary Kantian ethics, which I will take up in the next section, give sufficient reason for me to examine the potential for these new approaches to provide a foundation for the derivation of principles that may serve to guide us through an analysis of the practices of DTP marketing in the following chapters.[23]

3. The First Formulation of the Categorical Imperative:

A great deal of work has been undertaken in recent history in an attempt to resurrect Kant's ethics. The work of Christine Korsgaard, Onora O'Neill, Thomas Hill Jr., Barbara Herman, and many others has served to develop a new understanding of Kant's ethics that, not only answers many of the common criticisms that have been leveled against it, but creates an ethical theory that has strong potential to serve as a

[22] Beauchamp (2003), 264.
[23] A meta-ethical discussion of the debate surrounding differing approaches to the formulation of ethical theories would be a thesis in itself. Suffice it to say that there are significant concerns surrounding the enthusiastic acceptance of the common morality. These concerns combined with the relatively unnoticed advances made in the development of Kant's ethics provides strong reasons for the belief that such an approach may provide better grounds for the derivation of guiding principles than the work by Beauchamp and Childress based on the common morality.

valuable guide to issues of contemporary applied ethics. In this vein, Barbara Herman has attempted to develop a conception of the categorical imperative (CI) that may serve as a guide to moral deliberation and action. However, any attempt to reformulate a conception of Kant's ethics must contend with a host of criticisms that have been leveled against his theories. Therefore, as I discuss Herman I will demonstrate how her account may serve to avoid most of the criticisms that have been directed at Kant's ethics.

Probably the most well known and widely discussed aspect of Kant's ethics comes from his first formulation of the Categorical Imperative (CI), the Formula of Universal Law. In articulating the first formulation, Kant states that we must, "Act only according to that maxim by which you can at the same time will that it should become a universal law."[24] Thus, the CI sets up a procedure as a limiting function by which maxims may be tested. Through the CI procedure we are to test the maxims of an action by inquiring as to whether that action could be willed as a universal law. Unacceptable maxims will result in a contradiction and are thus ruled out.

Yet, much of the criticism by both proponents of and opponents to Kant's ethics have concentrated on how exactly the CI procedure is to be deployed and what precisely we are to gather from its use. Commentators have attributed two primary roles to the CI. Barbara Herman labels the first of these the derivation-of-duties model, whereby the CI procedure is deployed in order to develop a list of duties and obligations. Much of the criticism of this approach centers on the fact that it creates a rigid system of law-like rules. As Herman notes, "such a theory is rightly charged with insensitivity to moral complexity and righteous absurdity in requiring . . . that we keep all promises, tell no lies,

[24] Kant, Immanuel, *Groundwork for the Metaphysics of Morals,* Arnulf Zweig, trans. (Oxford: Oxford University Press, 2002) 421.

regardless of the consequences."[25] Thus, by using the CI in this manner, we derive a list of absolute duties that must be followed under all circumstances. The problem with this approach, and the reason why it doesn't sit well with so many commentators, is that we all know that the details of certain cases often make a very big difference. Yet, a rigorist set of absolute laws cannot allow for consideration of such details.

The second approach, which has emerged out of more recent endeavors to apply Kant's theories, has been an attempt to use the CI as an algorithm into which we can plug in a specific maxim, taking into account the details of a particular case, and the universalization test will tell us whether that specific action is permissible. Many have applauded this more recent approach because of its ability to side step the standard objections leveled against the derivation-of-duties model. When the CI is utilized as an algorithm and all pertinent details of the case are included in the maxim, the CI is then able to take into consideration the salient details of the case.

However, there is still a deficiency in the use of the CI as an algorithm for judgment. Herman's lengthy discussion of differing approaches to using the CI in this manner serves to illustrate the problems inherent in it.[26] Depending on the interpretation used, there are problems of false positives and negatives and the flaw that virtually any maxim can be made to pass or fail depending on how it is worded and which features are included or omitted.[27] These problems leave this approach open to the charge of

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[25] Herman, Barbara, *The Practice of Moral Judgment* (Cambridge: Harvard University Press, 1993), 133.
[26] Herman, Barbara, "Moral Deliberation and the Derivation of Duties," in *The Practice of Moral Judgment* (Cambridge: Harvard University Press, 1993).
[27] An example of such a problem would lie in the descriptive detail involved in a case of breaking a promise. At a highly general level, a maxim of "breaking promises for any reason" would be easily ruled out by the CI through the prevalently discussed result that such a maxim, when universalized, would lead to a world in which promise making would not exist. Since all who make promises would be expected to break them, the practice of promise making would cease to exist since the necessary trust required for the

arbitrariness and greatly undermines the ability of the CI to be a guide to moral judgment. As Herman notes, "difficulties with settling maxim content then undermine the adequacy of the method of judgment."[28]

Adding to the problems inherent in the question of maxim specification and the opposing approaches to the use of the CI is the problem of what precisely a contradiction in the CI is supposed to entail. In response to such concerns Christine Korsgaard defines three possible interpretations of contradiction in the CI, the logical, practical, and teleological.[29] Both Korsgaard and Herman dismiss the teleological interpretation as ineffective, however, they disagree over whether the logical or practical interpretations should prevail.[30] Under the practical interpretation, "your action would become ineffectual for the achievement of your purpose if everyone (tried to) use it for that purpose."[31] As such, you reach a contradiction when, by universalizing the maxim, you effectively frustrate the goal you set for yourself.[32] On the logical interpretation, "there

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practice would be destroyed. However, if we specify the maxim to a level of "breaking a promise when physical conditions prevent one from keeping the promise," we can begin to see how this more specific maxim may pass where the other fails. Since it will be understood that there was every intention of keeping the promise but factors outside of the control of the individual were responsible for the breaking of the promise, then, when universalized, such a maxim does not result in the destruction of trust and the expectation of the promise being kept as the other maxim does. Therefore, we may see how an action that most would consider unproblematic becomes problematic if it is not described properly.

[28] Herman, 143.

[29] Korsgaard, Christine M, "Kant's Formula of Universal Law," in *Creating the Kingdom of Ends* (Cambridge: Cambridge University Press, 1996).

[30] Korsgaard defines the teleological contradiction, saying, "it would be contradictory to will your maxim as a law for a system of nature teleologically conceived: either you are acting against some natural purpose, or your maxim could not be a teleological law. The maxim is inconsistent with a systematic harmony of purposes" (Ibid, 78). Korsgaard rejects this interpretation since it requires the acceptance of teleological purposes that an agent may herself reject. Thus, "unless we can show that the agent is committed to the purpose, it is possible to say that the system can do without the teleological arrangement because it can do without the purpose" (Ibid, 92). Since Herman does not even note the teleological interpretation as a contender, it seems safe to assume that she finds Korsgaard's criticism decisive.

[31] Ibid, 78.

[32] As an example we can again look to the practice of promise making. If one were to universalize the maxim of making promises you intend to break then no one would have the trust required to have faith in

is something like a logical impossibility in the universalization of the maxim . . . if the maxim were universalized, the action or policy that it proposes would be inconceivable."[33] Under this interpretation, universalization of the maxim does not merely frustrate an individual's goal but leads to a logical absurdity.[34]

Korsgaard argues that the practical interpretation is preferable through a discussion of what she calls "natural actions."[35] It is the tendency of the logical interpretation to produce false positives in not picking out clearly immoral acts as a contradiction that leads Korsgaard to conclude that the practical interpretation must be the correct one. Herman responds by pointing out that the practical interpretation is guilty of creating false negatives in the case of so called "coordination activities."[36] However, despite Herman's objection to the practical interpretation, properly understood her objections are misplaced. The problem lies in the formation of the maxims she

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your promise. Therefore, you have created a situation where practically you cannot achieve your goal of making a promise you intend to break since no one will trust you to keep your promise in the first place.

[33] Ibid, 78.

[34] Yet again we can examine the practice of promise keeping. If one were to universalize the maxim of making promises with the intention of breaking them then there could be no conception of promise making to begin with. We lose the possibility of promising even existing as a practice, and are left with a logical absurdity.

[35] Natural actions are those such as killing or harming another. Korsgaard introduces an example of employing a maxim of "killing in order to secure a job." Under the logical interpretation there is nothing about universalizing such a maxim that would result in the logical impossibility of killing to secure a job. However, from the standpoint of the practical interpretation such a contradiction can be discerned. If one universalizes a maxim of killing in order to secure a job then we can see how practically such a universalized practice would likely serve to thwart our goal of securing the job. Properly universalized we would no sooner acquire the position than have the next person kill us for the same purpose. Ibid, 98.

[36] Herman uses two examples to illustrate this problem. One is a maxim of "shopping after-Christmas sales to buy the next year's presents," and the other is "playing tennis at 10:00 on Sunday" since the courts will be empty because of church. Herman argues that there is no logical contradiction in the universalization of these maxims despite the fact that they may not be very effective or prudent. However, under the practical interpretation, universalizing that all should shop the after-Christmas sales for the next year's presents will result in after-Christmas sales being abandoned since there will be such high demand. In the case of the tennis courts, by universalizing a maxim of playing tennis at 10:00 on Sunday the courts will be most crowded instead of empty. Thus, under the practical interpretation the individual's goals will have been frustrated by the universalizing of the maxim. Yet there seems to be nothing morally wrong with such coordination activities and it is not clear why they should be rejected by the CI. Herman, 138.

wishes to test. It is only by specifying a certain time for the activity that she achieves the problematic results she relies on.[37] Thus, due to the strengths of Korsgaard's defense of the practical interpretation and the weakness of the objections raised by Herman in favor of the logical interpretation, I will rely on the practical interpretation for the purposes of this discussion.

Yet, even if we have resolved the problems surrounding the competing interpretations of contradiction in the CI, we have still not adequately addressed the problems of maxim formation noted earlier. The derivation-of-duties model is too rigid a system and its inattention to the particulars of a case make it insufficient as a guide to moral deliberation. However, attempts to use the CI as an algorithm are equally problematic since there is no clear way for properly formulating a maxim that avoids the charge of arbitrariness. It is also important to note that while utilizing the CI as an algorithm addresses the objections raised against the derivation-of-duties model as being inattentive to the details of a case, such a procedure still yields absolute rules, the only

[37] There are reasons to object to how Herman formulates the maxims beyond concerns that she has not properly captured the maxim in question. Joshua Glasgow argues that universalizing requires something more than merely proposing the maxim for all possible people. He argues that maxims must be universalized not merely across all persons but temporally as well. Glasgow develops this approach in response to concerns and criticism surrounding certain imperfect duties such as the development of our talents. He argues that by viewing universalization temporally that when we universalize a maxim of necessarily developing our talents to achieve certain ends, this means that we must be capable of invoking such a maxim at all times. This does not mean that we must at all times work to achieve that maxim but that we may not attempt to instantiate a maxim that will subvert it. Thus, a maxim that says that we will never develop our talents or allow them to rust when maximized temporally comes into conflict with the need to develop certain talents to achieve certain ends. Under the understanding that maxims must be universalized temporally as well as across all individuals we can see what is problematic with Herman's counterexamples. It is the fact that the maxims are universalized for only one specific time that allows her to reach her objection. However, if Glasgow is correct then these are not properly universalized maxims. Glasgow, Joshua M, "Expanding the Limits of Universalization," *Canadian Journal of Philosophy*, 33, no. 1, (2003): 23-49.

difference being they are more specific to the case. As a result, it may still be difficult to develop maxims that will address the problem of competing obligations.[38]

It is the problems of maxim formation that leads Herman to look at the CI procedure from the perspective of maxims. Herman adopts a procedure where the CI is used as a heuristic for moral deliberation and departs from both of the earlier attempts to use the CI in decision making procedures. Instead she utilizes the CI as a procedure for developing general guiding principles.[39] While this approach closely maps the derivation-of-duties model, what we derive are merely guiding principles that operate as a limiting function on human action, not absolute rules. This means that Herman's approach may effectively answer the objections leveled against the derivation of duties model due to its rigid, absolute structure. The CI is utilized to test sufficiently general maxims. Those that are rejected provide us with conditions where we should limit our possible choices of action. However, as guiding principles instead of absolute rules they may be overruled through the process of moral deliberation. As Herman notes, "the characteristic moments of moral deliberation will occur when an agent perceives her

[38] To illustrate the problems inherent to using the CI to create rules that determine how to handle a case, consider an example of coming across a drowning child while on the way to a promised meeting. In this specific case, if one stops to help save the child then one will fail to fulfill the promise to meet a friend. Under the derivation of duties model one will be presented with two competing duties. One must keep one's promise to a friend and yet one has a duty to aid someone in distress, at least when it carries little or no risk or loss to oneself. Under the rigorist derivation-of-duties model there is no clear way to proceed. Are we to say that one duty should always trump the other? That seems to be problematic because it is easy to find counterexamples where the duty to keep one's promise should win out (say the distress is relatively minor). Are we to attempt to specify the case to derive a particular maxim that will allow us to break our promise such as, "keep your promises unless you happen upon an individual in need?" Again the problems of specification of the maxim quickly come to light. It is also unclear in either case what one should do with the duty that is not fulfilled. Do we merely discard the duty to keep one's promise to a friend since another duty has overridden it? Neither approach seems to give us much direction in this scenario.

[39] I depart slightly from Herman's discussion here by utilizing the practical interpretation of contradiction in the CI instead of the logical interpretation she utilizes. However, this is a slight modification of her approach and merely refines what it means for us to reach a contradiction.

circumstances as exceptional or as containing conflicting moral considerations or directives."[40] Thus, the CI can be used to create a list of general principles serving a limiting function. However, it is when we believe that the specifics of a case may make a morally important difference that we enter into moral deliberation. As such, "the burden of proof is on the agent to show that her circumstances deviate in a morally significant way from those specified by the principle."[41] When we are faced with a situation that seems to depart from the general principle, we must discern what features of the case make it distinct in some morally salient way.[42] We may then use those identified reasons to engage in moral deliberation over the case and ask ourselves whether that case significantly differs from what was identified as morally problematic in the general principle.

It is important to notice that Herman's account of the CI acts as a limiting function on action, not as a required test for each action as some more demanding interpretations of the CI as an algorithm seem to require. It is the fact that many interpretations of the CI procedure as an algorithm seem to require us to present every maxim for potential action to the procedure before acting that has led many to criticize

[40] Herman, 146.
[41] Herman, 148.
[42] Let us return to the example above of competing duties of keeping a promise and saving a drowning child in order to see the advantages of Herman's method. While we may begin with general guiding principles of "keep one's promises" and "aid those in distress when it presents little risk or loss to oneself," these are not absolute rules that we must follow. Under Herman's approach we may see that the specifics of the situation raise morally salient reasons that may undermine the requirements to keep your promise. As such, it is easy to recognize that this is a situation where moral deliberation is necessary. One may then step back and realize that the need to save the drowning individual overrides the limiting function of the principle "keep one's promises." However, it is not the case that the duty to aid an individual under duress will always trump the principle to keep one's promises. Thus, it is as a limiting function that the principle operates, forcing us to articulate morally significant reasons for our violation of the limiting function of the general principle derived from the CI. Yet, we must still deliberate over the unfulfilled obligation. By breaking our promise to a friend we may derive additional duties of apology and restitution. Therefore, we must go back and reassess our obligations to keep a promise and under light of the new circumstances determine how best to fulfill that duty.

the approach as excessively demanding. However, because Herman utilizes the CI procedure as a method for developing general guiding principles she creates a moral free space in which we may operate without having to run every maxim for action through the procedure. It is only when we encounter a maxim that comes into conflict with our general guiding maxims that we must test the specific maxim. However, even if the maxim fails, there may still be morally salient reasons for accepting the maxim, in which case we must engage in moral deliberation. Hence, Herman's approach answers the problems of other approaches to the CI being too demanding or unacceptably rigid. Instead, the principles that are derived from the CI help us to identify circumstances where actions may be required or prohibited. Thus, we are generally free to live our lives without constantly having to engage in moral deliberation and incessantly submitting every action to the CI procedure to determine its acceptableness.

4. Rules of Moral Salience and Respect for Persons:

While Herman's interpretation of the proper use of the first formulation of the CI solves many of the criticisms leveled against the derivation-of-duties model and the use of the CI as an algorithm we have still not addressed the charge of arbitrariness in the formulation of maxims. Herman's requirement that maxims must be developed at a sufficiently generic level helps to alleviate certain concerns, however, it is clear that we need a more detailed understanding of how precisely maxims are to be formulated. In order to address this concern Herman introduces a concept she calls "rules of moral salience" (RMS).

For Herman, "the function of the RMS is to guide the normal moral agent to the perception and description of the morally relevant features of his circumstances of action."[43] Yet how are we to derive the RMS and if they are independent from the CI procedure what justification do they have? Herman argues that we are to derive the RMS from the "Moral Law" which requires us to respect the humanity of all persons. Herman states that, "I think of the RMS as an interpretation, in rule form, of the respect for persons (as ends-in-themselves) which is the object of the Moral Law."[44] As such, the RMS help to pick out the aspects of the case that are morally salient by forcing us to consider the case from the perspective of respect for persons. Therefore, the RMS must instruct us in three regards before we present a maxim to the universalization test. Those are:

1) Who is a moral agent or end-in-himself? What are the marks that distinguish ends-in-themselves from other entities?
2) What are the conditions of agency for ends-in-themselves? In what ways are such agents vulnerable? Are agents self-sufficient or dependent on others (and in what ways) for sustaining themselves as agents? What forms of action interfere with the exercise of agency?
3) What are the marks of reasonable claims and restraints?[45]

By helping us to identify these important features of the case we may avoid the charge of arbitrariness. Maxims are to be articulated in such a manner that they take note of such morally salient features. As a result, RMS can be used both as a mechanism to limit what maxims may be tested and to help us to identify situations and maxims that require further moral deliberation. Maxims that are shown to not properly respect the humanity of individuals need not be brought to the CI for consideration. However, at the same

[43] Herman, 78.
[44] Herman, 86.
[45] Herman, 86.

time, conditions that can be identified through the RMS as important because of considerations of respect for persons must be brought to the CI procedure and deliberated.[46]

Yet, beyond this Herman has little to say about what exactly RMS are to be or why respect for persons should operate in the manner it does concerning the development of maxims. Thus, a discussion of the second formulation of the CI, "respect for humanity" is necessary.[47] In my examination of Kant's second formulation of the CI, I will closely track the work of both Norman Bowie and Denis Arnold whose influential analysis of this account has already helped to inform practices particular to certain areas of business. In the *Groundwork of the Metaphysics of Morals,* Kant states, "act in such a way that you always treat humanity, whether in your own person or in the person of any other, never simply as a means but always at the same time as an end."[48] This is Kant's second formulation of the CI, the formula of humanity. As Arnold and Bowie point out, "Kant's defense of respect for persons is grounded in the uncontroversial claim that humans are capable of rational, self-governing activity."[49] However, we must first determine why we are to never treat humanity merely as a means but always as an end. What is it about humanity that prevents us from using it as a mere means? As rational

[46] Herman herself does not go into detail as to how exactly the RMS are to be used in conjunction with her distinct interpretation of the CI procedure. I have done my best to articulate how the two concepts are to relate, however it is important to note that this has not been clearly spelled out by Herman and is my interpretation of how we are to unite the two approaches.
[47] Herman does not tie her RMS to the second formulation but instead derives it from the "moral law." However, Herman sees the second formulation primarily as, "a further articulation of the features of rational agency that are properly responsible for contradictions arising in application of the formula of universal law" (personal correspondence). Hence, so far as the RMS are used as a mechanism for the identification of maxims that do not respect humanity and need not be applied to the CI procedure, this correlation is unproblematic and a more articulate discussion of the second formulation may aid us significantly in the identification of problematic maxims.
[48] Kant, 429.
[49] Arnold, Denis G. and Norman E. Bowie, "Sweatshops and Respect for Persons," *Business Ethics Quarterly* 8, 2, (2003): 221-242, 222.

individuals who are capable of setting and pursuing our own individual ends we are accorded dignity and for Kant dignity is priceless, meaning that nothing may outweigh or eclipse the dignity we are accorded as free and rational individuals.

> Morality is the condition under which alone a rational being can be an end in himself because only through it is it possible to be a lawgiving member in the realm of ends. Thus morality, and humanity insofar as it is capable of morality, alone have dignity.[50]

Thus, humanity must be respected because freedom to rationally set and pursue our moral ends is what gives us dignity and that dignity is beyond price. However, we still have not determined what it means to respect the humanity in persons. First, we must recognize that, to the degree that we acknowledge and respect the humanity in ourselves, we must do the same in all persons. To not do so would be inconsistent in our treatment of humanity. So we must respect the humanity in others by never using them merely as a means but always as an ends.[51] Yet how are we to understand what it is to respect the humanity in others? Arnold and Bowie rely heavily on the analysis of respect for persons provided by Thomas Hill Jr. According to Hill, respect for persons has two distinct requirements. First, we must never merely use a person as a means. This entails a negative duty to not violate the freedom of individuals and their ability to set and pursue their own ends. As a result, we may not engage in deceptive, manipulative, or coercive behavior since this necessarily undermines the ability of persons to make rational choices and to set and pursue their own ends. Engaging in such behavior

[50] As quoted in Arnold, 222.
[51] Arnold, 223.

undermines an agent's rational pursuit of her ends in favor of the pursuit of our own. It is an imposing of our own will on another.[52]

Secondly, we must treat humanity as an end. This is a positive obligation that goes beyond merely non-interference in the rational pursuit of another's ends. Bowie and Arnold characterize these positive obligations articulated by Hill as follows, "treating persons as ends-in-themselves requires supporting and developing certain human capacities, including the capacity to act on reason; the capacity to accept categorical imperatives; and the capacity to understand the world and reason abstractly."[53] Bowie adds to these positive obligations the obligations not to be indifferent to others and to be concerned with the physical welfare and moral wellbeing of others.[54] Therefore, through a more thorough understanding of what respect for persons entails it will now be easier to develop RMS that may inform our deliberation concerning the practices of DTP marketing.

5. Midrange Principles:

With a discussion of how we are to use the first and second formulations of the CI in hand, we are now left to develop a set of principles that can later be applied to the practices of DTP marketing. However, some may wonder how such principles are distinct from the RMS discussed above. As I read Herman, RMS are used as both a limiting function for the application of maxims to the CI procedure and as a mechanism to pick out the morally salient features of a case. RMS operate as a limiting function by

[52] Hill, Thomas E. Jr., *Dignity and Practical Reason in Kant's Moral Theory* (Ithaca: Cornell University Press, 1992) 50.
[53] Arnold, 223.
[54] Bowie, Norman E., *Business Ethics: A Kantian Perspective* (Malden: Blackwell Publishers, 1999), 64.

recognizing cases where persons are not properly respected. In these cases an individual may recognize that a maxim may be ruled out before it is even taken to the universalization procedure since it shows an inherent lack of respect for the persons involved in the action; namely, cases where individuals are used as means and not as ends-in-themselves. RMS can also be used to pick out the elements of a maxim that are important and must be included in its articulation. Thus, the manner in which a maxim involves another individual and their rational capacities must be a central component in the description of the maxim. While RMS may certainly serve a limiting function similar to that of a principle, they are not a guide to action. On the other hand, principles can be used to pick out duties and responsibilities required in certain situations, as well as serve as a limiting function on possible actions. Thus, principles provide a much richer and more robust guide to action than RMS.

I will develop four guiding principles in this section through appeals to both the theories of respect for persons discussed above and through the application of maxims to the universalization test of the CI procedure. I will begin by stating the principle to be derived and then follow with and explanation for and defense of the principle.

5.1. *Pharmaceutical companies are obligated to be trustworthy in their marketing practices.*

Trust is a central and founding element of all business practice. In fact, many have claimed that without trust business could not exist.[55] There are two primary mechanisms

[55] If I could not trust you to provide me with the product or service promised why would I ever give you the money demanded for such a product or service? Similarly, if businesses cannot expect payment for the

through which trust in a business context may be eroded that I will concentrate on here. Those are manipulation and deception. However, before we begin, it is vital to clearly articulate working definitions of manipulation and deception. In this regard I will rely on the account of manipulation developed by Michael Kligman and Charles M. Culver. Kligman and Culver argue that:

> The attempt to influence B's behavior takes on a manipulative character when the communicative stance or approach taken by A towards B loses this straightforward and open quality. A's primary intent is no longer to convince B, in a good faith manner, that acting as desired by A would be in keeping with B's rational assessments of outcome; it is now to procure or engineer the needed assent by bringing pressure to bear, in a deliberate and calculated way, on what he presumes to be the manipulable features of B's motivational system.[56]

However, there are many ways in which manipulation, so described, may be achieved. One strategy for manipulating an individual may play on characteristics of the individual's personality or certain psychological predispositions an individual or people in general may possess. Kligman and Culver term this "manipulation of personality traits" and go on to explain that:

> One can play on others' insecurity, gullibility, or fear, pander to their vanity, morbid curiosity, or superstitiousness, exploit their sentimentality, misplaced anger, or wishful thinking. One need not rely on character flaws or weaknesses alone to gain leverage over another. One can also appeal to the sense of duty, sympathy, friendship, or generosity in others, or utilize the rule-abidingness, industry, honesty, or cooperativity of one's fellows to advantage. In either case, it is the premeditated exploitation of some systematic character trait to achieve an ulterior purpose which stamps the behavior as manipulative.

As a specific form of manipulation, deception is another mechanism by which one may endeavor to manipulate others. While Kligman and Culver do not explicitly provide

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products or services provided why would they ever provide them in the first place? Thus, all business transactions rely on some minimal level of trust.

[56] Kligman, Michael and Charles M. Culver, "Interpersonal Manipulation," *Journal of Medicine and Philosophy*, 17, (1992): 173-197, 186-7.

an account of deception, there are two distinct methods of manipulation that they illustrate which I believe fall under this heading. First is their discussion of "deceptive communicative intent." They describe the practices as instances where:

> There is a difference between the actual communicative intent (A actually engages B because he needs action X from B in order to bring about O) and the projective communicative intent (A strives to create the false impression that he is engaging B in the interaction for other, more innocent reasons, in an effort to conceal his ulterior motives from B).[57]

The other mechanism discussed that falls under the heading of deception comes in their discussion of an imbalance of knowledge or information. Kligman and Culver cite Sociologist Peter Abell here, who claims that:

> If, in the process of changing B's preferences, A intentionally or otherwise controls B's access to relevant information, such that he either (a) reduces B's understanding of his situation (including implications of adopting one course of action rather than another or, (b) reduces the perception of means open to him, then A is manipulating B.[58]

Kligman and Culver go on to add that, "a manipulator might deliberately withhold or selectively present information, or exploit the ignorance of beliefs of his victim so as to be able to maintain control over his perceived options and steer him in the desired direction."[59] What is common to both of these accounts of manipulation is that they both rely on some form of misrepresentation of information. It is because of this common element that I group the two together under the heading of deception.

Equipped with working definitions of manipulation and deception we may now ask ourselves whether a maxim of "manipulating or deceiving individuals to increase

[57] Ibid, 188.
[58] Ibid, 192-3.
[59] Ibid, 193.

sales" is acceptable.[60] We will begin by examining the maxim from the perspective of respect for persons. To begin we must determine how exactly manipulation and deception treat persons as means and not ends-in-themselves. A useful place to begin is Sarah Buss's essay, "Valuing Autonomy and Respecting Persons." Buss questions the link between autonomy and our moral obligations towards one another.[61] While I will later argue against Buss's thesis, her discussion of the link between autonomy and moral obligations is useful in determining why manipulation and deception violate the second formulation of the CI.

Buss begins by accepting the Kantian claim that autonomy is intrinsically valuable. However, "the premise that autonomy is intrinsically valuable seems to imply nothing about the value of those who have and exercise this capacity except that they are themselves valuable insofar as they have and exercise it. In particular, it does not seem to imply that we fail to do justice to *their* value when we value them solely in their capacity as autonomous agents."[62] The problem lies in the relationship between autonomy and manipulation and deception. While manipulation and deception certainly influence an agent and limit autonomy, they do not fully prevent an agent from exercising their rational capacities or forming their own reasons for action. In fact this is what differentiates a manipulated or deceived agent from one who is compelled. So what is

[60] There is a great deal of debate in the literature over what precisely manipulation and deception entail. However, engagement in such a debate is well outside of the scope of this project. The accounts laid out above should be sufficient to explain why deception and manipulation are morally objectionable on Kantian grounds and should clearly indicate if the specific practices considered later constitute instances of manipulation and deception.

[61] For the sake of simplicity I will define autonomy merely as the ability of agents to set and pursue their own ends. There is a great deal to say about autonomy, however, such considerations are well outside the scope of this thesis. However, the very simple definition used above easily corresponds with Kant's language and will be sufficient for the discussion that follows.

[62] Buss, Sarah, "Valuing Autonomy and Respecting Persons: Manipulation, Seduction, and the Basis of Moral Constraints," *Ethics* 115 (2005): 195-235, 205.

objectionable about manipulation and deception cannot be that they prevent an agent from forming their own reasons for action.

Another possible answer comes from Herman. Herman claims that what is wrong with manipulation and deception is that the manipulator wishes to bring the agent under their causal control. By attempting to bring the victim under the deceiver's control the deceiver prevents the victim from being the source of reasons "all the way down."[63] In essence, the reasons for action are ultimately the reasons of the deceiver, not the agent. However, we may still ask what is meant by arguing that the agent must be the source of reasons "all the way down."

Buss astutely recognizes that this cannot mean that the agent acts without the presence of nonrational influences. We are constantly influenced in countless ways by nonrational or unconscious factors. Hence, such a requirement would mean that "true rational agency is not a conceptual possibility – at least not for human beings."[64] We are also prevented from claiming that the problem lies in the fact that the victim does not know of the intentions of the deceiver in their attempt to come to a rational decision since we are rarely aware (at least fully aware) of the intentions of others. Since we still consider ourselves as the author of our reasons despite this lack of knowledge, this is not an acceptable explanation either.[65]

So what are we to say? Despite the fact that Buss rejects it as an acceptable explanation, I believe the answer lies in the next explanation she considers. This explanation is that "deceit and manipulation are (usually) morally wrong because the

[63] Herman, 228.
[64] Buss, 212.
[65] Ibid, 213.

deceiver/manipulator treats his victim's reason, her capacity to govern herself, as a mere means."[66] Hence, by utilizing nonrational influences or altering/limiting access to information, a manipulator creates conditions where the victim is likely, through their own rational capacities and reasons, to come to a decision or action that corresponds to the desires of the manipulator. Hence, the manipulator does not treat the capacity of the victim to form their own reasons as an ends-in-itself but instead utilizes those capacities to encourage the victim to make a judgment that the manipulator desires.

However, Buss wishes to dismiss this explanation on the grounds that if this were truly the goal of the manipulator then "it must be that he *would* be willing to reduce her to an instrument *if this were possible*."[67] In essence, if the goal of the manipulator is to utilize the autonomy of the agent as an instrument then there should be no moral distinction for the manipulator between merely manipulating or deceiving and completely undermining the autonomy of the agent. Yet, "those who intentionally mislead or manipulate another person would not, as a general rule, be willing to treat this person as a mere instrument, even if they could do so for only a limited time and with respect to a very limited range of choices."[68] Since few who manipulate and deceive are willing to completely deny an agent of their autonomy then this means that the problem with manipulation and deception cannot be that they wish to treat the agent as a mere instrument.

However, I find Buss's objection unconvincing. Buss wishes to conflate the desire to utilize another agent's rational capacities for our own ends with the desire to

[66] Ibid, 216.
[67] Ibid, 216.
[68] Ibid, 216.

completely undermine their rational capacities and argues that since many who manipulate and deceive would be unwilling to do so this undermines the argument. Yet, should we accept this conclusion? The morally important distinction between acts of deception and manipulation and those where one completely usurps an agent's autonomy lies in a matter of degree. If autonomy is intrinsically valuable, as Buss is willing to concede, then there is a moral distinction between manipulation/deception and the complete usurpation of an agent's rational capacities. In cases of manipulation and deception the agent still maintains a level of control and power; hence the agent still possesses their intrinsically valuable autonomy, albeit at a rather limited level. The conclusion being that since manipulation and deception do less damage to autonomy than cases where one completely undermines an agent's autonomy, these acts are less objectionable. This is the reason that many who manipulate and deceive would be unwilling to completely undermine that agent's autonomy.

This distinction may also help us to work through what many may consider the overly inclusive definitions of manipulation and deception discussed above. It may be correctly remarked that such definitions will proscribe nearly all forms of marketing and even many of our normal interactions. However, by recognizing the moral significance of degrees by which one's rational agency may be undermined by such activities we may begin to see a moral distinction between many of these acts. We may grant that nearly all forms of persuasive marketing and many normal interactions are manipulative and deceptive; however, some are much more morally worrisome than others. This may mean that we have reason to wish to be more open and straightforward in all of our marketing and interactions with each other while still recognizing that there are certain

actions that are only minimally morally objectionable, while others that undermine our capacity to act for our own reasons to greater degrees are much more problematic.[69]

Therefore, it is largely the degree to which such actions are likely to successfully weaken an agent's ability to act for their own reasons that is objectionable. This is likely the underlying intuition that has guided much of the discussion of marketing and sales practices in business. It is common to place the requirements of honesty and transparency in these practices on a sliding scale based on the level of knowledge disparity between the marketer/seller and the consumer. As the disparity grows increasingly larger, the ability of the agent to maintain their own rational agency in the face of manipulative or deceptive information diminishes. Hence, manipulative and deceptive marketing becomes more morally problematic as the level of rational agency that may be retained grows smaller and the scope of the influence becomes more pervasive.

However, what is morally repugnant about manipulation and deception is that victims are not treated as an ends-in-themselves. Instead, their autonomy and rational agency is used as a means for the realization of the manipulator's goals. The manipulator does not treat the victim's autonomy as an ends-in-itself but merely as a tool that they may control through manipulation and deception for the attainment of their own ends. Yet, the degree and success of such attempts is variable, and as such, some are more objectionable than others. Therefore, according to the second formulation of the CI, a

[69] Even more, it may be argued that the advantages gained from marketing outweigh the rather minimal harms that are caused by manipulative and deceptive marketing techniques that have little impact on our rational agency. Further, there may be good reason in a world where many take advantage of our honesty and openness for us to be guarded and less than fully open and straightforward in our interactions. Certainly in a perfect world we would prefer complete honesty in our interactions, yet we do not live in that world.

maxim of manipulating and deceiving to increase profits fails. Yet, we must ask upon closer inspection just how objectionable the marketing techniques of pharmaceutical companies are. If there is only a minor knowledge disparity and the rational agency of physicians is only minimally threatened by these practices then there may be other reasons in favor of DTP marketing that override the rather minor moral objections to the practices. At that time we will be required to engage in moral deliberation to decide whether the benefits offer morally salient reasons to depart from the principle outlined above. However, if the knowledge disparity is great and the manipulation is shown to be highly effective and thus the threat to the rational agency of physicians significant, then there is strong reason to object to such practices on the grounds of respect for persons.

According to Herman's account, the fact that the maxim fails to properly respect the humanity of those being manipulated means that there is no need to progress further. Since the RMS help to pick out maxims which fail to show proper respect for persons there is no need to ask whether the maxim may pass the CI procedure. However, in the interest of providing the strongest defense of the principles I deploy, I will go on to show how such a maxim fails the universalization test as well. If one universalizes a maxim of "manipulating individuals to increase sales" then everyone who markets and sells a product will utilize manipulative and deceptive mechanisms to achieve their goal. While deception and manipulation may still function when an individual is aware that they are being manipulated and deceived, often the success of such endeavors depends on the fact that the individual being manipulated does not realize it is occurring. In order for the victim to not realize that they are being manipulated, a certain level of trust must be present. In essence, the victim must believe they are not being manipulated. However,

as far as individuals do in fact value their agency, there will be strong reasons for them to attempt to combat or remove themselves from interactions that are manipulative or deceptive. If this tendency holds true, and if everyone who markets or sells a product engages in systematic manipulation and deception, then all will be on their guard against such attempts.

It may be replied that virtually all forms of marketing and advertising are at least minimally deceptive and often times manipulative. Yet, advertising still exists. However, nearly all of us have come to realize that we must take the claims made in advertising with a grain of salt. We do not reject marketing claims outright because we recognize that there is often a degree of reliable or valuable information provided. Hence, persuasive marketing seems to operate on two levels, by manipulating and deceiving and by trying to rationally persuade us through reliable and accurate information. However, if marketing was universally manipulative and deceptive and did not have elements of rational persuasion we would likely reject such attempts outright. Thus, our skeptical receptivity to advertising likely lies more in the fact that we recognize some valuable characteristics to it rather than a claim that we would not reject such efforts were they to be universally manipulative and deceptive.

However, this healthy skepticism points to the fact that the knowledge that advertising is manipulative and deceptive means that such measures are not as effective as they would have been had individuals thought the techniques were trustworthy. Hence, the widespread recognition of these practices as manipulative or deceptive means that the goal of increasing sales is frustrated at the practical level. These implications are even more pronounced in the context of DTP marketing. The more technical a product

is, and the more dangers associated with it, the more trust is needed to protect the increasingly more vulnerable position of the consumer. Since the consumer has less ability to confirm the claims made and protect themselves trust plays a more important role as the product becomes more technical and this is especially problematic with regards to pharmaceuticals. Even more, as will be illustrated later, such practices are much more clearly manipulative and deceptive than those of general advertising. The recognition of this characteristic of DTP marketing has led to many reactions that provide empirical evidence for the claim that the universal employment of manipulation and deception will serve to frustrate the goal of increasing sales.[70]

Hence, with everyone aware of, and on guard against, manipulation the success of these marketing techniques becomes greatly undermined. It is here that the distinction between the practical and logical contradictions becomes vital. While universalizing such practices will not make it logically impossible to sell products through manipulative practices,[71] it is easy to see that, at the practical level, manipulation and deception will frustrate the goal of increasing sales. A final objection may be raised that because

[70] These trends include increasing numbers of physicians and hospitals who refuse to see pharmaceutical sales representatives, discussed on p. 57. There has been a dramatic increase in independent, third party pharmaceutical studies and education, called academic detailing, with the aim of providing accurate, unbiased information for physicians, which is discussed on p. 86. Also, increasing numbers of articles have been authored with the aim of aiding physicians in separating reliable, beneficial information from inaccurate, deceptive, and manipulative information provided by the pharmaceutical industry as discussed on p. 57. Growing numbers of medical schools require medical students and interns to be instructed in the critical examination of information provided by the pharmaceutical industry, as examined on p. 57. Even patients and consumers are growing increasingly savvy regarding the pharmaceuticals they use. This fact is evidenced in *Consumer Reports'* decision to produce an analysis of the effectiveness and price of competing pharmaceuticals, which is noted on p. 82. Finally, see Weintraub, Arlene, "The Doctor Won't See You Now," *BusinessWeek*, Feb. 5, 2007, , which claims that a primary reason for Pfizer's recent reduction to their staff of pharmaceutical sales representatives is the growing reluctance from physicians to engage in interactions with representatives.

[71] We may imagine practices that are so skillfully employed that even with individuals aware of and on guard against them, they may still be effective at manipulating at least some individuals. Even more, the fact that marketing continues to not only exist but effectively increase sales despite being widely characterized as deceptive shows that it is not logically impossible for manipulative sales practices to achieve their goal when universalized.

pharmaceuticals are so necessary, manipulative and deceptive marketing techniques will not be enough to prevent patients from purchasing and physicians from prescribing medications. However, I am not claiming that the universal endorsement of such practices will result in individuals not purchasing or prescribing medications. What I am claiming is that such practices will not effectively achieve their goal of increasing sales. So while many will still prescribe and purchase medications, sales will not have increased through the manipulative and deceptive techniques employed. Regardless, business as we know it operates largely due to a basic foundation of trust between the customer and the seller, a foundation that becomes increasingly more important the more technical and dangerous a product is due to the greater vulnerability entailed in such interactions. If such a foundation of trust is destroyed through systematic manipulation and deception it is difficult to imagine the system of business continuing to exist and function. Thus, since a maxim of "manipulating individuals to increase sales," fails the CI both at the level of respect for persons and through the universalization test the importance and central position of trust in these interactions is highlighted. Therefore we may derive the principle: *pharmaceutical companies are obligated to be trustworthy in their marketing practices.*[72]

5.2. *Physicians are obligated to be trustworthy in their decisions regarding patient care.* Since the practice of DTP marketing obviously involves physicians, it is crucial to be clear on the obligations physicians have which may have a bearing on their interactions with the pharmaceutical industry. So we may ask; if interactions with the pharmaceutical

[72] The task to determine which practices constitute instances of manipulation and deception and thus are antithetical to the principle is left to Chapter 3.

industry undermine a physician's ability to make decisions in the best interests of their patients, is this acceptable? Will a maxim of "physicians participating in interactions that threaten their ability to make independent decisions in the interest of patient care" pass the CI?

The practice of medicine is governed by a strong fiduciary duty. As originally articulated as a concept of law, fiduciary responsibility is defined by stating that, "the agreement to act on behalf of the principal causes the agent to be a fiduciary, that is, a person having a duty, created by his undertaking, to act primarily for the benefit of another in matters connected with his undertaking."[73] When applied to the practice of medicine, fiduciary responsibilities dictate that "the principal focus of medical practice should be the patient's interest. The physician's conduct in the clinical realm should consistently reflect this."[74]

Physicians have a well-established and long-standing ethic, which places patient care as its primary responsibility. In their *Code of Medical Ethics*, the AMA characterizes the patient physician relationship by stating that, "the relationship between patient and physician is based on trust and gives rise to physicians' ethical obligations to place patients' welfare above their own self-interest and above obligations to other groups, and to advocate for their patients' welfare."[75] This strong ethic is necessary because of the generally vulnerable position of the patient.[76] Patients seek the physician

[73] American Law Institute: *Restatement (Second) of the Law-Agency* § 13, (1957), 58.
[74] Freeman, Jerome W., MD, FACP and Brian Kaatz PharmD. "The Physician and the Pharmaceutical Detail Man: An Ethical Analysis." *The Journal of Medical Humanities and Bioethics* 8, no. 1 (1987): 34-9, 34.
[75] AMA, "The Patient Physician Relationship," In *AMA Code of Medical Ethics*, E-10.015.
[76] John F. Peppin argues against fiduciary responsibilities being sufficient to restrict marketing of pharmaceuticals. He contends that, as stated, the fiduciary responsibility should underlie all human interaction and as such, has no special bearing on drug marketing. However, what Peppin misses is the

as expert and must trust that expert to offer the best treatment and care possible. Without proper training, there is no way for the patient to know whether their physician is providing the best treatment for them. Since the relationship between patient and physician is clearly governed by duties of fiduciary responsibility, the patient is warranted in assuming that the decisions made by their physician are made in their best interests.[77] Thus, any decision that is influenced by considerations apart from patient care is deceptive. Since the patient comes to the physician as expert with the goal that the physician will make professional decisions in their best interests, a physician who fails to do so fails to respect the ends patients have set for themselves in seeking medical care. Physicians who make decisions based on considerations apart from patient care misrepresent themselves to their patients, thus deceiving them. As shown above, manipulative and deceptive actions show an inherent lack of respect for the humanity of the victim. Hence, the practice of allowing considerations outside of the interests of the patient should be rejected on the grounds that it does not respect the humanity of the patient.

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problematic disparity of power and information that permeates interactions in professions such as medicine and law. The patient seeks out the physician to aid in the pursuit of health. The physician is consulted because of their training and expertise in the exercise of medicine, which the patient cannot hope to achieve on their own. Because of the disparity of technical knowledge, the patient is naturally in a position of vulnerability. It is because of this inherent vulnerability that the exercise of professions such as law and medicine must be governed by respect for the principal who seeks out their services. So while I do not argue that some form of a fiduciary responsibility should underlie all relationships where an element of trust is present, it is the inherent vulnerability of principals endemic to these professions that makes the principle stronger and more binding. Since the vulnerability of the principal makes it problematic for them to guard against abuses of trust, active measures must be taken to protect them from such abuse. Peppin, John F. "An Engelhardtian Analysis of Interactions Between Pharmaceutical Representatives and Physicians." *The Journal of Medicine and Philosophy* 22 (1997): 623-41; Peppin, John F. "Pharmaceutical Sales Representatives and Physicians: Ethical Considerations of a Relationship." *The Journal of Medicine and Philosophy* 21 (1996): 83-99.

[77] The patient is especially warranted in maintaining such a belief when seen in the context of the rich and clearly articulated literature that discusses these responsibilities and in the statement by the AMA in particular since the AMA is supposed to govern the general practices of physicians here in America. Thus, there is both a strong implicit and explicit articulation of these duties that patients are both aware of and are warranted in expecting.

It is also easy to see how such a maxim would fail when universalized. As noted above, the strong fiduciary duty that governs the practice of medicine originates in the knowledge disparity between physicians and patients. The fact that patients seek out physicians predominantly lies in the fact that they can rely on the physician to utilize their greater expertise to further their own purposes (in this case better health). Therefore, such a relationship hinges on trust between patient and physician. However, if all physicians were to allow factors outside of the best interests of the patient to govern their decisions then the foundation of trust necessary for the practice of medicine would greatly diminish. It is unlikely that patients would continue to subject themselves to the whims of physicians who make decisions for reasons of personal gain or based on the interests and influences of third parties. At the practical level the lack of trust would make the process of providing care excessively cumbersome. Physicians must currently explain treatments to patients and obtain informed consent, however, one can imagine how difficult and time consuming this process would become if patients had very little reason to trust the opinions and motives of their physicians. Again, it is the betrayal and destruction of trust that is fundamental to the failure of the maxim. Therefore, it is trust that must be protected and we may derive the principle, *physicians are obligated to be trustworthy in their decisions regarding patient care*.[78]

5.3. *Pharmaceutical companies have a duty of nonmaleficence with regard to the patients who utilize their products.*

[78] Examination of practices that negatively affect physicians' abilities to make decisions in the best interests of their patients will follow in Chapter 3.

The principle of nonmaleficence has been most clearly articulated by Tom Beauchamp and James Childress in their seminal work, *Principles of Biomedical Ethics*. While I do not find the common morality upon which Beauchamp and Childress build their principles persuasive, their account of nonmaleficence does provide a good starting place for an examination of negative duties that surround actions that may directly or indirectly harm persons. Beauchamp and Childress define nonmaleficence by stating that, "the principle of nonmaleficence asserts an obligation not to inflict harm on others," and define harm in the nonnormative sense of "thwarting, defeating, or setting back some party's interests."[79]

It is easy to see how such a principle is derived out of the examination of respect for persons discussed above. Proper respect for the humanity of persons requires that we respect them as ends-in-themselves. As such, a negative duty of noninterference can be derived. It is quite clear that practices that prevent or undermine the ability of individuals to set and pursue their own ends or interests are clear violations of the requirements laid out under the formula of humanity. On a more specific level, we may see how certain practices within the pharmaceutical industry may negatively infringe on the ability of individuals to set and pursue their own ends by harming patients. This harm comes primarily in two distinct forms. The first is direct harm to the health and wellbeing of patients. A maxim of "increasing sales no matter the effects on patients" will fail because often the pursuit of profit will come at the expense of patients. Such harm undermines the pursuit of individuals' ends. As far as the primary interest of patients is the optimal treatment of their condition and the goal of overall health, such influences directly

[79] Beauchamp, Tom L and James F. Childress, *Principles of Biomedical Ethics* 5th ed., New York: Oxford University Press, 2001.

interfere with their pursuit of those interests and improperly respect their humanity.

The other manner in which interactions with the pharmaceutical industry may be seen to harm patients is less directly, through financial harm. Many claim that marketing of pharmaceuticals, and DTP marketing in particular, unnecessarily drive up health care spending, which through higher pharmaceutical prices or higher insurance premiums, have a negative financial impact on patients. Since money is necessary for the pursuit of nearly all ends an agent may set, especially those vital to survival including food, shelter, and health care, financially harming patients can be seen as frustrating or undermining their ability to set and pursue their own ends. Thus, such financial harm directly conflicts with the negative duties inherent to respect for persons.[80] Hence, maxims that harm individuals are prohibited through the requirements of respect for persons. Since these maxims are prohibited by the RMS through appeals to respect for persons we may derive a negative duty of nonmaleficence. Therefore, *pharmaceutical companies have a duty of nonmaleficence with regard to the patients who utilize their products.*[81]

5.4. *Pharmaceutical companies are obligated to not undermine the prudential expenditure of limited health care resources.*

As health care spending in the United States continues to outstrip the growth of the GDP, the sustainability of the industry becomes increasingly threatened. Eventually consumption of the GDP by health care spending will begin to threaten many essential

[80] I will leave the discussion of the universalization of such a maxim for the following principle. While both of these principles are closely related, their implications diverge significantly and deserve independent consideration.

[81] Discussion of physical harm to patients through improper prescribing will be developed in Chapter 3 while the discussion of financial harm will follow in Chapter 4.

elements of our federal government such as defense and maintenance of our national infrastructure. Ultimately we will reach a point of critical mass in which the system will become unsustainable and collapse. These are alarming and unfortunate realities that we presently face.[82]

Thus, under the realities of our current situation we may examine whether a maxim of, "undermining the prudential expenditures of health care resources in the pursuit of profit" may pass the CI. As each element of the health care industry engages in practices that drive up health care spending without corresponding increases in benefits then the current problem of unsustainable health care spending becomes dramatically exacerbated. Since the system already teeters on the verge of collapse, the universalization of such practices will very quickly lead to the destruction of the health care industry. Unfortunately, in order for this result to actually occur we do not need to imagine even the universal institution of such practices. All that needs to occur is that the system continues at the pace already set and this outcome will be an inevitability. Thus, there is an imperative for all elements of the industry to exercise prudence in the spending that they encourage.

As discussed above, increases in health care spending financially harm patients. If such increases in spending cannot be justified through benefits provided to patients by the new drugs or therapies, then it may be claimed that this does financial harm to patients and violates the obligation of nonmaleficence invoked above.[83] However, we

[82] The details of these concerns will be discussed at length in Chapter 4. For the present allow the claims to stand as a contingent aspect of the discussion of the principle.

[83] It is interesting to note that the principle developed here can be derived out of a more detailed discussion of nonmaleficence. However, the implications of this principle are so important and have such a wide bearing on the health care industry as a whole that it warrants independent treatment.

may also evaluate the maxim in reference to the universalization test. I develop this aspect of the issue separately from the discussion of nonmaleficence above because these practices have implications on justice as well as harm to individuals. Since the health care industry is so fragile, if the system collapses it will become difficult or even impossible to find care. Since the consequences of decisions concerning health care expenditures are not isolated to the individuals who make them, they inherently involve issues of justice.[84] The destruction of the health care industry will not only harm those who need care and will be denied it but will deny access to individuals who will need care in the future. Since it is difficult to claim that these individuals will be harmed by care that is not available it will be difficult to say that their interests should be respected under the principle of nonmaleficence. However, these implications are issues of justice since the unprudential expenditure of resources precludes the possibility of these individuals obtaining care in the future. Hence the principle, *pharmaceutical companies are obligated to not undermine the prudential expenditure of limited health care resources* may be derived.[85]

We have now developed four midrange principles that may offer guidance in the analysis of the specific practices that surround DTP marketing. These principles are:

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[84] Norman Daniels has done a great deal of work concerning the Kantian demands of justice and health care; Daniels, Norman. *Just Health Care*. Cambridge: Cambridge University Press. 1985; Daniels N, Light D, Caplan R. 1996. *Benchmarks of Fairness for Health Care Reform*. New York: Oxford University Press; Daniels N, Kennedy B, Kawachi I. 2000. *Is Inequality Bad for Our Health?* Boston: Beacon Press; Buchanan A, Brock D, Daniels N, Wikler D. *From Chance to Choice: Genes and Social Justice*. Cambridge University Press, 2000; and Daniels N. 2001 Justice, Health and Health Care. *American Journal of Bioethics* 1:2:3-15.

[85] Chapter 4 will discuss in detail the problem of me-too drugs and the charge that the pharmaceutical industry unnecessarily drives up health care spending.

1) *Pharmaceutical companies are obligated to be trustworthy in their marketing practices*
2) *Physicians are obligated to be trustworthy in their decisions regarding patient care*
3) *Pharmaceutical companies have a duty of nonmaleficence with regard to the patients who utilize their products*
4) P*harmaceutical companies are obligated to not undermine the prudential expenditure of limited health care resources*

Any aspects of DTP marketing that can be shown to violate the principles articulated above are susceptible to the charge that they are morally unacceptable. However, as Herman's account asserts, these principles are not absolute rules that cannot be overridden. If there are morally salient reasons that may provide sufficient grounds for the abandonment of these principles[86] then moral deliberation is required. Regardless, we may now proceed to the analysis of the particular practices that comprise DTP marketing and assess whether they may be defended on moral grounds.

[86] For instance, if the claim that profits at the current levels are necessary for the continued development and production of new and innovative pharmaceutical products is true, then it may give reason to question adherence to these principles. At such a point we would be required to step back and consider whether adherence to these principles, which could threaten the financial capability of pharmaceutical companies to continue to develop new and innovative therapies, carry consequences that are unacceptable. This claim will be weighed in the conclusion to Chapter 4.

Chapter 3

Marketing and Prescribing

Concerns over whether the practices of DTP marketing properly respect the humanity of those who are impacted generally center on two distinct groups. These are the physicians who are targeted by DTP marketing and their patients. The impact of these practices is especially worrisome because of the delicate nature of the patient physician relationship and the incredible power and responsibility that physicians are entrusted with. In this chapter I will examine the details of the practices of DTP marketing in order to determine whether they involve deception and manipulation and thus violate the first principle of, *pharmaceutical companies are obligated to be trustworthy in their marketing practices*. I will then examine whether these interactions interfere with physicians' abilities to make proper prescribing decisions in the best interests of their patients. If such interactions can be shown to negatively impact prescribing decisions and compromise physicians' abilities to make unbiased decisions in the interests of their patients then physicians are in violation of the second principle, *physicians are obligated to be trustworthy in their decisions regarding patient care*. As such, physicians are rightly charged with being complicit in the ethically unacceptable practices that make up DTP marketing. Finally, I will examine the impact that such interactions have on patient care. I will argued that based on a substantial body of empirical data, such practices do direct physical harm to patients through encouraging improper prescribing. As a result, these practices violate the third principle of;

pharmaceutical companies have a duty of nonmaleficence with regard to the patients who utilize their products.

1. Marketing or Education:

We may begin by examining the practice of pharmaceutical sales representatives (PSR's) visiting physicians to market a specific product, commonly referred to as "detailing." The pharmaceutical industry defends the practice of detailing by claiming that they provide valuable, unbiased information to physicians. In their "Code of Interactions with Health care Professionals," PhARMA[87] states that, "Informational presentations and discussions by industry representatives and others speaking on behalf of a company provide valuable scientific and educational benefits."[88] They go on to claim that, "Interactions should be focused on informing health care professionals about products, providing scientific and educational information, and supporting medical research and education."[89] Every major American pharmaceutical company voluntarily adopted PhARMA's code of conduct as a guideline for interacting with physicians, thus these companies have agreed that interactions should be governed by these considerations.

Even more, several companies independently hold themselves to similar standards regarding interactions with health care professionals. Merck states that, "Information furnished to our customers about our products and services . . . must be useful, accurate,

[87] The agency that serves as the representative body for America's leading pharmaceutical research and biotechnology companies.
[88] PhARMA, "Code of Interactions with Health care Professionals," http://www.phrma.org/files/PhRMA%20Code.pdf, 9 (accessed 3/22/07).
[89] Ibid, 7.

supported by scientific evidence where relevant, and presented honestly, fairly and by proper means."[90] Bristol-Myers Squibb affirms that, "Our advertising should always be truthful, and specific claims must be fair and substantiated."[91] While attempts by companies such as Merck and Bristol-Myers Squibb to reaffirm their commitment to such high standards are laudable, the fact that all of the major American pharmaceutical companies adopted the guidelines set out by PhARMA means that they have all agreed to hold themselves to these guiding principles.

Thus, it is clear that the industry wishes to portray interactions between PSR's and physicians as primarily an educative endeavor. Since the industry depicts the practice of pharmaceutical detailing in this manner, physicians have reason to assume that the information they receive from PSR's is both accurate and unbiased. Therefore, if it can be shown that the information provided by PSR's is inaccurate and biased then the practice of detailing is necessarily manipulative and deceptive. By portraying inaccurate, biased information as reliable and balanced the industry undermines physicians' abilities to pursue their professional goal of making the best possible prescribing and treatment decisions for their patients.

However, it is important to recognize that the pharmaceutical industry has not unnecessarily adopted such high standards for itself. There are persuasive arguments that support the need for information provided by industry representatives to be accurate and unbiased. Despite the fact that physicians are highly educated, there is still a significant

[90] Merck, "The Basis of our Success: Code of Conduct," http://a248.e.akamai.net/7/248/430/20061026224641/www.merck.com/about/code_of_conduct.swf, 8 (accessed 3/22/07).
[91] Bristol-Myers Squibb, "Standards of Business Conduct and Ethics," Nov. 2004, http://www.bms.com/aboutbms/corporate_governance/content/data/sbc3.pdf, 15 (accessed 3/22/07).

discrepancy in the knowledge that PSR's have over physicians. New pharmaceuticals are generally the most aggressively marketed. As such, the physician may have little or no knowledge of the mechanics or characteristics of the new product. This raises concern over whether the physician may have enough information to ask the right questions and effectively fill in the gaps left by inaccurate or biased information. Further, a PSR characteristically markets only one specific product, or at most a select handful of products. Thus, the expectation that the PSR is capable of reviewing and educating themselves on all of the pertinent information about a product is not unreasonable. However, physicians are notoriously busy and have a multitude of products and therapies that they must educate themselves about. Therefore, the expectation that a physician has the time and capacity to independently research and become an expert on each product she utilizes is unrealistic. The demands of their busy schedules combined with the incredible volume of ever changing information about each treatment and therapy means that it is often extremely difficult for a physician to be knowledgeable about all of the important aspects of each product she uses. Thus, at least to some minimum degree, physicians must trust the opinion of others to help inform and guide their decisions. This means that there is often a substantial discrepancy in the knowledge that physicians have pertaining to pharmaceuticals versus the knowledge it seems reasonable to expect PSR's to possess (or the knowledge they are at least presenting), placing them in a vulnerable position regarding the information they receive from PSR's. Since PSR's are presented as experts about the product they are marketing, they have the potential to be an excellent source of information about a specific product or treatment. Even more, the impossibility of physicians becoming experts on every treatment they employ means that they are in a

challenging position to attempt to assess the accuracy and fairness of information they receive. All of these considerations help to articulate why it is important that the information presented by PSR's be as accurate and unbiased as is possible.

However, no matter how PhARMA characterizes the interaction between PSR's and physicians, there is little doubt that PSR's are salespeople. Lexchin recognizes this dual role of PSR's, saying that while they have the goal of increasing prescription rates, they "are also supposed to be educators. They act as intermediaries to correct the informational asymmetry about pharmaceuticals that exists between the drug companies and doctors."[92] As far as PSR's are educators, they serve as agents of physicians. The fact that PSR's often operate as agents in the interests of physicians combined with the vulnerable position of physicians regarding many products entails that that the duties of PSR's to physicians as educators should always eclipse their duties to the pharmaceutical companies as salespersons. As such, "there is an obvious potential conflict of interest in the two roles of detailers. Increasing consumption of drugs is not always compatible with better prescribing or better health."[93] Dangers inherent in the dual role of PSR's means that they must strive at all times to hold their obligations to the physicians they interact with above the pursuit of increased prescribing. Thus, there is good reason for the pharmaceutical industry to profess such high standards for the information provided by PSR's.

[92] Lexchin, Joel. "Doctors and Detailers: Therapeutic Education or Pharmaceutical Promotion?" *International Journal of Health Services* 19, no. 4 (1989): 663-79, 664.
[93] Ibid, 664.

2. Gift Giving:

There has been much progress made in attempts to regulate and reign in the practice of gift giving associated with pharmaceutical detailing. PhARMA, individual pharmaceutical companies, and the American Medical Association (AMA) have all voluntarily adopted guidelines that severely restrict the practice. Under PhARMA's current guidelines, gifts have been restricted to "items primarily for the benefit of patients" with a value of less than $100 and items of minimal value . . . primarily associated with a health care professional's practice (such as pens, notepads, and similar "reminder" items with company or product logos)."[94] PhARMA's guidelines clearly state that gifts of "cash or cash equivalents" are not permitted, nor are items "intended for the personal benefit of health care professionals." While it is often unclear as to what products can be construed as "primarily for the benefit of patients" versus "intended for the personal benefit of health care professionals," the voluntary implementation of these guidelines by PhARMA indicates a commitment to eliminate the often times outlandish gifts given in the past.

PhARMA has also instituted more restrictive guidelines concerning the purchasing of meals for physicians. So long as they are provided in conjunction with informational presentations or discussions, "occasional meals (but no entertainment/recreational events) may be offered so long as they: (a) are modest as judged by local standards; and (b) occur in a venue and manner conducive to informational communication and provide scientific or educational value."[95] PhARMA has also addressed concerns raised around the practice of purchasing meals for friends

[94] PhARMA, 19.
[95] Ibid, 9.

and family of physicians by clearly stating that the "inclusion of a health care professional's spouse or other guests is not appropriate."[96] Finally, the often lambasted "dine and dash" programs, where physicians spend only a nominal period of time with the PSR and then are allowed to leave with takeout food for the whole family have been eliminated.

Similarly, the AMA has released its own guidelines that largely mirror those of PhARMA. According to the AMA guidelines, "any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function."[97] The AMA also allows, "gifts of minimal value . . . as long as the gifts are related to the physician's work (e.g., pens and notepads)."[98] Similar to PhARMA's guidelines, gifts are to be restricted to no more than $100. Finally, meals provided by industry must be modest and must include an educational component of independent value.[99]

Despite attempts to reform interactions between physicians and the industry, neither the AMA, PhARMA, nor PhARMA's constituent companies have shown a willingness to abandon the practices of gift giving. The industry defends the practices by arguing that gifts that are given are done so in the interest of patients. Further, "according to PhARMA, the exchange is balanced because gifts are given as

[96] Ibid, 9.
[97] AMA, "Gifts to Physicians from Industry," in *AMA Code of Medical Ethics*, E-8.061 (accessed 3/22/07).
[98] Ibid.
[99] Ibid.

compensation for the time physicians spend becoming educated about products."[100] Thus, items such as stethoscopes, textbooks, etc. are items that would ultimately benefit patients. Further, items of nominal value such as pens and notepads are "reminder" items and merely serve to remind the physician of the product being promoted. Finally, the purchasing of meals is justified by the fact that physicians are extremely busy. As a result, it would be difficult for many PSR's to gain access to physicians, much less spend time sufficient to convey the detailed, complex information about the product they are marketing, if they were not allowed to do so over meals. Despite their busy schedules physicians still have to eat. Therefore, why not use the time wisely to educate physicians about new pharmaceutical products? Finally, PSR's justify the purchasing of the meal as a customary small token of appreciation for the time spent by the physician educating herself about the product in question.

However, despite efforts to reign in the practice of gift giving and the justifications provided for its continued utilization, many continue to strongly object to the practice. Critics claim that the practice of gift giving sets up a subconscious reciprocal relationship between the physician and the PSR. There is concern that this relationship often has strong and far reaching implications on the prescribing decisions of physicians. If these claims can be substantiated by a sufficient body of empirical data then there is strong circumstantial evidence that indicates that the pharmaceutical industry uses the practice of gift giving as a means to capitalize on the subconscious desire to reciprocate the exchange. Since there is often no mechanism by which a

[100] Katz, Dana, Arthur L. Caplan, and Jon F. Merz. "All Gifts Large and Small: Toward an Understand of the Ethics of Pharmaceutical Industry Gift-Giving." *The American Journal of Bioethics* 3, no. 3 (2003): 39-46, 42.

physician can return the favor other than by prescribing the PSR's product, there is concern that prescribing decisions are often based on such exchanges instead of on the merits of the particular drug. Therefore, if these concerns can be substantiated by empirical studies, there is a strong indication that despite efforts to limit the practice, and despite arguments that attempt justified its continued use, the practice is inherently manipulative. As such, it capitalizes on deep seated social and psychological predispositions in order to influence prescribing behavior, undermining physicians' rational pursuit of providing optimal care and treatment for their patients.

3. Patient Care:

Beyond concerns over deception and manipulation of health care professionals, there is fear that interactions between industry and physicians harm patient care. Practices that can clearly be shown to harm or endanger patient care are problematic from both the perspective of physicians and the pharmaceutical industry. From the perspective of pharmaceutical companies, practices that undermine patient care are worrisome because they violate their obligation of nonmaleficence towards patients. That the pharmaceutical industry recognizes this special relationship with patients is clearly shown in their guiding principles. PhARMA states that all interactions with health care professionals are, "intended to benefit patients and to enhance the practice of medicine."[101] Further, a review of the mission statements of the top 5 most profitable U.S. pharmaceutical companies in 2004[102] reveals that all of the companies, with the

[101] PhARMA, 7.
[102] These are in order: Pfizer Inc., Johnson & Johnson, Merck & Co., Inc., Abbott Laboratories, and Bristol-Myers Squibb Company according to the 2004 SEC form 10-K for each company.

exception of Bristol-Myers Squibb, include a dedication to patient care as a guiding principle.[103] Most strongly is the statement by Merck that, "company decisions are driven by what is right for patients."[104] Marketing techniques that seek to promote the use of a product at the expense of patients clearly use patients as a means to the goal of increasing profits and violate the duty of nonmaleficence.[105] As a result, practices that can be shown to undermine patient care should be voluntarily abandoned by the pharmaceutical industry.

Secondly, issues surrounding patient care are even more worrisome from the perspective of physicians. If it can be shown that the practices surrounding DTP marketing negatively influence patient care then physicians not only frustrate the rational pursuit of health and treatment by their patients, but in violating their fiduciary duties they also deceive their patients. Thus, if claims that practices surrounding DTP marketing clearly harm patient care are substantiated then physicians are in violation of their duty to be *trustworthy in their decisions regarding patient care* and have a strong moral imperative to avoid interactions with the pharmaceutical industry.

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[103] Pfizer, http://www.pfizer.com/pfizer/are/index.jsp (accessed 3/22/07); Johnson & Johnson, http://www.jnj.com/our_company/our_credo/index.htm(accessed 3/22/07); Merck, http://www.merck.com/cr/ (accessed 3/22/07); Abbott Laboratories, http://www.abbott.com/global/url/content/en_US/10.10:10/general_content/General_Content_00003.htm (accessed 3/22/07); Bristol-Myers Squibb, http://www.bms.com/aboutbms/content/data/ourple.html (accessed 3/22/07). Bristol-Myers Squibb states a dedication to "extend and enhance human life by providing the highest-quality pharmaceutical and related health care products." Thus, while they show a concern for patients, according to their mission statement this consideration is limited to providing high quality pharmaceuticals and health care products.

[104] http://www.merck.com/cr/ (accessed 3/22/07)

[105] I will discuss the evidence that indicates that the pursuit of profit often harms patients later in this and the following chapter.

4. Accuracy and Bias:

Claims that information provided by PSR's is unreliable and biased are notoriously difficult to substantiate. Judgments about accuracy and bias are often highly subjective. Even more, interactions between PSR's and physicians are generally one-on-one, at a private table or behind closed doors. Thus, as is pointed out by Ziegler et al, "the one-on-one interaction between a pharmaceutical representative and a physician is hard to regulate."[106] Ashley Wazana's landmark analysis of 538 studies regarding the interaction between industry and physicians concluded that most physicians "believe that representatives provide accurate information about their drugs," however, they "are equivocal in their beliefs that representatives could provide accurate information on established or alternative drugs."[107] Yet, the claim that PSR's provide information that is strongly biased, and in this sense unreliable, seems to be almost universally accepted in the literature. Wazana notes that most physicians believe that PSR's "prioritize product promotion above patients' welfare."[108] Not surprisingly, there are numerous articles that discuss the problems inherent in utilizing information provided by PSR's, all recognizing that information provided is not likely to be balanced or fair.[109] Even more, there are

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[106] Ziegler, Michael G., MD; Pauline Lew, PharmD; Brian C. Singer, PharmD. "The Accuracy of Drug Information From Pharmaceutical Sales Representatives." *JAMA* 273, no. 16 (1995), 1296-8. 1296.

[107] Wazana, Ashley, MD. "Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?" *JAMA* 283, no. 3 (2000): 373-380, 375.

[108] Ibid, 375.

[109] Griffith, David, "Reasons for not seeing Drug Representatives," *BMJ*, 319, (1999), 69-70; Lexchin, Joel. "Doctors and Detailers: Therapeutic Education or Pharmaceutical Promotion?" *International Journal of Health Services* 19, no. 4 (1989): 663-79; Lexchin, Joel, "What Information do Physicians Receive from Pharmaceutical Representatives?," *Canadian Family Physician*, 43, (1997), 941-5; Prosser, Helen, Tom Walley, "Understanding why GPs see Pharmaceutical Representatives: A qualitative Interview Study," *British Journal of General Practice*, 53, (2003), 305-11; Strang, David, Micheline Gagnon, William Molloy, Michel BTdard, Peteris Darzins, Edward Etchells, Warren Davidson, "National Survey on the

numerous articles that attempt to provide guidance to physicians in an attempt to help them separate the useful information from biased, unreliable information.[110]

Beyond a mere predominance of opinion within the profession and the literature, there are a precious few studies that have attempted to objectively determine the accuracy and reliability of information provided by PSR's. The first of these studies was conducted by Elina Hemminki in 1977. The study analyzed the information provided in forty-six presentations. Hemminki found that in almost half of the presentations given PSR's did not mention side-effects and contraindications, even though they were listed in the *Remedia Fennica*. Other drugs for the same condition were often mentioned, however, in 78% of the cases the drug was preferred to the alternative drug, and 19% of the time the alternative was said to be equally good in principle but the presented drug was better because of some special feature.[111]

In 1986 Hemminki conducted a follow-up study. Once again strong indications of bias and disturbing omissions were observed. In this study Hemminki found that side effects were not mentioned in contradiction to the drug catalogue 67% of the time, up from 44% in the 1977 study. Contraindications were omitted 65% of the time, up from 46% in 1977. Once again competing treatments were often mentioned and 82% of the

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Attitudes of Canadian Physicians Towards Drug-Detailing by Pharmaceutical Representatives," *Annals of the Royal College of Physicians and Surgeons of Canada*, 29, no 8, (1996), 474-8.

[110] Carpenter, William T. "How the Doctor can Counter Commercial Bias in the dissemination of Pharmacotherapeutic Knowledge," *The Journal of Nervous and Mental Disease,* 190, no 9, (2002), 593-6; Shaughnessy, Allen F., David C. Slawson, and Joshua H Bennett, "Separating the Wheat from the Chaff: Identifying Fallacies in Pharmaceutical Promotion," *Journal of General Internal Medicine*, 9, no 10, (1994), 563-8; Shaughnessy, Allen F., David C. Slawson, and Joshua H Bennett, "Teaching Information Mastery: Evaluating Information Provided by Pharmaceutical Representatives," *Family Medicine,* 28, no 3, (1996), 166-7; Wager, Elizabeth, "How to Dance with Porcupines: Rules and Guidelines on Doctors' Relations with Drug Companies," *BMJ,* 326, (2003), 1196-8.

[111] Hemminki, Elina, "Content Analysis of Drug-Detailing by Pharmaceutical Representatives," *Medical Education*, 11, (1977), 210-5.

comparisons favored the PSR's drug. In 18% of the comparisons the drugs were presented equally but the PSR's drug was never the drug of second choice.[112]

A third study was conducted in 1995 by Ziegler et al. The study found that out of a sample of 106 statements made by twelve pharmaceutical reps in 13 presentations, that twelve, or 11% of the statements, were inaccurate.[113] In order to be considered inaccurate the statements had to contradict prescribing information in the 1993 *Physicians' Desk Reference* or literature quoted or handed out by the sales representative, a pharmacist and a physician had to independently assess the statement as incorrect, and a search of reference books, drug company brochures, and MEDLINE files provided no support for the statement. Of the inaccurate statements identified, all were favorable towards the drug being marketed and several could have been dangerous if taken at face value. While seemingly minor, an 11% rate of inaccurate statements is still significant and should raise concerns over the accuracy of the information being provided by pharmaceutical reps. Even more worrisome is the fact that these presentations were delivered in the presence of at least one faculty physician and with the knowledge that the presentation was being taped. Both of these factors raise concerns over whether a greater incidence of inaccurate statements may be common in circumstances of one-on-one meetings between reps and physicians. Certainly, it seems unlikely that the rate of inaccurate statements would be smaller in this context. Further, the study found that 49% of statements made about the promoted drug were favorable, 31% were neutral, and only

[112] Hemminki, Elina, "Commercial Information on Drugs: Confusing the Physician?," *Journal of Drug Issues*, 18, (1988), 245-57.
[113] Ziegler, Michael G., MD; Pauline Lew, PharmD; Brian C. Singer, PharmD. "The Accuracy of Drug Information From Pharmaceutical Sales Representatives." *JAMA*, 273, no. 16, (1995): 1296-8

19% were unfavorable.[114] The same study also found that all of the statements made about a competitor's drug were unfavorable and that the reps "usually do not mention adverse effects or better alternative agents."[115]

However, the findings of the three studies must be considered critically. The relevance of the Hemminki studies may be questionable both because of their age and the fact that they took place in Finland. Yet, despite the fact that the studies were conducted in Finland the pharmaceutical companies represented were multinational corporations, many residing in the United States. Therefore, it seems reasonable that these corporations should hold the PSR's to the same standards in each country they operate in. Certainly, codes of conduct concerning interactions with health care professionals are meant to apply universally to all employees of these multinational corporations, with the only exception being when local laws are more restrictive than the policies outlined in the codes. As for concerns over the age of the studies, these objections may be mitigated by the fact that each successively more recent study seems to substantiate the conclusions of the earlier studies. Finally, the fact that the Ziegler et al study was conducted in the United States with similar findings to the two earlier Finnish studies helps to assuage concerns that the findings are unique to Finland.

There is even reason to be concerned that PSR's may not be sufficiently educated to provide the reliable information that it seems reasonable to expect them to provide. Carl Elliot has highlighted this issue in discussing what is apparently a common

[114] Ziegler et al, 1297. While 19% incidence of unfavorable comments may be justified by claiming that there were not many negative aspects to be discussed this seems unlikely. Anyone familiar with the incredible number of side effects and contraindications of nearly every pharmaceutical should be concerned that such a small number of unfavorable comments were conveyed. However, without a greater knowledge of the details of the presentations the evidence is circumstantial.
[115] Ziegler et al, 1297.

sentiment of PSR's. Elliot quotes one PSR as saying that "Reps are the last to know" about potential problems with their drugs.[116] Concerns over the knowledge possessed by PSR's are mirrored in another study conducted by Hemminki. The study found that there was a tendency to emphasize capabilities as a salesperson over technical knowledge and education in advertisements for job openings for PSR positions. Hemminki presented PSR's with thirteen statements which they were asked to agree or disagree with. The mean percentage of correct answers was 62% and the study concluded that "some representatives' knowledge about clinical trials and tetrogenicity, two cardinal elements in their information, was inadequate."[117] Again the age of the study and the fact that it took place in Finland raises concerns over the relevance of the findings. However, the fact that again most of the PSR's worked for multinational corporations seems to suggest that the findings may be relatively safely extrapolated to PSR's in the United States.

Finally, there is disturbing evidence to suggest that even when PSR's restrict themselves to empirical data regarding the merits of their drug versus a competitor's, that the information may still be strongly biased. A study by Daniel Safer reviews recently published pharmaceutical industry sponsored comparative psychotropic drug trials in an attempt to discern whether design and reporting modifications are utilized to alter results in favor of the sponsoring company's drug. Safer discovered thirteen mechanisms through which studies are tailored to benefit the sponsoring company's drug. These are; using doses outside the usual range for competitive advantage, substantially altering the dose schedule of the comparison drug for competitive advantage, using self-serving

[116] Elliot, Carl, "The Drug Pushers," *The Atlantic Monthly*, April (2006), 2-13.
[117] Hemminki, Elina and Terttu Pesonen, "The Function of Drug Company Representatives," *Scandinavian Journal of Social Medicine*, 5, (1977), 105-14, 108.

measurement scales and making misleading conclusions from measurement findings, selecting the major findings and endpoints post hoc, masking unfavorable side effects, repeatedly publishing the same or similar positive studies to increase the impact, selectively highlighting findings favorable to the sponsor, editorializing for the sponsor in the abstract, publishing the obvious to emphasize a point, touting nonsignificant but favorable differences and negating dropout difference statistically, selecting subjects and altering the duration of trials to achieve a favorable outcome, withholding unfavorable results, and masking sponsorship. The result is that "an estimated 89 to 98% of comparative drug treatment studies funded by pharmaceutical companies yield results that are favorable to their company's product."[118]

Hence, there is very strong, persuasive evidence that suggests that the information provided by PSR's is not the reliable, unbiased educative tool the industry defends it as being. As such, the presentation of such biased and unreliable information is inherently deceptive and manipulative of the physicians it is directed towards. PSR's provide physicians with incomplete or misleading information with the goal of encouraging physicians to prescribe or increase their prescribing of the medication in question. As far as the physician believes this information to be reliable and makes decisions in the interests of their patients, the rational, autonomous capacity of physicians is used by the PSR in order to achieve their goal of increasing sales. Hence, the physician is used as a mere tool for the achievement of the PSR's goal of increasing sales, not as an end-in-himself. Hence, such practices are a clear violation of the principle of; *pharmaceutical companies are obligated to be trustworthy in their marketing practices.* Therefore, it is

[118] Safer, Daniel J, "Design and Reporting Modifications in Industry-Sponsored Comparative Psychopharmacology Trials," *The Journal of Nervous and Mental Disease*, 190, no 9, (2002), 583-92, 583.

imperative for the pharmaceutical industry to abandon such practices and for physicians to recognize the dangers inherent in interactions with PSR's and discontinue contact with them.

5. Manipulation Through Gifts:

Much easier to substantiate than claims of bias and inaccuracy are concerns that the practice of gift giving undermines the physician's ability to make rational prescribing decisions. There is an enormous body of social science data that examines the impact of gift giving. Evidence suggests that when a gift of any size is presented it creates a sense of indebtedness in the recipient.[119] Some even claim that reciprocal behavior is an adaptive mechanism that has helped advance human society.[120] Additionally, the degree that the recipient feels an obligation to reciprocate does not seem to be related to the size of the gift.[121] Even more, there is evidence that suggests that we are more receptive to information when it is received while eating.[122] Finally, pharmaceutical companies employ highly educated and intelligent marketers and it seems safe to assume that they would not invest the substantial resources in terms of time, money, and manpower in the providing of gifts to physicians if they were not aware of the impact that such practices have. Thus, there is a substantial body of social science data that indicates that the practices of gift giving by pharmaceutical companies capitalizes on deep seated social and psychological tendencies to try and reciprocate.

Even more disturbing is that this tendency operates on a subconscious level and as a result goes largely unrecognized and is denied by physicians. Wazana's analysis shows

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[119] Gouldner, Alvin W, "The Norm of Reciprocity: A Preliminary Statement," *American Sociological Review*, 25, (1960), 161-78; Levi-Strauss, Claude, *The Elementary Structures of Kinship*, Boston: Beacon Press, 1969; Mauss, Marcel, *The Gift*, London: Routledge & Kegan Paul, 1954.
[120] Leakey, Richard E. and Roger Lewin, *People of the Lake*, New York: Anchor Press, 1978.
[121] Cialdini, Robert B., *Influence: The Psychology of Persuasion*, New York: Quill William Morrow, 1993; Friedman, Hershey H. and Paul J. Herskovitz, "The Effect of a Gift-Upon-Entry on Sales: Reciprocity in a Retailing Context," *Mid-American Journal of Busniness*, 5, (1990), 49-50.
[122] Janis, Irving L., Donald Kay, and Paul Kirshner, "Facilitating Effects of Eating-While-Reading on Responsiveness to Persuasive Communications," *Journal of Personality and Social Psychology*, 1, (1965), 181-6.

that "most [physicians] deny that gifts could influence their behavior."[123] Physicians maintain that they still make rational, deliberate choices in their prescribing practices despite accepting gifts. However, as Dana and Lowenstein point out, "the deliberate choice view is inconsistent with social science research, which shows that even when individuals try to be objective, their judgments are subject to an unconscious and unintentional self-serving bias."[124] Hence, despite the conviction by physicians that they are not influenced by gifts, social science data suggests that this is merely a self-serving bias that justifies their acceptance of gifts. This conclusion is supported by findings by Wazana that show that, "receiving a gift and the number of gifts received correlated with the belief that pharmaceutical representatives have no impact on prescribing behavior."[125]

All of these findings illustrate how the practice of gift-giving serves to manipulate physicians in order to alter their prescribing behavior. The fact that the resulting obligations to reciprocate are largely subconscious and that physicians seem incapable of detecting the influence raises serious concerns over the practice. Even more, findings that indicate that the size of the gift has little impact on the resulting obligation to reciprocate has led Dana and Lowenstein to conclude that, "policies that make sense if bias as interpreted as a matter of deliberate choice (e.g., limiting gift size, educational initiatives, and mandatory disclosure of interests) are unlikely to be effective if bias is in fact unintentional and unconscious."[126] That the practice so effectively alters behavior should not be a surprise, otherwise why would the industry continue to defend gift-giving

[123] Wazana, 375.
[124] Dana, Jason, MS; George Lowenstein, PhD. "A Social Science Perspective on Gifts to Physicians From Industry." *JAMA* 290, no. 2 (2003): 252-255, 252.
[125] Wazana, 375-6.
[126] Dana, 252.

so fervently? As a result, it seems clear that, "the main objective of drug company gift-giving is to create relationships and interests on the part of recipient physicians that conflict with their primary obligation to act in the best interest of their patients."[127]

Thus, the practice is clearly manipulative and a violation of respect for the physicians PSR's interact with. In this case, nonrational means are utilized to influence the prescribing decisions of physicians. Physicians, in fulfillment of their fiduciary responsibilities, have the goal of making prescribing decisions that are in the best interests of their patients. By utilizing such nonrational means to influence the physician, PSR's subvert this goal and undermine the physician's ability to make prescribing decisions that are in the best interests of patients. Hence, such manipulative practices use physicians as a mere means for the realization of the ends of PSR's. Again, this clearly violates the first principle of; *pharmaceutical companies are obligated to be trustworthy in their marketing practices.*

However, many physicians welcome such interactions either due to the gifts they receive or because of the social reassurance they receive through the relationships they develop with PSR's. It seems reasonable to assume that many, if not most, physicians do not believe that these interactions influence them in the manner and to the degree that they do.[128] To the degree that physicians are aware of these influences and are complicit in these interactions, they do not properly respect the humanity of their patients and their goal of improving their health. For those physicians who do not realize the impact such interactions often entail, it is beyond time for them to acknowledge the overwhelming

[127] Katz, Dana, Arthur L. Caplan, and Jon F. Merz. "All Gifts Large and Small: Toward an Understand of the Ethics of Pharmaceutical Industry Gift-Giving." *The American Journal of Bioethics* 3, no. 3 (2003): 39-46, 42.
[128] This assumption is supported by the findings of Wazana and Dana discussed above.

evidence that indicates that despite their belief such interactions have no impact on their decision making that they do in fact have a substantial and pervasive influence. Regardless, physicians must recognize the fact that such interactions threaten their ability to make decisions in the best interests of their patients and as such, violate their fiduciary responsibilities and the second principle of, *physicians are obligated to be trustworthy in their decisions regarding patient care.* Therefore, it is once again imperative for the pharmaceutical industry to recognize the immoral nature of the practice and discontinue its use. On the other hand, it is also vital for physicians to recognize the preponderance of social science data that shows that the receiving of gifts does have a substantial impact on decision making and avoid the practice in the interest of being trustworthy in their interactions with patients and fulfill their fiduciary duties.

6. Harming Patients:

The issues surrounding the effects of DTP marketing on prescribing practices become more complicated when examined from the perspective of patient care. DTP marketing is clearly linked to prescribing practices that threaten the care of patients. Again, Wazana's landmark study is vital here. Wazana concluded that:

> Most studies found negative outcomes associated with the interaction. These included an impact on knowledge (inability to identify wrong claims about medication), attitude (positive attitude toward pharmaceutical representatives; awareness, preference, and rapid prescription of a new drug), and behavior (making formulary requests for medications that rarely held important advantages over existing ones; nonrational prescribing behavior; increasing prescription rate; prescribing fewer generic but more expensive, newer medications at no demonstrated advantage.[129]

[129] Wazana, 378.

Even more, studies suggest that prescribing decisions are often based on the influencing factors of pharmaceutical reps instead of being based on concern for which therapy options may best serve the patient.[130] These findings also substantiate the concerns raised above about the manipulative and deceptive nature of interactions between pharmaceutical reps and physicians. If information was reliable and unbiased it is reasonable to assume that such pervasive, negative effects would not be so overwhelmingly associated with interactions between physicians and PSR's. It is also clear that the practice of DTP marketing negatively impacts quality of care through improper prescribing, excessive prescribing, and the early adoption of newer, less proven, and possibly more dangerous medications.[131]

The dangers inherent in prescription drugs are well documented and are a primary reason for the prescribing system we use. Thus, prescribing of unnecessary drugs to patients places them at risk of potentially dangerous side effects. Further, excessive prescribing of a medication in many cases may also lead to increased risk of dangerous side effects and of overdose. Finally, prescribing patients medications that are not the best option for the treatment in question means that the treatment will likely not be as effective and may even fail.

Newcomer notes that, "researchers studying elderly patients found that 38 percent of those who received antidepressants, 19 percent who received oral hypoglycemics, 18 percent who received sedatives, and 13 percent who received nonsteroidal anti-

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[130] Dana, et al; Katz, et al; and Wazana.

[131] Anderson G.M., Beers M.H., Kerluke K. "Auditing Prescription Practice using Explicit Criteria and Computerized Drug Benefit Claims Data." *Journal of Evaluation in Clinical Practice* 3 (1998): 283-94; Lesar, T.S., Briceland L.L., Delcoure K., Parmalee, J.C., Masta-Gornic V., Pohl H. "Medication-Prescribing Errors in a Teaching Hospital: A Nine-Year Experience." *Archives of International Medicine* 28 (1997): 1569-76.

inflammatory drugs (NSAIDs) were given a potentially inappropriate drug."[132] The highly influential study by Lucian Leape et al, in the 80's showed that 3.7% of hospitalized patients had disabling injuries caused by their medical treatment, of which prescribing error was the number-one contributing factor.[133] Additionally, according to a study by Phillips et al, death certificates from 1993 showed that 7,391 deaths resulted from medication errors in America.[134] Even more unsettling is the claim that the "study seriously underestimates rates by recording only those cases actually identified by the physician."[135] I am not trying to claim that these results were usually or even predominantly caused by the influences of PSR's. Many of these errors may be attributed to problems such as misplacing decimal points when writing a dosage and similar mistakes. However, these accounts do serve to illustrate the dangers inherent in improper prescribing and indicate that great care need be taken to assure that proper prescribing does occur. Hence, to the degree that the influence of PSR's does negatively affect prescribing decisions this poses a serious risk to patients.

Particularly worrisome is the incredible effectiveness of DTP marketing in encouraging physicians to quickly adopt new, more expensive medications. Enthusiastic adoption of new pharmaceuticals raises serious safety concerns. Since harmful side-effects are often not identified until a drug has been on the market for several years, a policy of cautious, gradual adoption instead of rapid prescribing of new pharmaceuticals

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[132] Newcomer, Lee N, "Medicare Pharmacy Coverage: Ensuring Safety Before Funding," *Health Affairs*, March/April, (2000), 59-62, 60.
[133] Leape, Lucian L., Troyen A. Brennan, Nan Laird, Ann G. Lawthers, Russell A. Localio, Benjamin A. Barnes, Liesi Herbert, Joseph P. Newhouse, Paul C. Weiler, Howard Hiatt, "The Nature of Adverse Events in Hospitalized Patients: The Results of the Harvard Medical Practice Study II," *New England Journal of Medicine*, 324, no 6, (1991), 377-84.
[134] Phillips DP, Chirstenfeld N, Glynn LM, "Increase in US Medication-Error Deaths Between 1983 and 1993, *Lancet*, (1998), 643-4.
[135] Newcomer, 60.

seems to be the best strategy from the perspective of patient care.[136] An example that illustrates this problem is the heavy prescribing of Cox-2 arthritis medications. These are drugs that were heavily promoted both to physicians and directly to consumers. However, "studies show that the medicines are not more effective for pain relief that their predecessors were."[137] Their only advantage over standard aspirin for the relief of pain is their presumed decrease in the occurrence of stomach ulcers. Yet, "UnitedHealth Group pharmacy data show[s] that Cox-2 drugs now account for 40 percent of all prescription costs in this class, but only 14 percent of patients receiving the drugs have arthritis."[138] The problem of such rapid acceptance of a new therapy that has minimal advantages over existing drugs is highlighted by the heavily covered case of the withdrawal of Vioxx, a Cox-2 drug, from the market by Merck in 2004 after it was linked to increases in heart attack and stroke. If the data from UnitedHealth Group is any indication, many of those who were placed at risk or suffered adverse side-affects from Vioxx did so when they had no medical need for the drug or an existing therapy would have proved just as effective. The dangers inherent in improper prescribing are obvious. Excessive and improper prescribing can have debilitating effects on patients and in certain cases can even lead to death. The fact that DTP marketing techniques are so incredibly effective at altering prescribing behavior, often for the worse, means that many patients are invariable harmed

[136] Some may argue that the rapid prescribing of pharmaceuticals is beneficial since many side effects are often rare and will not be identified until a substantial number of patients are prescribed to the medication. However, I find such an argument troubling. While certainly rare side effects may be discovered more quickly by aggressively adopting new medications, how many additional patients may suffer those side effects due to the aggressive adoption of the medication? Instead, by employing a policy of gradual adoption one would hope that the number of patients who suffer that side effect would be minimized since as soon as a sufficient number have been identified proper action may be taken. This means that there is a potentially smaller pool of affected patients at the time of discovery than would be the case with a more aggressive policy.
[137] Newcomer, 60.
[138] Ibid, 60.

by the practice. Thus, pharmaceutical companies often harm patients in the pursuit of profits in clear violation of the third principle of; *pharmaceutical companies have a duty of nonmaleficence with regard to the patients who utilize their products.* The harm done also serves to highlight just how far such interactions threaten the fiduciary responsibilities of physicians to their patients. Not only are many physicians not prescribing the best treatment for their patients, but evidence suggests that many physicians are directly causing serious harm to their patients through improper prescribing that has been heavily influenced by interactions with PSR's. Therefore, these findings further illustrate how such interactions serve to violate the duty of physicians to *be trustworthy in their decisions regarding patient care*.

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Chapter 4

Health Care Expenditures

The final and most difficult aspect of DTP marketing is the claim that it unnecessarily drives up health care spending. Many have strong moral intuitions that there is something wrong with practices that unnecessarily or wastefully increase health expenditures; however, it is difficult to articulate what precisely is wrong with it. Companies that operate in the health care industry are in it to make money. However, the realization of the aims of increasing profits cannot come at the cost of the sustainability of the industry.

1. Reason for Concern:

As of 2004, nation health expenditures (NHE) in the United States reached nearly $1.9 trillion and accounted for 16% of the GDP. These figures are up from $966 billion or 13.7% of GDP ten years earlier. Even more disturbing is the fact that these trends are accelerating, seeing a 2.2% increase in consumption of GDP from 2000 to 2004.[139] Such alarming acceleration in health care spending raises concerns about the sustainability of our current health care system. With spending continuing to outpace the growth of the economy, it is inevitable that without reform this trend will eventually end in the collapse of our health care system. The demise of the health care industry raises sweeping concerns far outside the scope of mere economic considerations. With the failure of our

[139] Kaiser Family Foundation, "Trends and Indicators in the Changing Health Care Marketplace," http://www.kff.org/insurance/7031/print-sec1.cfm

health care system, it will be difficult and even impossible to find and receive the care that saves so many lives today.

Additionally, in 2003 health care spending on pharmaceuticals reached $179.2 billion. This only accounted for 11% of NHE in 2003, compared with hospital care (31%) and physician services (22%). However, pharmaceutical spending has increased at the highest rate of any component of NHE since 1990. While this trend climaxed in 1999, with a rate of increase of 20%, the 11% increase in 2003 still exceeded increases in hospital care (7%) and physician services (9%). Even more worrisome is the fact that while cost containment measures enacted in the 80's and 90's had at least limited success in restraining cost increases in both hospital care and physician services, these measures had little or no impact on the rates of increase on pharmaceutical spending. As of 2003 the rate of increase for hospital care is 50% lower and the rate of increase for physician services is 31% lower than in 1980, yet increases in spending on pharmaceuticals is 27% higher. Thus, while pharmaceutical spending only makes up 11% of NHE, this rate will likely continue to climb.[140] Certainly, in the increasingly fragile system we find ourselves faced with, these expenditures warrant examination.

These incredible rates of increase in spending have already had striking ramifications. Between 2004 and 2005, 1.3 million additional Americans became uninsured. This brought the percentage of non-elderly uninsured Americans to nearly 18%. Increases in spending in all sectors of health care serve to drive up health insurance premiums. Rising premiums coupled with the economic downturn in 2001 are seen as

[140] Kaiser Family Foundation, "Prescription Drug Trends," Nov. 2005, http://www.kff.org/insurance/upload/3057-04.pdf

the primary reasons for such large increases in the number of uninsured.[141] As a significant component of increasing health care expenditures, pharmaceutical spending bears some of the responsibility for this. Even more, increases in pharmaceutical spending has resulted in the establishment of tiered, cost-sharing formulas and increased drug copayments. In 2005, 74% of workers with employer sponsored coverage had cost-sharing arrangements with 3 or 4 tiers, 27% higher than workers in 2000. Average copayments for non-formulary drugs doubled from $17 in 2000 to $35 in 2005 and average copayments for formulary drugs increased from $13 in 2000 to $22 in 2005, an increase of 69%.[142] Thus, increases in health care expenditures are strongly tied to the rising number of Americans without health insurance. Even more, rising drug costs have clearly resulted in increasing out of pocket spending by those who still have coverage.

Therefore, in a fragile industry striving to maintain viability, any sector that shows exorbitant profits begs the question as to whether this is money well spent. For decades the pharmaceutical industry has been one of the most successful industries in the world. In fact, the industry has been the most profitable industry in America for most of the last decade, only recently slipping to fifth, with a 15.7% return on revenues in 2006.[143] Even more, the pharmaceutical industry has seen a return of between 14.3% and 18.6% for the last ten years. This is compared to a median return of 5.2% for all Fortune

[141] Kaiser Family Foundation, "The Uninsured and their Access to Health Care," Oct. 2004, http://www.kff.org/uninsured/upload/The-Uninsured-and-Their-Access-to-Health-Care-Oct-2004.pdf (accessed 3/22/07).
[142] http://www.kff.org/insurance/upload/3057-04.pdf (accessed 3/22/07).
[143] *Fortune 500* "Our Annual Ranking of America's Largest Corporations: Most Profitable Industries: Return on Revenues," 2006, http://money.cnn.com/magazines/fortune/fortune500/performers/industries/return_on_revenues/index.html (accessed 3/22/07).

500 companies in 2004, the highest median return in the last 10 years.[144] With the health care industry struggling to survive, how can the pharmaceutical industry justify such huge profits?

Finally, a key component to the incredible profitability of the pharmaceutical industry has been the incredible success of advertising. The pharmaceutical industry pours vast sums of money into advertising, increasing the rate every year. In 2004, pharmaceutical companies spent an average of 32% of their revenues on marketing, advertising, and administration,[145] up from 27% in 2001.

2. Health Care as a Distinct Business Model:

Problems of inefficiency and unprudential expenditures of resources are usually not a major problem within business due to corrective market forces. For instance, as one company begins to introduce newer more expensive products with little or no advantage over older ones, new companies step up and offer products that do offer advantages at a similar price or sell a similar product at a cheaper price. However, pharmaceuticals are highly problematic in this regard. Pharmaceutical companies are granted strong monopoly rights over their medications. Thus, there is little capacity for competing companies to step in and offer a similar product at a cheaper price. Even more, the highly technical nature of pharmaceuticals, coupled with the lengthy process of testing and approval, means that often a pharmaceutical company may have no competition for many years. These problems are exacerbated by the complex relationships involved in

[144] http://www.kff.org/insurance/7031/ti2004-1-21.cfm (accessed 3/22/07).
[145] Families USA. "Health care for People or Drug Industry Profits" http://www.familiesusa.org/assets/pdfs/The-Choice.pdf (2005) (accessed 3/22/07).

prescribing drugs. Patients are the primary consumers; however, insurance companies are the primary purchasers of the medication. Even more complicated is the fact that physicians make the ultimate choice as to which medication to prescribe. So offering a product at a cheaper rate does not have the same competitive force that it has in an open market. Since both the physicians and the patients generally have little or no interest in the amount being charged to the insurance company, they are minimally affected by differences in price. The system of sharing costs through insurance also means that, unlike in the standard business model where the impact of financial decisions are generally restricted to the customer paying for the product or service and the vendor selling them, that financial decisions in the health care industry have a far reaching impact on all who participate in the system. Finally, the highly technical nature of pharmaceuticals makes it exceedingly difficult to determine the advantages and disadvantages of one product over another.

Thus, we begin to see why comparisons between health care businesses and the standard business model tend to fail. The allowance of strong monopoly rights combined with the highly technical nature of pharmaceuticals results in stifled competition. Further, the highly complex system, where physicians determine treatments, patients receive them, and insurance companies pay for them, means that pricing plays a minimum role in the choice of products or treatments. Additionally, as noted above, increases in spending in one sector of health care have widespread ramifications in all other sectors. To illustrate this let's look at pharmaceuticals. Increased drug spending affects insurance companies. In order to compensate for increased spending, insurance companies raise premiums, which negatively affects patients and institute cost

management procedures that limit procedures and medications that physicians may employ in the treatment of disease. Therefore, it should be apparent that the health care industry departs from the standard business model in important ways that raise serious concerns when we analyze the implications of unprudential expenditure of health care resources.

3. A Means or an End?

The first tact in addressing considerations of health care spending is to approach it from the perspective of patients. If DTP marketing does needlessly drive up health care spending then it is often patients that feel that impact. Granted, much of the effect is indirect since insurance companies bear the brunt of actual health care spending. However, there is certainly a trickle down effect through increases in insurance rates. As health care spending continues to rise, insurance companies are forced to increase their premiums in order to keep up. As a result, it is patients that pay for these increases through higher premiums. Further, as insurance rates increase; greater numbers of patients are priced out of coverage. Without coverage, the implications of unnecessary health care spending are even more dramatic as the full cost is carried by individual patients. The result is that many patients will not be able to afford the care that they need. If these claims may be substantiated then, by financially harming patients, DTP marketing is a clear violation of the third principle of; *pharmaceutical companies have a duty of nonmaleficence with regard to the patients who utilize their products.* Further, since it is clear just how fragile the health care industry is, if the claims that DTP marketing unnecessarily drive up health care spending are confirmed then those practices

also violate the fourth principle of, *pharmaceutical companies are obligated to not undermine the prudential expenditure of limited health care resources.*

4. Me-too Drugs:

The most complex aspect of the debate surrounding DTP marketing is the claim that it drives up health care spending. Despite the huge expenditures by the industry, money spent on marketing is not passed on directly to the consumer through higher drug prices. This is because of the incredible success of DTP marketing. One study found that for each dollar spent on detailing, there was a return of $10.29 for large, new products and no less than $1.27 on older products.[146] Thus, money spent on DTP marketing is more than made up for by increases in revenues.

However, the adoption and rapid prescribing of new, more expensive drugs over cheaper existing treatments and the mistaken prescribing of medications to individuals who do not suffer from the corresponding condition have the obvious cumulative effect of increasing health care costs. Yet, the avenue through which DTP marketing seems to drive up health care spending the most is by creating a market for so called "me-too" drugs. These are drugs that are developed with little or no advantage over existing therapies. However, despite strong indications that they have no distinct advantages over existing alternatives, they are touted as "new and improved." Thus, physicians and patients are led to believe that these new treatments offer some special advantage over the existing alternative. The success of DTP marketing and its ability to alter prescribing practices and encourage formulary requests where, "most of the requested drugs

[146] Liebman, Milton. "The Right Media Mix is the Key to Maximizing ROI." *Medical Marketing & Media*, May (2001).

presented little or no therapeutic advantage over existing formulary drugs,"[147] means that a market for drugs is often created merely by marketing efforts instead of due to reported benefits. In this environment it is easy to see why there would be significant motivation to research and develop a new drug based on the makeup of an existing product. Since demand for the drug may be effectively created by aggressive marketing to physicians, there is no need to spend the time, money, and effort to create a new, truly innovative drug. Further, the attrition rate for the development of new drugs is widely cited as one of the primary expenses involved in the research and development of a new medication. However, the success rate may be dramatically improved if a drug is based on a slight alteration of the molecular formula of an already successful drug. This practice is encouraged by the patent process, which requires only slight modification on a formula and proof that the therapy is more effective than a placebo, not more effective than existing alternatives, in order to obtain a new patent. Finally, with blockbuster drugs bringing in over $1 billion in revenues, and often developed for chronic conditions which will maintain sales over extended periods, gaining even a mediocre percentage of the market share, especially with decreased R&D costs, provides a significant incentive to produce me-too drugs. Even further, since these newer drugs will have a more recent patent that extends exclusive rights beyond those of the currently existing competitor's drug, market share should increase over time as the competing drug is phased out through direct generic competition.

Of course the pharmaceutical industry denies that this happens. They claim that development of me-too drugs largely stems from projects that are independently

[147] Wazana, 375.

developed simultaneously between two companies. They further claim that the industry is driven by small, incremental developments over existing molecular formulas as much as it is by large leaps in the development of new molecular entities (NMEs). That NMEs are no guarantee of improvements in therapy is supported by the example of Cox-2 drugs, which offered no significant advantages for pain relief over existing therapies. However, there is also little evidence to suggest that significant benefits are obtained from slight alterations to existing drugs.[148] This has led Marcia Angell to conclude that; "the idea that patients respond differently to me-too drugs is merely an untested – and self-serving hypothesis."[149] Certainly, if this is a defense that the industry wishes to continue to utilize they must find stronger support for it than currently exists.

However, it is extremely difficult to determine which therapies are me-too drugs and which are truly beneficial and innovative new therapies. The primary hindrance to identifying which drugs are me-too's is that the FDA merely requires that pharmaceutical companies show that a new drug is more effective than a placebo instead of requiring head-to-head comparisons with the most effective existing treatment option. This practice makes it exceedingly difficult to determine the relative merits of a new drug over existing alternatives. This has led Angell to call for the FDA to reform their approval process and require pharmaceutical companies to demonstrate a significant advantage over existing treatment options before they are approved. By instituting a more stringent

[148] The pharmaceutical industry widely cites the practice of trying different antidepressants until an effective treatment is discovered as an example of how small alterations in chemical formula may have a significant impact on the success of a drug. Since these drugs are often only a very slight alteration on the chemical formula of alternative treatments, they argue that this slight difference is responsible for the success of some treatments where others fail. However, this is a highly controversial claim since the mechanics of depression and antidepressants are not clearly understood. There are also a myriad of factors that influence the success of one treatment versus another, including the effects of counseling, changes in the conditions surrounding the patient's life, and the ability of patients to improve on their own.
[149] Angell, 90.

approval process, "there would be far fewer me-too drugs, because not many of them would pass that test. The companies would have no choice but to look for important new drugs, instead of taking the easier and cheaper route of spinning out old ones."[150] This would have the additional benefit of removing one of the primary motivations for aggressive DTP marketing since truly beneficial and innovative new drugs tend to market themselves.

Yet despite difficulties involved in the identification of me-too drugs, it is possible to get a rough idea of the relative predominance of these types of medications. What is shown is that there is a striking prevalence of these drugs compared to innovative, beneficial therapies. In order to determine this we may look to the FDA's classification of new drugs as an indication of the prevalence of me-too's. In 2004, 31 (27%) of the 113 newly approved drugs were NMEs. Only 25 (22%) of the 113 were classified as having a "significant improvement compared to marketed products in the treatment, diagnosis, or prevention of a disease," with only 17 of the NMEs falling under that category.[151] Even more troubling is that, with the exception of the last two years, these ratios have steadily fallen over the last 15 years while marketing expenditures have increased over the same period.[152] While it may be argued that these classifications underestimate the beneficial potential of new pharmaceuticals, the data clearly indicates a troublesome predominance of me-too drugs.

Adding to the evidence above is the fact that the problem of more expensive me-too drugs flooding the market has become so widespread that *Consumer Reports* has

[150] Angell, 76.
[151] http://www.fda.gov/cder/rdmt/pstable.htm (accessed 3/22/07)
[152] Abrams

begun to analyze comparative studies in an attempt to aid patients in the selection of the best treatment for their money. As of now, there are sixteen distinct conditions with sufficient me-too drugs to warrant a study by *Consumer Reports.* An examination of these reports shows concrete examples of more expensive, patent protected me-too drugs that offer no significant advantage over existing treatments, and help to illustrate how much the adoption of these more expensive treatments escalates health care spending.

A prime example of the introduction of these more expensive me-too drugs is the development of Prilosec. When Prilosec, AstraZeneca's blockbuster heartburn medication went off patent protection, they poured enormous amounts into the marketing of Nexium, the next "purple pill." Further, there are now three additional proton pump inhibitors; Prevacid, Protonix, and Aciphex. Now that Prilosec has gone off patent protection and is available over-the-counter, it costs an average of $24 a month. This is compared with an average monthly cost of $245 on the high end and $119 on the low end for alternative, prescription treatments. Yet, Prilosec is "as effective for most people as the more expensive prescription alternatives."[153]

Another example is Claritin. The first of the new generation of antihistamines, Claritin was a huge blockbuster for Schering-Plough. Once again, several alternative treatments quickly followed, in this case; Zyrtec, Clarinex, and Allegra. Claritin, now sold over-the-counter and available as a generic, costs as little as $3 a month. This is compared to the patent protected alternatives which range in monthly price from a high of $182 to a low of $52. This while "analysis indicates that the four second-generation

[153] *Consumer Reports*, "Drugs to Treat Heartburn, Ulcers, and Stomach Acid Reflux: The Proton Pump Inhibitors: Comparing Effectiveness, Safety, and Price," http://www.crbestbuydrugs.org/PDFs/PPIs.pdf, 5. (accessed 3/22/07).

antihistamines do not differ in any consistent way in either effectiveness or safety or the side effects they cause."[154] Such therapies illustrate how dramatically aggressive prescribing of patent protected alternatives drives up health care spending.

These examples help to paint a picture of the business structure of pharmaceutical companies, where high expenditures on DTP marketing create a market for non-innovative, me-too drugs. Adding to the problem of me-too drugs is the way that pharmaceutical companies utilize deceptive and manipulative practices in order to alter the prescribing practices of physicians. The success of DTP marketing techniques means that, more often than not, the competitive effect of cheaper, generic alternatives can be effectively mitigated. Further, me-too drugs are not inherently a form of competition. They cannot be tied to lowered prices, nor are they marketed as cheaper than competing patent protected alternatives. This has led Angell to conclude that, "the me-too market operates more like an oligopoly than like a competitive market; it is simply expanded and shared."[155] Thus, through the mechanisms discussed in Chapter 3, the pharmaceutical industry encourages the adoption of these newer, more expensive medications that offer little or no advantage over existing treatments. When combined with a system where there are limited incentives to seek the cheapest treatment option, the result is a system where me-too drugs dominate.[156] Since new drugs carry high price tags due to strong

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[154] *Consumer Reports*, "Treating Allergies, Hay Fever, and Hives: The Antihistamines: Comparing Effectiveness, Safety, and Price," http://www.crbestbuydrugs.org/PDFs/Antihistamines.pdf, 9. (accessed 3/22/07).

[155] Angell, 90.

[156] Some may object to the discussion of me-too drugs by saying that we see nothing wrong with offering a slightly different or better alternative at a higher price for other products. However, the problem with me-too's is that the use of deceptive and manipulative marketing techniques means that the choice of the more expensive me-too drug is often not a rational choice. This is contrasted with there not being a problem with someone rationally choosing to spend extra money on a luxury car when a cheaper alternative would serve their purposes. Further, the nature of the health care industry means that additional money spent on a more

monopoly protection, this trend dramatically increases health care spending, which is in turn born by patients and insurance companies. This financial harm directly violates the third principle of; *pharmaceutical companies have a duty of nonmaleficence with regard to the patients who utilize their products.* It is also vital to recognize that since these me-too drugs carry no significant advantages over existing alternative treatments, yet carry exponentially higher price tags, by encouraging the adoption and prescribing of me-too drugs through DTP marketing, the pharmaceutical industry greatly undermines the prudential expenditure of health care resources and threatens the sustainability of the industry as a whole. As such, DTP marketing violates the fourth principle of; *pharmaceutical companies are obligated to not undermine the prudential expenditure of limited health care resources.*

expensive drug option is not solely born by the patient who makes that choice. Instead it is born by all the individuals who share health coverage with that individual, raising issues of justice. Thus, while a decision to spend additional money on a luxury item generally only affects the person who makes that choice, decisions to utilize more expensive treatment options have far reaching effects on a multitude of individuals.

Chapter 5

Conclusion

It should now be clear that DTP marketing ultimately manipulates and deceives physicians. Further, DTP marketing is clearly tied to negative influences on prescribing behavior that undermines the patient, physician relationship and endangers patients' care. Finally, as the primary mechanism through which a market for me-too drugs is created, DTP marketing drives up health care spending. For all of these reasons there is a strong moral imperative for PhARMA and the AMA to voluntarily instituted measures that ban the practices discussed here. However, even if a voluntary ban is enacted by PhARMA and the AMA, this is not the end of the story. It is vital for us to consider the possible ramifications of such a ban and to attempt to determine how, and in what form the industry may continue to function.

1. Can the Industry Regulate Itself?

Despite a clear moral imperative for both PhARMA and the AMA to voluntarily abandon the practices of DTP marketing, there is strong reason to doubt their ability to effectively curtail such exchanges. Previous discussions serve to starkly illustrate the corrupting influences of profit. DTP marketing is the primary mechanism through which the industry maintains the huge profits they have come to enjoy for so long. It is naïve in the extreme to expect them to readily discard their most effective tool for generating profits. Even more, there is evidence that companies are already abandoning the modest reforms that have been only recently enacted. Kassirer claims that, "already, less than a

year after the PhARMA guidelines were issued, there is evidence that the companies are violating their own guidelines on meals, and despite the new AMA guidelines, physicians are still accepting their invitations."[157]

Further, limitations on the types and size of gifts to physicians and strong curtailment of PSR's ability "wine and dine" physicians has resulted in greater efforts being expended in the less well regulated area of continuing medical education (CME). Physicians are increasingly utilized as so called "thought" or "opinion leaders." These physicians speak on behalf of pharmaceutical companies about certain drugs and usually receive substantial honorariums in return.[158] The rise of such practices can be traced to the institution of more restrictive codes of conduct by PhARMA and the AMA. Worrisome practices such as these have led Kassirer to conclude that, "gifts and subsidies are so important to the marketing efforts of industry that the companies will undoubtedly find creative ways to continue the largesse."[159]

Physicians are complicit in the failure of reform as well. Despite a strong professional ethic, physicians are only human and the corrupting influence of money is all too well known. More importantly, is the fact that studies show that for the most part physicians feel they are immune to the influencing effects of gifts.[160] As long as physicians are unwilling to recognize the dramatic affects that can be correlated to the acceptance of gifts from industry, they are unlikely to voluntarily abandon such practices. Thus, if physicians and the industry are not capable of effective self-regulation then this

[157] Kassirer, 10.
[158] Angell, Elliot, and Kassirer.
[159] Kassirer, 9-10.
[160] Wazana,

opens the door for federal regulation of interactions between industry and health care professionals.

2. Academic Detailing:

There is additional concern that by banning the practice of pharmaceutical detailing, physicians will lose access to one of their primary sources of information on new drugs and therapies. While there is good reason to doubt the value of information provided by PSR's, the question of where physicians should turn to find reliable information about pharmaceuticals remains. Of even greater concern is the fact that comparative studies of competing therapies are predominantly funded by pharmaceutical companies. Clearly, industry funding of such comparative studies invites the inclusion of dangerous bias and the tweaking of studies to benefit the sponsoring company's drug.[161] Thus, information provided by the industry and industry funded studies all raise concerns over the corrupting influence of profit and illustrate the difficulties inherent in eliminating bias. However, a reliable alternative to industry sponsored detailing already exists. Indications show that attempts made by academic institutions to conduct independently funded research and to independently disseminate the results of such studies have been immensely successful at removing inaccuracy and bias from research and information provided to physicians, clearly demonstrating the superiority of such an approach.

However, there is still the question of who is to foot the bill for such independent research. There may be strong reasons for insurance companies to wish to support such

[161] Safer.

efforts since decreased prescribing of more expensive therapies with little or no advantage would be financially beneficial to insurance companies. Further, since pharmaceutical companies will no longer be able to rely on DTP marketing to promote their drugs, they will have to rely on the merits of the drugs themselves. As a result, companies will have to concentrate on developing truly innovative and beneficial therapies. If this change of focus does in fact occur, then it will be in the best interests of the industry to fund independent research since this will be the only remaining mechanism through which pharmaceutical companies may be able to encourage the use of their product. Further, funding of independent research would represent only a small portion of the extravagant expenditures currently directed towards marketing. Additionally, it can be argued that the pharmaceutical industry has an obligation to fund such independent research. As discussed previously, the industry's duties to physicians and patients extend beyond mere negative duties, and include positive duties to aid both in the pursuit of the best treatment and health care. Again, these duties are reflected in the mission statements of nearly all of the most profitable U.S. pharmaceutical companies. Therefore, funding of reliable, independent research would likely be the most effective mechanism through which pharmaceutical companies may fulfill these obligations to patients and physicians. Finally, there are already extensive and costly demands that we have seen fit to place on the pharmaceutical industry. These are part of the cost of operating in the market that they do. In return, pharmaceutical companies have been granted strong protection of their intellectual property rights which has been instrumental in the substantial profits they continue to report. As such, it seems

reasonable to look to them to once again fund an essential element of the system they operate in.

However, care will have to be taken to insulate academic institutions conducting this research from the pharmaceutical companies. As such, a tax system based upon revenues could be imposed on pharmaceutical companies and then dispersed through government grants to academic institutions. A gradated tax system based on revenues means that all companies would share the burden proportional to their success and market share. More importantly, measures that serve to distance the academic institutions responsible for research means that much of the corrupting influence of profit may be mitigated. Through this, a reliable source of information about pharmaceuticals may be created in which the interests of both patients and physicians are protected.

3. Innovation:

As damning as criticism of DTP marketing may seem, there is still a difficult defense that the pharmaceutical industry may raise in opposition to these claims. It is the same defense rolled out every time the high profits of the industry are cited as a reason for regulation of drug pricing. The argument is that high profits are required to encourage investment in pharmaceutical companies, which is in return required for investment in R&D. In order for the industry to continue to develop new, innovative drugs, such high profits must be maintained.[162] Therefore, any reforms that place the status quo at risk, threaten to stifle innovation. It follows that since DTP marketing is so

[162] This line of reasoning is best articulated by Ian Maitland. While his argument does not directly address DTP marketing or me-too drugs, it is easy to extend it to encompass these issues; Maitland, Ian. "Priceless Goods: How Should Life-Saving Drugs be Priced?" *Business Ethics Quarterly* 12, no. 4 (2002): 451-80.

successful at generating high profits for the industry, any measures taken to regulate its practice may result in a decrease in the development of new, innovative drugs. Even more, the argument may be extended to claim that the profits generated from these drugs are funneled back into R&D and helps to drive the development of new, innovative drugs. Thus, what is at play is a consequentialist claim that while the marketing of me-too drugs may be deceptive and wasteful, it is a necessary evil for the continued production of new, innovative drugs. As such, it may be argued that by funneling the profits from me-too drugs back into R&D, the huge potential benefits of newly developed pharmaceuticals outweighs the costs involved in DTP marketing. However, I will show that one need not object on these grounds, and instead, that the argument that regulation will stifle innovation simply does not hold.

The first objection to the argument that regulation will stifle innovation is that it seems that most of the research on truly innovative drugs does not come from the pharmaceutical industry itself. According to Marcia Angell, "at least a third of drugs marketed by the major drug companies are now licensed from universities or small biotech companies, and these tend to be the most innovative ones."[163] Further, it seems that most of the research portion of R&D comes from NIH grants. While this is a claim that has been frequently cited as justification for government regulation of pharmaceutical pricing, the industry counters by citing a study conducted by the NIH to determine the extent to which federal funding of research had led to the development of new innovative drugs.[164] The study found that of the top 47 drugs on the market in 2001,

[163] Angell, 8.
[164] Department of Health and Human Services National Institutes of Health, "NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected: A Plan to Ensure

only four could be definitively linked to NIH funding of research. While this has been widely touted by the industry as proof that most of the truly innovative research stems from internal R&D by pharmaceutical companies instead of through public funding of the NIH, in reality the study merely points out that the NIH had not been vigilant in its tracking of the development of new pharmaceuticals that resulted from federal funding. As Angell points out, "what the facts really show is that the NIH, in violation of the Bayh-Dole Act, failed to keep proper records of patenting and licensing arrangements."[165] However, even if there is only a limited correlation between NIH funding and the development of innovative or blockbuster drugs, this does not mean that NIH funded research has no bearing on the creation of innovative new drugs. It is important to note that, "even though the NIH spends nearly as much money on research as does the industry, it concentrates on basic research. Only about 10 percent of clinical trials are sponsored by the NIH, usually in academic medical centers."[166] Since the NIH spends such significant sums on basic research it means that NIH funded research is the primary source of research into the underlying mechanisms of disease, which is necessary for the successful development of new treatments.[167] Thus, in one form or another, much of the cost for initial research into new, innovative drugs is born by public funding through the NIH, leaving the pharmaceutical industry merely responsible for the development side of the equation. While development carries the brunt of the cost of bringing a new drug to market, it seems that most of the truly innovative work takes place

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Taxpayers' Interests are Protected," July, 2001, http://www.nih.gov/news/070101wyden.htm (accessed 3/22/07).
[165] Angell, 71.
[166] Angell, 30.
[167] Angell, 22.

outside of the industry, calling into question the degree to which decreased profits may stifle innovation.

Since it seems reasonable to conclude that most of the truly innovative research comes from outside of the industry, it follows that the majority of internal research is committed to developing slight alterations on existing drugs in order to develop new me-too's. Therefore, even if decreased revenues were to affect R&D, it is likely that this would only significantly impact the development of new me-too drugs. Finally, it seems apparent that the exorbitant expenditures made on marketing serve primarily to create a market for me-too drugs. Thus, the increased revenues derived from the success of DTP marketing serve mainly to increase profits and supply a feedback loop that allocates revenues into the development of additional me-too drugs, further driving increases in marketing.

In the end, a brief glance at the allocation of revenues by the top seven pharmaceutical companies shows that the claim that any loss of revenue will negatively affect innovation is patently false. Let us not forget that pharmaceutical companies are immensely successful. This is not an industry struggling to maintain viability. As has been widely cited, the industry has been the most profitable industry in America for most of the last decade, only recently slipping to fifth.[168] A 2005 report by Families USA points out that spending on marketing, advertising, and administration by the top seven pharmaceutical companies accounts for 32% of company revenues, whereas spending on R&D was only a meager 14%. Even further, these companies reported 18% of revenue

[168] *Fortune 500,* http://money.cnn.com/magazines/fortune/fortune500/performers/industries/return_on_revenues/index.html (accessed 3/22/07).

as profits. By eliminating most of the expenditures on marketing, an inefficient and wasteful section of the industry is merely trimmed away. If resource allocation into R&D does suffer, this will be a decision made by corporations who have concluded that continued profits at the currently exorbitant levels are more important than the development of innovative pharmaceuticals. However, even if this is their initial reaction, it seems obvious that it would only be a temporary outcome of regulation. With the denial of the industry's ability to continue to profit from the proliferation of me-too drugs, the only way for these companies to remain viable will be for them to return to a primary focus on creating innovative new drugs. Therefore, counter to claims made by the industry, it is likely that development of innovative new medications will increase in the long run. In the end, we wind up with a more streamlined, efficient industry with a much desired shift of focus back to innovation instead of the current impetus to take the easy route and concentrate on the development of me-too drugs.

4. Only a few Bad Apples?

Finally, it is important to attempt to gauge whether this is truly an industry wide problem or whether it is only confined to a select few corporations. It is unfortunate that the studies utilized to substantiate the claims made here do not address this concern. There is an underlying assumption that all pharmaceutical corporations are guilty of the problems discussed. The fact that all of the major pharmaceutical companies invest heavily in DTP marketing seems to substantiate this assumption.[169] Further, all of the major pharmaceutical companies allow some form of gift giving. Regrettably, based on

[169] Families USA, 2002; 2004; 2005.

the information provided in the studies discussed, there is no way to determine whether some corporations provide more inaccurate and biased information than others.

However, an examination of the mission statements and codes of conduct of the top five U.S. pharmaceutical companies does help to give some indication of the corporate culture of the individual companies. Despite a stated adherence to PhARMA's guidelines concerning gift giving, Abbott Laboratories' code of conduct permits entertainment of business contacts and generally shows a relaxed attitude to the practices of gift giving.[170] Similarly, Bristol-Myers Squibb allows for the provision of entertainment and the furnishing of event tickets.[171] These statements in the code of conduct of both of these companies contradict restrictions laid out in PhARMA's guidelines, which clearly forbid the provision of entertainment and the giving of event tickets. Thus, these statements seem to send an unclear message to the PSR's of these corporations and at least minimally indicates a corporate culture that is more concerned with the pursuit of profit than the protection of the interests of physicians and patients.

These companies may be compared to Pfizer, who looks to PhARMA's code as a guide to interactions with health care professionals.[172] Similarly, Merck cites PhARMA's code as the primary guide to interactions, however, Merck makes an additional effort to emphasize that they, "wish to safeguard the public's confidence in physicians to make decisions solely on the basis of patient health."[173] Further, the widely discussed case of Merck developing and freely distributing Mectizan as a cure for river blindness adds further evidence to a corporate culture that is highly committed to patient

[170] Abbott, 14.
[171] Bristol, 15.
[172] Pfizer
[173] Merck, 9.

care. Therefore, the strong commitment to PhARMA's guidelines by Pfizer and Merck may indicate a corporate culture more concerned with the implications of DTP marketing practices than Abbott Laboratories and Bristol-Myers Squibb.

Finally, Johnson and Johnson goes well beyond a clearly stated adherence to PhARMA's guidelines by stating that all guidelines and corporate policies are designed to "limit even the appearance of improper influence."[174] This commitment is reinforced by the fact that they restrict the value of gifts their PSR's are allowed to give to $25, well below the industry limit of $100 set by PhARMA. Thus, Johnson & Johnson's code of conduct seems to indicate a corporate culture that is admirably concerned with limiting possible influence through their DTP marketing practices. However, it is important to note that Johnson & Johnson is the only company out of the top five U.S. pharmaceutical corporations to enact more restrictive guidelines than those proposed by PhARMA. Even then, Johnson & Johnson has not voluntarily eliminated any of the practices discussed. Thus, while some corporations may be more guilty of employing objectionable practices than others, the assumption that the problems extend across the entire industry seem to be valid.

[174] Johnson & Johnson, 6.

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