DIRECT-TO-CONSUMER ADVERTISING OF PHARMACEUTICALS: A MODERN ETHICAL REVIEW AND ANALYSIS OF PRACTICE AND CONSEQUENCE IN AMERICA

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Abstract page

The purpose of this research essay is to examine the effect of direct-to-consumer (DTC) marketing of pharmaceuticals on key stakeholders in the United States. Compared to the human history of medicine, even in its modern sense, the implementation of business driven medical policy (and resulting advertisements) is quite new. To provide a background and define the place this paper holds in the biomedical ethical academic conversation, I examine in a literature review some of what has been previously discussed on this topic. Additionally, provided is a short history of practices and legislation in both the US and comparable industrialized countries.

I argue the American pharmaceutical industries' employment of direct-to-consumer marketing is unethical because it changes the doctor-patient relationship in an unacceptable way, which leads to a decrease in the potential quality of patient care that can be feasibly rendered and an increase in negative outcomes.

The analysis portion is conducted in subsections using three moral philosophies. The Prima Facie section, in line with what the principles are designed for, is a first glance and overview of the situation as it stands now. The section on Utilitarianism is the heart of my argument and provides a quantitative analysis of the effect of DTC advertising. The last method, Kantian philosophy, wraps up and reinforces the findings of the first two analytical sections.

In conclusion, I bring together the information explored, return to my argument, and compare the results before wrapping up with a prescriptive method for resolving the issues currently created by pharmaceutical marketing.

Contents

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Introduction

In the United States of America, medicine is big business. While medicine originated as an art, and later blossomed into the use of evidence based science steeped in a long history of humanism and gentry, the advent of fiscally motivated medical policy is comparatively new. Pharmaceuticals have many beneficial properties and have revolutionized the field of modern medicine. Without the leaps and bounds of scientific advances which proliferate the research and implementation of drug therapies, human life expectancy and medical care would not be where they are today. The purpose of this paper is not to criticize the pharmaceutical industry but to define the climate which allowed for the development of current pharmaceutical marketing techniques and to determine the moral worth of such practices through analysis of the effects of advertising on doctors, patients, and the efficiency and wellbeing of the healthcare system.

In this paper, following the introduction, I give a detailed yet not exhaustive literature review. By assessing those whom have come before myself I am able to acquaint my readers with the previous academic conversation while beginning to give shape and definition to the role this paper will play in the scheme of biomedical ethics within healthcare and the medical humanities. I outline the history of patient directed marketing of medications and current practices in comparable industrialized countries. Through the exploration of that has come before I lay a foundation upon which to build my analysis, argument, and conclusion. Once the premise has been substantiated, I progress into a current ethical analysis of direct-to-consumer marketing of pharmaceuticals. I employ multiple moral philosophies to evaluate the ethical standing of this practice in relation to key stakeholders. It should go without saying, since this is an ethical review, the modern practices of pharmaceutical commercial dealings are legal

within the country in question--unfortunately this legal status is not always accompanied by subsequent equal moral standing. It is my opinion, from personal observation and academic study, that the legal code is in place to provide a structure of checks and balances on the behavior of the public, and to level the field to a universal morality. Meaning, despite the origin of the individual (cultural, religious, or otherwise) the governing officials denote a set of obligatory rules that can be agreed upon due to their derivation from basic moral premise. The system was created to have legality follow morality, and yet all too often individuals incorrectly argue for the upright moral standing of a practice on the basis of its legal status. In part, this paper seeks to investigate if consumer directed advertising of pharmaceuticals, in the United States, is falling into the legality-driven-morality trap. Once this has been ascertained, I will discuss a prescriptive method for pharmaceutical marketing, which, if implemented, could realign the legality of the practice with the underlying moral concepts. In the analysis, I will explain each of three philosophical systems of thought and then follow with the analysis using that system, before progressing onto the next code of ethics. The philosophies used are Prima facie principles, Utilitarianism, and Kantian thought.

Statement of argument

The medical field is a rapidly evolving area of study and practice. Physicians, as the purveyors of the noble healing arts, are born out of a mentality to strive for knowledge and ever higher standards of care. This approach is vital to the well-being of both the physicians and those served by their work. Because of the progressive nature of medicine, we, in the field of medical ethics, are faced with the task of systematically addressing, ever emerging, moral dilemmas. Compared to the history of the medical field, consumer directive advertising is very much still in its infancy. Already there as been a

plethora of debate surrounding the moral standing of this practice, and its truly long-range effects have yet to be seen. Legal thought generally breaks direct-to-consumer marketing into three subcategories, to be addressed in depth later in this paper; however, it is the most controversial of these that is my primary focus. America is one of only two industrialized nations that employ this questionable marketing practice.[1] While it is not unethical or immoral, indeed it may be beneficial in some respects, to promote knowledge about pharmaceutical solutions--it is the current execution of this practice in this country I call into question. I argue the American pharmaceutical industries' employment of direct-to-consumer marketing is unethical because it changes the doctor-patient relationship in an unacceptable way, which leads to a decrease in the potential quality of patient care that can be feasibly rendered and an increase in negative outcomes.

Clarification of terminology and scope

Before delving into the bulk of the analysis it is necessary to first clarify the scope of this paper and the terminology used herein. The terms prescription medications, pharmaceutical drugs, and regulated therapeutic substances will be employed to signify drugs that can only be obtained from a pharmacist with a prescription. Medications in this classification, versus over-the-counter substances that can be purchased whenever the consumer sees fit, are generally newer and may contain active ingredients deemed to be addictive.[2] [3] In addition, direct-to-consumer marketing, direct-to-consumer advertising,

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[1] "Keeping Watch Over Direct-to-Consumer Ads." U.S. Food and Drug Administration. Accessed June 10, 2015. http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107170.htm.
Last Updated: May 10, 2010 Archived material

[2]"Prescription Drugs and Over-the-Counter (OTC) Drugs: Questions and Answers." U.S. Food and Drug Administration. Accessed June 24, 2016.
http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100101.htm.
Page Last Updated: 01/07/2015

[3] Krans, Brian. "The Most Addictive Prescription Drugs on the Market." Healthline. Accessed June 24, 2016. http://www.healthline.com/health/addiction/addictive-prescription-drugs#Overview1.
Medically Reviewed by George T. Krucik, MD, MBA on May 16, 2011

and reasonably similar labels will be used interchangeably and will stand in for the following definition. Direct-to consumer marketing is the intentional dissemination of information, produced or commissioned by the pharmaceutical company, with the intended audience of the immediate consumer.[4] This can be through radio, television, and websites including social media, mobile in application advertisements, printed periodicals, or any other popular media source.[5]

When discussing the ethical standing of any practice it is imperative to be precise of language. While I have defined direct-to-consumer marketing as a term, in real world application there are three distinctive types into which this form of promotion is regulated in its execution. The first type is labeled as Help-seeking.[6] Within this category the disseminated materials provides the consumer with information about a specific disease or condition.[7] Although the advertisements will encourage viewers and readers to speak with a healthcare professional to find out more about treatment options, should they suffer from the covered ailment, the Help-Seeking advertisements cannot give specific names (branded or otherwise) to the available drug therapies. The second form of direct-to-consumer advertising is Reminder advertisements.[8] Reminder marketing materials are the opposite of the first group defined. Unlike advertisements classified as Help-seeking, Reminder ads do talk about, or name, a specific drug; however, they cannot mention the

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[4] Ventola, C. Lee. "Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic?" Pharmacy and Therapeutics. October 2011. Accessed June 24, 2016. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278148/. Digital peer-reviewed journal.

[5] Ibid.

[6] Lyles, Alan. "Direct Marketing of Pharmaceuticals to Consumers." *Annu. Rev. Public Health Annual Review of Public Health* 23, no. 1 (2002): 73-91. Accessed May 2016. doi:10.1146/annurev.publhealth.23.100901.140537.

[7] Ibid.

[8] Ibid.

medication's indications.[9] The third, and last, type of direct-to-consumer advertising is the most liberal in terms of what they companies are allowed to say, but may also be seen as an amalgamation of middle road of the types already discussed. It is titled the Product claim subtype. Product claim advertisements show, or tell about, both the prescription drug name, generally branded, and the conditions for which it is an approved treatment.[10] The ads that take advantage of this allowance, to state both product and indication, are supposed to give adequate if not equal time and weight to risks and benefits to avoid unduly influencing patients, however, because the pharmaceutical companies do not always adhere to this, and for many other reasons, this group is the most controversial. While the first two subtypes of direct-to-consumer advertising are less invasive to the medical process and likely carry adequate benefit to off-set what ever negative consequence they may incur, this has yet to be firmly established in regard to the Product claim type. Because the Product claim group does not have clearly defined moral standing, it is this grouping within the larger category of direct-to-consumer marketing of prescription medications, that will serve as the primary focus of this thesis of ethical inquiry.

Ethics in marketing and medicine are respectively complicated, but push them into the same sphere of interaction and it creates a plethora of interrelated topics. While it would be impossible to address all of them in a paper of this length, it is worth noting was some of the surrounding issues may be encountered. Pharmaceutical companies push

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[9] "U.S. Food and Drug Administration." Keeping Watch Over Direct-to-Consumer Ads. Accessed June 24, 2016. http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107170.htm#TypesofDTCAds. Last Updated: May 10, 2010, Archived

[10] U.S. Food and Drug Administration." Keeping Watch Over Direct-to-Consumer Ads. Accessed June 24, 2016. http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107170.htm#TypesofDTCAds. Last Updated: May 10, 2010, Archived

for the most prescriptions sold (i.e. the greatest financial gain) for each drug they produce. This potentially leads to a mistaken miracle cure mentality. The correct title for this would be promotion of off-label use, or otherwise publicizing the positive effect of drug X, which was produced for condition Y, when taken for unrelated disease Z. This can be considered the direct neighbor topic of my focus. While I cover the ethics of advertising to patients, of prescription medications for their intended usage categories, Off-label promotion and use has the same target audience but a different purpose. On the other side, another related aspect is label-approved usage being marketed with the aim of informing and influencing physicians' prescribing practices. The third difficulty in that same vein is prescriptions, which are legitimately written, with or without the influence of marketing, and are then intentionally abused in use by the consumer. The last outside issue is illegal promotion to patients, or when the pharmaceutical companies use international websites to circumvent the restriction on direct-to-consumer marketing in the country from which the information is accessed, but not produced. Although, in practice, this may be a grey area, for the purpose of this analysis it is an illegal and likely immoral action. While these issues are relevant, they do not fall within the scope of this paper.[11] I have as my focus the legal act of direct-to-consumer marketing of pharmaceuticals in the United States of America, its effect on the physician-patient relationship, and the long-term ethical implications of continuing to allow such advertising practices.

Literature review

There are hundreds of articles that could have been included in this review. However, I had to choose a select few that would both give the climate of this ethical issue and help to put into perspective the reasoning and purpose of my moral inquiry. While there is overlap among the publications selected this is because most of them provide some introduction on the shared topic. Despite the reiteration of some information, each goes on to discuss the topic from a new perspective or has additional points of support not mentioned in the others. For having such a short history the subject of direct-to-consumer marketing of pharmaceuticals has a proliferation of writing published on its intricacies, and yet I feel there are still gaps in the academic conversation surrounding it.

A Decade of DTC Advertising of Prescription Drugs

Published in 2007, ten years after the full relaxation of the American Food and Drug Administration's (FDA) policy governing direct-to consumer marketing, the New England Journal of Medicine article titled *A Decade of Direct-to-Consumer Advertising of Prescription Drugs* gives a well-rounded introduction to begin my literature review.[12] The decade to which the piece is referencing is not the beginning of regulation (or acceptance) of direct-to-consumer advertising, but rather marks the year the FDA first allowed for the advertisements to be run on television meant for the masses.[13] Donohue et. al. highlight the notion that even from the beginning there has been apprehension surrounding the use of this marketing practice, especially in popular media.[14] Almost a decade ago, at the time of its publication, the article cites several studies conducted, which denote that while the practice, "helps to avert underuse of medicines to treat

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[12] A Decade of Direct-to-Consumer Advertising of Prescription Drugs Donohue, Julie M, PhD; Cevasco, Marisa, BA; Rosenthal, Meredith B, PhD. **The New England Journal of Medicine** 357.7 (Aug 16, 2007): 673-81.

[13] Ibid.

[14] Ibid.

chronic conditions…" it also, " leads to some overuse of prescription drugs."[15] Additionally, another unforeseen complication with the new marketing techniques was that it was so effective in promoting sales it caused a rapid expansion of the patient population partaking in therapies; this coupled with the advertisement of medications which had been only recently approved for use, compounded into a disaster of unanticipated side-effects with no system "post-marketing surveillance" in place to track occurrences and warn other users.[16] Following the necessary removal, from market, of a new drug that had been intensely promoted via media sources, the FDA was urged to impose new restrictions on direct-to-consumer advertisements for newly developed medications.

The remainder of the publication focused in on the effect of direct-to-consumer marketing on prescription drug demand, the evolution of advertising in their timeframe, and tracking the changes and practice of its regulation. In the section "Industry-Wide trends in Promotion" it is detailed that promotional spending jumped to $29.9 billion, a increase of $18.5 billion over the span of ten years. More interestingly, and to the point of this paper, the direct-to-consumer segment of marketing expenditures saw a 330% expansion during the same timeline. While the author is quick to point out that promotion to professionals still far outweighs the cost of consumer directed materials, I must offer a rebuttal. The percentage of promotional spending allocated to physicians versus consumers cannot be compared. If however the time comes when pharmaceutical companies are allowed to have their representatives hold lunch conferences with

[15] Ibid.
[16] Ibid.

individual patients to discuss their choice in prescription medications there may begin to be a leveling in the ratio of physician and consumer directed advertising expenditure.

Aside from providing a succinct background, this article highlights the relationship between the companies, the governmental policy, and role of the FDA. The drug administration, although not directly taking action (i.e. not advertising the drugs themselves) does play a significant part. A longer or more in-depth paper of inquiry might research the fiscal connections of the individuals involved in the FDA and pharmaceutical companies to ascertain why it appears the FDA's allegiance is falling in line with the corporations over concern for the safety of the people, however, in a small part, this article will be revisited in this paper while discussing the rights and responsibilities of government agency.

Understanding Prescription Drug Advertising / Be Smart About Prescription Drug Ad

The website that serves as the focus of this section of review is a collaboration between the FDA and the non-profit organization (NPO) EthicAd.[17] The front page indicates to patients that a medical professional should be their top resource in assessing the proper medications for their specific conditions and yet the rest of the information is geared toward self-sought education on prescription drugs and their advertisement. For the consumer, this may be just as confusing as, the often conflicting, information presented in the direct-to-consumer advertisements themselves. From the rest of the information provided in the *Be Smart About Prescription Drug Advertising, A Guide For Consumers*, there appears to be a genuine interest in communicating useful information

[17]"Prescription Drug Advertising." U.S. Food and Drug Administration. Accessed June 24, 2016. http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/.

to those who seek it. The lower portion of the main page provides easy to understand definitions, of the three types of patient directed prescription marketing, along with an example of a correct and incorrect execution of each type.[18] The second sub-link, headed *Background on Drug Advertising*, places the idea of advertising in context with the FDA responsibility to public health and welfare. The writing states that although the FDA oversees this practice, direct-to-consumer advertising has never been covered under federal law.[19] The article states the information previously available to pharmacists and physicians, to share with patients as relevant, but that during the mid-1980s the companies granted public access to the same information.[20] The page closes with a statement that asserts the FDA shifts the way they regulate the commercial activities of pharmaceutical companies according to direct feedback from the public.[21] One of the following sub-linked pages is a glossary of terms.[22]

While it has only nineteen entries, and the information should be available to patients, with the definitions ranging from *Adequate Provision* to *Substantiation*, I have two concerns.[23] The first, that the terms and their explanations may be above the level of the substantiated public reading comprehension level, could be addressed by reformatting the presentation of information from glossary to inclusion in an engaging in-text format. The second concern is the placement of the important terms as the fourth sub-link. These terms are being used in the pages which proceed this, if the author wants a layperson to

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[18] Ibid.

[19] "Background on Drug Advertising." U.S. Food and Drug Administration. Accessed June 24, 2016. http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm071964.htm.

[20] Ibid.

[21] "Background on Drug Advertising." U.S. Food and Drug Administration. Accessed June 24, 2016. http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm071964.htm.

[22] "Drug Advertising: A Glossary of Terms." U.S. Food and Drug Administration. Accessed June 24, 2016. http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm072025.htm.

[23] Ibid.

be able to understand their text (and has clearly identified these terms as potentially difficult but of great importance) then it would behoove them to ensure the reader has been exposed to the terminology before encountering it as a key point in the main text.

The remainder of the pages contain a set of questions and answers about different aspects of direct-to-consumer marketing, including what the advertisements are not required to disclose, and a list of questions to ask oneself when considering a drug for which one has seen an advertisement.[24] [25] From the perspective of this paper, the FDA sponsored website does not introduce novel concepts to build upon. It does, however, provide insight into the level of consumer awareness surrounding the techniques of direct-to-consumer advertising since this is the most comprehensive and reliable patient directed source on this material.

Although this section was originally reserved for a small article published in the Journal of Psychosocial Nursing & Mental Health Services, under the title, *Understanding Prescription Drug Advertising*, however the full text of this was a referral to the above website.[26] [27] It is worth noting however, the research discovery process of my eventual source because it is clearly built to inform the public and yet it was not uncovered through routine internet search engine use but in a publication of psychosocial nursing—a periodical which I highly doubt is being widely read by patient consumers

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[24] "Prescription Drug Advertising: Questions and Answers." U.S. Food and Drug Administration. Accessed June 24, 2016. http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/UCM076768.htm.

[25] "U.S. Food and Drug Administration." Prescription Drug Advertising: Questions to Ask Yourself. Accessed June 24, 2016. http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm071915.htm.

[26] Understanding Prescription Drug Advertising Anonymous. **Journal of Psychosocial Nursing & Mental Health Services** 46.11 (Nov 2008): 10.

[27] Note: The article, which directs to the FDA sponsored website, was also published anonymously in the Journal of Gerontological Nursing.

affected by the advertising the informative website explains. Even now, when the information is available to the people, I must question if they are finding and using it to their advantage.

If indeed the consumer accessing the information, while the first article implicated the FDA in a negative light, this website is a point in favor of the FDA's ethical consideration. The information gleaned from the review of this content will be used again be used in the rights and responsibilities section of government agencies, but also the patients' rights and responsibilities section, and later in evaluating the effect on the doctor-patient relationship.

Direct Marketing of Pharmaceuticals to Consumers

The article, *Direct marketing of pharmaceuticals to consumers*, published in the 2002 Annual Review of Public Health, holds the aim of examining the motivations for patient directed marketing, its evolution, and indication of its effects with special respect to the application to health services and its outcomes.[28] In the document, Alan Lyles concedes the topic has enthusiastic debaters on both sides of the issue. He cites those in favor herald this form of advertising as a direct extension of the autonomy and empowerment to which patients are entitled.[29] Critics of the practice rebuff this notion, argue that it is inappropriate, and that it frequently causes misinformation. The author neither agrees or disagrees with his in-text quotation of Mr. Holmer, who argues that the pharmaceutical companies do not make physicians' prescribing decisions.[30] However, I must respond to indicate the obvious notion that the companies' motives are for financial

[28] Direct marketing of pharmaceuticals to consumers, Lyles, Alan. **Annual Review of Public Health**23: 73-91.
[29] Lyles, p 73.
[30] Ibid.

gain, and if the advertisements did not measurably influence physicians' prescribing practices that rather costly style of marketing would be discontinued.

Lyles moves on to discuss the role of managed care. He says, managed care has outlined policies that effectively lower the impact of physician targeted marketing tactics, (by controlling doctors prescriptive authority) but because the doctors covered under managed care also have imposed time constraints, surveys are showing a trend of plummeting patient confidence in their doctors and the medical institution.[31] The majority of poll respondents marked that they thought their healthcare plan would sacrifice the quality of care for the purpose of cutting costs. Lyles explains that direct-to-consumer advertising, "reflects the consumer's growing role in prescription drug decisions in managed care, desire for information, and distrust in their providers."[32]

The section on regulatory background will be covered, and cited, in the history section of this paper, and the background of patient autonomy will play a key part in examining the change in the doctor-patient relationship. Because I build off of Lyles foundational argument later in this thesis, his section on autonomy is of particular importance for the literature review. Advertising that piques the interest of patients raises the likelihood that they will approach their physician in regards to the condition.[33] "Supporting patient autonomy, however, will require physicians to employ a variety of communication skills [which they may or may not possess] to encourage patients to be active partners in their own care."[34]

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[31] Lyles, p 74-75.
[32] Ibid.
[33] Lyles, p 75-82.
[34] Ibid.

"DTC is one component of a broader marketing and communication plan for businesses, it represents and investment of resources that can be evaluated by its return on investment. Although purely financial models may measure the achievement of business goals they are silent on health consequences."[35] The heart of the issue in this piece lies within these unmentioned health consequences. While the FDA does have a set of criteria to which the patient targeted ads must adhere, the real number of "enforcement actions" against companies who violate the prescribed guidelines is fewer would be expected. And furthermore, because many people believe that, "television advertising implies drug safety," it becomes clear that the post-airing review practice is insufficient as a stopgap to the dissemination of misinformation and consumer damage. [36]

The health consequences mentioned above can be seen in the data reported on in the *Patient Awareness* section. Following a survey, which inquired about advertisements for ten chosen medications, 91% of respondents had knowledge of at least one medication.[37] However, in the selected group of those who actually suffered from the conditions and might benefit from the use of the prescriptions in question, eight out of the ten medications, were unknown to more than half of the patients. This startling contrast indicates the targeted ads are falling short of their intended audiences.[38] Though the author concedes there may be a way to ethically, and with regard to medical consequences, use direct-to-consumer marketing for its benefits, a serious public health

[35] Lyles, 3.
[36] Lyles, 3.
[37] Lyles, 3.
[38] Lyles, 3 of 9

risk is undertaken when patients fail to understand advertisements and make inappropriate demands for prescriptions.[39]

Beyond raising basic awareness for prescription drugs, the educational potential of DTCA appears to be failing." Of the drugs selected for the study, Claritin® alone had a patient awareness of its existence and indication above 70%, with Lipitor® falling at 40% and the rest under 33%.[40] For a three-year span starting in 1997 32% of consumers who saw an advertisement brought the conversation to their doctor. Within this group 26% specifically requested the drug advertised, and 71% received the prescription. Because the primary goal of the companies is not education but bottom-line sales, this information can answer the query into the effectiveness of the advertisements from the perspective of the company. Assuming a random pool of 10,000 U.S residents, 9,100 will have seen the commercial for a given drug; approximately 537 (or 5.3 percent) of them will have subsequently sought out and actually received the prescription in question.

While proponents of the marketing technique cite it has the potential to support respect for autonomy, backed by the 47% who responded that they felt the ads aided them in making better decisions regarding their own healthcare, these responses, "reflect beliefs and not necessarily that patient autonomy is increasing."[41] In fact 24% of respondents marked that they felt the targeted commercials made it, "seem like a doctor is not needed to decide whether a drug" was the correct treatment for themselves.[42]

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[39] Lyles, 3.
[40] Lyles 4.
[41] Lyles 4.
[42] Ibid.

Lyles asserts that this marketing, by creating a direct line of communication between the manufacture and the consumer, places additional liability on the companies involved.[43] This is because the transaction removes the physician, who would normally serve as the learned intermediary.[44] Additionally, through this practice, pharmaceutical companies disrupt the functioning chain of command for negotiating healthcare policy with other industry parties and open themselves up to civil litigation.[45]

DTCA has a known, mostly positive, impact on the industry.[46] What is not known is the impact on public and the author believes there is a need for more research.[47] Now, more than a decade later, there is more information than was available then, but I agree that additional focused research is need. The priorities of the market conflict with public health, and unintended consequences of the practice necessitate increased attention and manpower to correct issues as they arise.[48] This creates an overall increased workload for physicians which is a problem for both the providers and patient care.[49] The article asserts that banning consumer directed advertising would not fix the issues because much of the information available is not from a regulated source.[50] If this is the case, that the information will be there regardless of the regulations in place, and the information is also harmful; it is a morally and logically flawed to not work on one issue because

[43] Ibid.
[44] Ibid.
[45] Ibid.
[46] Ibid.
[47] Ibid.
[48] Ibid.
[49] Ibid.
[50] Lyles.

another issue is also present. In conclusion, Lyles believes (for better or worse) the focus should be on working with the system that is already in place. [51]

Info- impact of pharmaceutical direct advertising: opportunities and obstructions[52]

The article, written in 1998, is now quite outdated. However, I included this in my selection for a very important reason. Even at that point, only a year after the expansion to television advertisements was allowed, they recognized that direct-to-consumer advertising was rapidly expanding and the companies had no intention to slow down. The author cites that the early reports indicate the marketing technique had a significant impact, with doctors polled in 1989 and again in 1995, there was a fifty percent increase in patient requests for specific, name brand, medications.[53] This appears, to me, to be a red flag that direct-to-consumer marketing does not radically promote new patients to seek healthcare, but rather impacts the current patients to request brand names. At the time of the article, more companies were beginning to recognize the potential value of DTC advertising and the number of companies participating was increasing substantially.[54] It is likely that the practice is effective because the allowance of patient targeted marketing gives pharmaceutical companies additional points of contact.[55] While it does have the potential (or intention) of creating more knowledgeable consumers, there are other factors that need to be taken into consideration including the rise of baby

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[51] Ibid.
[52] The impact of pharmaceutical direct advertising: Opportunities and obstructions Pinto, Mary Beth; Pinto, Jeffrey K; Barber, Joseph C. **Health Marketing Quarterly** 15.4 : 89-101.
[53] Ibid.
[54] Ibid.
[55] Ibid.

boomers and managed care, changing consumer prescription practices as well. "roadblocks" limit the utility of DTC. Researchers, and analysts, should understand both pros and cons of the practice.[56]

After the legalization of DTC one of the first campaigns was for baby formula- although not a prescription it signaled a shift in thinking. Previously the decision to bottle / breastfeed was heavily influenced or initiated by physicians.[57] The "push promotional strategy" was the first step in consumers becoming "active decision makers" The author proposed potential dangers arising from the public's general lack of medical knowledge and the associated propensity of jumping to inaccurate conclusions.[58] Together they aid the clash of consumer wants with physician knowledge. Many doctors felt the ads we based in fact but emphasized the benefits of efficacy and speed which would more easily mislead consumers.[59] There are different types of marketing materials which adhere to stringent FDA guidelines. The first is too vague as they do not mention the purpose of the medication, and the other is too technical in its adequate explanation of risks and benefits, both types can contribute to a misinformed patient.[60]

The author, a clear proponent of managed care (which seeks to minimize visits to the doctor) argues that DTC marketing disturbs the system by encouraging patients to see doctors for the advertised drug.[61] Pinto, like most of the authors reviewed, suggest more research is needed; however, most if not all the proposed areas of research has since been explored.

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[56] Pinto.
[57] Ibid.
[58] Ibid.
[59] Ibid.
[60] Ibid.
[61] Ibid.

She concludes that due to the significant increases in DTC spending, the pharmaceutical companies must be receiving comparable returns on the investment, and cites the "absence of a well-structured policy by the FDA" for the frequent confusion surrounding drug advertising.[62] Her core belief is that providing more information will allow "for maximum flexibility in advertising while working to maintain the lid on healthcare costs." It is clear that the financial aspect of healthcare, DTC, and its effects are the author's (and many people's) primary concern, however, it is my opinion that a large part of the *perceived* effectiveness of medical treatments has its roots in the human interaction. assessing DTC as a business model, from both sides of the issue, has already been done and shown to be inadequate.[63]

Perspective: DTC Advertising Benefits Far Outweigh Imperfections.[64]

Pat Kelly recognizes that two equally astute academics can look at the same information and argue for opposing conclusions. The author Pat Kelly, president of the U.S Pfizer Pharmaceutical Group, states, "Our position as a pharmaceutical company is plain: We believe that any health information for consumers that is accessible, accurate, and motivating is beneficial if it leads to more, and more productive, physician/patient encounters."[65]

Kelly makes several important points. Arguing that the venue of direct-to-consumer communication acts as a catalyst for consumers to take an active part in advocating for and managing their healthcare. The publication says one of the benefits is that it encourages patients to talk to their doctors and facilitates the deepening of the

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[62] Pinto.
[63] Ibid.
[64] PERSPECTIVE: DTC Advertising's Benefits Far Outweigh Its Imperfections
Kelly, Pat. Health Affairs, suppl. WEB EXCLUSIVES (Jan-Jun 2004): W4-246-8.
[65] Ibid

doctor-patient relationship.[66] "positive force in reducing racial and ethnic disparities in health" (no because the continued disparity in the population reached by DTC, particularly Hispanic groups-cite). Later the cost of advertising raising the cost of prescription medication is addressed. This is the one area where I may agree, in part, with the writing. Spending money on advertising actually lowers the per unit overhead cost because it results in an increase in sales. So while more is spent on healthcare it is due to a greater number of prescriptions being filled rather than more expensive medications. However, there is concern in that respect as well because advertising could potentially sway doctors and patients against the generic equivalent and toward the more costly brand name medication.

The piece ends with the impression that it is all about the patient. "many consumers lack the context required to judge if a medicine…is a miracle or a waste of money. Clearly, more understandable and accessible health information for consumers is needed, not less."[67] While that may seem noble, the catch is they believe the answer is for the companies to jump in and provide that information with an increase in targeted marketing as a response. (my opinion- ironic that this is the only piece that definitively sides with the pro DTC crowd. It cannot be taken seriously because of the glaring conflict of interest. Additionally, the footnoted sources are dominated by unpublished papers and presentations that have either yet to be peer-reviewed or are from in-house conference slideshows. The whole thing is poorly disguised pharmaceutical propaganda.

Direct to Consumer Advertising: Its Effect on Stakeholders.[68]

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[66] Kelly 2 of 3.
[67] Ibid.
[68] Direct-to-Consumer Advertising: Its Effects on Stakeholders

Written by a team based out of University of Houston Texas medical center college of pharmacy, the report asserts prescription drug research is an expensive undertaking, and that advertising helps to ensure the success of the final product and return on investment. Aside from meeting its aim of promotion direct-to-consumer advertising has a significant effect upon the medical establishment. "it influences the attitudes and behaviors of its stakeholders."[69] The article gives a short history of types of patient targeted marketing, their rise, and regulation; before thoroughly exploring the effects on stakeholders and surrounding debate. In the first group addressed, physicians, the author establish the three moral duties. These will be discussed later in my report under the section on physician rights and responsibilities.

From their research the authors generalize that physicians seem to have a negative opinion surrounding direct-to-consumer advertising of pharmaceuticals particularly due to the insufficient information provided. This leads to misinformed patients who disrupt the efficiency of the doctors, "and causes the physician to spend more time with each patient and having to 'unsell' the drug." While the proposed benefit of spurring patients to seek out information from physicians seems noble enough, unfortunately when patients mention specific advertisements doctors report feeling pressured to prescribe it. The physicians also cite they give the drug in question, even if they are ambivalent about its clinical appropriateness. For pharmacists, little research has been conducted, but from what has been gathered it seems most pharmacists—despite wanting the supposed benefits (i.e increased knowledge of and conversation surrounding prescriptions) of

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Montoya, Isaac D, PhD, CHS, CLS, CMC; Lee-Dukes, Gwen, MD; Shah, Dhvani, BTech. **Journal of Allied Health** 37.2 (Summer 2008): 116-20. Accessed online though ProQuest January 29, 2015.

[69] Montoya, 116.

direct-to-consumer marketing—do not support its continued practice. Pharmaceutical companies take differing angles on the subject, though I would personally venture to say they are all in favor. The piece in review notes that the, "manufacturers believe direct-to-consumer advertising does help them enhance their brand recall, sales volume, and brand loyalty."[70] From my perspective this is likely true. If I were to evaluate the marketing technique as an effecting business strategy then I would probably end on the side in support of the practice, but because this is an ethical review and analysis I must argue that this information has a place, in my paper, only in so far as to give complete information. The benefits for the pharmaceutical companies do not stand up as support for a practice which is affecting such widespread and unfavorable change for other stakeholders.

Despite evidence to the contrary, reports show that consumers believe, prescription advertisements do not harm their interactions with their doctors and yet "advertising has shifted the delivery of healthcare from the 'traditional paternalistic' model where information exchange is only one way…to a 'shared decision-making' model where information exchange is two ways and both the physician and the consumer participate in the decision-making process."[71] Those in favor of direct-to-consumer marketing lobby for its full employment and point to what they identify as a consequential improvement in public health. On the other hand, the opponents' points are clearer in outlining some of the risks such as: seeking medication over alternatives,

[70] Montoya, 119
[71] Montoya, 118.

inability of public to understand the advertisements themselves, pressure on the physician, overtreatment, lack of continuity of care, and self-medication.[72]

In conclusion the article, from the summation of materials, reaches the decision that benefits should be maximized and harm minimized. The recommendation is to follow the advice of The Committee on Bioethical Issue of the Medical Society of New York; to reexamine and revise regulations with the aim of preventing the worsening of the relationship between doctors and patients. In practice they would advise for the prohibition of all unsolicited patient targeted advertisements.

The article, "Direct to Consumer Advertising: It's effect on stakeholders, is closely linked with my own analysis and would serve as a worthy introduction as it lays the foundation of my paper. However, the bulk of the analysis in this thesis is ethical, and not only so, but also from multiple schools of thought with the aim to more exhaustively understand the effects of direct to consumer marketing on stakeholders and follow with a prescriptive recommendation of how the advertising technique in question might better be employed to the advantage of all, but particularly vulnerable, stakeholders.

The DTC Dilemma[73]

The DTC dilemma is concerned with the reason for the heated debated and controversy of direct-to-consumer marketing of pharmaceuticals. The paper denotes that pharmaceutical companies should ask themselves the following questions. Why does the issue have a continued air of controversy? Do the known benefits adequately offset any long-term negative impact? And are there changes to the policy and practice that could

[72] Montoya 119.
[73] The DTC dilemma, Shaw, Michael. **Pharmaceutical Executive** 21.5 (May 2001): 104-112.

help address concerns while still allowing the products to meet the companies' aims? The answers to these questions are important because until the issue is fully addressed there may be ongoing, and permanent, damage to the institution of medicine. A large red flag should be noted when medical insiders, such as those in the field of medical education, issue statements along the lines of the following, "In many ways, academic medicine has been asleep at the wheel by not exercising more responsibility for the direction that healthcare has been taking for the past 20 years."

The shift in practices, from advertising to professionals to the current use of consumer directed materials, forced the loss of the learned intermediary. While the pharmaceutical companies and health professionals both operate within the scientific and have much overlap in knowledge and expression of language, "no common language exists for industry to communicate with consumers…[and so] ads [for controlled medical substances] have adopted the language of [generic] consumer advertising."[74] Although the article states it is not an issue for physicians that the pharmaceutical industry now communicates directly with patients, they do take notice and in turn criticize that, "most DTC ads are aimed at consumers' emotions rather than their intellect," and the issue that, "most [materials] fail to provide full and impartial information about the product and the condition for which it is indicated in a form understandable to the average consumer."

The biggest roadblock to policy reform is the challenge for the companies to understand the gap between how its actions are intended and perceived by them versus how others might view them.[75] "the gap between those expectation and the perceptions of pharma companies and their ad agencies lies at the heart of the public crisis of

[74] Shaw, 2.
[75] Ibid.

confidence."[76] Because the advertising fills a position previously held for physicians the pharmaceutical companies are acting as, "de facto healthcare providers."[77] Direct-to-consumer advertising, by initiating this role swap, was disturbed the confidence of the people. In the past, patients have trusted their doctors, and the information they provide, because there is in place a system, "of ethical standards to which healthcare providers are expected to adhere, including the commitment to place the good of patients above all other considerations."[78] The perspective of my paper, or rather the reason the pharmaceutical companies should take notice, is this: if they want to garner the trusted status that will allow them engage in the provision of health information, then they must follow an equally stringent set of ethical principles. While I suspect that the companies' current practices violate the guidelines for moral practices, my paper will explore a full analysis before drawing any firm conclusions.

Action is needed. Although publications from EthicAd, the NPO involved in the website addressed earlier in this review, suggest that pharmaceutical companies should have the opportunity to implement their own, "voluntary standards for DTC without legislative interference." many within the industry think they have fulfilled their duties by using an independent advisory board, and testing advertisement materials for knowledge on their educational value, but this is not enough. [79]

What Are The Public Health Effects of Direct to Consumer Marketing[80]

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[76] Ibid.
[77] shaw 2.
[78] Ibid.
[79] Shaw 3.
[80] What Are the Public Health Effects of Direct-to-Consumer Drug Advertising?: e145 Almasi, Elizabeth A; Stafford, Randall S; Kravitz, Richard L; Mansfield, Peter R. **PLoS Medicine** 3.3 (Mar 2006): e145.

The article, *What Are the Public Health Effects of Direct-to-Consumer Drug Advertising,* is broken down into subsections each detailing the apparent opposing views of the four authors. Almasi and Stafford's viewpoints are grouped together and offer a valuable insight. They acknowledge that direct-to-consumer advertising can lead to over prescribing, but argue that the advertisements may be inadvertently producing the positive induction of the placebo effect. Explanation of the phenomenon, link to advertising, is offered with the introduction of two theories. Pavlovian conditioning would explain the phenomenon because the commercials associate the drug therapy with idyllic images of individuals in situations that would be impossible were they not symptom free (i.e. the arthritis sufferer enjoying a game of tennis). While the theory of expectancy-value, where "individuals are receptive to signals confirming their initial expectations"[81] would give an alternate (or additional) reason for the occurrence of placebo-enhanced outcomes. It is unsettling to think that television advertisements could heavily influence such a vital area of the public's personal lives through the creation of an emotionally conditioned response, however, it can also be seen as a benefit because a placebo induced or enhanced outcomes could lead to improved patient adherence to medical directives.[82] Despite, or perhaps because of, this benefit the pair advocate for stricter guidelines governing advertising, to safeguard against individuals forming "unreasonable expectations" and to, "lessen the negative impacts."[83]

The following section, containing the viewpoint of Kravitz, highlights that there are many entities on each side of the pro-con debate, and advises that this is—in his

[81] Almasi, 2.
[82] Ibid.
[83] Almasi, 3.

opinion—because the practice itself has aspects that are both good and bad.[84] He says that despite these three things: the costs of drugs are increasing, some medications are overprescribed, and some are under prescribed—Direct-to-consumer advertising should not be banned but more heavily regulated. The practice should be used "to deliver public health benefits when the condition to be treated is serious and when the treatment is safe, effective, and underused."[85] As such the practice should have a governing policy that its benefits are "maximized and risks minimized within our free market system."[86]

The last author represented within this article is Mansfield. Although he has by far the most negative opinion of advertisements targeted to consumers, his piece is perhaps the most realistic. He exposes idea that the pharmaceutical companies only take advantage of the opportunity to use direct-to-consumer marketing when the drug will yield a significant return on investment, their chief aim is not to increase knowledge but to persuade the purchase of more prescriptions. Because of this, advertisements focus more of the benefits over risks, and lead to patients believing they are more fully informed than they truly are. Another negative aspect highlighted, is the ads can create false anxiety surrounding normal experiences that are portrayed as symptoms. Patients, thinking they are well informed, fail to seek additional information from other reliable sources before searching out a prescription for their conditions. Mansfield cites two causes for the ultimate classification of direct-to-consumer advertising as negative. One, already discussed, is the "normal human vulnerability to be mislead," and the other is "payment systems that reward drug companies for increasing sales of expensive drugs

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[84] Ibid.
[85] Almasi, 4.
[86] Ibid.

regardless of the impact on health." He concludes, it is unfeasible to properly regulate direct-to-consumer advertising and the most responsible action would be to ban its use entirely, and replace it with information provided by more trustworthy sources.

Stress From Deceptive Drug Ads and Corruption[87]

The article from Paul Rosch details several instances of deceptive advertising that bring to light the larger issue of corruption.[88] While the focus of my thesis is to analyze the ethical merit of properly executed marketing (i.e. within the current guidelines), it is important to note that even if the practice is morally permissible, which has yet to be established, usage outside the governing rules is unacceptable. Originally, the approval for use came in order to have an additional educational venue for the public, yet the companies have capitalized on this as a promotional outlet. Rosch reiterates this, mirroring what I reviewed in previous articles, that the pharmaceutical companies would not continue the practice of direct-to-consumer marketing if it were not profitable for them. And the statement is validated, at least in part, as in the study cited in the text under review, for each dollar spent on drug advertisements targeting consumers, the companies have seen a $4.20 return.[89]

Research is expensive, the companies may view advertising as a way to secure the success of their products; however, with such a great investment, there may be temptation to venture into unethical territories - especially when results do not go as planned.

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[87] STRESS FROM DECEPTIVE DRUG ADS & CORRUPTION Rosch, Paul J, MD, FACP. **Health and Stress** 5: 1-13. Accessed through http://search.proquest.com.ezproxy.drew.edu/docview/274968481?pq-origsite=summon&accountid=10558

[88] Rosch 1-13

[89] Ibid.

Additionally, there is immense competition within the industry, and in an effort to out-sell others, some have shown to take advertising to hyperbole. As already noted, there is a natural human tendency to be mislead. This means the advertising tactics which marginalize normal occurrences make it more likely people will choose the new, more costly versions of medications instead of the over-the-counter or generic varieties.[90] This exhibited preference is simply because the consumer is under the impression the new one is more effective despite any concrete evidence of that fact.[91] The same behavior can be seen when consumers rush to purchase the newest version of smart phone or tablet when its features are not any different than the same one they purchased six months ago. There is generally no defined enhancement between the current and the new, but they always want the newest version for its image of superiority and/or social status.

The move past hyperbole to deception is highlighted in the discussion on Pfizer's commercials for Lipitor®. The commercial in question shows Dr. Jarvik, in his white coat, claiming to be a cardiologist who prefers Lipitor for himself and his family. He is shown in various outdoor sports activities, and he appears to be happy and healthy.[92] To top it all off, the commercial made a claim of efficacy in that Lipitor created a 36 percent reduction in heart attacks for the people who used it.[93] In actuality, the person portraying Dr. Jarvik in the commercial is not a licensed medical doctor and does not treat patients.[94] Additionally, it has come to light that he does not actually participate or know how to do the sports he was shown to be doing (a stunt double was used for the actual

[90] Rosch
[91] Ibid.
[92] Ibid.
[93] Ibid.
[94] Ibid.

action shots), and he is not a consumer of Lipitor.[95] As for the claim of efficacy, the commercial held a disclaimer in small type that stated the findings were based on a difference of two heart attacks in the 100-person test group versus three heart attacks seen in the 100-person control group - both of which participated in the study for ten years.[96] Taken as a comparison of the whole, that would be only a difference of one percent, but they chose to compare only in the number of attacks seen (two vs. three), which allowed their claim of a 36 percent reduction in heart attacks for users.[97]

In a period of less than two years, Pfizer spent nearly $260 million on advertisements of Lipitor; this amount seems exorbitant, but the advertisements were so effective that in the last year of the advertisements, Lipitor was responsible for $12.6 Billion in profit.[98] Following this, consumer reports did a case study of viewer reactions towards the Lipitor commercials.[99] Of the patients polled, 65 percent felt the advertisement showed doctors prefer Lipitor, 29 percent of the polling group definitely thought Dr. Jarvik sees patients regularly, and 90 percent felt the doctor was credible and the claims of the commercial were accurate.[100]

The above information only serves to define that incomplete reporting and research cannot ever be trusted, for the data is too easy to manipulate in the direction desired. Furthermore, even if the raw data was given, based on average education and perception of the pubic, most people would be unable to interpret and understand the information at a level required to make a decision advocating in their own best interests. It is worth

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[95] Ibid.
[96] Rosch
[97] Ibid.
[98] Ibid.
[99] Ibid.
[100] Ibid.

noting, however, that the majority of medical professionals would easily be able to understand this information and translate it to their patients in a meaningful way. This would allow for the healthcare provider and their patient to work together in a more fluid way while maintaining a respect for the doctor's expertise and the patient's autonomy. This cycle of deceit is shown to continue, most famously, in the situation surrounding the ENHANCE study for Vytorin and the resulting scandal which followed. Vytorin is combination of two different drugs (Zetia and Zocor), which were combined because their manufacturers believed they would be more effective together than separately.[101] To this point, Vytorin was approved by FDA in 2004 because it was shown to lower LDL by 52 percent, making the new, combined drug more effective than Lipitor).[102] The ENHANCE study, which was supposed to prove this, was originally scheduled to run 2002 through 2006, and the results were scheduled to be reported in November of 2006. However, the disclosure was postponed to March of 2007 so a third party could review the data.[103] In January of 2007, the hired consultant told the parent companies that the results seen were not significantly different than those seen in other studies of similar medications, and the problems were not original to their drug.[104] The two companies did not find the consultant's findings favorable, so instead of providing the results at that time as promised, they rescheduled the reveal for November 2007.[105] A deadline which they also conveniently missed. The media then became suspicious that negative results were being hidden, and rightly so, because the company made another excuse and

[101] Rosch
[102] Ibid.
[103] Ibid.
[104] Ibid.
[105] Ibid.

announced they were changing the end-points of the study, along with its qualifications for success, based on the advice of a consulting group of medical professionals.[106] This change to the research qualifications caused such a backlash in the community that within a month, the company rescinded their changes.[107]

At this point, U.S. Congress stepped in to investigate the postponement and to determine if there was any evidence of a cover up during the time the drug was being heavily promoted through active direct-to-consumer advertising. Following this action, in January 2008, the companies involved in the ENHANCE study revealed that Vytorin was no more effective than Zocor when taken by itself.[108] Full results of the research were shared publicly in March 2008, and the data suggested Vytorin may have actually contributed to an almost doubling of cases of Atherosclerosis, although the findings stated this implication was not *statistically* significant in the study.[109] The Congressional investigation uncovered that some results of the study were unfavorable as early as 2005; the companies promoting Vytorin were aware of this; and they vigorously continued to promote the drug in spite of this knowledge.[110] Further support of their knowledge the results would be unfavorable comes in the fact that one company's president sold a large portion of his shares just before the results were provided publicly.[111]

The impact of this knowledge is astounding. In 2006, it is known that Vytorin prescriptions accounted for an average of $261.5 million in monthly costs to consumers, whereas in Canada, where Vytorin was not approved, prescription costs for Zetia was on

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[106] Ibid.
[107] Ibid.
[108] Rosch
[109] Ibid.
[110] Ibid.
[111] Ibid.

average $6.6 Million monthly.[112] Additionally, in 2007, $202 million in was spent advertising Vytorin to Americans, despite the fact that at this point is was abundantly clear to their manufacturers that the drug was effectively doomed.[113] The implication behind this behavior is aptly defined by a statement found later in Rosch's paper where he notes, "It is estimated that the ban on direct drug advertising to consumers probably saved Canadians with high cholesterol and their drug plans $150 million in 2006 alone.[114] It should be emphasized that the criteria that led to the approval of ezetimibe were established by drug companies rather than any independent agency and are now being questioned."[115]

Through the rest of the paper, Rosch goes on to detail the results of several other scandals of pharmaceutical companies actively promoting their products after learning of negative or neutral (no) effect from research.[116] The main point of which is that the practice is rampant in the pharmaceutical manufacturing and advertising arena, and the FDA has little power currently to curtail this. In my opinion, Rosch's article is just one of many that support and present an overarching theme of a more sinister implication in the impact of this type of advertising on the consumer as a whole in regards to a *disregard* of negative effects to the user in favor of business success. Furthermore, it is a first hand account of the dissatisfaction in how direct-to-consumer marketing affects patients and the relationship between the patient and their healthcare providers.

Conclusion of literature review

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[112] Ibid.
[113] Ibid.
[114] Rosch
[115] Ibid.
[116] Ibid.

Much has been written on medical advertisement; however, this has been primarily from the perspectives of physicians, stakeholders with substantial and direct financial interests, and academics within the discipline of pubic health. This paper fills in the gap by addressing DTC marketing of pharmaceuticals in the current atmosphere and through a direct ethical analysis and then following-up with a prescriptive suggestion of how DTC marketing could be employed to maximize the benefits and what needs to be done to first accomplish the reparation of the doctor-patient relationship.

History of DTC in the United States and Comparison to Other Countries

The advertising of controlled substances directly to consumers became legal, in the united states, in the mid 1990s; however, in order to fully understand the impact of this marketing today, one must look at the related events of the previous few centuries. Samuel Hopkins Adams, born 1871, was highly influential in the early movements of drug safety and regulation.[117] One might even go so far as to say without is politically charged writings, regulations would not have evolved to the point of protecting patients and consumers- even as little as we do today. He frequented circles with Upton Sinclair, and was an avid Muckraker.[118] The term "Muckraker" was originated by President Teddy Roosevelt for the contemporary writers of the day who had a passion and ambition for "airing the dirty laundry" of business and government.[119] They played a significant role in social justice movements- most famously in the arena of corporate America. Adams focused namely on promoting public health through exposing the evils of the

[117]Fee, Elizabeth. "Samuel Hopkins Adams (1871–1958): Journalist and Muckraker." American Journal of Public Health. 2010. Accessed June 24, 2016. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2901284/.
[118] Ibid.
[119] Arthur Weinberg and Lila Weinberg, eds, The Muckrakers (Champaign, IL: University of Illinois Press, 2001).

patent medicine industry.[120] Patent medicine, as it was called in the early 20th century, was not a new occurrence and has gone by many names throughout its long history. Dating back to ancient civilization, under the name nostrum remedium (or our remedy), these medications were composed primarily of various herbal compounds and, by the 19th century, largely in alcohol bases.[121] The proprietary blends boasted impressive claims of curative power and sold well to the American public; however, despite their manufactures' lofty promises, the medications were unregulated, inconsistent, addictive, and often dangerous. Just before the legislative reform for medications in the United states Adams published his writings saying,

> *Gullible America will spend this year some seventy-five millions of dollars in the purchase of patent medicines. In consideration of this sum it will swallow huge quantities of alcohol, an appalling amount of opiates and narcotics, a wide assortment of varied drugs ranging from powerful and dangerous heart depressants to insidious liver stimulants; and, in excess of all other ingredients, undiluted fraud [122]*,[123]

As a response to Adams call to action, in 1906, Congress passed the Pure Food and Drugs Act to form the Food and Drug Administration.[124] Though the original Food and Drugs act was fairly limited in its provisions, for the first time in the history of America, this allowed for the governance, regulation, and standardization of advertising and selling practices around food and drugs under one Federal agency.[125] It was not until 1911, however, when the Supreme Court came to a decision in the case of United States v. Johnson, that the 1906 Food and Drugs Act was used as a foundation to enforce

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[120] Ibid.

[121] "History of Patent Medicine : Patent Medicine Exhibit." Hagley Museum and Library. Accessed June 24, 2016. http://www.hagley.org/online_exhibits/patentmed/history/history.html.

[122] Samuel Hopkins Adams, The Great American Fraud (New York, NY: P.F. Collier & Son, 1906).

[123] "Chronology of Direct-to-Consumer Advertising Regulation in the United States." Academia.edu. Accessed June 24, 2016. http://www.academia.edu/278465/Chronology_of_Direct-to-Consumer_Advertising_Regulation_in_the_United_States.

[124] Ibid.

[125] Ibid.

regulation or protect the consumer. The decision in the United States v. Johnson effectively compelled manufacturers to list all ingredients in drugs.[126] Following the Supreme Court decision, Congress sought to limit the potential for extortion of the consumer, so in 1912 the Sherley Amendment was passed banning false therapeutic claims of efficacy.[127] It was later stated by the FDA that proving malfeasance with intent would be too difficult to accomplish in a court setting.

In 1933, the FDA sought a complete revision of the 1906 Food and Drugs Act. Along with the revision, the FDA wanted greater authority in enforcing previously passed regulations. However, it took a great tragedy at the hands of a drug manufacturer to bring about the next major change in drug regulations. Following the death of 107 people who took an untested drug in 1938, the Federal Food, Drug, and Cosmetic Act of 1938 was enacted, which required proof of drug safety before marketing.[128] Notably, this change in legislation made significant advances in consumer protection by extending drug regulations to include cosmetic and therapeutic devices. Consumers were further protected under the Wheeler-Lea Act, which allowed the Federal Trade Commission to govern advertising of products, including pharmaceutical agents.[129] Lastly, but definitely not least significantly, in 1938 the FDA also decided that certain drugs would require supervision by a qualified expert.[130]

Building on the foundation created by the Federal Food, Drug, and Cosmetic Act of 1938, Congress passed the Durham-Humphrey Amendment in 1951. The Durham-Humphrey Amendment expanded the list of drugs requiring medical supervision,

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[126] Ibid.
[127] Ibid.
[128] Chronology, academia.edu
[129] Ibid.
[130] Ibid.

restricted sales, and brought about a requirement for certain drugs to be prescribed by a licensed practitioner.[131] This restriction in use created a shift in the advertising of pharmaceuticals away from the consumer and toward the new target of the "qualified professional".[132]

With public support due to events surrounding the FDA denial of Thalidomide in US markets, the FDA was able to pass additional regulations in 1962- more specifically, the Kefauver-Harris Amendment. This new amendment required drug manufacturers to furnish proof of both safety and efficacy of a drug to the FDA before it could be brought to market.[133] During this time, the FDA also gained jurisdiction over prescription drug advertisements. After the Kefauver-Harris Amendment, the FDA had ensured that the drugs coming to market were monitored for safety and efficacy, but despite the partnership between Congress and the FDA, the consumer still did not have easy access to the full details of the medications they were taking.[134] In order to remedy this, the FDA worked with Congress to further clarify drug information for the patient / consumer, finally passing the Packaging and Labelling Act in 1967.[135] This new act required that drug information had to be provided to the consumer.[136] The final piece to the legislative grouping came in 1970, when the FDA began requiring package inserts for patients providing information related to the benefits and risks of taking the drug in question.[137]

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131 Ibid.
132 Ibid.
133 Ibid.
134 Chronology, academia.edu
135 Ibid.
136 Ibid.
137 Ibid.

In 1993, although at this point advertising was mainly directed at physicians, a more strict regulation of consumer directed advertising is enacted.[138] The new requirements necessitated that drug manufacturers disclose *all* possible side effects and contraindications within the marketing materials.[139] In addition, it was asked by the FDA, that manufacturers voluntarily submit marketing materials for review.[140] In support of big business, and under the guise of educating the consumer, the FDA drafts the publication of the guidelines for direct to consumer advertising in 1997 following two years later, in 1999, with the final version: Guidance to Industry: Consumer-Directed Broadcast Advertising.[141] This allowed advertisements of controlled substances on radio, television, and other media which did not provide a balance of time allocated for both promotion and risks.[142] At the time of this writing, the latest update, to product labeling requirements for medications, was in 2006.[143]

Drugs are generally regulated at the federal level in most countries. That regulation usually also includes guidelines around how those drugs are promoted and distributed. With the exception of the United States and New Zealand, no other country in the world currently allows for the direct-to-consumer advertising of pharmaceuticals. I will be using Canada as an example of how a country might regulate advertisements when they are banned from being marketed directly to the consumer. I have chosen to use Canada because of its close geographic proximity to America, developed financial infrastructure, and level of technological advancement.

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[138] Ibid.
[139] Ibid.
[140] Ibid.
[141] Ibid.
[142] Chronology, academia.edu
[143] Ibid.

As stated previously, Canada does not allow any direct-to-consumer advertising to their public at large. Under this restriction, Canadian legislature defines an advertisement as "any representation by any means for the purpose of promoting directly or indirectly the sale or disposal of any drug."[144] The restriction in place is notable because of the difference in per capita spending on pharmaceuticals when compared with USA. The per capita spending on prescription drugs in Canada for 2015 was $761 USD per person; this can be compared to the American expenditure of over $1000 per capita for the same period.[145] [146] While many factors affect these numbers DTC is a likely culprit for the majority of the difference. This claim is backed by the experience of New Zealand.

Much like the United States, New Zealand allows for the promotion and advertisement of prescription drugs directly to their nation's population.[147] In New Zealand, this is because of a lack of regulation to ban the practice, rather than direct legislation enacted for its allowance. Frequently cited is the opportunity for educating the public on their health; however, an article written by an Australian source, is more honest in stating the intentions of DTCA, stating the practice is, "designed to drive choice rather

144 "ICLG: harmaceutical Advertising 2016 - International Comparative Legal Guides." Pharmaceutical Advertising 2016. Accessed June 24, 2016. http://www.iclg.co.uk/practice-areas/pharmaceutical-advertising/pharmaceutical-advertising-2015/canada.

145 "Pharmaceutical Spending per Capita by Country 2015 | Statistic." Statista. Accessed June 24, 2016. http://www.statista.com/statistics/266141/pharmaceutical-spending-per-capita-in-selected-countries/.

146 "Financial Statistics." OECD Library. Accessed June 24, 2016. http://www.oecd-ilibrary.org/sites/health_glance-2011-en/07/04/index.html?contentType=/ns/Chapter,/ns/StatisticalPublication&itemId=/content/chapter/health_glance-2011-63-en&mimeType=text/html&containerItemId=/content/serial/19991312&accessItemIds=. Viewed same information as above citation

147 "The Impact of Advertising Prescription Medicines Directly to Consumers in New Zealand: Lessons for Australia." NPS MedicineWise. Accessed June 25, 2016. https://www.nps.org.au/australian-prescriber/articles/the-impact-of-advertising-prescription-medicines-directly-to-consumers-in-new-zealand-lessons-for-australia.

than inform it."[148] An example of this type of misdirection was seen in 2002 when an advertisement for an inhaler spurred a large number of patients to request a change to a costlier medication, only to return when a new ad ran and ask for another switch.[149] Many primary care physicians, who handled the patients making the requests, felt the commercials promoted false information, unnecessarily agitated patients, and undermined their ability to use their best medical judgment to chose medication for treating patients.[150] This was especially true in cases where the patient in question was well-managed on the current medication and any possible negative effects of long-term use of the other medication had yet to be discovered.[151] Another instance of this manipulation was seen when televised ads for onychomycosis (a fungus that discolors the nail and is generally considered a cosmetic rather than health issue) resulted in droves of self-diagnosed patients seeking treatment and a subsequent doubling of prescriptions for the promoted medication.[152] The DTC marketing has clearly affected the doctor-patient relationship in New Zealand, and the resulting change in prescribing practices has been displaced to an increased financial burden on the New Zealand taxpayers.[153]

Based on the given information, it can be deduced Canada's better position on spending in regards to prescription medications is a result of their ban on direct-to-consumer advertisements for drugs. Additionally, since New Zealand suffers from similar issues as the United States in the area of prescription and purchase of medications, and they are the *only* other country which allows direct-to-consumer advertising of

[148] Ibid.
[149] Ibid.
[150] Ibid.
[151] Ibid.
[152] Ibid.
[153] Impact, nps.org

pharmaceuticals, their problems can also be attributed to that practice. The question I must ask at this point is, would placing a ban or stricter restrictions on direct-to-consumer advertising of pharmaceuticals in America be able to fix the issues the US currently suffers as a result of the advertising which has been allowed for the last 20 years? I will address this later but first I will analyze the current situation.

Stakeholders

In order to properly conduct an ethical analysis one must first define the relevant stakeholders. First, the idea of a stakeholder must be defined in concrete terms of the subject. All endeavors, investments, and practices have a slightly different idea about the sphere of who is affected by their individual influences, in general the idea would hold that a stakeholder is any entity with a substantial direct, or indirect, interest in the practice, (company etc.) who may experience consequences subsequent to the execution (value fluctuation etc.) of the concept in question. In terms of stakeholders in healthcare, I use the following definition, "Any person or party who provides, receives, manages, or pays for healthcare…[additionally those] with an interest in the financing, implementation or outcome of a service, practice, process or decision made by another"[154] Although there may be some application in eventually trying to explore this topic in relation to all its stakeholders, this paper will only have the opportunity to handle a select few. I include for consideration: Patients, physicians, pharmaceutical companies, and government agencies. While these are the key stakeholders, I must note because of constraints of scope I have omitted for deliberation the interests of patient family members, layperson caregivers, and the managed care and insurance industry. Inclusion

[154] Segen's Medical Dictionary. S.v. "Stakeholder." Accessed February 12, 2015 from http://medical-dictionary.thefreedictionary.com/stakeholder

in the selected category of stakeholders both allows for certain rights, and denotes varying responsibilities, which must be accounted for during the conduction of ethical analysis.

Patients as Stakeholders

As explained previously in the definition of stakeholders, patients are stakeholders because they are the receivers of medical care and have both a direct and indirect interest in the practice of Direct to Consumer advertising of pharmaceuticals. Their direct interest in the practice of Direct to Consumer advertising for pharmaceuticals stems from the potential it has to influence their ability to choose their treatment and also because marketing can be expensive - these additional costs may be deferred to the consumer. Their indirect interest, something they may not even be aware of, results from the fact that whether or not they are not asking for the drug directly, it may affect their access to appropriate care based on the bias of the medical model toward patient autonomy. Furthermore, this bias could also have potentially serious consequence if the patient is not possessing the intellect, knowledge, or experience to make these decisions for themselves. as the level of autonomy afforded may create a false sense of ability to make decisions they are not legally qualified to make on the basis of education alone.

Patient Rights

All patients have the right to the best possible medical care available, given reasonable and just distribution of resources, which is to be provided in a manner that is respectful to their individual situation, needs, and personal beliefs. This includes an implied assertion that the patient is also not to be discriminated against on basis of age, race, religion, gender, sexuality, citizenship / immigration status, education, intellect, language fluency,

or any other trait or symptom they may exhibit. In addition to the classical definition of discrimination, the protection also needs to extend into the realm of associative discrimination, or bias, based on the experiences or actions the provider may observe in their other patients.

Patient Responsibilities

It is the responsibility of the patient, or their guardian, to seek treatment, to be forthcoming and truthful in their communication, and to follow all instructions regarding the course of treatment given by their healthcare provider to the best of their ability; this includes seeking clarification when they do not understand the orders given.

Doctors as Stakeholders

Doctors should be classified as stakeholders because they are both directly and indirectly affected by the practice of direct to consumer marketing of pharmaceuticals.

Doctors are directly affected by changes in patient behavior based on advertising they may have seen and now desire to receive treatment for as a logical remedy for their self-diagnosed condition. It goes without saying, of course, that this situation will almost inevitably cause a problem in the physician-patient relationship, which may also result in the mistreatment of the patient's actual illness. For example, imagine for a moment that a person sought out a computer expert because their computer was experiencing slowness, crashing, and problems with connecting to the Internet. If that same person insisted the computer repair person use a fancy antivirus they saw an advertisement for, because they heard that computer viruses cause the same symptoms their computer was exhibiting, it would at the very least cause friction in the relationship with the technician. At worst, the underlying issue of low memory and a fragmented hard drive, would be completely

missed or made worse by the addition of an antivirus program, which would have no effect on the actual cause of their problem.

Doctors are also directly affected by the practices of pharmaceutical companies in relation to how the drugs are marketed and promoted to the provider. In the past, and even now to a lesser extent, pharmaceutical companies would send representatives to meet with physicians. These representatives would shower the provider with certain perks (i.e. fancy meals, rounds of golf, etc.) and samples of the drug they were promoting. With the shift in focus toward Direct to Consumer marketing, physicians are receiving fewer visits from pharmaceutical reps, and as a result also receive less perks from their relationship with the pharmaceutical companies. For the physicians that began their practice before the Direct to Consumer marketing shift, this can lead to a further bias towards companies that still provide those perks or may create a resistance to use of pharmaceuticals that are "new" as a result of their lack of engagement or experience with the drug in question. For physicians that are new to practice, this can lead to a complacency in their research and effort in continued education on the best drugs currently available. In the most severe cases, physicians may choose only to prescribe the drugs which the patient requests. It is worth noting, however, this decline in the pharmaceutical industry advising physicians directly actually presents an excellent opportunity for greater discovery on the part of the physician, and a more effective treatment of the patient, so long as the physician is willing to put in the effort to actively research and seek out information on emerging drug capabilities and side effects, and they are highly efficient at communicating with the patient.

Lastly, but definitely not least, doctors are indirectly affected by their conscious or subconscious bias based on the current patient status quo. This is to say if the majority of the patients seen requested treatment based on advertised medication, or most are knowledgeable of treatments due to advertisements, etc., it may lead to a change in how the doctor treats patients or prescribes medications as a result of that commonality. Therefore, if a patient that does not conform to the status quo of their current practice enters with a complaint, the doctor may be unable to effectively treat them.

Doctors' Rights

Doctors' rights are simple. Just as patients have the right to access to the best possible medical care, doctors have a right to access to the best possible medical treatment options, and the unencumbered ability to determine best course of treatment according to their education and experience - tempered by the needs of the individual and their personal beliefs. Doctors also have a right to reasonable access to patients for treatment and communication, as well as to practice unhindered by policies and practices of those not directly involved in the care of the patient. This includes, but is not limited to, undue interference from unrelated government entities and private corporations who only seek to advance their own political or financial agenda (as determined / evidenced by their mission statements, actions, and/or historical support or obligation to shareholders).

Doctors' Responsibility

It is the doctors' responsibility to treat each patient to the best of their ability, to use their education and experience to the fullest extent toward that end, and to ensure that each patient - or indeed each individual complaint or visit of each patient - is treated as a singular and unique interaction free from bias drawn of interaction with other patients or

the physician's personal beliefs. For example, if the doctor decides a patient is seeking drugs for recreational purposes based on their visits over a three-day period in which they complain of back pain and request narcotics multiple times, this does not mean that another patient coming in during the same period with a similar complaint, and also requesting narcotics, does not have a legitimate need for the medication. To treat the second patient with any bias derived from the prior experience with the first patient would constitute a violation of the second patient's right to adequate and non-discriminatory care. Another example, more central to the issue of how Direct to Consumer marketing affects the physician / patient relationship, is how patient communication and participation, both on the front side (in the telling of their complaints) and on the back side (in their compliance with the physician's instructions for care), can affect a physician's judgment of the few patients who may not fit with the status quo of their day to day practice. More specifically, just because the majority of the patients a physician sees are forthcoming and truthful with their complaints, and/or they always follow directions for the prescribed course of treatment and continued care, does not mean that all patients will be that way, and this should not affect the level of care each patient receives. Ultimately it is the physician's responsibility to effectively compartmentalize their interactions with each patient while effectively drawing from their experience with each to continually improve their ability to provide medical services.

Pharmaceutical Companies as Stakeholders

Pharmaceutical companies have some of the largest stakes in the arena of Direct to Consumer marketing of pharmaceuticals, as the practice is closely tied to their current

business model and it provides a significant contribution to their yearly profits. As such, any changes to the rules or regulations of the practice, or any shift in consumer / social perception of the practice, would have a profound impact on pharmaceutical industry.

Pharmaceutical Company Rights

Pharmaceutical companies, when set within the bounds of capitalism or any similar free market system, have rights which mirror those of any other business set within the same system. They have the right to conduct business however they see fit and to offer their goods or services to consumers. They also have the right to operate free of prejudice due to the type of goods or services they produce and without discrimination for any wrongdoing of a company outside their own which produces similar goods or services.

Pharmaceutical Company Responsibilities

Pharmaceutical companies have several responsibilities in relation to their practice of Direct to Consumer advertising. Firstly, they have a responsibility to transparency in their practice, in the marketing of their pharmaceuticals, and in the function and side effects of the advertised drugs when dealing with consumers, physicians, and government agencies. They also have a responsibility to follow all set rules and regulations regarding manufacture, safety, and advertising of those same medications. And last, but definitely not least, they have a responsibility to respond in a prompt manner to any claims of wrongdoing, safety violations, or improper advertising campaigns with full compliance to any investigation, sanction or penalty imposed, and rectification of the issue up to and including resolution with their consumer base and compensation for any damages.

Government Agencies of the United States as Stakeholders

The United States government, specifically the office of the Food and Drug Administration (FDA), made itself a stakeholder when it volunteered to moderate the rules and regulations which dictate the manufacture, distribution, and advertising of pharmaceuticals, as referenced in the previous section on the history of medical advertising in the United States. Since taking up the mantle of governance over pharmaceuticals, their stake is most overtly seen in their sub-agencies acting to carry out their mission. Part of the mission of the FDA's Center for Drug Evaluation and Research (CDER) is to ensure that companies that sell prescription drugs also provide information that is truthful, balanced, and accurately described. CDER's Office of Prescription Drug Promotion (OPDP) oversees prescription drug ad activities. OPDP does this work by: (1) looking for and taking action against advertisements that violate the law; (2) educating industry and others about the specifics of the law; and (3) encouraging better communication of promotional information provided both to healthcare professionals and to consumers.[155]

The Rights of the FDA as a Governing Body

.It is the right of the FDA to have access to records; research results (both published and private); business plans and practice histories; double-blind, third-party research and results on efficacy and safety of the drugs in question; and all marketing materials used to promote the same. Additionally, since they have volunteered themselves as a governing body, and they are accepted as the standard for review, the FDA also has the right to

[155]"U.S. Food and Drug Administration." Background on Drug Advertising. Accessed June 25, 2016. http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm071964.htm.

create, update, and enforce rules and regulations around the manufacture, use, and advertising of medications.

Responsibilities of the FDA as a Governing Body

The FDA has a responsibility to uphold their loyalty to the people they seek to protect through their governance of pharmaceutical production, use, and advertisement. Due to the ever changing nature of the pharmaceutical industry, the FDA must also maintain their knowledge base about the various pharmaceuticals being designed, used, and advertised. In regards to advertising, this includes both the effects of the advertisement on the populus (social impact, trends to malpractice, and long-term negative side effects, etc.), and the need to stay current on the present technologies used to advertise pharmaceuticals as well as any future technologies which may be employed at a later date. For example, currently search terms entered on the web in search engines can now generate cookies, which can be utilized for targeted web ads on the current site, but even extending to other sites viewed in the future. In the future, an extreme version of this technology may evolve to identify conditions based on physical markers and then push advertisements based on that identification at a later date across multiple media platforms (smartphones, tablets, digital billboards, etc.). In either case, it is necessary for the FDA to continually evolve their monitoring of advertising practices to ensure all parties and media vehicles are following the guidelines and regulations set by the FDA.

These responsibilities are paramount to the continued endorsement of the FDA as the recognized governing body. If they are unable or unwilling to maintain these responsibilities, especially in areas of advertising, they should not continue to participate

in regulation at any lesser level. This is because, their involvement at the lesser extent will create an illusion of the vetting and approval of the product, policies, and practices across the board, which can lead to unintentional harm to the very people they are attempting to protect.

Prima Facie

The idea of Prima facie principles was first described by the philosopher W.D. Ross, and the purpose is to prescribe a set of simple guidelines, facilitate a conversation, by which to measure the moral standing of a given situation or action.[156] In general, the chosen concepts are few enough and such a universal nature to insure their use can be agreed upon by people of nearly any religious, cultural, national, and socio-economic background.[157] Although there are differing ideas on which principles should be included in the list of Prima facie duties, the suggestions are as far ranging as fidelity and harm-prevention to gratitude and self-improvement.[158] For the purpose of this report, because of the specific attention paid to the medical nature of the subject, I will use the 4 principles selected by Beauchamp and Childress: Non-maleficence, justice, beneficence, and autonomy.[159] In *Medical ethics: four principles plus attention to scope*, Raanan Gillon noted each "principle is binding unless it conflicts with another moral principle," when this is the case it comes to a point in the analysis when the person (laymen, ethicist,

[156] Gillon, R. "Medical Ethics: Four Principles plus Attention to Scope." *Bmj* 309, no. 6948 (1994): 184. doi:10.1136/bmj.309.6948.184.
[157] Ibid.
[158] "A Simple Ethical Theory Based on W. D. Ross." A Simple Ethical Theory Based on W. D. Ross. Accessed June 25, 2016. http://people.wku.edu/jan.garrett/ethics/rossethc.htm.
[159] Beauchamp, Tom L., and James F. Childress. *Principles of Biomedical Ethics*. New York: Oxford University Press, 2009.

or otherwise) will have to chose which principle to most closely adhere.[160] As it stands, most situations subject to ethical analysis will not fully follow, or violate, all principles it is necessary to rank the principles in order of importance.

It is obvious that each of the following are important to consider, and in evaluating a moral issue if any action would allow those involved to follow all of four of the principles then that would be the best moral action, however, this ranking will serve the cases where it is not a possibility. The ranking is listed in order from most to least important, but even the lowest ranked guideline is still essential to consider. Non-maleficence, or the principle of non-injury and harm prevention, should be considered the most important principle to which actions and policy should adhere. Particularly when considering ethical issues within the medical field, as this paper does, non-maleficence is not to be violated as it directly mirrors the central principle of physicians- first do no harm. Next is autonomy, or respect for the stakeholders' self-governance. Justice, of these four principles, can be the most difficult for which to solidly and succinctly provide a definition. "the terms *fairness*, *desert* (what is deserved), and *entitlement* have been used by various philosophers to explicate justice. These accounts interpret justice as fair, equitable, and appropriate treatment in light of what is due or owed to persons."[161] Within the arena of medicine, which is made up of finite resources, this most poignantly applies in terms of distribution of said resources. This standard is an important and flexible (if not subjective) part of the analysis because when properly applied it takes into consideration the circumstance of the individual. Additionally, justice is partially defined by injustice; meaning resources may need to be unequally distributed to achieve the just

[160] Gillon.
[161] Beauchamp, pg 241.

balance, when one individual or group under consideration has been harmed by another's actions. An extreme example of this might be treating the party who is not at fault in a drunk driving motor vehicle accident, before the person who is the cause, when equally critical patients need surgery and there is only one surgical team. The last Prima Facie principle is beneficence, while this is ranked of the lowest importance, that is only in comparison to the others and as stated previously all should be considered, and when possible all should be adhered to.[162] The decision to place beneficence below all others is only to say that one should not, and cannot ethically, forfeit the use of another principle and cite the use of beneficence as justification. The reasoning for this is because of the definition of beneficence. Beneficence is the active aspect of non-maleficence in that it encompasses the essence of action toward promotion of good.

In regards to Direct to Consumer advertising of pharmaceuticals, non-maleficence only applies to two of the stakeholder groups: 1) the pharmaceutical manufacturing company, and 2) the United States Government. For both parties, there is a direct responsibility to "do no harm", or prevent harm in the case of the FDA having imposed itself as the governing body, as non-maleficence dictates; specific to the advertisements themselves, or the practice of Direct to Consumer advertising of pharmaceuticals, neither the prescribing physician or the patients in question have the ability to influence the potential for harm which may be caused by the aforementioned ads.

When addressing the status of non-maleficence on the part of the pharmaceutical companies, their primary responsibility is to not mislead or spread false information

[162] Ibid.

through direct statements or through omission of determining factors. This should be evaluated on a case by case basis of individual advertisements because self-regulation is highly biased; profit-driven companies will often push to get away with what they can in order to increase their bottom line. Unfortunately, case by case evaluation it is not practical because of work-hours necessary by an unbiased third party and long feedback time. If an advertisement is approved, but then violates patients' rights or causes harm to the physician-patient relationship (which impedes the reasonable practice rights of doctors), it could potentially be years before this is recognized. Furthermore, it may be difficult to attribute direct causation to the advertisement itself, as the distance of time, along with numerous other contributing factors, can obscure the origin. For this reason, I propose to evaluate the practice as a whole with the scientific standard of inquiry.[163]

Demonstrating that the practice of advertising is morally sound can only be accomplished through rigorously attempting to disprove, and failing. And, in at least one case (as discussed previously in the case of the enhance study), it has been shown that patients derive misleading information from at least one advertisement of this nature, which bears proof that the Pharmaceutical Industry is violating its responsibility of non-maleficence through its practice of DTC.[164] [165] Furthermore, information gained from such campaigns can directly influence the patient's actions when interacting with their physician and may lead to the pursuit and administration of an improper medication.

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[163] This claim is based on the scientific method, which I consider common knowledge, and upon my previous academic experience.

[164] Lyles, pgs 5-13.

[165] Aikin, Kathryn J., Ph.D., John L. Swasy, Ph.D., and Amie C. Braman, Ph.D. "Patient and Physician Attitudes and Behaviors Associated With DTC Promotion of Prescription Drugs — Summary of FDA Survey Research Results." *U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research*, November 19, 2004, 1-92. Accessed June 25, 2016. http://www.fda.gov/downloads/Drugs/ScienceResearch/ResearchAreas/DrugMarketingAdvertisingandCommunicationsResearch/UCM152860.pdf.

Since pharmaceutical companies are not fulfilling the requirements of their ethical responsibilities in the practice of patient directed advertising, and this is harm, there is sufficient evidence to conclude that the companies violate non-maleficence. As such, after addressing the FDA, I will come back to introduce how this is affected when evaluated under the justification principles of double effect.

Endorsement and approval of an act already proven to violate non-maleficence aside, it is important to evaluate the culpability of the FDA separately. Is the FDA, as the acting governing body, fulfilling their responsibility to non-maleficence in regards to DTC? To better evaluate this, we should actually ask another question. Has the FDA done all they could to prevent or mitigate the harm caused by DTC? Were this being explored 15 years ago, at first glance, the FDA may not have violated the principle of non-maleficence. In the early 1900s, the FDA put guidelines in place to limit harm to the consumer in regards to advertising of products which make various health claims.[166] This legislative reform was the basis on which all future advertisement was evaluated, and had been effective (with some revision over the years) at providing the protection it was originally created to give. Jump forward to the mid 1990s, and pharmaceutical companies had found a way to effectively skirt the regulation by way of review and approval. The new advertising practices of direct to consumer targeting had no known harm, as it was fairly new in its current form. However, as of today, there is an acknowledged link. In fact, the negative effects may actually be exacerbated by the fact that a government agency (the FDA) has endorsed and approved both the drugs themselves and the advertisements being used to promote them. When the negative effect of the endorsement

[166] Chronology, 79.

and approval is considered, the government agency, which was created and self-identifies to regulate such matters, should be also be held morally culpable for failing to rectify the known violation of harm prevention. [167] Now seeing the practice is having an observable negative effect, at the very least, the FDA has a moral obligation to adjust policy in order to realign with the guideline of non-maleficence.

Non-maleficence, autonomy, and beneficence are closely linked, and some may even argue that there need not be a distinction, especially between the two which denote harm prevention and to promote benefit. That being said I believe each holds unique merit even if just to give triple attention to the issues they address. Another important aspect to acknowledge in relation to this is the idea of double effect. The doctrine of double effect is relevant in situations (or applicable to actions) that have two or more consequences when one or more of these foreseen but unintended side effects is negative or harmful. This principle is frequently seen invoked in the course of ethical debate surrounding physician assisted suicide and abortion. To ensure a solid understanding of how double effect may be applicable to the discussion of direct to consumer advertising of pharmaceuticals, I will first expound on the concept with examples of how it is commonly applied before switching back to the topic at hand.

The principle of double effect acknowledges that one action may have more than one consequence. In order for double effect to rule a course of action, that has a foreseen negative effect, morally admissible, it must meet the conditions set forth. The four conditions are as follows: 1) on a linear scale of morality, the act must fall at neutral or closer to good, 2) the actor cannot intend the negative consequence and if the good effect

[167] Aikin.

can be attained without the bad is should be (though it is permissible to have knowledge of the consequence so long as it is not intended), 3) the action cannot morally attain the good effect through the means of the bad effect, 4) the intended good must proportionately equal or outweigh the foreseen negative. [168][169][170]

The first example where double effect clearly plays a factor is in chemotherapy. A doctor may evaluate chemotherapy to determine if it is morally sound, as this action does not initially meet the prima facie principle of non-maleficence. Administering chemotherapy has a clear and foreseen negative effect; the treatment is clearly toxic and known to cause feelings of illness, aches, general pain, and reduced immuno-capacity due to damage of healthy tissue. As described previously, this knowledge of the negative effect, and the subsequent violation of the prime directive of non-maleficence, dictates the action must be evaluated with double effect to ensure it falls within the grounds of morally admissible action. It should be noted, this principle of required evaluation under double effect applies in any situation where the action or treatment of a patient seems to break the directive of non maleficence but meets all other criteria under the purview of prima facie evaluation. Continuing on in the case of administration of chemotherapy it is clearly acceptable. As we look at how chemotherapy falls within the four conditions, we must

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[168] McIntyre, Alison. "Doctrine of Double Effect." Stanford University. 2004. Accessed June 25, 2016. http://plato.stanford.edu/entries/double-effect/.

[169] Beauchamp, pg 162.

- [170] Four conditions:
    a. *The nature of the act* - the act must be good, or at least morally neutral, independent of its consequences.
    b. *The agent's intention* - the agent intends only the good effect, not the bad effect. The bad effect can be foreseen, tolerated, and permitted, but it must not be intended.
    c. *The distinction between means and effects* - the bad effect must not be the means to the good effect. If the good effect were the causal result of the bad effect, the agent would intend the bad effect in pursuit of the good effect.
    d. *Proportionality between the good effect and the bad effect* - the good effect must outweigh the bad effect. That is, the bad effect is permissible only if a proportionate reason compensates for permitting the foreseen bad effect.

first ask, “what is the nature of the act?” At its core, this action is a physician giving a medication to a sick patient - an act that not only pertains to their job but it also meets the second criterion because although the negative effects of chemotherapy are well documented, and foreseen, the intent is to heal. Both act and intention are morally good. Additionally, the last piece of the second condition (the negative effect must be reduced or avoided if possible) is satisfied through the medical community’s continued search for more effective, less invasive, and less destructive alternatives to current cancer treatment. Delving deeper in evaluating the means vs. the effect, the good effect (of curing the cancer) cannot be attained without the negative side effects, yet the side effects do not cure the individual (e.g. the bad is an effect of, and not the means to the cure). In looking at how the use of chemotherapy meets the requirement of the third condition (the negative effect is not the means to the cure), it becomes readily apparent that it also meets the fourth condition in that the benefit of extended life, and potential return to future health, easily balances, and in many cases far outweighs, the temporary discomfort of the side effects presented in the course of chemotherapy.

In a second example, we evaluate another physician’s patient - a woman who was sexually assaulted and subsequently became pregnant now seeks an abortion, as she does not want to raise a child that reminds her of her ordeal. The act of the abortion is again, at its core, a medical procedure performed within the scope of a doctor's practice under the intent to help the patient. In this case, the agent intends to help the patient, however, the second requirement of double effect is not met because the same outcome (not having to raise the child) could be achieved without negative effect of the abortion by mitigating the mental component through counseling and diverting the responsibility of raising the

child through adoption. The action of aborting the pregnancy can have no other outcome than to end the life of the fetus, and the good effect is only attained through this harm. Thus, in this case, the act of abortion also violates the third condition that states the negative effect cannot be employed as a means to attaining the good effect. Additionally, the abortion does not follow proportion of benefit to outweigh the negative effect, as a few months of discomfort does not outweigh the loss of an entire life. This situation, where ending the life of the fetus is only being undertaken to ensure the woman does not have to raise the child and may avoid further mental trauma, violates three of the directives required for double effect to justify the action. Thus, under this particular set of situations, the doctor's action would not be justified by the principle of double effect. It is worth noting, however, the analysis of the same action may produce a different conclusion were the situation to be different (i.e. the mother is guaranteed to die if she carries to term, or the unborn child has a severe condition that would cause them unnecessary suffering and a short life). Therefore, each situation requires evaluation individually and separately from all similar situations - this is to say each individual action must stand on its own merit to be deemed morally acceptable.

Having seen one example that is justified and one that is not justified through the double effect evaluation, I would like to return to the topic of DTC and examine if double effect can justify the use of this marketing tactic in the space of the pharmaceutical industry. The nature of the act, looking only at the core, is advertising for the purpose of spreading information about the drug in question, and the intent of the action is to proliferate use of the drug for patient treatment and to increase revenue for the company. Morally, both of these things are neutral or good. The agent's intention to educate and sell goods is not

inherently bad. However, the second half of the second criterion may not be met, as it states that one must avoid the bad effect if at all possible. Advertising directly to the consumer is proven to achieve the desired good effect (patient treatment and increased revenue); however, this also has a negative effect of changing the doctor-patient relationship. As this negative effect is separate from the means of advertising, DTC also meets the third directive of double effect (the bad effect cannot be the means to attain the good one). However, as the proportion of benefit gained by the company in their increased revenue and the increased use of the drug for treatment does not balance or outweighing the negative effect of the patient missing out on the best possible medical care. Essentially, no amount of profit or potential treatment of a target group will outweigh the fracture of the doctor-patient relationship and the decline in the quality of potential healthcare of several hundred million people. Based on this analysis DTC marketing violates two of the four directives, and therefore is not morally justifiable using the doctrine of double effect.

The next issue to address is how DTC affects autonomy of stakeholders. While autonomy is applied differently for each stakeholder group, it is a right of each. For patients, autonomy is seen as their right to have their personal beliefs and preferences honored. When evaluating the actions of the doctor, in relation to honoring the patient's desire for a drug specifically requested due to their exposure to DTC, the doctor seems to be upholding their responsibility to the patient's autonomy. While it is admirable and good that the doctors continue to do their duty in upholding patient rights, it is inadvertently allowing a violation to their autonomy due to a lack of full education and temperance against the doctor's knowledge and experience. When examined further, this can even be

tantamount to a veiled manipulation on the part of the pharmaceutical companies, which at best is disingenuous and at worst is willfully deceitful. This does not serve to place blame solely on the pharmaceutical companies, but does place in clear definition the extent to which DTC violates both doctor and patient autonomy.

Moving on to the next Prima Facie principle, justice, my evaluation of DTC as a practice has to shift focus. Justice, as a concept, encompasses the fair and equitable allocation of resources with consideration of entitlement or need. In this respect, DTC must be evaluated under the guidelines of justice to see if the rights of any stakeholder merit more consideration or stronger value than those of any other stakeholder group. If the responsibility is not met by a stakeholder, then the rights of the affected group would be violated and tip the scales of justice away from the affected party and toward the offender. In this case, justice dictates that to restore balance, the rights of the affected stakeholder group would then outweigh those of the offending group. Thus, as it has been determined through the evaluation of DTC under non-maleficence, the patient and physician stakeholder groups are entitled to greater consideration and compensation for the wrongdoing on the part of the pharmaceutical companies and the FDA. This is to say that the practice of DTC as it currently stands is in violation of the principle of justice. The concept of justice, and its application toward achieving balance, will be explored in depth in the next section.

Beyond the standard of non-maleficence, DTC also bears evaluation under the concept of beneficence. Does the action itself satisfy the requirement of beneficence through the essence of action and intention toward the promotion of good? For the pharmaceutical companies, they are most concerned with promoting their company, improving market

penetration through expanded use of their product, and increasing revenue through increased sales. From the perspective of the pharmaceutical companies, DTC is rather effective at attaining their goal. They are a business industry, and would not continue with a practice if it did not prove to be beneficial to their meeting their business objectives. Alternatively, both the patient and the healthcare professional are only concerned with the efficacy of the advertised medication in treatment applications. In this regard, there is some beneficence gained from DTC, as it does promote visits to the doctor regarding perceived symptoms. And, even in situations where the drug is not prescribed, the increase in conversation with the healthcare provider is ultimately a good thing. In regard to the government agencies beneficence is adhered to through the practice of DTC because the right of beneficence is followed because it allows and contributes to the continued existence of the FDA (and the resulting jobs). The responsibility the FDA has to beneficence, however, is not satisfied as the FDA is not actively doing anything to promote the benefits enjoyed through DTC. It would seem that beneficence is generally honored in the practice of patient directed pharmaceutical advertising. Sadly, this is not enough. Beneficence is important, but as state previously, cannot take the place of the primary medical directive of harm-prevention.

The above section of analysis using the prima facie principles is only a starting point; and yet there is an emerging pattern that may hint at the outcome of this ethical analysis—the tipping of the scales against the positive moral worth of the current employment of direct-to-consumer advertising of pharmaceuticals. This perspective gives a direction by which to guide further analysis using more concrete methods.

Utilitarianism

As discussed earlier in this report, it can be agreed upon that morality should drive legality, and not the other way around. Historically, utilitarian theory was built around the heart of this issue, and in relation to the moral quandary at hand, the application of utilitarianism lends itself completely. Classic utilitarianism, as we know it today, originated with the philosophers Jeremy Bentham and John Stuart Mill.[171] Originally, this concept was brought about to evaluate the ethicality of laws; it was introduced mainly as a test to define unethical laws and how to identify them. One of the most difficult aspects of dealing with consumer directed marketing in the medical field, in addition to the numerous stakeholders with conflicting interests, is the legality of the potentially immoral practice. It can be seen, from the history already discussed, that direct to patient advertisements of have been legal in their current capacity since 1997. Clearly, the question is not if this practice is legal, but if it is moral. The action that should be carefully avoided is the blanket acceptance of the advertising practice, because of its legal standing, as morally permissible.

Using Utilitarian thought I strive to evaluate direct-to-consumer advertising to see if employment of this technique produces the greatest good for the greatest number, or if there would be more overall utility in changing, or abolishing the practice. For the purpose of remaining objective within this analysis I will assume that each positive and negative consequence of advertising targeted to consumers produces one, respectively positive or negative, arbitrarily assigned and titled utility point per individual. After the thoughtful listing of such points they will be mathematically calculated to produce a real

[171] Driver, Julia. "The History of Utilitarianism." Stanford University. 2009. Accessed June 25, 2016. http://plato.stanford.edu/entries/utilitarianism-history/.

number value of utilitarian worth. This total number will objectively classify the practice of direct-to-consumer marketing of pharmaceuticals as morally permissible, in the case of a positive value, or unethical to continue, in the case of a negative value.

Patient impacts

An 81 percent reach, as calculated using the number of respondents from the study that stated they had knowledge of the advertisements, would produce a number of 232956000 for the purpose of assigning general utility points within the category of impact upon patients.[172] Each consequence which acts upon the consumer group will have a value of (-) or (+) 1 before being multiplied by the number above to generate a point value equal to the number of consumers upon which it would have an impact.

The patient impact category is calculated based on data extrapolated from the FDA study produced in 2002.[173] Each subsection of the study (seeking information, visits to healthcare provider, patient opinions about DTC advertising, and other important findings) are given proper weighted attention based on the responses obtained from the survey. The table assumes that the data gathered is more or less representative of the general population of the United States in the year of the survey.[174]

Table 1- Utilitarian Analysis of DTC impact on Patient Stakeholder Group

	Total US population	**Percent reached**	**Percent affected**	**positive or negative impact**	**Resulting utility point value**

[172] Aikin.
[173] Ibid.
[174] I would like to have a more current survey as well as a larger sample size. This is what is currently available as the survey is outdated by over a decade.

Education	**287600000**	**0.81**	**1**	**Positive**	**232956000**
seek info	**287600000**	**0.81**	**0.43**	**Positive**	**100171080**
talk to doc for info	**287600000**	**0.81**	**0.18**	**Positive**	**41932080**
Expected to receive prescription	**287600000**	**0.81**	**0.0462**	**Negative**	**-10762567.2**
Understate risk	**287600000**	**0.81**	**0.6**	**Negative**	**-139773600**
Reluctant to talk to provider about ads	**287600000**	**0.81**	**0.1**	**Negative**	**-23295600**
improved communication	**287600000**	**0.81**	**0.43**	**Positive**	**100171080**
Ask for prescription by brand name	**287600000**	**0.81**	**0.1248**	**Negative**	**-29072908.8**
overstated positive	**287600000**	**0.81**	**0.58**	**Negative**	**-135114480**
Seems drug will work for anyone	**287600000**	**0.81**	**0.42**	**Negative**	**-97841520**
Ads cause anxiety about personal health	**287600000**	**0.81**	**0.17**	**Negative**	**-39602520**
difficult to understand	**287600000**	**0.81**	**0.225**	**neg**	**-52415100**

Based on the information available, the table above shows that, with a combined utility score of -52648056, utilitarianism would dictate that, considering only the impact the practice has on patients, direct-to-consumer marketing is an unethical practice.

Physician impacts The same study published by the FDA that was used for the patient impacts is also used for the physician impacts.[175] A 46 percent reach, as calculated using the number of respondents from the study, would produce a number of 390711 for the purpose of assigning general utility points within the category of impact upon patients.[176] [177] Each consequence which acts upon the physician group will have a value of (-) or (+) 1 before being multiplied by the number above to generate a point value equal to the number of healthcare providers upon which it would have an impact.

Study results are extrapolated against the known population of total licensed medical doctors (MD and DO) for the year 2002.[178] Subsections for the doctors polled were: specific patient encounters (perceived benefits and problems of DTC exposure, patient drug requesting behavior, denial of requests, and pressure to prescribe) and general opinions about DTC advertising (including opinions about patient understanding of marketing materials, problems, benefits, and overall impressions).[179] Each of these is considered in the quantitative analysis of DTC marketing utility for the healthcare provider group.

Table 2- Utilitarian Analysis of DTC impact on Physician Stakeholder Group

	Total population of physicians	Percent responded	Percent affected	positive or negative	Resulting Utility Point value

[175] Aikin.
[176] Ibid.
[177] Rounded to the nearest whole person from 390711.12
[178] A calculated average between known 2000 and 2004 values
[179] Aikin.

Increase in questions	849372	0.46	0.73	Positive	285219.1176
Patient asked for specific drug by brand name	849372	0.46	0.65	Negative	-253962.228
Doctors believe DTC is beneficial	849372	0.46	0.41	Positive	160191.5592
Doctors believe DTC leads to problems	849372	0.46	0.18	Negative	-70328.0016
Doctors observe patient is confused by DTC	849372	0.46	0.41	Negative	-160191.5592
Encounters with patients Where they were asked for a drug And patient did not have relevant diagnosis	849372	0.46	0.1031	Negative	-40282.31647
Doctor gave patient the prescription They asked for by name	849372	0.46	0.416	Negative	-162535.8259
Doctors felt pressured to prescribe the Medication the patient wanted	849372	0.46	0.175	Negative	-68374.446
Doctor felt Patient negatively influenced their care due to DTC	849372	0.46	0.9	Negative	-351640.008
Doctor perceived that patients thought not only doctor capable of medical decisions due to DTC	849372	0.46	0.18	Negative	-70328.0016
Doctor perceived that Patients understand benefits of drugs Seen in DTC	849372	0.46	0.78	Positive	304754.6736
Doctor perceived that Patients do not understand risks of drugs seen in DTC	849372	0.46	0.6	Negative	-234426.672
Doctor perceived that patients do not understand limits of drugs seen in DTC	849372	0.46	0.7	Negative	-273497.784
Doctor perceived that patients Do not understand who should Avoid the drug	849372	0.46	0.75	Negative	-293033.34
Doctor perceived that patient Was confused about the relative Risks and benefits of medication	849372	0.46	0.65	Negative	-253962.228
Doctor perceived that patient overestimated benefits of prescription	849372	0.46	0.75	Negative	-293033.34
Doctor perceived that patient Questioned their given diagnosis	849372	0.46	0.38	Negative	-148470.2256
Doctor perceived an increased Tension in relationship with patient	849372	0.46	0.28	Negative	-109399.1136

The calculated total of utility points for this impact group is -2033300, by the requirements of utilitarianism, and from the perspective of the affected physician group, DTC advertising is not an ethical practice.[180]

Pharma impacts Utilitarian calculation searches for the greatest good for the greatest number based on given information. As the patient population vastly outnumbers the individuals affected in the pharmaceutical industry, even if the benefit of job creation and increased sales is included, the benefit seen by the pharmaceutical industry as a whole cannot outweigh the negative utility number calculated for the doctor and patient groups. The biopharmaceutical industry directly employees 854,000 people and supports another 3,400,000 jobs in related positions. Given no study of the impact on these individuals, I will assume one positive utility point per person within this group to fully account for the benefit provided.[181] Therefore, a quantitative analysis would provide a total utility value of positive 4254000.

Government Impacts

The government agencies impacted by direct-to-consumer marketing receive both positive and negative utility points. The positive is job creation; negative comes from the criticism faced from the public and other nations because of improper regulation and violation of the harm prevention principles. Overall, it is fair to say that the utility points would likely be close to neutral and would not sway the total as calculated. However, it is also worth noting, just as stated with the pharmaceutical industry, no benefit to the governing bodies can possibly outweigh potential harm to its people.

[180] rounded from -2033299.74

[181] "Economic Impact." The Pharmaceutical Industry. Accessed June 25, 2016. http://www.phrma.org/economic-impact.

Utilitarian Conclusion

The values for the patient, physician, pharmaceutical, and government groups, in that order, are as follows.

(-52648056) Utility points + (-2033300) Utility points + (4244000) Utility points + (0) = -50437356 Utility points

This sum total is a negative value and thus it can be concluded that, in consideration of all stakeholders, a quantitative utilitarian analysis deems the practice of direct-to-consumer advertising of pharmaceuticals an unethical action.

Kantian Analysis

Kantian though dictates that one should always act in such a way so that one could will everyone else to behave in the same manner.[182] Another way this can be considered is the rule to never treat people as a means to an end, this stems from the premise which holds true all beings with moral agency are an end unto themselves. Using this logic, DTC marketing shifts from an issue of medical ethics to a dilemma of moral business principles and practices; however, I will still evaluate the medically based stakeholders.

Looking at the rights and responsibilities of the physician in relation to DTC marketing and Kantian thought, it should first be noted that the doctors will have few duties arising from this practice. As discussed they maintain their obligation to provide the highest standard of medical care of which they are able, and to listen to the questions and concerns of their patients with compassion. With this, healthcare providers garner the right to practice unencumbered by non-medical policy issues and outside manipulation of their patients as it interferes with the provision of adequate health care.

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[182] Cole, Darrell Ph.D. "Introduction Biomedical Ethics" Lecture course at Drew University. Unpublished personal notes.

The next Kantian analysis is for the patient group. As discussed in the section on patient rights and responsibilities they have an obligation to seek treatment, to communicate honestly (and seek clarification when necessary), and to follow all instructions for treatment given by their healthcare provider. Patients also have a human right to the best possible medical care available, according to availability and with just distribution, furnished in such a way that due respect is maintained for their individual situation. Patients witness the advertisements and are influenced by the information and the medium on which it is presented. Some consumers move forward with a changed opinion and go to their doctor for more information. Although it could be argued that patients approaching their physicians, after viewing pharmaceutical advertisements, as treating the doctors as a means to the end of receiving a prescription for the medication they want, I argue that this is not the case. Due to the nature of the physician-patient relationship, and the subsequent rights that the medical model grants to patients, I believe it is important to take under consideration the intent of the patient. Since the majority of consumers of pharmaceutical substances do not aim to abuse them, and therefore are most likely not looking to manipulate their doctors, or the medical system purely for want of a drug they saw advertised. Furthermore, I assert that patients communicating with doctors is among their inherit rights, and to deprive them of such rights or for an ethicist to chastise the patients for exercising this right would be further damaging. While the patient group may be the most negatively impacted, their part in direct-to-consumer advertising is not overtly unethical. It would likely, from a Kantian perspective, be of a benefit to the consumer group were direct-to-consumer marketing changed from its current use, however, because it is not the patients whom are behaving unethically, it

should not be the moral burden of the patients to ensure the implementation of this change.

Looking at the pharmaceutical and government rights and responsibilities, through a Kantian lens, is where the real issues of responsibility arise. When used from a business perspective and purely to generate revenue, unethical because they employ advertising techniques which prey on psychological instinct. This uses laypeople, or rather soon to be patient consumers, who observe the marketing materials, as a means to influence the prescribing practices of physicians toward the end of material gain for the pharmaceutical company and its stakeholders.

From a business standpoint DTC marketing is highly lucrative, yielding an attributable profit of 420% on each dollar invested.[183] While banning the practice would undoubtedly affect the pharmaceutical industry's bottom-line, the negative aspect (of a decrease in pharmaceutical sales) would only serve to strengthen my argument. If patient exposure to advertising impacts the bottom-line profit it is a direct reflection of the control the direct to consumer advertising exerts on physicians' prescribing practices.

While American culture is based on a free market, this thesis is centered around the effect on medical care and the doctor patient relationship. According to Kantian ethics consumer directed advertisements of prescription medications is highly unethical because it uses beings with moral agency as a means to an end, and in doing so creates a system of actions that no reasonable person would wish for everyone else to pursue: A system in which egoistic motives drive action and are sufficient to override both the theoretical and functional rights of others.

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183 "Impact of Direct-to-Consumer Advertising on Prescription Drug Spending." Prescription Drugs Pro Con. June 2003. Accessed June 25, 2016. http://prescriptiondrugs.procon.org/sourcefiles/Impact-of-Direct-to-Consumer-Advertising-on-Prescription-Drug-Spending-Summary-of-Findings.pdf.

Medical Impact

A main point of argument established by those in favor of unrestricted consumer directed advertisements is the idea that this practice leads to a more informed, and therefore more satisfied patient. I concede, it is possible that rise in sales is due to a decrease in the social stigma or the patient's personal embarrassment regarding their condition; however, I must note that many experience the increase of autonomy within medicine, as a negative occurrence.[184]

While determining concrete causation would be nearly impossible, due to the sheer number of variables involved, there is a strong correlation in the timeline between the rise of the business of medicine (with subsequent introduction and expansion of DTC marketing) and the rise of medical autonomy. Interestingly the business of medicine began/expanded from 27.2 billion dollars to 255.3 billion dollars in the 20 years before the change of the AMA guidelines to favor autonomy over paternalism and physician beneficence with the greatest increase year-over-year seen in the last six years. [185] [186] It would seem to be a real possibility that it was the shift toward financial motives, which drove the rise of autonomy. I would even go so far as to say it is the fiscal motivation, of those that sought to capitalize on the evolving American medical system, that has distorted the public opinion so far that the FDA, as the governing body of medical marketing, believe by allowing the current advertising practices they are providing the masses with another layer of autonomy. While for governing bodies or medical

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[184] "Minnesota Medicine." Minnesota Medical Association. Accessed June 25, 2016. http://www.minnesotamedicine.com/Past-Issues/Past-Issues-2008/April-2008/Commentary-April-2008.

[185] GEIGER, H. Jack. "An Overdose of Power and Money." New York Times. Accessed June 25, 2016. http://www.nytimes.com/books/98/12/06/specials/starr-medicine.html.
Published January 9th 1983

[186] Cummiskey. "The Medical Relationship: Autonomy and Beneficence." Bates.edu. Accessed June 25, 2016. http://www.bates.edu/philosophy/files/2010/07/GME-Ch.-V-The-Medical-Relationship.pdf.

legislation to deprive patients of the opportunity to advocate for themselves, or to know about new treatment modalities for previously existing diseases, would be negligent at best, it is important to note it was the companies themselves who advocated for the relaxation of marketing regulations and the result was the provision of *less* information, not more. Similar aspects of autonomy, without the negatives associated with outside manipulation, are afforded through the access to healthcare information. I would never advocate for limiting the information available to the public; however, no one should have forced upon them the idea that they must take advantage of rights that do not benefit them. Autonomy, as a justification in debate by the pro-pharmaceutical advocates, does just that. This is to say because the general public lacks the knowledge and experience of having a medical degree, the practice of DTC marketing provides patients with self-sabotaging information under the illusion of increased autonomy. Autonomy as it is upheld now is no different than the facade of autonomy (read fraud and misinformation) that spurred the formation of the FDA in the first place.

It is worth noting that although Samuel Hopkins Adams wrote about the danger and fraudulence associated with patent medications, until the mid-twentieth century all medications, and medical treatments, were primarily natural agents denoted to specific uses through trial and error with no real scientific, evidence based guarantee of safety or efficacy. As such, even after the legislation of the past century, and the protection it attempts to afford the public consumer, I believe, were Samuel Hopkins Adams alive today, he would have intense objections to direct to consumer advertising of pharmaceuticals. This claim is supported by the following parallel:

In 1906, 75 million dollars was spent on patent medicine (at the time there were no prescriptions necessary), and in that year the total population of the United States was 85,450,000.[187] From these two numbers, one can calculate the per capita expenditure ($0.88) that caused such an outrage it lead to the formation of a new government agency. In 2015, the American public spent 328 billion dollars on prescription medicine, and the population that year was 320,220,000. [188] [189] As above it is now possible to calculate the per capita spending ($1024.30) there are many factors that influence the large difference. One which I can adjust for, inflation, and more which I cannot. One of these contributing factors is the return of DTC, as we know it today, in the 1990s. [190]

Table 3- Per Capita Drug Expenditure For Select Years (Inflation Adjusted)[191]

Year	US Population	Total Retail Drug expenditure (patent / prescription medications)	Per Capita Drug Expenditure	1906 Equivalent	2015 Equivalent
1906	85,450,000	$75,000,000.00	$0.88	$0.88	$23.10
1960	180,671,158	$2,700,000,000.00	$14.94	$4.86	$121.46
1970	205,052,174	$5,500,000,000.00	$26.82	$6.62	$165.47
1980	227,224,681	$12,000,000,000.00	$52.81	$6.15	$153.68

[187] "Historical National Population Estimates: July 1, 1900 to July 1, 1999." Census.gov. April 11, 2000. Accessed June 25, 2016. http://www.census.gov/popest/data/national/totals/pre-1980/tables/popclockest.txt.
Revised date: June 28, 2000

[188] "U.S. Health Agency Estimates 2015 Prescription Drug Spend Rose to $457 Billion." Reuters. May 2016. Accessed June 25, 2016. http://www.reuters.com/article/us-usa-healthcare-pricing-idUSKCN0WA2O0.

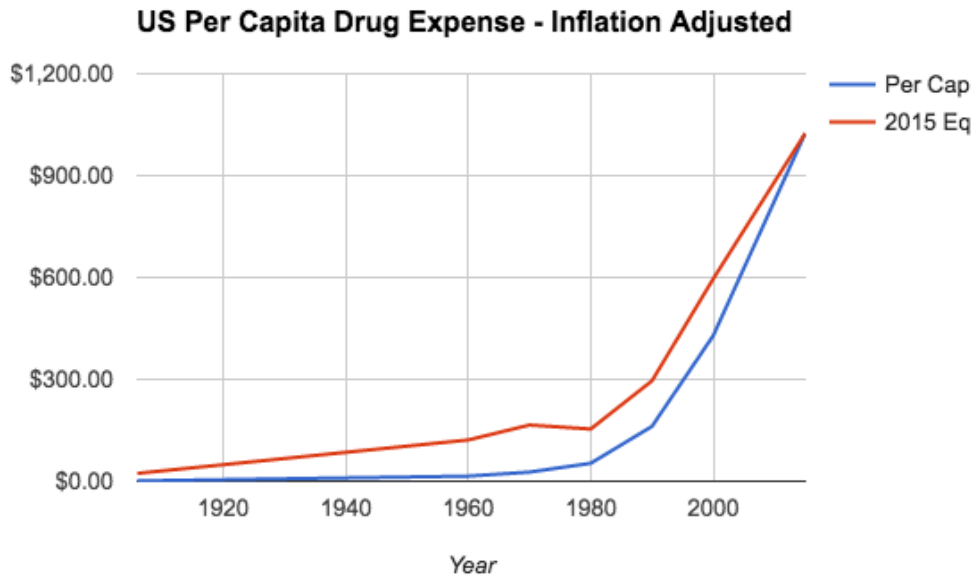
[189] "US Population by Year." US Population by Year. Accessed June 25, 2016. http://www.multpl.com/united-states-population/table.

[190] rounded from 1162.30779

[191] "Inflation Calculator." DaveManuel.com. Accessed June 25, 2016. http://www.davemanuel.com/inflation-calculator.php.

1990	249,464,396	$40,300,000,000.00	$161.55	$11.83	$295.63
2000	282,160,000	$121,000,000,000.00	$428.83	$23.84	$596.08
2015	320,220,000	$328,000,000,000.00	$1,024.30	$40.97	$1,024.30

Table 4- Graph of Inflation Adjusted Per Capita Drug Spending vs. Year[192]



If $0.88 was an outrage, what is 40.19? Money aside, I believe that his greatest objection was with the mass consumption of opiates, narcotics, a wide range of other depressants

[192] Inflation Calculator

and stimulants, and, "in excess of all other ingredients, undiluted fraud."[193] If the consumption is the same, or more, the regulations set in place by the FDA are clearly not effective in protecting the public; the relaxation of their standards to allow for patient directed marketing as we know it today only worsens an already grave situation.

Regardless of whether a change in the doctor-patient relationship actually occurs as a result of DTC marketing, it is important to note that the surveys discussed previously indicate there is a perceived change in that relationship from the perspective of both the doctor and the patient. If nothing else, the perception of a change is just as impactful, if not more so, than if a proven change had occurred. This is because both parties inevitably change their behavior in the relationship to compensate for the perceived change. Due to this fact, a perceived change can be taken as proof of actual change because of its effect on the dynamic of the doctor-patient relationship. The perception aside, I believe there has also been a direct change to the relationship, and the potential quality of care, as a result of DTC.

Throughout the paper I have explored how DTC affects the patient. Most importantly, however, in my employment of quantitative utilitarian analysis, it was observed just how profoundly negative that affect has been. In the literature review, opposing viewpoints were taken into consideration, but on the whole those that are not tied (financially or otherwise) to the practice of DTC have spoken out against it. The Marketing professionals working for the pharmaceutical companies use psychological techniques of business universal sales tactics in their advertising campaigns. This manipulates the public into wanting, and subsequently seeking, medications from which they may not

[193] Chronology.

need. The biggest danger here is that the pharmaceutical industry champions this practice as educating the public while promoting increased autonomy. As shown above, this autonomy is only illusion. Autonomy is the principle that honors the rights of individual and self-determination. Education is providing access to truthful and complete information. Intentionally manipulating the desires and beliefs of the public with media materials full of misleading information - information based on cherry-picked data no less - is not education. And following that, supporting the patient / consumer's decision to seek out the product based on the false information provided, it is not promotion of autonomy either.

By examining the evidence provided it is clear there is, effectively, be it perceived or real, a change to the physician-patient relationship. While the world is not a clean lab where direct control can be exerted on factors to determine influence and causation, the information found and analyzed for the purpose of this paper shows strong correlation. Not only is there a change, but because of the nature of this change, healthcare providers are unable to provide an exemplary level of care that takes full advantage of their education, training and expertise. Because of this, patients cannot receive the quality of care they deserve. Effectively, the practice of intentional misinformation for the purpose of personal financial gain negates any potential benefit the American pharmaceutical industry may be claiming is gained from their use of DTCA. Furthermore, when combined with the proven negative effects seen stemming from DTCA discussed throughout this paper, the pharmaceutical industry's actions in using DTCA cannot be deemed anything other than unethical.

Proposal of Ethical DTC Marketing

Returning to the question I posed earlier, would placing a ban or stricter restrictions on direct-to-consumer advertising of pharmaceuticals in America be able to fix the issues the US suffers as a result of the current advertising? My response is this- it is our moral imperative to try. Even if it will not *negate* the harm, it may prevent further violations. As such, it is with sound moral backing that I state, we, as a medical community, should push for a shift toward disease awareness, rather than prescription medication brand recognition. This will ultimately serve to benefit the doctor-patient relationship, clarify the physician's role in twenty-first century medicine, improve patient care, and the overall medical experience.

To accomplish this, I recommend an immediate ban on all television, radio, print, and web format prescription drug advertisements for a minimum of 10 years. Any violation will result in a large financial penalty and all parties with involvement in the production and dissemination of the material in question will be held criminally liable. To accommodate for this change, there will be a six-month transitional period to allow for all advertisements to be withdrawn from circulation. During this time, no new advertisements may be created or published, and any advertisements that are found to be released after the start of the transitional period will be subject to the penalties as prescribed by the updated restrictions. The system needs to rest and in the meantime, the medical community as a whole needs to focus on working to curb spending without sacrificing patient care. I would concede that prescription education and promotion may continue throughout the ban to the healthcare provider, but the pharmaceutical manufacturer must make *all* data available to the healthcare provider, and the companies cannot offer incentives for prescribing their drug. Going forward, and after exhaustive

studies, advertisements may be reintroduced to the public for the express purpose of education only. Furthermore, upon reintroduction, consumer directed advertisements must be approved by an independent analyst paid for by the manufacturing company but chosen and assigned by the FDA. This will provide a blind and objective analysis of the advertisement, and its potential effects on the public, while maintaining a gap to prevent tampering or bias. Each advertisement also needs to prominently feature a disclosure that the campaign is paid for by an unnamed pharmaceutical agency; as mentioned previously, it can only bring disease awareness; and the advertisement cannot run until 18 months after initial FDA approval. Additionally, for each advertisement a company wants to run for a product they manufacture, they must also fund one public health campaign raising awareness for the most prevalent diseases and the non-drug treatments available. Lastly, pharmaceutical companies should collectively fund research conducted by the FDA every 10 years to check on the perception of DTC marketing materials so the FDA can adjust regulations accordingly.

Conclusion

Looking at the current state, it is clear the system is broken and practices are unethical. However, the situation is not completely irredeemable. Though profits are certainly a consideration for agents of the pharmaceutical industry, they have still chosen to pursue a field that requires dedication to innovative research and a passion for bettering the wellbeing of the public at large. I have evaluated patient directed marketing techniques, as they are now employed, using several philosophical schools of universal ethics and conclude that they are not morally sound. I challenge my readers to use their own belief

system and do the same. For I believe, no matter the measuring stick, any thorough and unbiased examination will come to the same conclusion. The only logical next step to take is to begin correcting the problem. If we act now, and we are diligent in our efforts to correct the violations, we can not only return to the initial intent of advertising (education, and promotion of doctor-patient communication), we can move beyond that goal to a brighter future than we could have imagined.

VITA

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Graduate:			
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