DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION PHARMACEUTICALS – A PRESCRIPTION FOR CHANGE

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Abstract

of

DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION PHARMACEUTICALS

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A 1997 Food and Drug Administration (FDA) guideline change allowed pharmaceutical companies to target audiences through television and print media whereas before, the FDA requirements were so extensive that advertising to consumers was unprofitable. The onslaught of advertisements for prescription pharmaceuticals since 1997 has resulted in an increase in drugs prescribed to consumers, and a higher likelihood of a consumer receiving a prescription for a requested drug when that drug has been advertised. The informational value of advertisements to consumers varies widely, and the majority of consumers hold misperceptions about the federal requirements of pharmaceutical advertisements, many believing that the advertisements are government-approved or that the drugs advertised are “completely safe”.

The literature review revealed that the arguments supporting direct-to-consumer advertising (DTCA) of prescription pharmaceuticals were theoretical in nature and unfounded while the research supported the conclusion that DTCA causes a net harm to societal health.

A criteria-alternative matrix was used to evaluate various public policy alternatives using four criteria: cost to implement, effect on the cost of medications, effect on societal health, and effect on reducing the number of drug advertisements in violation of FDA guidelines. After evaluating how well the policy alternatives satisfy the criteria, the alternatives were further assessed to determine how feasible they would be to implement considering the current political climate.

The policy alternative with the greatest benefit to society is a ban on DTCA in the U.S, however, that policy alternative is the least likely to be implemented due to the current political climate and the influence of the pharmaceutical industry. As other countries consider allowing DTCA, it is essential that they take note of the deleterious effect DTCA has had in the United States.

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Chapter 1
INTRODUCTION

Why does advertising of prescription pharmaceuticals matter? Drug advertising has a palpable effect on human behavior. As you will find in the next chapter, advertising drugs to consumers results in patients requesting these drugs when they visit their doctors, and more prescriptions written for advertised drugs. The impact of drug ads ripples throughout the whole health care system, increasing profits for the companies that manufacture them, changing insurance costs, and of course, directly impacting the patient’s health. The ultimate question that this paper seeks to answer is “What effects does direct to consumer advertising (DTCA) have on the state of societal health; does DTCA result in a net gain or loss to societal health?” While much of this question is answered by the literature review, the Criteria and Analysis chapters go beyond identifying the effects of DTCA by evaluating policy options that could minimize DTCA’s deleterious effects.

This paper explains pharmaceutical advertising to consumers, the changes in consumer and physician behaviors that result from it, and its implications for the health care system and American society. The Background chapter summarizes the status of health care system in the United States and the role of the Food and Drug Administration (FDA) in regulating drug advertisements. Direct to consumer advertising is defined in the next chapter, then the trend toward self-education of consumers regarding their health is explored. Next, this paper summarizes the results of surveys and studies conducted by
other researchers concerning the effects of DTCA, and philosophical arguments for and against DTCA. This is followed by a discussion of how to evaluate the effects of DTCA, with an emphasis on the criteria to keep in mind when assessing its relative benefits and perils.

This paper utilizes a criteria alternatives matrix (CAM) to visually frame the policy alternatives to DTCA and the criteria used to evaluate the policy options. One of the benefits of using a CAM for analysis is its simplicity. The matrix displays the policy alternatives along the first column, while the criteria are displayed along the first row, at the top of the table. The matrix visually displays the information and a summary of the analysis in each of the remaining cells, making it easy for the reader to see the benefits and perils of each alternative examined.
Chapter 2

BACKGROUND

What is DTCA?

Print, television, and radio advertisements directed toward end consumers are collectively called direct-to-consumer advertisements (DTCA). These differ greatly from advertisements and strategies intended to encourage doctors to write more prescriptions for the drugs advertised. The goals of both DTCA and physician-directed advertising are identical - to increase demand for the prescription drug advertised - but the target audience is different. It makes perfect sense to promote drugs directly to physicians. They write the prescriptions and therefore, need to know about different treatment possibilities. This type of marketing is called “physician detailing” by the pharmaceutical industry. While physician detailing has a long-standing history, recent cultural and social shifts have resulted in more people taking greater responsibility for their health than before (Wilkes, Bell and Kravitz 2008, 112), propelling the rise of DTCA. This trend can be seen by the growing popularity of consumer-driven medical reference websites such as WebMD and HealthCentral, as well as health-centered television shows such as Dr. Oz and The Doctors. As the pharmaceutical industry’s interface with the public shifts toward stronger consumer self-education, DTCA is paying off for drug companies with a return on investment averaging $2.20 for each dollar spent (Auton 2006, 27). Money spent on television advertising for prescription drugs has risen each year since 1997 (Auton 2006, 27).
Health Care in the United States

During the past decade, medical costs have risen significantly in the United States, with yearly cost increases surpassing inflation. The United States spends substantially more money on health care than any other country in the Organization for Economic Cooperation and Development (OECD), and the United States spends more per capita on health care than any other United Nations member country except for East Timor (World Health Organization 2009). In 2008, the United States spent $7,681 per person on health care, accounting for 16.2 percent of the nation’s Gross Domestic Product (GDP) (Centers for Medicare and Medicaid Services). Despite slower growth in overall health expenditures, the share of GDP devoted to health care increased from 15.9 percent in 2007 (National Health Expenditures 2008). In addition to the high cost, another troubling aspect of health care in the United States the lack of access to it. Approximately 15 percent of Americans are uninsured, most of whom either cannot afford large insurance premiums or have pre-existing medical conditions and are considered “uninsurable” by the private companies who sell health insurance.

In response to this, medical system reform has long been a topic of debate in federal Congress and in the state legislatures. On March 23, 2010, Congress passed and the President signed into law the Patient Protection and Affordable Health Care Act, a culmination of months of debate over health care coverage, access, efficiency, cost, and quality (Democratic Policy Committee 2009). Some aspects of the law took effect immediately, while other provisions will be implemented over several years. The Patient Protection and Affordable Health Care Act’s primary benefits are an increase in the
number and percentage of Americans who have health insurance and increased regulation of health insurance companies, including establishment of a cap on the percentage of health care insurance premiums that can be spent on billing and administration and prohibition of dropping clients from insurance rolls when they are sick.

*The FDA’s Role in Regulating Drug Advertisements*

The FDA’s Division of Drug Marketing, Advertising, and Communications (DDMAC) is charged with regulating advertisements for prescription drugs. The chief purpose of DDMAC is to protect and promote public health by looking for and taking action against advertisements that break the laws (Background on Drug Advertising 2009). While prescription drug advertisements serve to better educate consumers to some extent about diseases and treatment options, they are not public service announcements. As the next chapter will illustrate, they are often not balanced when it comes to reporting the risks involved with the treatment course advertised.

DDMAC is charged with regulating advertisements of drugs, but this power is severely limited, as the FDA and DDMAC have the authority to regulate only those advertisements that are misleading or in violation of the law. This power comes from Section 502 of the Federal Food, Drug and Cosmetic Act and the implementing regulations of Title 21 of the Code of Federal Regulations (U.S. Food and Drug Administration Testimony), in concert with First Amendment free speech rights. It is important to note that nothing in the Food, Drug and Cosmetic Act or the Code of Federal Regulations prohibits advertising of drugs (even controlled substances) in any form (U.S. Food and Drug Administration Testimony).
FDA regulations require that advertisements for prescription drugs present a “fair balance” of benefit and risk information, and not omit material facts. For print advertisements, all risks included in the product labeling must be disclosed in a brief summary. Similarly, broadcast advertisements must disclose all information related to side effects and contraindications, or make adequate provision for the full product labeling in concert with the ad (U.S. Food and Drug Administration Testimony).

Because the federal laws do not prohibit advertising of prescription drugs, the FDA only has the power to regulate and enforce that drug ads contain a fair balance of risks and benefits, with full disclosure of significant side effects and contraindications. A necessary restriction on the FDA, then, is that the agency typically cannot prevent erroneous ads from airing or being printed; its regulatory power is strictly post-hoc.

The FDA’s ability to successfully regulate the content of drug advertisements is limited to its regulatory power. In most instances, this only allows for FDA review and action to occur after the advertisement has been aired or printed. Companies whose advertisements who do not meet the legal requirements for content or balance will receive a notice of violation letter from DDMAC describing the offense and, in most cases, requiring the company to pull the offending advertisements. In the most egregious cases, the FDA requests the pharmaceutical company take corrective which typically involve retractions that must be aired or printed in the same markets as the original advertisements.

Chapter 3

LITERATURE REVIEW
**Fair Balance and Adequate Provision: Revised FDA Guidelines**

In 1997, the FDA relaxed its rules concerning the advertisement of pharmaceuticals. Specifically, the changes allowed television advertisements for prescription medications to make “adequate provision” for disclosure of the drug’s labeling requirements by referring consumers to a toll-free number or a website for more information on the drug advertised. The “adequate provision” requirement presumes that advertisements comply with the following criteria:

- The advertisements make adequate provision for the dissemination of approved or permitted package labeling in connection with the broadcast presentation (e.g.; toll-free number, web site, print advertisements, publicly available brochures or pharmacists and physicians).

- The advertisements are not false or misleading in any respect. For a prescription drug, this would include communicating that the advertised product is available only by prescription and that only a prescribing health care professional can decide whether the product is appropriate for a patient.

- The advertisements present a fair balance between information about effectiveness and information about risk.

- The advertisements include a thorough *major statement* conveying all of the product’s most important risk information in consumer-friendly language.

- The advertisements communicate all information relevant to the product’s indication (including limitations to use) in consumer-friendly language (Guidance for Industry 1992, 2).

This was a significant change to the FDA guidelines, which had previously required drug manufacturers to fully disclose each warning, side effect, precaution, and counter indication from the drug label in print and television advertisements (Gellad and
Lyles 2007, 476). These full disclosure requirements (called the “brief summary” requirement) made television advertising impractical as a means of reaching consumers, as the full disclosure of long lists of side effects and warnings were likely to inhibit the interests of viewers and decrease their willingness to ask their doctors about the drugs advertised. An easy way to envision the onerous nature of a full disclosure of possible side effects is to locate a typical drug advertisement in a magazine and then turn the page, imagining that the many lines of fine print are being read rapidly in a hushed voice-over. The required disclosure in a magazine advertisement can often take up to two 8x11 magazine pages. While television advertising of prescription drugs was not banned de jure prior to 1997, the disclosure requirements created a de facto ban. Since the FDA guideline changes, the surge in television pharmaceuticals advertising has been overwhelming. While only one prescription drug was advertised on television in 1991, by 2000 at least fifty were, and the money spent by pharmaceutical companies on print and television advertisements skyrocketed from less than a billion dollars in 1998 to 4.2 billion in 2005 (Hartley and Coleman 2008, 109).

Stakeholders in the debate over the merits and drawbacks of DTCA include insurance companies, doctors and health care providers, consumers, pharmaceutical companies, and several government regulatory agencies including the FDA and Centers for Medicare and Medicaid Services (CMS) (Hartley and Coleman 2008, 126). They are divided into two camps: those who believe the benefits of DTCA outweigh its potential negative impact on the medical system, and those who feel the costs and risks outweigh the benefits of DTCA to the consumer.
Fueling the Debate

Why is DTCA such a heavily debated topic? For several reasons, including the recently changed guidelines allowing television advertisements in the United States and the fact that DTCA is allowed in only two nations -- the United States and New Zealand. A few other countries are considering allowing DTCA, namely, Australia, Canada, and some European countries (Auton 2006), and this possibility of DTCA becoming more widespread also fuels the debate. An additional factor is widespread concern among physicians and consumer groups that DTCA intervenes in and undermines the physician/patient relationship (Mintzes 2002). On the other side of the table are the major media outlets and pharmaceutical companies, who generally believe that DTCA is a positive consumer information source, or that DTCA should be allowed as a matter of free speech.

DTCA Adds Value

DTCA could be beneficial to consumers, as they learn about health conditions and treatments through advertising (Calfee, Winston and Sempski 2002, 674) and possibly receive treatment for previously undiagnosed conditions (Parker and Pettijohn 2003). For example, a viewer may be exposed to an advertisement for a cholesterol-reducing drug, then later make an appointment with his or her doctor and ask about treatment for high cholesterol. There are many potential ramifications of the consumer viewing the ad, including reduced risk of stroke, lowered cholesterol, and higher overall health of the consumer. Proponents of DTCA argue that it promotes general awareness of new drugs and conditions, leading to better informed and healthier consumers (Parker and Pettijohn...
Proponents argue that one of the ways that DTCA could result in better-informed consumers is if consumers typically receive or search for little to no information about diseases and treatment options. If this is true, then DTCA would provide more information on potential side effects of drugs than the consumer would typically receive from his or her doctor or pharmacist or through independent research (Macias, Pashupati, and Lewis 2007), and DTCA would result in increased knowledge about diseases and drugs.

Many researchers studying the effects of DTCA have speculated that it creates the largest societal and individual benefits when the drugs advertised are for under-diagnosed diseases and diseases for which a lack of treatment results in more costly surgeries and treatments later on if not diagnosed in the early stages (Gellad and Lyles 2007; Macias, Pashputi, and Lewis 2007). In these cases, DTCA would reduce the likelihood that the medical condition would persist undiagnosed, with the potential to reduce long-term health care costs, in addition to benefiting those consumers who are diagnosed and receive treatment. My review of the literature found no study to support these claims, however it should be noted that any study attempting to measure the prevention of diseases would be hard to come by, as the outcomes would be very difficult to identify and accurately assess.
A differing perspective is that the primary consequences of DTCA are higher insurance and health care costs, with few benefits to the consumer. Critics of DTCA argue that the information provided to consumers through advertisements -- particularly television advertisements -- is limited and biased toward drug treatment over lifestyle changes such as diet and exercise (Wilkes, Bell, and Kravitz 2000). Of 106 televised instances of DTCA surveyed in 2004, none mentioned lifestyle changes as an alternative to medication, 18 percent mentioned that lifestyle changes may be insufficient to manage the medical condition, and 19 percent only suggested lifestyle changes in combination with the advertised drug (Frosch, Krueger, Hornick, Cronhom and Barg, 2007). Another objection is that some consumers who view the advertisements and subsequently obtain a prescription for the advertised drug may not actually need medical treatment at all (Calfee, Winston and Sempski 2002, 674; Hartley and Coleman 2008; 109). Evidence indicates that DTCA results in increases in requests for both the drug category and the brand name of the drug advertised, leading to more prescriptions and higher health care costs (Parker and Pettijohn 2003, 279; Mintzes 2002, 279; Khnafar, Polen and Clausen 2008). Furthermore, if consumers view the advertisement on television and then ask their doctors to prescribe that particular drug, cheaper generic forms of the same drug or other similarly effective but less-advertised drugs are theoretically less likely to be prescribed (Gellad and Lyles 2007,478), which increases health care costs. Because of the debates over benefits and costs associated with DTCA, New Zealand and the United States are currently the only countries that allow television-based DTCA (Mintzes 2002, 478), although the European Union is considering allowing such advertisements.
While the conclusions of research vary on whether DTCA raises or decreases overall health care costs, it is almost universally agreed that DTCA raises the cost of prescriptions. For drugs with many competing and equally effective alternatives, advertising would be an indication of a competitive market in which prices experience downward pressure. However, the drugs advertised in DTCA are generally new to the market and the market leaders for the conditions they treat (Roth 1996). Because advertised drugs tend to be newly developed, they are unlikely to see much competition from other manufacturers until their patents expire and generic forms of the drug can be marketed and sold. When a drug for which there is no substitute is created, its price is uncontrolled, and will likely be high in order to recoup the research and development investment associated with bringing it to the market.

Another factor raising the monetary costs of DTCA is the number of medications that are prescribed directly due to advertising. It is estimated that between fifty and seventy-five percent of requests for prescriptions are fulfilled (Hartley and Coleman 2008, 114). If these drugs were not advertised, patients would not request them and the number of prescriptions written for the advertised drugs would be significantly lower. This can be called “advertising-induced demand” (Gellad and Lyles 2007, 478), and this concern regarding an increase in inappropriate prescriptions is the reason why the American Academy of Pediatrics opposed DTCA in 1991 (Wilkes, Bell and Kravitz 2000, 120). Banning DTCA would likely result in fewer prescriptions written for the drugs that would otherwise be advertised if DTCA was allowed, but it is tenable if prohibiting DTCA would result in lowered overall health care costs. If the drugs that
would have been prescribed with DTCA prevent or treat costly diseases, then the increase in prescription spending under DTCA would be a bargain. If, on the other hand, the advertised drugs treat trivial or over-treated, minor diseases and conditions, then banning DTCA would result in health care savings for society (Wilkes, Bell and Kravitz 2000, 122).

Advertising’s purpose is to sell the consumer something: be it an idea, feeling, or ultimately, a product. Many critics argue that direct to consumer advertising of pharmaceuticals is inappropriate, because the medium of magazine and television advertising is ill-suited to educating consumers (Macias, Pashputi and Lewis 2007), and its motives tend more toward generating profits for large pharmaceutical companies rather than improving societal health. In order to increase profits, drug advertisements tend to mix emotional stories with informative content, which target human feelings such as shame or anxiety (Bell, Kravitz and Wilkes 1999’ Royne and Myers 2008), eventually leading some consumers to ask their doctors for prescriptions for the drugs advertised. A study of 106 DTCA on television conducted in 2003 found that while most advertisements used a combination of rational and emotional appeals (Macias, Pashputi and Lewis 2007, 249), 40.3 percent appealed primarily to emotions (Macias, Pashputi and Lewis 2007, 246). A similar study of television advertisements in 2004 found that while all used rational appeals, 95 percent also used emotional appeals to sell their products (Frosch, Krueger, Hornick, Cronholm and Barg 2007, 9). For many researchers, the nature of the television medium coupled with the profit motive means that DTCA is ill-
suited to providing consumers with useful, balanced information about medical conditions and treatment options.

Adding to this further is the FDA regulation, which requires ads to be “fair and balanced”, yet is rarely enforced. Consequently, several studies have found that a significant proportion of drug advertisements are not balanced with regard to disclosing their products’ risks and benefits. A 1996 study showed that one third of all print advertisements sampled were not balanced at all; not adequately disclosing the risks of the drug yet fully explaining potential benefits (Roth 1996). The 2003 survey of television advertisements found that 14 percent did not disclose side effects, and two of the 106 surveyed ads disclosed benefits with no disclosure of risks, which was a violation of the fair balance requirement of the FDA (Macias, Pashputi and Lewis 2007, 248). The Roth study was performed on 208 print advertisements, accounting for approximately 80 percent of all advertisements placed in media at the time. The 208 examples were selected randomly and analyzed for content, then coded. The Macias study was equally credible, using videotaped television advertisements from seven networks over a seven-day period, which were then analyzed and coded for content. These studies indicate that DTCA is more concerned with promotion of the advertised drugs and less concerned with providing quality, balanced information to consumers.

A 1999 analysis of 320 print advertisements of pharmaceuticals found in magazines found that the informative quality of the ads varied greatly, with only 27 percent including a cause or risk factor for the medical condition, 24 percent mentioning
supportive lifestyle changes, and 9 percent mentioning the drug’s success rate (Wilkes, Bell and Kravitz 2000, 117).

Furthermore, the educational value of DTCA is dependent on the knowledge and understanding of the consumer watching and reading them. In a randomized telephone survey of 329 residents of Sacramento County, half of respondents thought that drug advertisements had to be sent to the federal government for approval. Even more telling is that 43 percent believed that only “completely safe” drugs could be advertised (Bell, Kravitz and Wilkes 1999). These misconceptions undermine the integrity of any educational value DTCA has to the public.

Evidence of Increased Prescriptions due to DTCA

Studies have produced conflicting data about the prescribing impacts of DTCA. A quantitative study of pharmaceutical demand for cholesterol-reducing drugs before and after the 1997 FDA “adequate provision” rule change found no evidence that DTCA increases short-term demand (Calfee, Winston and Semske 2002, 675). Using a regression analysis, Calfee’s study found that advertising expenditures had an insignificant effect on prescription demand. The analysis was conducted looking at the value of three and six-month stocks, money spent on advertising, company revenues, and 30-day, 60-day, and 90-day prescriptions. The study acknowledges that it may be difficult to distinguish DTCA’s causal effect on short-term rises in prescriptions because of the many steps it takes after seeing an ad to actually get a prescription for cholesterol-reducing drugs. A typical chain of events for a single patient may involve an initial visit to the doctor, a second visit to review test results, perhaps trying a change in diet and
exercise, a third visit to the doctor, and then maybe a prescription (Calfee, Winston and Sempski 2002, 681).

A convenience sample of 2,500 US residents (427 reporting) found that 44 percent of patient-initiated discussions with their doctor regarding television ads of allergy medications resulted in a change of treatment, and 39.1 percent of patient-initiated discussions about asthma medications seen on TV resulted in a change of treatment (Khanfar, Polen and Shields 2008,131). These results are similar to a 2003 study by Murray and Pollack, which found that of the survey respondents who requested a medication from their doctor, 81.4 percent received a prescription (Khanfar, Polen and Shields 2008,132. The results of these two studies are similar in showing that a patient has a significant likelihood of getting a change in treatment (may it be a referral or a new medication prescription) if they request a medication from their doctor. The studies are also similar in that they do not measure whether the patients requested a prescription from their doctors as a direct result of DTCA or for other reasons.

One study of patients and physicians in Sacramento and Vancouver in 2000 and 2001 did note direct evidence of advertising’s influence. Of the 12 percent of patients who requested a prescription during their office visit, 42 percent of those requests were for drugs directly advertised to consumers. The study found that patients who requested an advertised medication had a 50 percent higher probability of receiving the requested medication than those who requested a medication that was not advertised (Mintzes 2002, 278).
In reviewing the literature, I found that the benefits of DTCA are entirely theoretical and unproven, while the adverse effects of DTCA have been proven in numerous studies. The literature review exposed evidence of increased prescriptions being written due to DTCA, in addition to an increase in the likelihood that a patient receives a requested medication if that medication is advertised. Also, the informative qualities of advertisements vary widely, and a substantial percentage of the advertisements’ audience hold detrimental misconceptions about the truth in advertisements, among them the perception that only safe drugs are allowed to be advertised. In conclusion, the solidly proven detrimental effects of allowing DTCA in the United States far exceed the value of the theoretical benefits. The results of the literature indicate that the detriments of DTCA outweigh its benefits. The following chapter seeks to define the criteria used to qualitatively and quantitatively evaluate some of the policy alternatives that could be implemented in an effort to increase the benefits of DTCA to society while minimizing its deleterious impacts.
Chapter 4

CRITERIA TO EVALUATE DTCA

What is most at stake in the debate over DTCA is the state of societal health, and whether DTCA results in a net gain or loss to societal health. Research suggests that DTCA is beneficial if the drugs advertised are for under-treated and under-diagnosed medical conditions (Wilkes, Bell and Kravitz 2000, 121). The potential for some consumers to benefit from DTCA must be assessed in contrast to those who may be harmed by DTCA, including the net harm that DTCA creates to the overall cost of health care. Another element to consider is the intensity of benefit or harm caused by DTCA - are the benefits small but the harms severe (Wilkes, Bell and Kravitz 2000, 121)?

The high returns on pharmaceutical companies’ investments in DTCA, the likelihood that a patient will receive a prescription if he or she asks for one, and the increased spending on advertisements in the past decade all speak to the influence of DTCA on the medical industry in the United States and, to a lesser extent, the impact of the 1997 guidelines change opening the door to television advertising of prescription drugs. The next chapter will delve further into the impact these changes have on the different stakeholders in the debate surrounding DTCA, followed by a format and outline for evaluating the benefits and costs of DTCA.
The Stakeholders

When assessing the impacts of DTCA, one of the first questions to ask is “Who is impacted by DTCA”? Not everyone is involved or affected by the advertising of prescription drugs on television or in magazines. And the answer to the question of “Who?” is the stakeholders.

As mentioned before DTCA has many stakeholders, from the magazine ad salesperson earning a commission from every ad spot she sells, to the chemist working for a large pharmaceutical manufacturer, among many others. But, for the purposes of this paper and to highlight only those with a substantial stake in the debate, I am limiting the discussion of stakeholders to include pharmaceutical companies, the federal government, health insurance companies, patients and medical consumers, and doctors and medical providers.

Desired Outcomes

After identifying the stakeholders involved with DTCA, the next question to ask is “What criteria are important when assessing the impact of DTCA?” Essentially, what are the desirable outcomes for the stakeholders when considering policy alternatives to the status quo? Earlier in this paper I mentioned that the issue of DTCA would be assessed from a public policy perspective with improved societal health being the ultimate goal. Because of this perspective, the impacts of DTCA and the policy alternatives will be discussed as they apply to all the stakeholders identified in the previous paragraph, but the critique and analysis will be slanted to find the options that will most benefit societal health.
As the previous chapter has illustrated, there are both negative and positive outcomes stemming from the 1997 FDA decision to allow DTCA in the United States. The most effective and positive policy alternatives to the existing DTCA policy and practice will maximize the desirable outcomes while minimizing the negative ones.

The known negative externalities of the existing DTCA policy are an increase in prescription drug costs to recoup advertising expenditures and increases in the number of prescriptions written and filled, leading to higher health care costs. Other plausible but unsubstantiated negative externalities include consumers being misled or confused by the information presented in DTCA and higher overall health care costs for society.

Known positive externalities of the existing DTCA policy include greater freedom of speech for pharmaceutical companies stemming from an additional way to promote their products other than physician detailing and the consequential higher return on investment for pharmaceutical companies. Other possible but unsubstantiated positive externalities include a more informed society, fewer under-diagnosed medical conditions, and lowered overall health care costs.

Answering the question of the intensity of benefits and drawbacks to DTCA, the literature confirms that the drawbacks to DTCA are severe, while the benefits, if any, are slight.
Criteria to Evaluate Policy Alternatives

The table presented in the following chapter lists policy alternatives along the far left column. When selecting criteria, I chose to evaluate the options using criteria that counterbalance the known and plausible negative externalities of the existing DTCA policy. While other outcomes from a change in DTCA policy or practice are desirable, it is impossible and beyond the scope of this paper to try to completely solve health care affordability issues, access to doctors, or the scope of insurance coverage in the United States. Instead, this paper attempts to illuminate the effects of current FDA policy allowing DTCA and evaluate policy options that may minimize the negative effects of DTCA while capitalizing or increasing its benefits.

The criterion “minimal cost to implement” was chosen because cost should always be a factor when considering changes to existing policy, creation of a new policy, or elimination of an existing policy. If the FDA considers changing its position on DTCA, the cost to implement changes will certainly be a factor in the discussion. Because exact costs are unknown and only speculative, I use a scale to represent the projected cost of a policy change to the federal government, ranging from very inexpensive to very expensive. Alternatives rated as inexpensive or very inexpensive would either reduce current costs or have no effect because they create few negative impacts to the staffing necessary to review DTCA. Those alternatives listed as expensive increase the size of the government bureaucracy and regulatory staff, and so are more costly options to implement.
The second criterion used to evaluate DTCA policy alternatives is whether the alternative would likely lower the cost of prescriptions. Increased cost of prescription drugs is one of the known negative externalities stemming from DTCA. With the escalating cost of health care, lowering the cost of pharmaceuticals becomes a priority. Again, a scale is used to estimate the extent to which an alternative may result in lower prescription cost, ranging from no effect to a large reduction in prescription drug cost. Alternatives likely to lower the cost of prescription drugs do so by reducing the money likely to spent on pharmaceutical advertising in the future.

Positive effect on societal health is the third criterion. I stated in the preface that there would be an emphasis on overall health of the public during the analysis of possible policy alternatives and changes to current DTCA policy. This is represented by this criterion. It seeks to answer the question, “Is this policy helpful or detrimental to the public’s health”? Improved societal health can be expressed as a reduction in preventable diseases, better knowledge of conditions and treatments, and more people receiving needed medical treatment.

The last criterion addresses the problem of drug advertisements that violate the FDA guidelines. As the DDMAC and FDA are underfunded and many ads slip through the cracks of their regulation, reducing the number of ads violating the FDA guidelines is a desirable outcome. Also, reducing the number of ads aired and printed would create the effect of lowering the number of violating drug ads, and this is reflected in the table.
Chapter 5

POLICY ALTERNATIVES

This chapter reviews five policy alternatives that improve or alter existing policy and practice concerning direct to consumer advertising in the United States. Many of these alternatives have been suggested in articles reviewed in Chapter 2- Literature Review, and a few of them are alternatives I think are possible improvements to the current system. For the sake of comparison, a “no change” scenario alternative is included. The inclusion of a “no change” alternative in a public policy analysis is a common occurrence, and represents a scenario where change naturally occurs outside of any deliberate policy decision.

Perhaps the most obvious alternative to counteract the negative externalities of existing DTCA policy is to reverse it, banning DTCA in the United States. This could manifest as a reversion to pre-1997 FDA policy on pharmaceutical drug advertising, or elimination of all forms of DTCA – in print, televised, or otherwise.

Another policy alternative is to impose a DTCA moratorium for drugs that are new to the market. To be most effective, the moratorium should be either for brand new drugs (drugs less than two years on the market), or new drugs within the seven-year period where new formularies are protected from cheaper generic competition. The idea of a DTCA moratorium was suggested by authors Almasi, Stafford, Kravitz and Mansfield, read during the course of the literature review.
Yet another option is increased regulation by the federal government. This third alternative proposes that all advertisements be pre-approved by the FDA prior to publication. If this policy alternative is implemented, we can expect that the pre-approval process would only need to happen for a few years before the pharmaceutical companies would thoroughly understand what is acceptable and what is not, provided also that the guidelines became more clear, and the penalties for violation of the guidelines more severe.

The fourth policy option included in the matrix is a change in the FDA guidelines themselves. Requiring that the brief summary be included in the main ad copy and not allowed to be in tiny fine print on the backside of advertisements will likely only alleviate some of the negative effects of print DTCA, with no change to radio or television advertisements. Still, this alternative merits consideration because the seamless incorporation of risk information into advertisements brings those risk factors into prominence for the consumer viewing the ad, resulting in fewer violating drug advertisements and consumers who are better informed of the risks of taking new medications.

The fifth alternative on the matrix is the creation of an ad campaign promoting the use of generic medications instead of brand-name ones. The intent behind this alternative is to inform consumers of the cheaper alternatives to brand-name medications, using the same media the large pharmaceuticals use to promote their products. One variation of this alternative would be to tax pharmaceutical companies and use the money generated to fund the generic medication advertising campaign.
Table 1 – Criteria/Alternatives Matrix

<table>
<thead>
<tr>
<th>Policy Alternatives</th>
<th>Cost to Implement</th>
<th>Effect on Cost of Prescription Medications</th>
<th>Positive Effect on Societal Health</th>
<th>Effect on Violating Drug Advertisements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ban DTCA</td>
<td>Very inexpensive</td>
<td>Moderate reduction</td>
<td>Likely</td>
<td>No violating ads</td>
</tr>
<tr>
<td>Moratorium on ads for drugs less than 2 years old</td>
<td>Very inexpensive</td>
<td>Slight reduction</td>
<td>No effect</td>
<td>Fewer violating ads</td>
</tr>
<tr>
<td>Pre-approve all ads</td>
<td>Expensive</td>
<td>No effect</td>
<td>Unknown</td>
<td>No violating ads</td>
</tr>
<tr>
<td>Move brief summary to main ad copy</td>
<td>Inexpensive</td>
<td>No effect</td>
<td>Likely</td>
<td>Fewer violating ads</td>
</tr>
<tr>
<td>Create ad campaign for generic Rx’s</td>
<td>Expensive</td>
<td>Moderate reduction</td>
<td>No effect</td>
<td>No effect</td>
</tr>
<tr>
<td>No change</td>
<td>Very inexpensive</td>
<td>No effect</td>
<td>No effect</td>
<td>No effect</td>
</tr>
</tbody>
</table>

All alternatives above attempt to mitigate the negative externalities of DTCA through more regulation except for the creation of the ad campaign for generic medications. The next section will evaluate each of these alternatives using the criteria of cost to implement, predicted effect on the cost of medications, overall impact on societal health, and whether the policy alternative would result in fewer violating drug advertisements.
Policy Alternative 1- Banning DTCA

Banning DTCA rates high concerning the criteria of cost, with an estimated minimal cost to implement. To implement this policy alternative, the federal government would either revoke the 1997 FDA policy guidelines change making television ads infeasible, or eliminating all forms of DTCA, including print media. Revoking an existing law is inexpensive, and the federal government would save money by banning DTCA through the elimination of the analysis and legal team that currently reviews pharmaceutical advertisements. Because DTCA is currently legal in the United States, it necessitates an industry that clarifies the guidelines under which advertisements are legal, as well as a team that enforces those regulations. Prohibiting DTCA would eliminate the corresponding regulating industry.

My analysis indicates the elimination of DTCA would likely decrease the cost of prescription medications, and this policy alternative ranks relatively high on this criterion compared with the others. Because the cost of advertising new drugs directly to consumers is very costly at a cost that exceeds 4.2 billion dollars annually (Hartley and Coleman 2008,109), it is another finding of this analysis that the elimination of advertising for these drugs is likely to decrease the cost of advertised drugs to consumers significantly. When this specifically significant cost savings for advertised drugs is accounted for across the breadth of all prescription pharmaceuticals, this analysis expects a “moderate” decrease in the cost of prescription pharmaceuticals on the whole. Some of the money currently spent on advertising to consumers may be directed to physician detailing if this policy alternative were adopted. However, it is unlikely that most of the
money would be diverted, as this analysis presumes the pharmaceutical companies are already spending close to the optimal unregulated amounts on physician detailing.

As for the criterion of improved societal health, it is unknown what impact banning DTCA would have. Although there is the possibility of a decrease in valuable knowledge among consumers if DTCA were banned, the review of literature found that oftentimes, consumers of pharmaceutical advertisements are misled by advertisements, or mistakenly think that only safe drugs can be advertised (Bell, Kravitz and Wilkes 1999). These misconceptions among consumers lead to the conclusion that the effect of banning DTCA on overall societal health is unknown, or negligible.

*Policy Alternative 2 – Moratorium on Ads for Drugs Less than 2 Years Old*

Authors Almasi, Stafford, Kravitz and Mansfield in their article “What are the Public Health benefits of Direct-to-Consumer Drug Advertising” suggested a moratorium on advertising for new drugs as an alternative to existing policy. Because advertising expenditures are highest for drugs that are new to the market and those which have no competition from other pharmaceutical companies (Roth 1996), this alternative would lower the high prices of new medicines by preventing them from being advertised for the first two years they are available. Another expected outcome per this analysis is that this moratorium alternative would likely mitigate mishaps such as the Vioxx scandal, where FDA approval of a new COX-2 inhibitor drug for arthritis use was “prioritized,” the drug was heavily advertised on television, and then ads had to be immediately pulled after the FDA advisory panel voted to pull it from the market; finding that it significantly increased the risk of heart attack or stroke (Angell 2005, 265-270).
A two-year moratorium on DTCA for drugs less than two years old ranks highly on the “minimal cost to implement” criterion of the matrix, with a rating of “very inexpensive”. It is predicted to be marginally more expensive than the alternative of a complete ban on DTCA, but would still save money over the status quo because there would be fewer advertisements for the FDA to review.

A two-year moratorium on advertising for new drugs would also likely decrease the overall cost of prescription medications, but not significantly. Currently, pharmaceutical companies spend their advertising dollars where they are likely to yield the highest return on investment. If advertising new drugs is not an option, then it can be assumed that some of this advertising budget would be diverted to the promotion of other drugs or otherwise expended to similar ends. Even so, the related advertising budgets would be expected to decrease in the event a two-year moratorium is enacted, and this policy alternative would therefore likely result in a slight reduction in the cost of prescription medications.

As for improving the societal health, the impact of a two-year advertising moratorium would likely have no impact. A two-year advertising moratorium would not result in better information about drugs or health conditions, but simply delay the initial onslaught of advertising to which consumers are subjected immediately following FDA approval. Similarly, I would not expect fewer violating drug advertisements resulting from this policy, as the content of advertisements is not regulated, just their timing.
Policy Alternative 3 – Pre-approve All Ads

Another policy alternative is to require federal pre-approval of all DTCA. This option is much more expensive than policy alternatives one and two, as it requires a larger staff in order to pre-approve all ads before they are printed or aired, and is one of the most expensive alternatives to implement. The same federal staff that currently comprises DDMAC would perform pre-approval. This staff would review each proposed television, radio, and print advertisement to ensure they meet the guidelines and are fair and balanced prior to publication.

Regarding the effect on the cost of prescription drugs, pre-approval of all advertisements would likely have no impact. Currently, the cost of federal regulation and oversight of DTCA is borne by taxpayers, and an increase in the cost of this oversight would likely be paid through taxes as well. Because the cost of regulation is not paid for by the pharmaceutical companies, I expect requiring pre-approval of all advertisements would not have an effect on the cost of prescription medications.

The pre-approval of all prescription drug advertisements would have unknown effects on overall societal health. It is likely that many advertisements would contain a better balance of benefit and risk information than under current practice, but it is unclear whether this translates to greater societal health.

By far the biggest benefit of adopting this policy alternative is fewer violating drug ads. By requiring pre-approval, there would be very few, if any violating advertisements publicized. This policy alternative along with the first one (banning


DTCA) are the only two policy alternatives examined likely to approximate one hundred percent effectiveness in eliminating drug advertisements that violate FDA guidelines.

Policy Alternative 4- Move Brief Summary to Main Ad Copy

The fourth policy alternative entails moving the brief summary ad copy from where it is usually located on the backside of the advertisement in very fine print to the main page of print ads. This is a very obvious change for print ads, but a similar change for television and radio ads would need to be fairly nuanced. Television and radio ads fulfill the brief summary FDA requirement by including a faster-talking voice-over addition to their regular, coercive ad copy. This policy alternative may require television and radio ads to seamlessly incorporate the brief summary requirement into the main language of the ad instead of tacking it on to the back as a disclaimer.

Requiring greater prominence for the summary of risk information would be inexpensive to implement. As is the case with the first and second policy alternatives, all it would require is a policy change to existing law.

Although alternative four ranks fairly highly on the cost to implement criterion, it ranks poorly in terms of its likelihood of lowering the cost of prescription medications, where it is predicted to have no effect. Requiring the integration of the brief summary requirement throughout ads would not change the quantity of advertising nor their costs, and so the cost of advertising would still be passed along to consumers through higher drug costs, as is the case with existing DTCA policy.

As for its effect on societal health, integration of risk information within the body of ads will likely have little effect. The consumers who view an ad with integrated risk
information may be slightly better informed than if they were viewing an ad with the standard fast-talking or fine-print disclaimer stuck on the end, but the net expected benefit is negligible at best.

Finally, integrating the brief summary information requirement would likely result in fewer drug advertisements in violation of FDA guidelines. In a review of television advertisements, the most-frequented violation found was the absence or relative absence of risk information. Presumably, requiring that risk information be more prominently featured in advertisements will result in fewer advertisements in violation of FDA guidelines.

*Policy Alternative #5- Ad Campaign for Generic Prescriptions*

Policy alternative number five proposes an ad campaign be created in the public interest to provide a counterbalanced alternative to pharmaceutical company-driven ad campaigns. This advertising effort might be funded by pharmaceutical companies themselves via a tax, or might be funded by the federal government via other funding sources. The idea behind advertisements for generic drugs is to educate consumers about cheaper medicine options, ultimately leading a better-informed society.

Creating a generic drug advertising campaign is one of the most expensive policy alternatives analyzed in this paper. In order to be viable, the ad campaign would need to be a national campaign, perhaps using billboards, television ads, or other highly-visible media to reach consumers who are barraged by ads for drugs manufactured by the larger pharmaceutical companies.
The second criterion used to assess the policy alternatives is the ability of the alternative to lower the cost of prescriptions. This is one area where the option of a generic ad campaign really shines. Ads promoting the availability and effectiveness of generic medications will likely result in consumers asking for cheaper medications to treat their symptoms and diseases, resulting in lowered costs of prescriptions overall.

An ad campaign for generic medications will likely have no significant impact on the health of society overall. Those who view the ads may be better informed about medication options, but the ads are unlikely to have a direct impact on their health. Essentially, the purpose of an ad campaign would be to improve the quality and diversity of medication information for consumers by encouraging them to ask their doctors about replacing high-cost brand-name medications with cheaper, generic alternatives. A campaign advertising generic medications could also be expanded to advertise non-medication treatment options, such as diet and exercise.

As for the last criterion - the possibility that the policy alternative will result in fewer violating drug ads - the creation of a generic drug campaign will have no effect. What consumers would see if this alternative was implemented is more drug advertisements, because now there would be public service advertisements promoting generic drugs in addition to the ads we are used to seeing. However, the content of the prescription drug ads would not change, and so implementing this policy alternative would no effect on the number of drug advertisements violating FDA guidelines.
Policy Alternative #6- The No Change Policy Alternative

Policy alternative #6 is the “leave present conditions the same” option, and it is included in this chart for comparison purposes. As there are often changes in the public policy environment that occur naturally, without deliberation or intent, inclusion of the “no change” scenario in the table accounts for the unaccountable, and serves as a baseline from which other alternatives can be compared. Examples of what may occur under the “no change” scenario include government implementation of changes to their DTCA policy or regulation, or a change in public opinion about DTCA.

While the “no change” option is included in the list of policy alternatives, it does not in any way improve upon our current system, rather it represents the status quo. As such, the “no change” alternative would be free to implement, and would have no effect on the cost of prescription medications, societal health, or drug advertisements that violate FDA guidelines.
None of the six policy alternatives are a panacea for the ill effects of DTCA, but most of the alternatives analyzed alleviate some of the drawbacks and all have a reasonable chance of being implemented.

In policy analyses, there is typically one further criterion used to evaluate policy alternatives, and that is political feasibility. While some choose to include this variable within a matrix or include it in the evaluative process from the start, I’ve chosen to consider it outside of the matrix as a dynamic, yet important factor to consider when implementing any changes to existing policy. Political feasibility is a factor that can change dramatically over time, so to keep this analysis current well into the future, factoring it into the final analysis and keeping it removed from the matrix will allow future readers to separate its impact in the analysis easier than if it were included in the matrix. This chapter reviews the alternatives presented in the matrix and discusses how each policy option compares when evaluated with the criteria chosen, and then goes one step beyond and discusses the political feasibility of implementation within the existing environment. The political feasibility of a policy alternative is the key determinant of the likeliness of it being adopted and implemented, and it is the reason why no policy change is likely to be implemented in the near future.

While the first policy alternative would be very inexpensive to adopt and the benefits to doing so would be great, it is the least politically viable option of those included in this assessment. Banning DTCA is not likely to happen because of the large
amounts of money the pharmaceutical industry invests in its relationships both elected politicians and people who are appointed. One example of this is representation on the FDA’s advisory boards. In 2004 while conducting hearings on the safety of Vioxx, ten out of 32 advisory board members disclosed that they had direct financial ties to Merck, Vioxx’s manufacturer (Angell 2005). Large financial donations buy influence, and it is this influence that is likely to keep strong anti-DTCA policy changes from being adopted.

The second alternative (moratorium on advertising of drugs less than two years old) would be more likely to happen, because it is a much more industry-friendly option. Even though this policy alternative increases the amount of regulation on DTCA than currently exists, it would still be politically feasible to adopt and implement, because most stakeholders can see it as a compromise solution. One drawback to adopting this alternative is that it would likely have a reduced benefit when evaluating it with the criteria I’ve chosen. Because it is a less-drastic policy change, its positive effects are also mitigated.

The third policy alternative assessed is pre-approval of all ads prior to being printed or aired. This alternative is among the most costly to implement, and the government’s role in regulating DTCA would be significantly increased. In 2009 the FDA’s DDMAC had 18 analysts researching and reviewing DTCA, and pre-approval of all ads would increase this number greatly in addition to increasing the Department’s staff numbers from 52 well into the hundreds (Kiester 2009).

This would effectively eliminate misleading drug advertisements, but would likely only have a small effect on improving societal health. Pre-approval of all ads has a
low chance of being implemented among all alternatives studied, but along with the option of a two-year moratorium, can be seen as a compromise among the stakeholders involved.

Moving the brief summary requirement to the main body of print advertisements is another incremental change, but one that ranks low on all of the criteria. Of all the policy alternatives assessed, this one is balanced but creates few positive effects when it comes to reducing violating drug ads, lowering the cost of prescriptions, and improving the societal health. This would result in a very minor change from the status quo, and has little likelihood of being implemented because it is a policy option to which few stakeholders see significant benefits. Moving the brief summary requirement to the main body of print advertisements would do nothing to regulate television advertisements, and would not result in a decrease or increase in the cost of regulation.

Policy alternative number five suggests creating ads for generic drugs to be comparable to those for prescription medications. This policy option would be expensive to implement, for a predicted “moderate” reduction in the cost of prescription medications. As for improving societal health and reducing violating drug ads, this alternative does not create much positive change in either of those two categories. Politically, this alternative has little chance of implementation, because it is costly and an ad campaign for generic prescriptions is unlikely to competitively rival the multi-billion dollar ad campaigns undertaken by the pharmaceutical industry. In order to truly provide an alternative that rivals the efforts of the pharmaceutical industry, the government would
need to expend significant additional resources. This is one case where spending more money does not necessarily equate to fewer deleterious effects.

Overall, the policy alternative of banning DTCA is the most promising in achieving the goal of improved societal health, but has the largest political feasibility hurdle of all of the alternatives considered. No other alternative comes close to reducing the cost of prescriptions, reducing ads that are in violation of FDA guidelines, or cost so little to implement. However, the policy option that represents the most rational course of action before political considerations is also the most unlikely to be implemented with those considerations accounted for, and this situation certainly applies here. Although on paper, banning DTCA seems to solve all of the ills associated with it, it is politically the least likely alternative to be adopted. The money and influence behind prescription pharmaceuticals is great, and after twelve years of being barraged by advertisements for the latest and greatest medications, American consumers are accustomed to it. One other factor influencing the likelihood of implementation of this policy alternative and any other alternative contemplated is the state of discourse. Currently, DTCA is not on the political radar, despite the prominence of health care costs and reform in the public discourse. While there has been substantial discussion in Congress and on the federal level concerning rising health care costs and universal coverage, prescription advertising has not been in the spotlight at all. In fact, in 2009 there were only two proposed bills addressing DTCA - the Informed Health Care Decision Making Act and the Say No to Drugs Act. (Chung 2009). The former would require clinical effectiveness disclosure in advertisements, and the latter would have prevented pharmaceutical companies from
deducting the cost of advertisements as a business expense. Both bills have died in committee. In conclusion, the American public has not seen DTCA as an issue, and it is unlikely that a ban (or any other alternative considered) will be implemented in the foreseeable future.

Despite the conclusion that a ban of DTCA in the United States would increase societal health, result in a decrease in the price of prescription medications, be inexpensive to implement, and result in no violating drug advertisements, it is unlikely to be implemented for a lack of political momentum and countervailing pressure from the pharmaceutical industry. While it is easy to understand the forces behind the 1997 FDA guideline change, it is much harder to revoke such a privilege once given. The pharmaceutical industry invests heavily each year to maintain its influence over politicians and consumers. It would take a sea change in public opinion or to how our political system functions in order to eliminate DTCA in the United States.

In European countries, it may be increased political involvement by the public, less financial or political interest by drug companies, or both that prohibits DTCA. Although Europe, Canada and Australia currently do not allow DTCA, they will likely consider it soon (Auton 2006); as the debate unravels in these countries, researchers and political observers will notice how the influential forces behind the DTCA effort are similar and dissimilar to the forces in the United States. Hopefully, countries considering allowing DTCA will see its effects in the United States and in New Zealand, and ideally, propose stricter, clearer guidance to the pharmaceutical industry, continue to ban DTCA.
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