

**SHOULD THE FDA RESTRICT DIRECT TO CONSUMER
ADVERTISING OF PRESCRIPTION DRUGS?**

Final Report

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ABSTRACT

Many argue that changing the way the FDA regulates direct-to-consumer (DTC) advertising of prescription drugs will be an important part of controlling health care and prescription drug costs. This report concludes that the confusing nature of some of these advertisements may be leading to unnecessary excessive spending on drugs, and that the FDA's current enforcement scheme is unable to control this. This report assesses the costs, benefits, and distributional implications of either a total ban on broadcast DTC advertising or an enhanced FDA with greater jurisdiction and enforcement powers. This report finds that either option is an improvement over the status quo but that a total ban eliminates an important consumer empowerment tool while enhancing the FDA retains this tool but has a greater negative impact on pharmaceutical firms and the government.

PREFACE

This report synthesizes research done by previous studies of this issues that have been done by the Kaiser Family Foundation, National Institute for Health Care Management, General Accounting Office, Public Citizen, and others to provide a comprehensive assessment of this important issue. It also draws on articles published in the journal *Health Affairs* and the *New England Journal of Medicine* and uses physician and consumer survey data collected by the FDA to build support for its arguments.

The report was written as part of a health policy capstone course for Duke University Graduate students. It has been designed to assist members of Congress and their staff in deciding whether pass legislation that would alter the way the FDA regulates DTC advertising.

ACKNOWLEDGMENTS

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EXECUTIVE SUMMARY

In 1997, the FDA modified its guidelines so that pharmaceutical companies could effectively use direct-to-consumer (DTC) advertising to promote their prescription drug products to potential patients through the broadcast media for the first time. Since that time, there has been rapid growth in the types and uses of DTCA. Current regulations specify that prescription drug advertisements cannot be false or misleading, and must present a “fair balance” between benefit and risk information. However, many debate whether these ads are in fact meeting these requirements. This report looks at these issues and assesses the impact of two policy options that might remedy them: 1) a total ban on DTC advertisements and 2) enhancement of the FDA’s authority and capacity to enforce a revised regulatory scheme.

DTCA Background

There are three categories of pharmaceutical advertisements aimed at consumers: product-claims, reminder, and health seeking advertisements. A staff of approximately 30 people at the FDA reviews each advertisement retrospectively. These individuals are responsible for reviewing the nearly 36,700 pieces of promotional material and 486 broadcast advertisements. If a company’s ad is found to violate the regulations, they are generally set a warning letter that threatens further enforcement actions. To place DTC advertising in perspective, however, it is only 15 percent of the overall advertising budget of

drug companies. The majority of product promotion funds are still spent on detailing (drug representative visits to individual doctor offices) and sampling (the giving of free drug products to physicians who in turn pass them along to patients for free).

Why look at DTCA?

Rising pharmaceutical costs are now the fastest growing component within health care system, and DTCA is seen as one of the primary drivers. U.S. spending for prescription drugs was \$140 billion in 2001, which is more than triple what it was in 1990. In 2000, \$2.5 billion was spent on mass media advertising of prescription drugs, and roughly half of this was on TV ads. The limited resources and ability of the FDA to monitor these ads has caused some groups to ask whether consumers are getting accurate information. Some believe people who respond to a DTC ad are often unaware of side effects. Others believe that DTC ads often overstate the benefits of treatment with a drug.

Policy Options

Option A: Ban DTC through the Broadcast Media

In essence, this would be a return to the pre-1997 regulatory scheme, where the heavy information requirements precluded the possibility of conveying all the required information in a broadcast ad.

Option B: Enhance FDA's Jurisdiction and Enforcement Capabilities

This would be a switch to prospective mandatory review program and would require additional staff and resources for the FDA.

Benefits of Either Option

This report finds that although a total ban would decrease total drug spending it would not provide significant benefit beyond decreasing doctor and patient frustration with inaccurate ads. In contrast, an enhanced FDA could provide a powerful consumer educational tool that would help both patients and physicians.

Costs of Either Option

A total ban would reduce the treatment of under-treated disease categories and would eliminate a useful means of informing consumers about their health choices. On the other hand, Option B would possibly increase advertising approval times and costs.

Equity Assessment

The burden of the total ban would be placed on consumers and physicians who no longer have an alternative means of informing themselves about drug products. An enhanced FDA option primarily burdens the government and pharmaceutical industry that must create and abide by a stronger regulatory scheme.

I. INTRODUCTION

Why Reform DTCA?

In 1997, the FDA relaxed its rules about the required content of mass media advertising for prescription drugs. Prior to this point, any direct-to-consumer (DTC) advertising had to contain all risk information associated with the medication. The amount of mandatory information was so large that such advertising was impractical (GAO, 2002).

Since the issuance of the new provisions, there has been an explosion in the number and kinds of television and radio advertisements that have been used to promote pharmaceuticals. A recent study found that the general awareness of advertising for prescription drugs grew from 63 percent in 1997 to 85 percent in 2002 (Prevention Magazine, 2002). Patients have become increasingly willing to view DTC advertisement claims as an important additional source of health information. Another recent consumer survey confirmed this trend by indicating that one-third of respondents reported asking their doctor for information about medications described in a DTC ad, and three quarters of doctors filled those prescriptions (Wilkes, 2000).

There are two chief concerns related to DTC ads, one related to costs and the other related to quality. Overall, health care costs continue to rise. In particular, drug spending is now the fastest growing health care expense. Retail spending on prescription drugs has grown between 13 percent and 20 percent each year since 1995 (NIHCM, 2000). Many point to the increase in DTC

advertising as a significant contributor to the overall rise in health care costs. They note that the drug categories for which DTC advertising is most commonly used are often the most expensive and the most frequently used medication. In addition, they point out that majority of DTC advertising is done for newer products that have no generic competitors (KFF, 2003).

On the quality side, there is a concern that the vague or misleading nature of some DTC advertisements will lead consumers to seek drugs that are not appropriate for them. Due to physicians' time constraints during their clinical encounters with patients, many speculate that false and misleading advertisements can result in dangerous and/or less effective prescriptions being written for patients. Since 1997, the FDA has found more than 90 DTC advertisements that violated federal laws and regulations. In the majority of the cases, warning letters were sent to the drug companies responsible for these advertisements well after the promotional campaign had been completed. Some suggest that many more harmful advertisements are proceeding unchecked. Despite a rise in total dollar volume spent on DTC advertising from \$791 million in 1996 to \$2.5 billion in 2000, the number of staff allocated to reviewing advertisements has only increased from 11 in 1996 to 14 in 2001(Wolfe, 2001).

Purpose of This Report

Duke University graduate students wrote this report to fulfill the requirements of a PPS 255S.02 Health Policy Analysis course. This course brings people with diverse backgrounds together to work on their writing,

analysis, and presentation skills. They hone their skills while researching and writing about important contemporary health policy topics.

The participants of the course selected the topic of this report as an important policy issue, and it was randomly assigned to a group of three. When writing the report the authors set out to provide clear analysis and supporting evidence that would assist members of Congress and their staff in deciding whether to restrict DTC advertising.

Main Findings

We draw the following major conclusions about how DTC advertising should be regulated:

- 1) Although in some cases DTC advertising has proven beneficial, there are, in many cases, serious accuracy issues with certain advertisements.
- 2) The current regulatory regime is insufficient to monitor and control the content of broadcast prescription drug advertisements. In particular, the reliance on a retrospective review system lets many harmful advertisements air before they can be corrected.
- 3) Resolving these issues will not only improve the knowledge level and health of patients and reduce the burden on physicians to correct false impressions, but it will also reduce the costs of unnecessary drug prescribing.

4) More research needs to be done to determine the impact of different types of DTC ads on the health care of Americans in terms of quality adjusted life years.

Organization of the Report

Following this introduction, we break the analysis into several important parts. In Section II, we provide vital background information about the history, types, and use of DTC advertising and compare drugs to other types of products. We also provide more details about the current regulation of DTC advertising and discuss its alternatives. With this information in mind, the report states the problem with DTC advertising as it is currently regulated. Before discussing our policy options, we describe the criteria we will use to assess them. The majority of the report is an analysis of the benefits, costs, and equity considerations of two options: a total ban on broadcast DTC advertisements and an expansion of the FDA's jurisdiction and enforcement capabilities. We end the report with a conclusion that compares our options to the criteria we have created and provides suggestions for further research on this topic.

II. BACKGROUND

History of DTC Advertising

The first advertisement for a patent medication was perhaps the one placed in a newspaper by Boston's Nicholas Boone in 1708. This was followed in the next two hundred years by advertisements for patent medications such as Bateman's Pectoral Drops, Turlington's Balsam of Life, and Dr. Benjamin Godfrey's Cordial. The advertisements for these drugs claimed they could cure or treat dandruff, stomach ailments, rheumatism, baldness, and infidelity. These advertisements were disseminated through newspapers, magazines, and traveling medicine shows. Thus, 'by the early 1800's, the press and the drug industry had developed a strong symbiotic relationship' (Wilkes, 2000).

The Food, Drug, and Cosmetic Act was passed in 1938. This legislation gave the FDA authority over the labeling of pharmaceuticals. The Federal Trade Commission (FTC), however, maintained control over the advertising of these products. This changed in 1962 when the Kefauver-Harris amendments introduced the notion of consumer protectionism into the realm of pharmaceuticals. There was now a requirement to prove the safety and efficacy of all drugs. These amendments also reassigned authority for drug promotional material review to the FDA (Wilkes, 2000).

The initial requirements were not unlike those that exist today. All drug advertisements must have: specifications of contraindications, information about side effects and effectiveness, and a well-balanced view of benefits and costs.

Furthermore, these regulations also held created standards for font size and readability of information (Wilkes, 2000). These rules controlled the way information was disseminated through most of the 20th century, with advertisements targeted mainly toward physicians.

In 1981, however, the pharmaceutical industry first proposed changing the existing marketing paradigm to include consumers. Then FDA Commissioner Arthur Hull Hayes asked the industry for a voluntary moratorium on direct-to-consumer advertisements while the FDA reviewed their proposal. The FDA conducted its review, and in 1985, published a notice in the *Federal Register*, stating 'current regulations were sufficient to safeguard the consumer from false or misleading information' (Wilkes, 2000). This was disappointing to the pharmaceutical industry. They realized that the considerable content requirements in the current regulations would prevent them from using electronic media to reach consumers.

In 1997, however, the FDA issued a draft proposal for new guidelines for broadcast direct-to-consumer advertising following a public hearing and debate. Under these guidelines, the pharmaceutical industry could, for the first time, provide both the drug's name and the condition it was intended to treat without having to disclose all of the contraindications. The new guidelines did not, however, change the rules that state that advertisements cannot be false or misleading. Drug companies were still obligated to present a fair balance between the risks and the benefits of a drug product and reveal facts that are material to the representations made in the advertisement or the consequences

of using the product as advertised. Depending on the medium, they must either disclose all the risks listed in the product's labeling, or make 'adequate provision[s]' to disseminate to the advertisement's audience through other means such as a toll-free number, internet site, or pharmacists (GAO, 2002). Exhibit 1 below depicts some of the requirements for print and broadcast product claim advertisements.

Exhibit 1: Selected Requirements for Content of Print and Broadcast Product Claim Advertisements (Source: GAO 2002)

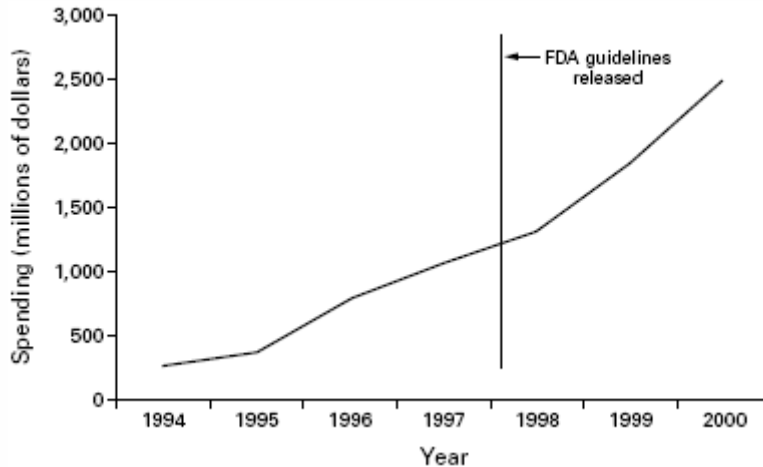
Advertising medium	Regulatory requirements	Explanation
Print and broadcast	Cannot be false or misleading	Must present information that is not inconsistent with product label
	Must present fair balance	Must include risks and benefits of a drug product
	Must present "facts material"	Must present information relevant to representations made, and describe consequences that may result from recommended use
Print only	Must describe risks	Must disclose all risks in a product's labeling
Broadcast only	Must describe risks	Must present major side effects and contraindications* in audio or audio and visual form
	Must make "adequate provision" for directing consumers to labeling information, or provide a brief summary of all necessary information related to risks	Must provide additional sources where consumers can find complete information, such as a toll-free telephone number, a Web site, and a print advertisement in a magazine, and by contacting their physicians; otherwise must summarize risks

*Contraindications are symptoms or conditions that make a drug treatment inadvisable.

Sources: 21 C.F.R. § 202; FDA, *Guidance for Industry: Consumer-directed Broadcast Advertisements* (Washington, D.C.: FDA, Aug. 1997).

Since the issuance of the new guidelines, the use of DTC advertising by pharmaceutical companies has increased dramatically. As shown in exhibit 2, spending on DTCA has more than doubled going from \$1.1 billion in 1997 to \$2.5 billion in 2000, in 1997 (NIHCM, 2000).

Exhibit 2: Spending on direct-to-consumer advertising between 1994 and 2000 (Source: Rosenthal et al, 2002)



Types of DTC Advertising

There are three types of direct-to-consumer advertisements of prescriptions drugs: health-seeking advertisements, reminder advertisements, and product-specific advertisements. Of the three types of advertisements, the FDA only regulates the latter two.

Health-Seeking Advertisements merely discuss a disease or condition and suggests that patients see their doctors (Woodcock, 2003). These advertisements are educational in nature and do not mention specific drugs and are therefore not regulated by the FDA. An example would be a 1989 advertisement by Upjohn [Pharmaceuticals] that encouraged men who were concerned about hair loss to talk with their physicians about the matter. In this advertisement, Rogaine was never mentioned but it was understood that that was what a physician would likely prescribe (Wilkes, 2000).

Reminder Advertisements mention product names, but do not give product indications or make any claims. This type of advertisement provides some minimal information such as dosage, form, and cost but does not discuss a product's use, safety, or effectiveness. The FDA does not require these ads to provide risk information (GAO, 2002).

Product-Specific Advertisements include both the drug's name and therapeutic use and are required to provide balanced information about side effects and efficacy (Woodcock, 2003). Most of the advertisements currently aired fall into this category. The inclusion of additional information causes this category to be the most prone to containing inaccurate representations of a product.

Prescription Drug Advertising versus General Product Advertising

Prescription drug advertising differs from advertising for general products because of the distinct nature of pharmaceutical products. As one author put it:

Health differs from typical consumer needs because health is a fundamental necessity; the consumer cannot often adequately assess for the absence or presence of disease; treatment requires special expertise; and misdiagnosis, mistreatment, or non-treatment may have profound consequences ... DTC prescription drug advertising differs from general product advertising because the former creates demand for a product: that the consumer is poorly prepared to evaluate; that may be inappropriate or harmful to the patient; and to which [physicians control consumer access] (Berger et al, 2001).

Neither patient nor physician clearly understands the actual costs of prescribed medication. Sick individuals are particularly vulnerable to the allure of DTC drug ads because of their acute desire to get better. DTC advertisements

often also promote the subset of medications that hold the greatest potential for toxicity, adverse reactions and inter-drug reactions (Berger et al, 2001).

Current FDA Regulatory Jurisdiction and Enforcement

Current rules recommend that pharmaceutical manufacturers voluntarily submit DTC advertisements to the FDA for review. For the most part, however, the FDA relies on consumer complaints to alert them about problematic advertisements. Therefore, most are only reviewed after they have been disseminated to the public. If the FDA deems an advertisement to be untruthful or unbalanced, it can send a 'notice of violation', instructing the pharmaceutical company to change or withdraw the advertisement. Alternatively, the agency can send a 'warning' letter, which may tell the maker to run corrective ads or send corrective letters to doctors. If a company ignores these warning letters, the agency can take legal action in court to enforce compliance. The FDA, however, does not have the authority to levy fines, which might discourage companies from disseminating inaccurate ads in the first place. Some examples of these violations are described in the Exhibit 3, referenced from a 2003 Consumer Report:

Exhibit 3: Types of direct-to-consumer advertising violations and a description of repeat offenders (Source: Consumer Reports, 2003)

CR's analysis of the drug-ad complaints

The spectrum of violations. Based on our computer-assisted analysis of FDA regulatory letters sent to drugmakers from January 1997 through November 2002, the table below shows the types of alleged violations in drug ads or other promotions. Consumers and physicians were exposed to the most common and worrisome violation—omitting or minimizing drug risks—at roughly the same rate. But a far greater proportion of promotions with bogus drug-superiority claims were aimed at doctors. (Note: The total number of violations listed here is greater than the total number of letters because many letters referred to multiple violations.)

TYPE OF VIOLATION	TYPE OF AD OR PROMOTION	
	CONSUMER	PHYSICIAN
Risks omitted, minimized, or obscured	27%	27%
Improper labeling	23	15
False or misleading efficacy claims	12	15
Distracting or misleading images or sound	11	5
False or misleading superiority claims	7	18
Promoted approved drug for unapproved use	5	9
Failed to submit ad to FDA for review	4	5
Inadequate description of patients or disorders	2	2
Minimized need to see doctor	2	0
Promoted unapproved drug	0	3
Other	7	1
TOTAL NUMBER OF VIOLATIONS	277	1,007

Most-cited drugs. This table lists the brand-name drugs whose ads or other promotions prompted at least five FDA letters citing violations since 1997, according to our analysis. Of the dozen drugs, four are competing allergy drugs and two are competing asthma drugs. The makers of all 12 drugs said they complied with the FDA's request to withdraw the ads or other promotions, though they didn't necessarily agree they were misleading.

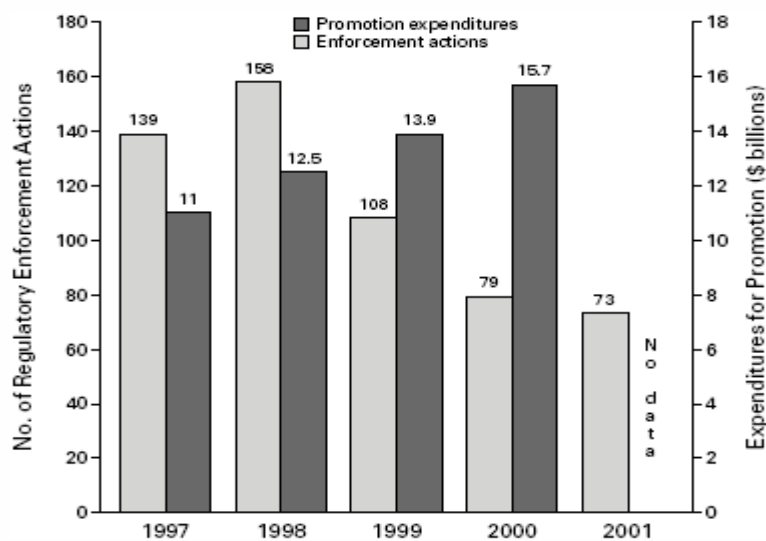
DRUG	MANUFACTURER*	USE	TOTAL LETTERS
Claritin (loratadine)	Schering	Allergies	11
Avapro (irbesartan)	Bristol-Myers Squibb	High blood pressure	7
Flonase (fluticasone)	Glaxo Wellcome	Allergies and other nasal problems	7
Flovent (fluticasone)	Glaxo Wellcome	Asthma	7
Celebrex (celecoxib)	G.D. Searle; Pharmacia	Arthritis symptoms	6
Vanceril (beclomethasone)	Schering	Asthma	6
Xenical (orlistat)	Hoffmann-La Roche	Weight loss	6
Zyrtec (cetirizine)	Pfizer	Allergies	6
Allegra (fexofenadine)	Hoechst Marion Roussel; Aventis	Allergies	5
Avandia (rosiglitazone)	SmithKline Beecham; GlaxoSmithKline	Type 2 diabetes	5
Ditropan (oxybutynin)	Alza	Bladder problems	5
Pravachol (pravastatin)	Bristol-Myers Squibb	High cholesterol	5

*Manufacturer may have changed since FDA letters were sent.

Since 1997, the Division of Drug Marketing, Advertising, and Communications of the FDA's Center for Drug Evaluation and Research have had a staff of approximately 30 individuals. In 2002, only 20 people were responsible for reviewing the nearly 36,700 pieces of professional and consumer promotional material and 486 broadcast advertisements (Woodcock, 2003). In January 2002, a shift in policy by the Department of Health and Human Services (HHS) required a legal review of all regulatory warning letters about drug ads. This, unfortunately, delayed the FDA-violation response times from two to eleven weeks. This meant warning letters were only being sent after the promotional

campaign had ended (GAO, 2003). Studies done to estimate compliance with FDA regulations found, however, that these guidelines were violated in up to 40 percent of all advertisements (Berger, 2001). The following graph indicates how promotional expenditures on all prescription drug advertising (discussed in the next section) relate to the number of FDA enforcement actions:

Exhibit 4: Promotion expenditures compared to enforcement actions
(Source: FDA web site)



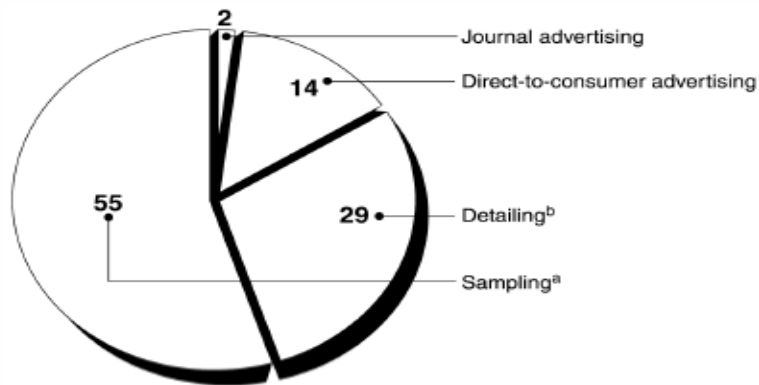
FDA Actions Enforcing Drug Advertising Regulations and Drug-Industry Expenditures for Promotion. Data on promotion are as reported by Rosenthal et al. Data on enforcement actions (warning letters and notices of violation) are from the FDA Web site. FDA enforcement data for 2001 were extrapolated from data for the first 11 months.

Alternatives to DTC Advertising

This report focuses on broadcast direct-to-consumer advertising of prescription drugs. This in no way encompasses the entire scope of pharmaceutical prescription-drug marketing. Direct-to-consumer marketing is only a small part of the overall marketing of prescription drugs. The primary means of promotion remain: *sampling*, which is the distribution of free product to physicians which they can in turn give to their patients, and *detailing*, which are

repetitive visits to physician's offices to share information. The figure below, based on GAO data from 2001, provides a quick breakdown of the various sources of prescription drug advertising.

Exhibit 5: Types of Pharmaceutical Product Promotion (GAO: 2001)



^aThe practice of providing samples during sales visits to office-based physicians.

^bSales activity of pharmaceutical sales representatives directed to office-based and hospital-based physicians.

Source: IMS Health, "Total U.S. Promotional Spending by Type, 2001."

The table below provides a comparison between spending on DTC advertising and spending on promoting products to health care professionals. To provide some further clarification on their relative importance, it encompasses the three other wedges of the pie chart provided earlier.

Exhibit 6: Spending on direct-to-consumer advertising and other types of promotion to health care professionals. (Source: Rosenthal, et. al. 2002)

SPENDING ON DIRECT-TO-CONSUMER ADVERTISING AND PROMOTION
TO HEALTH CARE PROFESSIONALS, 1996 THROUGH 2000.*

VARIABLE	1996	1997	1998	1999	2000
Direct-to-consumer advertising					
Television (millions of dollars)†	220	310	664	1,127	1,574
Print and other (millions of dollars)‡	571	759	652	721	893
Total (millions of dollars)	791	1,069	1,316	1,848	2,467
Percentage of sales	1.2	1.5	1.6	1.8	2.2
Promotion to professionals					
Office-based promotion (millions of dollars)	2,458	2,785	3,386	3,607	4,038
Hospital-based promotion (millions of dollars)	552	579	671	713	765
Journal advertising (millions of dollars)	459	510	498	470	484
Free samples (millions of dollars)	4,904	6,047	6,602	7,230	7,954
Total (millions of dollars)	8,373	9,922	11,157	12,020	13,241
Percentage of sales	12.9	13.8	13.7	11.8	11.8
Total promotional efforts (millions of dollars)	9,164	10,991	12,473	13,868	15,708
Percentage of sales	14.1	15.3	15.3	13.6	14.0

*Data are from IMS Health and Competitive Media Reporting. The percentage of sales was computed with the use of estimates of industry sales from the Pharmaceutical Research and Manufacturers of America.

†Data include spending on advertising on network and cable television as well as on "barter syndication" television (a system whereby local television stations pay for syndicated programs by yielding a portion of their commercial time, which is sold to advertisers by the programs' packagers).

‡Data include spending on magazine, newspaper, radio, and billboard advertisements.

Pharmaceutical company spending on DTC advertising in broadcast media is still in the development stages and therefore, it is a small proportion of overall promotional activities and costs. This sector, however, is seeing the greatest growth, tripling in the period between 1996 and 2000 (Rosenthal, 2000). As shown in exhibit 6, direct-to-consumer advertising only represents an investment of 2.2 percent of total sales revenue relative to promotion to physicians, which represents approximately 11.8 percent.

III. PROBLEM STATEMENT

The larger issue, rising health care and drug costs, focuses attention on DTC advertising. In reality, however, not all advertising is harmful and not all drug spending is wasteful. Many of the instances in which consumers become aware of particular prescription drugs through DTC advertising are, in fact, beneficial and lead to better more cost-effective outcomes (Calfee, 2001).

Therefore, the real issue here is that misleading information in some DTC advertising leads to excessive and unnecessary utilization of certain types of prescription drugs. The advertisements, which encourage patients who are unaware of potential side effects or who visit their doctors seeking benefits they will not get, are at the root of the problem with DTC advertising. Former FDA Commissioner Dr. David Kessler said it best when he said:

'Misleading advertisements can result in significant adverse consequences ... needless injury and even death may occur because physicians have been persuaded to prescribe products for uses for which they have not been adequately tested or to substitute therapies that may be less safe or less effective alternatives' (Kessler, 1992).

The best remedy appears to be enforcement of the FDA's guidelines regarding advertising content. Unfortunately, the FDA lacks the inability to adequately enforce regulations because it relies on a retrospective review system and can only send warning letters when it finds violators. Additionally, the small number and type of resources allocated to monitoring DTC prevents any honest assessment of its inaccuracy and too often results in greater confusion among the patient population

IV. CRITERIA FOR EVALUATING OPTIONS

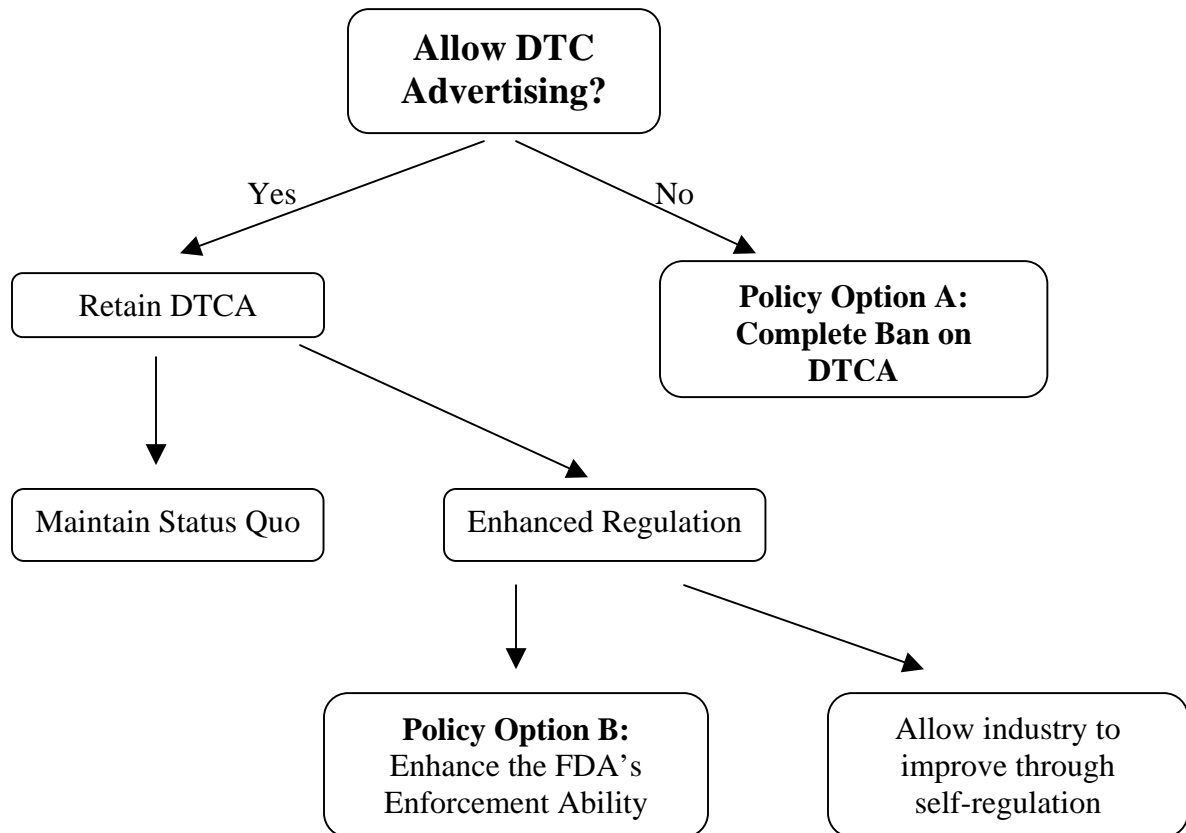
Before developing the eventual proposed options, criteria were defined that could be used to measure the benefits and drawbacks of each option. Options, which did not appear to have the ability to meet a sustainable number of the criteria, were rejected outright. The following criteria were also used:

- Control excessive drug spending
- Ability to empower consumers in their health care choices
- Improvement in health outcomes
- No adverse effect on doctor-patient relationship
- Cost-effectiveness of implementation
- Equity of financial burden

V. POLICY OPTIONS

The following figure provides a schematic representation of the thought process that helped us to arrive at the two policy options that are analyzed in this report.

Exhibit 7: Development of Policy Options



The first decision that needs to be made is whether, as a whole, DTC advertising provides a benefit to society that outweighs the possible harm caused by low quality advertisements that drive up unnecessary costs. To evaluate this situation we proposed the first option.

POLICY OPTION A: COMPLETE BAN ON DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS THROUGH THE BROADCAST MEDIA

This option would be a return to the pre-1997 amendment state where there effectively would be a total ban on the pharmaceutical industry's ability to use the broadcast media to market their products to the public. This policy option eliminates all the costs and negative issues related to direct-to-consumer advertising indicated in earlier sections by ending the practice entirely. Therefore, no misinformation or misleading advertising would enter the market. This option, however, would also cost society all of the benefits, especially the educational value, associated with such advertising. Finally, this option would affect different stakeholders in different ways. We address these last issues in the equity assessment section of this report.

POLICY OPTION B: ENHANCE THE FDA'S JURIDITICION, AUTHORITY, AND ENFORCEMENT CAPABILITIES

This option would allow the FDA to require prospective mandatory review of all broadcast advertisements. It would also give them the legal authority to impose civil monetary penalties on companies, especially on those that repeatedly violate the law (Wolfe, 2002). Finally, it would provide the FDA with the additional staffing and resources that they would need to enforce these new requirements.

This policy option acknowledges the benefits of direct-to-consumer advertising as well as the pharmaceutical industry's right to advertise and market their products. Furthermore, if basic economic theory is to be applied, advertising generally leads to greater competition and more efficient market mechanisms. Since pharmaceutical drugs are and should be designated in a different class than general products, as described earlier, this may be considered a 'special case'.

VI. BENEFITS OF THE OPTIONS

This section reviews existing analysis and data about DTC advertising to determine the positive impacts of both options. Specifically, we discuss how changing the regulation of DTC advertising might affect spending on prescription drugs. Survey data is also used to assess how changes in the regulation of DTC advertising will influence the lives of patients and physicians. Finally we evaluate how option A and B will affect the pharmaceutical industry.

Option A: Ban broadcast DTC advertising

Drug Costs

Decrease in spending on all types of drugs

DTC advertising is an important contributor to the total amount of spending on prescription drugs. The 50 most heavily advertised drugs had combined sales of \$41.3 billion in 2000 and accounted for 31.3 percent of all drug sales in 2000 (NIHCM, 2001). There are probably several reasons why so much money was spent on these drugs. In many cases they are also the newest, most effective, and most widely applicable. However, the total dollar spending on the top 50 advertised drugs is too large to be purely coincidental. An end to DTC advertising would moderate the total dollar impact of prescription drug costs because it would remove this important driver of demand.

Decrease in rate at which prices of drugs are increasing

Several studies have found that the drugs that are the most heavily advertised through DTCA are also responsible for the biggest percentage increase in rising prescription drug costs. Retail spending on the most heavily advertised drugs rose 31.9 percent compared to a 13.6 percent increase in all other drugs between 1999 and 2000 (NIHCM, 2001). A Kaiser Family Foundation report estimated that \$2.6 billion or 12 percent of the total growth in spending on prescription drugs between 1999 and 2000 was directly attributable to DTCA (KFF, June 2003). Although drug costs will likely continue to rise in any case, an end to broadcast DTC advertising will dampen the phenomenal growth in spending on prescription drugs.

Patient impact

Decrease in patient confusion about potential treatments

An FDA survey of physicians found that only five percent of physicians believed that patients who had seen DTC advertisements understood the possible risks and negative effects of the advertised drugs. 75 percent of physicians believe DTC ads cause patients to believe a drug works better than it does and even fewer believed that patients understood the drug efficacy or the appropriateness of a particular drug's use for their treatment (FDA Physician Survey, 2001). Another Kaiser Family Foundation study found that although broadcast advertisements are able to communicate successfully basic information such as the name of the medicine and what it treats, they often leave

consumers with mixed messages about potential side effects and where to get more information about medicines (KFF, November 2001). Ending the broadcast advertisements would eliminate the confusion described above but it would also force consumers to look elsewhere for information about drugs.

Physician impact

Decrease in doctor frustration

Twenty-eight percent of physicians said they felt very or somewhat pressured to prescribe a specific brand name drug when the patient asked for it. It is believed that some physicians will prescribe products that they believe are not necessarily essential to the health of their patients in an effort to maintain relationships with their patients (Lewis, 2003).

Reinforcement of the doctor patient relationship

The elimination of DTCA would put authority over treatment and care decisions back in the hands of physicians. Consumers would be less aware of new pharmaceutical products and, therefore, more reliant on the informed opinion's of their physicians about their health choices. This means those with professional training, knowledge, and expertise will be able to provide information to their patients without the influence of biased drug company misinformation.

Pharmaceutical Industry Impact

Can reallocate revenues to other projects

In 2000, the pharmaceutical industry spent \$2.5 billion on DTCA (Family Practice Management, 2002). If a total ban on this type of advertising was put into place, all of this money could be allocated to other projects. Specifically, it could be put toward basic research and development, drug design, and clinical trials. Alternatively, it could be invested in other types of marketing like detailing and sampling. The net effect of this reallocation of resources will depend on whether the spending on DTCA was justified or wasteful.

Option B: Enhance FDA's Jurisdiction and Enforcement Capabilities

Drug Costs

Decrease on spending on unnecessary drugs

The FDA physician survey found that, eight percent of physicians believed that patients who saw DTC ads would try to 'influence their course of treatment in a way that would have been harmful to him or her'. Twenty-six percent said that the patients who were asking for a prescription did not have the condition or a need for the drug (FDA Survey, 2001). This is clear evidence that consumers are viewing ads and asking for treatments that they do not understand or need. If existing rules regarding information and content are enforced before misleading advertisements are aired then this problem can be alleviated.

Patient impact

Will correct consumers' misunderstanding about regulation of DTC advertisements

Despite greater consumer awareness of advertisements, it clear the public does not understand the nature of DTC ads. For example, a recent study found that half of the respondents thought that drugs that are advertised directly to the consumer, had to have prior government approval; moreover, 43 percent believed that only 'completely safe' drugs could be advertised, and approximately 20 percent believed that only 'extremely effective' drugs with no serious side effects could be marketed directly to consumers. None of these claims are true but if this option were implemented then that would change (Bell, 2003).

According to *Health Affairs*, 40 percent of DTC ads include claims that the new products are 'new and improved'. Many of these products are simply 'me-too' products that offer few advantages over older drugs; they often have safety profiles that are not well understood. This option would allow the FDA to make sure that all DTC ads educate explain to the public that many new drugs are riskier than time-tested products (Wilkes, 2000).

Increase in consumer empowerment

As patients seek and gain more control over their health care, well-regulated DTC advertisements can play a more important role. DTC ads will allow patients to feel like they have a better understanding of their available treatment options. As Dr. Woodie Zachry and Dine Ginsburg point out, however,

'DTCA can be an effective tool to increase patient awareness of their therapeutic choices, encourage patients to seek more information, and help them draw closer to autonomous choices, but only if the presentations provide fair and balanced information on the benefits and risks of therapy'. In the absence of this fair and balanced DTCA information, consumers must rely solely on the judgment of the physician to determine the course of their care (Zachry, 2001).

Physician impact

Decrease in physician frustration

Much of the wasted time in physicians' offices is time spent explaining to patients that certain treatments they have seen advertised are not right for them. The number one concern of physicians polled in the FDA survey was, 'time correcting misconceptions' (FDA Survey). Recent studies show that physicians already suffer from severe time constraints and that wasted time can limit their abilities to deliver preventative care (Yarnall, 2003). Correcting misleading advertisements before they are broadcast to the public would improve the accuracy of DTC ads and would directly address these misconceptions.

Bolster the doctor-patient relationship

When consumers bring more baseline information to a visit with their physicians, they are able to have more informed discussions about their care. Often times, patients are reluctant to discuss treatment of embarrassing conditions or to admit that they have not been following their recommended

course of treatment. A recent survey of the American Medical Association physicians found that 38 percent of the physicians believed there was an improved physician-patient relationship when a patient had seen an accurate DTC advertisement. This is in part because patients felt greater information parity with their physicians. The reverse can occur, however, when a patient presents himself or herself in physician's office with poor or misleading information. Specifically, only 22 percent of physicians said their relationship was improved after viewing a DTC advertisement; 16 percent said it worsened the relationship (Murray, 2003). The benefit of this option, therefore, is that it allows the positive effects of informative advertisements but will minimize the negative effects of misleading advertisements whereas a total ban would eliminate both.

Pharmaceutical Industry Impact

Set standards for the pharmaceutical industry

The GAO has found that the current voluntary retrospective enforcement scheme does not completely deter pharmaceutical companies from making misleading claims in subsequent advertisements. In fact, GlaxoSmithKline, Schering, and Merck have all been cited more than 5 times (GAO, 2002). A possible reason for this is the competitive nature of the pharmaceutical market. Each company has found it necessary to take a more aggressive advertisement strategy to garner a greater percentage of the market share. The only feasible

response to a competitor's misleading non-FDA-reviewed advertisement is airing another misleading ad.

One benefit of a clearer and stronger regulatory scheme is that it will put an end to this 'one-upmanship'. All advertisements will be revised prospectively so all companies will be competing on a level playing field.

Possible increase in consumer confidence in pharmaceuticals

Pharmaceutical firms are struggling to build popular support. Despite offering many powerful and beneficial therapies, the industry, as a whole, has developed gotten a reputation for greed and arrogance. Improvement of DTC advertisement, a key component of the industry's public image, will help change public opinion for the better.

Benefits Summary

A quick comparison of the benefits of the two options reveals that in many ways they are similar. The total ban has the biggest effect on drug spending, provides some benefits to both physicians and patients. The enforcement option also has some impact on spending positive effect on physicians, but it also significantly empowers consumers to make their own informed health care choices. For both options, there is some benefit to the pharmaceutical industry. Exhibit 7 provides a graphical summary of the benefits accrued from each policy option discussed in this report.

Exhibit 7: Graphical Representation of Benefits

Category	Option A: Ban broadcast DTC advertising	Option B: Enhance FDA's Jurisdiction and Enforcement Capabilities
Drug Costs	Decrease in drug spending on all types and rate at which prices are increasing	Decrease on spending on unnecessary drugs
<i>Assessment</i>	++	+
Patient impact	Decrease in patient confusion about potential treatments	Will correct consumers misunderstanding of regulation of DTC, Increase in consumer empowerment
<i>Assessment</i>	+	+++
Physician impact	Decrease physician frustration, Reinforcement of the doctor patient relationship	Decrease physician frustration, Bolster doctor patient relationship
<i>Assessment</i>	++	++
Pharmaceutical Industry Impact	Can reallocate revenues to other projects	Sets standards for the industry, Possible increase in consumer confidence in pharmaceuticals
<i>Assessment</i>	+	+

VII. COST ASSESSMENT OF POLICY OPTIONS

According to pharmaceutical industry estimates, approximately \$3 billion was spent on DTC drug advertising last year (Young, 2003); roughly 40 percent of that spending was on 10 drugs, determined to be ‘mainly new, expensive drugs for long-term use by large population groups’ (Mintzes, 2002). Findlay’s 2001 study states that DTC ads ‘send a strong signal that prescription drugs are just another consumer product – like soap, cereal, cars, snack foods, or, for that matter, OTC drugs. Prescription medicines have not been perceived in that way in the past’.

Prescription drugs are not like any other consumer product. Advertising aims to get consumers to buy products. Prescription drugs are part of a complex system of medical care that must be regulated by science and careful human judgment, and not driven by profit motives. Earlier in this report, prescription drugs were described as belonging to a different and unique class of products. This means that pharmaceutical advertising holds a greater responsibility to its target audience than do general products. The marketing of these products must, therefore, be held to a far more stringent standard to minimize misleading or inaccurate information from being disseminated. The two policy options under consideration address the problem from different angles. Implementation of either policy would impose costs on society for moving away from the status quo. Here, we provide a more detailed discussion of these costs.

Option A: Ban broadcast DTC advertising

The primary option discussed here is the return to the effective total ban on broadcast direct-to-consumer advertising. This would result in a number of costs, both monetary and non-monetary. These costs would include an increase in under-diagnosed and untreated diseases, a decrease in consumer empowerment, a decrease in the demand for prescription-only medications, a negative effect on the doctor-patient relationship, and a proportional increase in the burden on doctors to share health information.

Consumers

Increase in under-diagnosed and untreated diseases

DTC advertisements have the benefit of reaching a wide audience. They serve an educational purpose by making a great number of individuals aware of and active in their own health care. The greatest volume of DTC advertising is targeted at chronic problems, such as asthma and allergies.

Evidence confirms that people respond to DTC advertisements. A consumer survey reported in *Health Affairs* found that, of the approximately 86 percent of the people who saw a DTC ad in the last year, about 35 percent were prompted to discuss the advertised drug or their health concerns during visits with their doctors. The *Health Affairs* survey also found that although one-quarter of the people who visited their doctors were there to discuss a new concern, about one-third talked about a possible change in treatment for an ongoing condition (Weissman, 2000). This indicates that DTC advertisements

might direct patients toward improved treatments or, at least, increases their awareness of different alternatives to their current course of care.

According to the same *Health Affairs* survey, 43 percent of DTC advertising related new diagnoses would be classified as 'high priority' by the Agency for Healthcare Research and Quality (AHRQ) and the Institute of Medicine, (IOM). Some examples of such diagnoses include high cholesterol, hypertension, and diabetes (Weissman, 2000). Early pharmacological treatment of these diseases has been shown to improve long-term health outcomes. All of the benefits listed above, however, will be eliminated with a complete ban on broadcast DTC advertisements.

Decrease in consumer empowerment

Sally Shankland (2003) has argued that 'DTC pharmaceutical promotion has unquestionably created value. It has created a healthy sense of empowerment among patients, reduced undiagnosed disease, and created unsurpassed brand awareness for drug companies'. In January 2003, the FDA released the preliminary results of its physician survey confirming that 'DTC advertising, when done correctly, can serve positive public health functions, such as increasing patient awareness of diseases that can be treated and prompting thoughtful discussions with physicians that result in needed treatments being prescribed' (Young, 2003).

Other surveys found that 83 percent of physicians felt that DTC advertising gave 'patients [the] confidence to talk to their doctor[s] about their

concerns'. He discovered that 72 percent of physicians felt that DTC advertising 'encourag[ed] people to follow treatment instructions or advice from their doctor[s]' (Murray et al, 2003).

These beneficial effects of DTC advertising will also be eliminated with a total ban. These costs will be borne by society as a whole, and will result in less empowered individuals. This, in turn, will result in a greater dependence on physicians as the sole information source.

Physicians

Decrease in the beneficial effects of DTC advertising on the doctor-patient relationship and proportional increase in a doctor's health information sharing burden

A survey conducted by Rosenthal et al (2002) found that 'many patients, [(25 percent of those surveyed)], had initiated conversations with their doctors about a drug they saw on television'. DTC advertising can also enhance the doctor-patient relationship, as patients become more aware of conditions and medical treatments and discuss them with their physicians. Furthermore, it was found that 'patients who discuss information from DTC advertising with their physicians may have more frequent and productive communications with them. These visits may lead to query-specific care, as well as more broadly focused health activities' (Berger, 2001). Banning DTC advertising in its entirety would have the cost of negating these beneficial effects.

A total ban on broadcast DTC advertisements would negate the educational benefits afforded by direct-to-consumer advertising of prescription

drugs. The overall effect of this policy, however, would increase the burden on physicians to educating patients regarding symptoms and illnesses. In as sense we would revert to the paternalistic dynamic that dominated the physician-patient relationship for most of the 20th century.

Pharmaceutical Industry

Decrease in demand for drugs

According to a September 2000 National Institute of Health Care Management report, 40.7 percent of an overall \$17.7 billion increase in 1999 drug expenditures can be attributed to the sale of 25 top selling drugs promoted directly to U.S. consumers. Moreover, the sale of these drugs grew by 43 percent during that same year compared with a 13.3 percent growth in sales for all other drugs (Fintor, 2002). A new study by the Kaiser Foundation (2003) found that 'for every 10 percent increase in DTC advertising, drug sales...increased by an average of 1 percent'. Since DTC advertising in such an important sales driver a total ban on broadcast DTC advertising will result in a loss of revenue to the pharmaceutical companies.

Government

There will be little if any cost to the government to put a total ban on broadcast DTC advertising in place. Any attempt to violate the federal regulations in this area will be quite blatant and could be met with immediate legal action, so companies will avoid trying to air advertisements in the first place.

Option B: Enhance FDA's Jurisdiction and Enforcement Capabilities

According to the GAO, the FDA has issued regulatory letters for five percent of the broadcast advertisements it reviewed between 1999 and 2001. Although these letters were found effective in halting the dissemination of particular misleading advertisements, some pharmaceutical companies were repeatedly cited for sending misleading advertisements (GAO 2001). The FDA lacks the legal authority to impose civil monetary penalties on companies, even when they repeatedly violate the law (Wolfe, 2002). Increasing the enforcement requirement will require expanding the FDA's authority to levy monetary penalties. This could be costly to implement because it would require adequate staffing and resources. Further, the GAO report notes that 'the FDA generally does not have the authority to pre-approve advertisements before they are disseminated'. This suggests that the FDA's jurisdiction must be enhanced in that perspective as well, which further increases the cost of enforcement.

Consumers

Possible increased in drug costs

Similar to a total ban stricter regulation of broadcast DTC advertising could potentially result in a loss of revenue to the pharmaceutical companies. The pharmaceutical industry could potentially shift these costs to consumers. Aside from the monetary costs associated with this cost shifting, this policy might also

result in the social costs of making newer, potentially better drugs less available to a larger segment of the population.

Physicians

There will be little if any negative impact on physicians from an enhanced FDA. The advertisements that patients bring in to their offices will be of a higher quality and will not cause them the same level of frustration that they have before.

Pharmaceutical Industry

Slower approval times

Requiring all advertisements to receive FDA approval before dissemination will result in advertisements taking longer before they are aired or printed. As alluded to earlier in this report, in January 2002, HHS began requiring legal review of all proposed regulatory letters about drug ads to make sure the FDA has a strong case before proceeding against a particular drug-makers. That extra step has held up FDA letters from 2 to 11 weeks, according to a report by the General Accounting Office (GAO), the investigative arm of Congress, made public in December. It concluded that legal review has taken so long that 'misleading advertisements may have completed their broadcast life cycle before the FDA issued the letters'.

The proposed policy mandates that all new advertisements would have to be approved before dissemination and, as illustrated above, this would only

result in a slowed bureaucratic mechanism. This would manifest itself as higher costs to both the FDA and the pharmaceutical industry.

Increase in advertising costs, leading to increase in drug promotion costs

According to the October 2002 GAO Report, 'prescription drug spending has risen steadily over the past decade'. Spending on prescription drugs now represents 10 percent of health care expenditures in the United States, and adults aged 65 and older spend nearly three percent of their total household expenditures on medications. Increases in overall drug spending are the result of three types of changes in drug prices and drug use: increases in utilization, that is, the number of prescriptions dispensed; price increases; and a shift from older drugs to new, more expensive drugs (newly marketed drugs are generally more expensive than older drugs in the same class). The National Institute for Health Care Management Foundation (NIHCM) reported that overall spending on prescription drugs in the United States increased 17.1 percent from 2000 to 2001: an increase in the number of prescriptions accounted for a 6.7 percent increase, price increases for a 6.3 percent increase, and shifts to higher-cost drugs for a 4.1 percent increase.

Since every advertisement is now being held to a higher standard, it is likely that there will be an increase in advertisement production costs would result in increased drug promotion costs to the pharmaceutical companies. The pharmaceutical industry spent \$2.5 billion on DTC advertisements in 2000 (NIHCM, 2001). If they are forced to shift to longer advertisements or more

content then this cost will go up. These increased costs could then be passed on to the individual consumer in the form of increased drug prices.

Government

Increase in staffing needs

The FDA is too understaffed to deal with the current numbers of DTC advertisements that it views. In fact, ‘the entire Division of Drug Marketing, Advertising, and Communications has had only 28 to 30 employees since 1997’ (Wolfe, 2002). Yet, since 1997 spending on DTC ads has more than doubled. From 1999 to 2000 alone, spending on mass media DTC advertising has grown by more than 35 percent.

Mandating further enforcement and approval before airing DTCA will require significant increases in staffing. These new staffers would process DTCA before dissemination. They would also enforce the regulations in case of potential violations after approval, and levy monetary penalties for such violations.

Costs Summary

Our discussion of the potential costs of these two policy options highlights the following contrast:

- The cost of a total ban on DTCA of prescription drugs (option A) will be borne by consumers, who will be deprived of an informative tool and thus

lose some empowerment, and by the pharmaceutical industry, which will lose significant revenue.

- The cost of increasing the jurisdiction of the FDA (option B) will fall on the government, which will have to allocate the requisite human and financial resources to allow this agency to enforce and regulate DTCA drug ads. This burden also falls, to a lesser extent, on the drug industry, which will be required to operate in a more tightly regulated environment (with potential loss of revenue from decreased drug sales).

Exhibit 8: Graphical Representation of Costs

Category	Option A: Ban broadcast DTC advertising	Option B: Enhance FDA’s Jurisdiction and Enforcement Capabilities
Consumers	Increase in under-diagnosed and untreated diseases Decrease in consumer empowerment	Possible increased in drug costs
<i>Assessment</i>	-	-
Physicians	Decrease in the beneficial effects of DTC advertising on the doctor-patient relationship and proportional increase in a doctor’s health information sharing burden	None
<i>Assessment</i>	-	N/A
Pharmaceutical Industry Impact	Decrease in demand for drugs	Slower approval times Increase in advertising costs, leading to increase in drug promotion costs
<i>Assessment</i>	---	--
Government	None	
<i>Assessment</i>	N/A	--

VIII. EQUITY ASSESSMENT OF POLICY OPTIONS

To highlight the distinct nature of each option, the equity considerations of both options must be addressed. Specifically, the question of who will bear the financial and personal burden of either option is discussed in this section. Each will have various distributional implications on the following stakeholders: consumers (individual and societal levels), the physicians, the pharmaceutical industry, and the government.

Option A: Ban broadcast DTC advertising

Consumers

The Individual

Most surveys conducted to assess the impact of DTC advertising on individuals indicate that a significant number of respondents have benefited from them. This benefit is mostly in terms of additional knowledge about new drugs, being informed about the symptoms of certain medical conditions, and being prompted to seek a physician's advice. Option A jeopardizes the ability of DTC advertising to empower individuals and denies them an important educational tool.

Society

If, as under the status quo, the public's exposure to DTC advertising has the positive effect of informing the public about diseases and their treatments, banning DTC advertising will adversely affect societal morbidity and mortality

rates. The societal burden will therefore increase because of the allocation of resources and taxpayer money to treat conditions that could have been prevented through the 'public information/education' component of DTC ads of prescription drugs. To put this into perspective, one could consider the following findings from an FDA-conducted survey that highlight the positive impacts of DTC advertising:

- most physicians indicated that their patients asked some pertinent questions after seeing a DTC ad
- physicians recognized that their patients believed the ads made them more aware of possible treatments
- physicians believed that the DTC ads increased their patients' overall involvement and interest in their health care

There is an additional cost to society from an advertising ban. Advertising bans have traditionally been associated with 'anti-consumer' consequences such as higher prices, decreased incentive for research and development, less consumer information and fewer choices (Conover 2004).

Physicians

This option would empower physicians and will enhance their prescriptive authority and independence. As discussed earlier, this option will minimize

patients exerting unnecessary pressure. A ban on DTC advertising will increase physicians' time efficiency with patients.

Pharmaceutical Industry

As alluded to earlier, a ban on DTC advertising will significantly reduce revenue for pharmaceutical companies, due to the absence of advertising -driven drug sales. In 2001 for instance, out of a total \$19.1 billion in promotional advertising spending, drug companies only spent \$2.7 billion on DTC advertising (Price, 2003).

Government

Under a total ban, the FDA will need minimal financial and human resources for monitoring broadcast media advertising. These resources could be redirected to other areas, such as drug research and development.

Option B: Enhance FDA's Jurisdiction and Enforcement Capabilities

This policy option will provide the FDA with the tools to enforce the rules governing mass media DTC advertising of prescription drugs and is likely to produce the following distributional effects:

Consumers

The Individual

The primary criticism discussed in this report is that DTC advertising of prescription drugs are misleading. The side effects that could result from the use of these drugs are often significantly understated by the ads. In fact, 58 percent of surveyed physicians (FDA study) strongly agreed that DTC ads make the drugs seem better than they really are (Lewis, 2003). Under this option, the individual will be properly educated and protected from misleading DTC advertising, as all prescription drug ads will have to be approved before dissemination by the FDA. This policy option maximizes consumer empowerment.

Society

The burden on society from inaccurate DTC advertising of prescription drugs will be significantly reduced, if not eliminated under this policy. This option will enhance society's faith in the FDA, as discussed in earlier sections.

Physicians

The FDA's prospective review of DTC ads is predicted to alleviate physicians' burden of correcting patients' misconceptions regarding DTC advertising of prescription drugs. Physicians' own perception of DTC ads is also estimated to change; physicians will view DTC ads as educational tools intended to provide accurate information concerning new prescription drugs and treatments.

Pharmaceutical Industry

Bolstering the FDA enforcement capability will be conducive to a more consumer-protective regulatory environment. A more stringent approval process of DTC advertising of prescription drugs to have the following implications on the pharmaceutical industry:

- the drug industry will be forced to reshape its drug ads according to the new FDA guidelines
- reduced DTC advertising induced drug sales, since ads will be subjected to a more rigorous scrutiny prior to dissemination;
- this measure will lead to a slower DTC advertising approval process.

Government

The government will bear the financial burden of the cost of enforcement. Increased FDA jurisdiction regarding DTC advertising of prescription drugs will require the government to allocate more human and financial resources to maximize operational efficiency. The government will also have to balance consumer safety and regulation of the pharmaceutical industry in a manner that would not stifle research and development of new pharmaceutical products.

Equity Synopsis

Under current circumstances, DTC advertising of prescription drugs continues to operate in a loosely regulated and enforced environment. The drug industry is the ultimate beneficiary and the majority of the consumers and

physicians are unhappy about the adverse effects of DTC advertising. Either proposed option presents a better, and more equitable alternative to the status quo.

IX. Conclusion

A total ban on broadcast DTC advertising of prescription drugs would result in a reversal to the pre-1997 status. This option values public interest over the interests of the pharmaceutical industry. While it will eliminate the misleading information present in some DTC advertising, it will divest the pharmaceutical industry of an important marketing tool, as well as a significant source of revenue. It will also deny consumers a valuable means of education and empowerment in their own care. This policy will reduce the pharmaceutical profits from DTC advertising generated drug sales and could potentially increase drug costs for consumers.

Alternatively, policy option B aims to enhance the FDA's jurisdiction and enforcement capabilities regarding to DTC advertising. This policy option allows the pharmaceutical industry to continue using DTC advertising as a marketing tool within a stricter regulatory environment. It hopes to ensure that the public will no longer be exposed to ads that provide inaccurate and incomplete information, and will alleviate the pressure on physicians to prescribe particular drugs due to patient insistence. This option could result in a loss of revenue from drug sales due to a slower DTC advertising approval process by the FDA.

Implementation Considerations

A total ban on broadcast DTC advertising of prescription drugs will probably lead to a great deal of litigation. The pharmaceutical industry could potentially challenge the ban on the grounds of equal protection. Alternatively,

the industry may view the ban as an infringement on the right to free speech. The cost of litigation could be quite significant for the government and the industry.

The alternative option analyzed in this report would result in increased costs associated with greater staffing needs for review and enforcement. The increased monies required to fund this option could be raised in two ways: through a marginal increase in taxes or through a fee to pharmaceutical companies. The former method of revenue generation would be borne by consumers. This may be considered to be inequitable by some. The other method of revenue generation would result in a fund maintained and administered by the FDA. Here, pharmaceutical companies would pay an annual fee to be permitted to submit advertisements for review and approval from the FDA. This could be modeled on existing programs such as the Prescription Drug User Fee Act (PDUFA). As the monies received would be placed in a common pool, there would be little potential for abuse.

Comparison of Options to Criteria

If cost to the government or the public is of primary concern, option A, a total ban on DTC advertising would be the preferred policy option. If the problem is defined as misinformation and inaccurate dissemination of information, then option B, an enhanced FDA would be the preferred policy option to implement. This latter option may also prove the most equitable and likely to be implemented, as it provide the consumer and health care professionals with

accurate information regarding medications and treatments, while simultaneously permitting pharmaceutical companies to advertise to consumers. Exhibit 10 provides a graphical representation of a comparison of the policy options based on the criteria delineated earlier in the report.

Exhibit 10: Graphical Representation of Comparison of Policy Options to Criteria for Evaluation

Criteria	<u>Option A</u> Total Ban	<u>Option B</u> Enhanced FDA Jurisdiction
Control excessive drug spending	+++	++
Ability to empower consumers in their health care choices	+	+++
Improvement in health outcomes	+	+++
No adverse effect on doctor-patient relationship	+++	+
Cost effectiveness of implementation	+++	+
Equity of financial burden	+	++

Suggestions for Further Study

Currently, very few studies have been conducted regarding the appropriateness of prescribing occurring due to DTC advertising. This raises an

important question regarding whether the additional drug prescribing actually provides a real health benefit. There is evidence indicating that DTC advertising does decrease under diagnosed and under treated disease. Advertising, however, has also been showed to create demand for particular brands of advertised drugs that pressure physicians into prescribing them. Studies that focus on the impact of DTC advertised drugs in terms of quality of life years could prove critical to a better understanding of this currently blurred dynamic.

Much currently available research and survey data in this area is focused in two particular categories. The first category highlights the educational and disease-prevention attributes of such advertising, and is primarily conducted by the pharmaceutical industry. The second category promotes the view that DTC advertising is misleading. This research is conducted primarily by consumer protection and advocacy organizations.

One potential means to address this disparity could be the establishment of a national, FDA-controlled database that would capture consumer feedback on their personal experiences with DTC advertising, either positive or negative. This would provide policy makers with unbiased data, allowing for a well balanced view of the issue at hand.

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