Ask Your Doctor About...
Prescription Drug Advertising, Patient Autonomy, and the Role of the FDA

by

Jennifer Wilson

B.A. (Yale University) 2001

A thesis submitted in partial satisfaction of the
Requirements for the degree of
Master of Science
in
Health and Medical Sciences
in the
GRADUATE DIVISION
of the
UNIVERSITY OF CALIFORNIA, BERKELEY

Committee in charge:

Jodi Halpern, M.D. Ph.D., Chair
Joyce Lashof, M.D.
John Swarzberg, M.D

Spring 2006
The thesis of Jennifer Grace Wilson is approved:

Chair

2/24/06

Date

Roger L. Leslie

2/27/06

Date

2/24/06

Date

University of California, Berkeley

Spring 2006
Ask Your Doctor About . . .
Prescription Drug Advertising, Patient Autonomy, and the Role of the FDA

© 2006

by

Jennifer Grace Wilson
Table of Contents

Part I: Introduction 1
Part II: Background 3
Part III: Analysis: DTCA, Patient Autonomy, and the Role of the FDA 22
Part IV: Policy Implications 43
Part V: Conclusions 69
Appendix A: Timeline of important DTCA policy developments 72
Appendix B: Drugs ranked in terms of year 2000 DTC spending 73
References 74
I. Introduction

Americans see an average of nine drug advertisements on television per day.\(^1\) In the words of Senate Majority Leader Dr. Bill Frist, “we are barraged by them.”\(^2\) Yet despite the prevalence of direct-to-consumer advertising of prescription drugs (DTCA), the only solid consensus among doctors, drug manufacturers, patients, and policy-makers seems to be that as a marketing strategy, *DTCA works*. The billions that drug companies pour into promoting their newest and most expensive products lead to astronomical sales of advertised drugs. But just as the commercial success of DTCA has led to greater investment in advertising by industry, so has it led to growing debate over whether DTCA actually promotes the public health. Indeed, the recent controversy around Vioxx—one of the most heavily advertised drugs ever—highlights lingering questions about whether DTCA can ever properly serve its “two masters: the promotional interest of the pharmaceutical industry and the public’s health needs.”\(^3\)

Over the years, various stakeholders have argued for and against the value of DTCA in a variety of ways. Some have argued that DTCA exacerbates underlying problems with the prescription drug market structure, while others have argued that DTCA is a baby-step towards correcting the information asymmetry that exists between patients and doctors, and may help consumers make better choices. Public health officials have warned that DTCA will drive inappropriate prescribing and inefficient drug spending, while big

---

pharma and its allies have countered that to actively withhold drug information from consumers is insupportably paternalistic.

As a medical student with a strong belief in patient education and empowerment, it is this last contention—the one that puts DTCA critics on the defensive—that interests me most. Does permitting prescription drugs to be advertised directly to patients truly advance the rights of those patients? Would stricter regulation of DTCA really be unjustifiably paternalistic? Either way, what improvements could be made in our current regulatory regime to maximize the benefits of DTCA for patients, not only in terms of their well-being, but also in terms of their fundamental right to share in decisions about their own care?

Before tackling these questions, it is important first to review the history of DTCA in the United States, including how it came to be so prevalent, how it has been regulated, and how physician and consumer attitudes have changed since it first debuted. Once I have covered this background information, I will analyze—from a normative perspective—how DTCA in fact impacts patient autonomy, and how current DTCA policy affects that impact. Finally, I will consider the policy implications of this analysis, as well as its broader implications for how we think about prescription drugs, patient autonomy, and the role of the FDA.
II. Background

The history of DTCA in the United States

Neither the peddling of pharmaceuticals directly to patients nor the controversy surrounding it are new developments in Western medicine. In the 19th Century, the United States was awash not only in unregulated “patent medicines,” but also in newspaper advertisements promoting them. In fact, patent medicines were among the first products to be mass-marketed, and many modern advertising techniques were pioneered by patent medicine promoters. “By the late 1800s, you could buy Kick-a-poo Indian Sagwa and Wheeler’s Nerve Vitalizer and Mrs. Winslow’s Soothing Syrup and Lydia Pinkham’s Vegetable Compound to cure—well, to cure almost anything…” By the end of the 19th century, one heavily-illustrated patent medicine Almanac was printed for every two Americans.

Despite the prevalence of the practice, patent medicine advertising was never welcomed by physicians. They opposed the dissemination of pharmaceutical information directly to consumers for two main reasons: first, doctors wished to protect patients from harm by preventing them from using unsafe medicines, or from using otherwise safe medicines improperly; and second, doctors sought to guard their professional territory from so-called “quacks.” These were not new concerns. As early as 1555, the Royal College of

---

6 Hawthorne: 36.
Physicians in London ordered that “no physician teach people about medicines or even tell them the names of medicines,” and in the United States, the AMA campaigned against the advertising and sale of “proprietary drugs” directly to the public from the time of its founding in 1847. In fact, it was partly due to the AMA’s efforts (in concert with growing social agitation about the total lack of regulation) that Congress passed the first Federal Food and Drug Act in 1906, establishing physicians as the gatekeepers for prescription drugs, and acknowledging that the public needed protection not only from dangerous nostrums, but also from false and misleading information about pharmaceuticals in general.

In reality, it took a series of 20th century regulatory changes (see Appendix A) to actually achieve the sweeping goals of that first Food and Drug Act. Most important were the 1938 Federal Food, Drug, and Cosmetic Act, which granted the Food and Drug Administration (FDA) jurisdiction over labeling for all drugs; the 1951 Durham-Humphrey Amendment, which defined separate classes for prescription and over-the-counter medications; and the 1962 Kefauver-Harris Amendment (passed in the midst of the thalidomide tragedy), which transferred jurisdiction over the advertising of prescription drugs from the Federal Trade Commission (FTC) to the FDA (while leaving over-the-counter drug advertising under the jurisdiction of the FTC).

With consumers restricted from purchasing prescription drugs directly, and with physicians firmly established as the sole purveyors of prescription drug information,

---

10 Pinkus: 141.
advertising of medications to consumers gradually waned and was replaced instead by advertising to physicians.\textsuperscript{11} In fact, DTCA was virtually absent from the 1950s through the end of the 1970s, and as recently as the early 1980s, top drug makers in the United States found the idea of marketing drugs directly to consumers practically abhorrent.\textsuperscript{12} In response to queries from congressman John Dingell, thirty-one out of thirty-six drug company executives wrote letters expressing not only their negative opinions on the idea of DTCA, but detailing quite prophetically all the potential pitfalls of the practice.\textsuperscript{13} As the chairman of Abbot Laboratories wrote, "we believe [DTCA] introduces a very real possibility of causing harm to patients who may respond to advertisements by pressuring physicians to prescribe medications that may not be required."\textsuperscript{14}

But in some ways, those drug executives were behind the times. Beginning in the late 1960s, amidst growing social opposition to physician's exclusive control of health care knowledge,\textsuperscript{15} the FDA itself had begun to acknowledge "the importance of the patient understanding a prescription drug and deriving the maximum benefit from it," and developed the concept of the patient package insert (PPI).\textsuperscript{16} The first PPI focused on how to use isoproterenol inhalers, but the second PPI, developed for birth control pills, included not only instructions for use, but also safety and efficacy information. Despite strong opposition from health care professionals and industry alike, by the end of the

\textsuperscript{11} Pinkus: 141.
\textsuperscript{13} Crister: 35.
\textsuperscript{14} Crister: 36. This response and many others like it are recounted in meticulous detail in Greg Crister's recent book, *Generation Rx*.
\textsuperscript{15} Pinkus: 153.
1970s, the FDA proposed and enacted a regulation requiring PPIs for all prescription drugs.\textsuperscript{17} Although this regulation was never meaningfully enforced (and was subsequently rescinded in 1982 under the Reagan administration), many commentators view PPI’s as an indicator of increased emphasis on patient autonomy and education with regard to prescription drugs, and perhaps even as “the breakthrough concept that ultimately led to DTC advertising.”\textsuperscript{18}

In the early 1980s, following a key Supreme Court case in which the Court struck down a Virginia statute that prohibited licensed pharmacists from advertising prescription drug prices,\textsuperscript{19} pharmaceutical manufacturers began to test the waters with the very first examples of contemporary DTCA. Several companies ran what they called “public service campaigns”, which were essentially print advertisements for prescription drug products such as Rufen (a branded generic ibuprofen) and pneumococcal vaccine.\textsuperscript{20} In 1982, in response to a growing number of proposed DTC advertisements submitted to the Division of Drug Advertising and Labeling (now known as the Division of Drug Marketing, Advertising and Communications, or DDMAC), FDA commissioner Arthur Hull Hayes, Jr. formally requested that pharmaceutical manufacturers comply with a “voluntary moratorium” on DTCA while the FDA studied the issue.

By 1985, the FDA had completed several studies on DTCA showing that 66% of the 1500 consumers surveyed regarded DTC promotion as useful, and 74% of them “strongly

\textsuperscript{17} Pines: 489.
\textsuperscript{18} Pines: 489.
\textsuperscript{19} Crister: 38.
\textsuperscript{20} Lyles A. Direct Marketing of Pharmaceuticals to Consumers. \textit{Annual Review of Public Health} 23 (2002): 76.
supported their physician as the decision-maker in the prescription of drugs."\(^{21}\)

Reassured by these findings, bolstered by comments from consumers, and citing concerns about freedom of speech in light of recent court rulings, the FDA ruled that DTC advertisements would be permitted so long as they met the same criteria the FDA had already set for advertisements directed at physicians.\(^{22}\) Specifically, this meant that DTCA could contain only information consistent with the product’s approved labeling, that it must provide a *fair balance* of a drug’s risks and benefits, and that it must include the *brief summary* of the full package insert which includes the drug’s adverse effects, contraindications, warnings, and indications for use.\(^{23}\) The FDA also requested that all advertisements be submitted to DDMAC upon their release, conceding that it did not have the legal authority to require prior approval of any prescription drug advertisements.\(^{24}\)

At the same time that it was clarifying its jurisdiction over and regulation of DTCA, the FDA formally recognized three different categories of advertisements: (1) *Product-claims advertisements*, which promote a specific product for a specific purpose; (2) *Help-seeking advertisements*, which provide information on diseases or conditions and encourage viewers to pursue medical consultation; and (3) *Reminder advertisements*, which mention the name of the product but not what it is used to treat. Of the three types of advertisements, only the first type, (product-claims advertisements) are considered


\(^{24}\) Kessler and Pines: 2409
drug advertisements by the FDA. Therefore, only product-claims advertisements trigger the fair balance and brief summary requirement, meaning that only these advertisements must contain detailed information about side effects.\textsuperscript{25}

Nonetheless, the brief summary requirement was a “de-facto barrier” to product-claims advertisements on television or radio, since the format of a thirty-second television or radio spot does not permit the complex and comprehensive information contained in the brief summary to be properly conveyed.\textsuperscript{26} Consequently, as pharmaceutical companies began to advertise their products in the broadcast media, they avoided product-claims advertisements and used only health-seeking and reminder advertisements.

The problem with this trend was precisely that: the health-seeking and reminder advertisements sparked many questions, but were extremely poor sources of drug information for consumers. In the words of PhRMA consultant and former FDA official Wayne Pines,

\begin{quote}
Consumers could not tell, in some instances, what the product was for, or indeed whether the product being advertised was a prescription drug or another product. Within FDA, there was growing recognition that these and the many other such commercials fundamentally were noncommunicative. This recognition led, in August 1997, to the landmark draft guidance that permitted product-specific advertising on television.\textsuperscript{27}
\end{quote}

The limited utility of health-seeking and reminder advertisements, coupled with the departure of FDA commissioner David Kessler (then a well-known opponent of expanding DTCA), “led to a reconsideration of the guidelines for broadcast

\textsuperscript{25} Kessler and Pines: 2469.
\textsuperscript{26} Kessler and Pines: 2469.
\textsuperscript{27} Pines: 489.
advertisements.\(^{28}\) New draft guidelines from the FDA, issued in 1997 following Kessler’s departure, attempted to solve the problem of confusing DTCA by amending the brief summary requirement for broadcast advertisements: instead of including the entire brief summary, broadcast DTCA was required to include only a *major statement* containing the most important product risks, provided it also made *adequate provision* for consumers to access the full package labeling (by providing a toll-free number, a web address, a concurrent print advertisement, and a referral to a health care provider).\(^{29}\) Two years later, following a period for public comment, the FDA finalized the 1997 draft guidelines with almost no revisions.

**DTCA spending since 1997**

In the three years following the issuance of the broadcast DTCA draft guidelines, pharmaceutical companies’ spending on DTCA more than doubled, reaching $2.5 billion in the year 2000.\(^{30}\) The most recent data put DTCA spending at around $4.5 billion annually, making the top-ranked advertised drugs among the most heavily advertised consumer products in the United States.\(^{31,32}\) Although the upswing in DTCA spending began before the change in the broadcast guidelines, the acceleration in spending since 1997 has been accompanied by a substantial shift in media purchased for DTCA: while television advertisements consumed 27% of DTCA spending in 1997, by the year 2000,

\(^{28}\) Lyles: 77.
\(^{29}\) Lyles: 77.
\(^{32}\) In the year 2000, for example, more money was spent advertising Vioxx (the top-promoted drug that year) than was spent on ads for Pepsi cola, Budweiser beer, or the top brands of Nike sneakers. NIHCM: 5.
television ad spending accounted for between 57% and 64% of total DTCA expenditures.\textsuperscript{33}

It is important to note however, that despite this explosion in DTCA spending, the pharmaceutical industry still spends more money promoting its products to physicians than to patients.\textsuperscript{34} In this respect, DTCA should be seen as an integral part of a two-pronged marketing strategy, in which DTCA is often coordinated to coincide with drug promotion campaigns aimed at physicians.\textsuperscript{35} This expanded marketing strategy is seen by some as pharmaceutical manufacturers' response to the growth of managed care in the U.S.: as more and more people were covered by health insurance plans that included a prescription drug benefit, and as these plans started covering more of the cost of prescription drugs than ever before, health insurance plans tried to control doctor's prescribing practices to limit costs.\textsuperscript{36} Pharmaceutical companies therefore expanded their marketing activities, both in terms of scope and in terms of budget, in order to preserve market share for certain expensive "blockbuster" drugs in crowded therapeutic classes. Specifically, the advertising dollars are spent almost exclusively on newer, more expensive drugs intended for long term use by large population groups.\textsuperscript{37} For example, drugs such as antiarthritis, antihyperlipidemics, antihistamines, antidepressants, proton-pump inhibitors, and erectile dysfunction drugs are consistently among the drugs with the highest DTCA budgets (see Appendix B).

\begin{itemize}
\item \textsuperscript{33} Lyles: 80.
\item \textsuperscript{34} DTCA accounted for just 16% of total prescription drug promotion in 2000 — $2.5 billion of $15.7 billion (does not include money spent on educational meetings). NIHCM: 2.
\item \textsuperscript{35} NIHCM: 5.
\item \textsuperscript{36} Lyles: 74.
\item \textsuperscript{37} Mintzes (2002): 908.
\end{itemize}
Enforcement of DTCA guidelines since 1997

Even as DTCA has increased exponentially, FDA regulation of DTCA has declined. In October 2002, the General Accounting Office (GAO) issued a report on FDA regulation of DTCA that “concluded that FDA’s effectiveness was ‘limited’ and ‘compromised’ by its inability to verify that it receives all newly disseminated advertisements.”38 In response, FDA commissioner Mark McClellan promised more aggressive enforcement of DTCA guidelines, but since then enforcement has continued to decline.39 In a 2004 perspective piece in Health Affairs, Representative Henry Waxman reported that FDA enforcement actions against false and misleading advertisements in 2002 fell by more than 70 percent compared with the period from 1999 to 2000, even though the number of advertisements reviewed increased, and the number of complaints about ad content remained constant.40

Additionally, as the enforcement actions have declined, the time delay between ad submission and enforcement action has increased, “exposing millions of consumers to false or misleading advertisements for months before the advertisements were withdrawn.”41 According to the GAO, “delay between ad placement and FDA citation averaged 177 days in 2003, up from 41 days in 2002”—a time lag that in some cases resulted in a violation notice not being sent until after the advertising campaign had

---

40 Waxman: 257.
41 Waxman: 257.
ended all together.\textsuperscript{43}

The decline and delay in enforcement actions against false and misleading drug advertisements are due to several factors. First, because drug companies are not required to submit their advertisements before disseminating them, it is difficult for the FDA to verify that it receives all newly released advertisements.\textsuperscript{43} [In the past, the agency has issued regulatory letters to companies that failed to submit their advertisements to DDMAC when they were first released.\textsuperscript{44}] Secondly, the division in charge of reviewing advertisements is understaffed and underfunded: there are forty employees in DDMAC, responsible for reviewing over 52,000 promotional pieces each year.\textsuperscript{45} Although congress authorized a doubling of funds for DDMAC back in 2002, the administration has yet to request those funds, and DDMAC remains underfunded.\textsuperscript{46} Finally, in late 2001, the Department of Health and Human Services (HHS) “instructed the FDA that no regulatory letters could be issued until the FDA’s Office of the Chief Counsel (OCC) reviewed them.”\textsuperscript{47} This policy change preceded a precipitous decline in enforcement actions by the FDA, which many attribute to the decisions of Daniel Troy, former attorney to the pharmaceutical and tobacco industries, and newly appointed Chief

\textsuperscript{44} Gahart MT et al.: 120.
\textsuperscript{45} Sugarman-Brozan A. Testimony before the FDA Public Hearing on Direct to Consumer Advertising (November 2, 2005).
\textsuperscript{47} Gahart MT et al.: 120.
Counsel of the FDA by President George W. Bush. [Mr. Troy resigned the post in November 2004, following reports that he had “stalled efforts to investigate complaints about ephedra . . . an herb used in a dietary supplement suspected as a factor in at least 100 deaths.”]

In some ways, however, the decline in enforcement actions is not as important the effect of those actions when they are taken. According to Representative Waxman, FDA enforcement actions have thus far had “little deterrent effect”:

The FDA’s enforcement actions in 2003 were restricted to sending warning letters to drug manufacturers requesting that they cease running an advertisement. Although the FDA has the authority to take stronger actions with more deterrent effect, such as court actions or ultimately fines, the agency has not done so. . . . There simply is no incentive for drug manufacturers to tell the whole truth to consumers, and there is no real penalty for them if they do not.

These assertions are supported by the fact that the FDA has sent repeated regulatory letters to the same pharmaceutical companies, sometimes for new advertisements promoting the same drug.

For example, the FDA issued four regulatory letters to stop misleading advertisements for the allergy drug Flonase marketed by Glaxo Wellcome in 1999 and 2000. The violations cited in the letters include unsubstantiated efficacy claims, lack of fair balance, failure to provide any risk information on the major side effects and contraindication of the drug, failure to make adequate provision for disseminating the product labeling, and failure to submit the advertisement to the FDA.

48 Schultz S. Mr. Outside moves inside: Daniel Troy fought the FDA for years; now he's helping to run it. US News (March 24, 2003). Available at http://www.usnews.com/usnews/health/articles/030324/24fda.htm
49 Schultz.
50 Waxman: 257.
51 Gahart MT et al.: 120
52 Gahart MT et al.: 120.
This enforcement history reveals that despite the time and effort put into developing DTCA guidelines, there is no assurance that the guidelines are adhered to, or that the drug advertisements consistently contain accurate information, let alone a "fair balance" of risks and benefits.

**FDA survey data**

As DTCA has evolved, patient and physician attitudes toward the practice have changed. In its ongoing review of DTCA, the FDA has conducted three surveys on the impact of DTCA on doctors and patients: one in 1985 before the voluntary moratorium on DTCA was lifted, one in 1999 before the 1997 draft guidance on broadcast DTCA was finalized, and one in 2002 to reassess the impact of DTCA on the physician-patient relationship. Although other surveys have been conducted by independent researchers, the FDA relies heavily on its own research when considering policy changes, so special attention is paid to those results in this paper.\(^5\) Selected results are summarized below, focusing first on patients' attitudes, then on those of physicians.

**Patients' Attitudes About DTCA**

The most recent FDA survey was conducted by telephone in 2002, and asked questions about patients' attitudes about DTCA, as well as about how DTCA had affected their

---

health-related behavior. The results showed significant ambivalence about DTCA on the part of patients: while 58% agreed with the statement that “advertisements for prescription drugs make the drugs seem better than they really are,” and only 32% of patients claimed they “liked” seeing advertisements for prescription drugs, a strong majority agreed that DTCA made them more aware of available treatments and provided them with enough information to decide whether to discuss the drug with their doctors.\textsuperscript{54}

In general, patients were slightly less positive about DTCA than they were at the time of the 1999 survey, with more patients disagreeing strongly that DTCA helps them make better decisions about their health.\textsuperscript{55}

Confirming previous findings that DTCA motivates patients to seek information and care, however, many patients reported taking action with regard to their health on the basis of a drug advertisement: 43% reported having been motivated by an advertisement to look for more information about the drug or about their health, and 18% reported that an ad had caused them to ask a doctor about a medical condition or illness that they had not talked to a doctor about previously.\textsuperscript{56} With regard to the effects of DTCA on the patient-physician relationship, 73% of patients disagreed (most of them strongly) with the statement that “advertisements for prescription drugs make it seem like a doctor is not needed to decide whether a drug is right for me,” as opposed to the 23% who agreed.\textsuperscript{57}


\textsuperscript{55} Aiken K.

\textsuperscript{56} Aiken K.

\textsuperscript{57} Aiken K.
Physicians’ attitudes about DTCA

Just as the results of the patient survey suggest that patients are split over the benefits and harms of DTCA, the physician survey revealed significant ambivalence among doctors about the impact of DTCA. In terms of general attitudes toward DTCA, 40% of physicians felt that DTCA has had a positive effect on their patients and practices, while 32% felt the effects were negative, and 28% reported it had no effect.58 The most common reason for supporting DTCA was that it promoted discussion, while the most common reason for opposing it was the time that had to be spent correcting misconceptions created by DTCA.59 Moreover, a majority of all physicians reported that patients confuse the relative risks of drugs (65%), that advertisements lead patients to overestimate the efficacy of the drugs (75%), and that DTCA had “caused some tension” between them and their patients (62%).60,61

According to the FDA, the collective results of these surveys confirmed that “the benefits of prescription drug advertising far outweigh the drawbacks.”62 Others have criticized this interpretation as “overly optimistic”.63 Regardless of the validity of the interpretation, however, the FDA survey data, like the other available survey data,

---

59 Aiken L. 755.
61 Aiken K.
62 Stanek S. Debate persists over drug advertising’s side effects. Chicago Tribune (Mar 9 2004). Quoting Peter Pitts, associate commissioner for external relations at the FDA.
undoubtedly reveal at the very least that doctors and patients alike remain ambivalent about the impact of DTCA, recognizing both its potential benefits and its potential risks.

**Regulatory changes since 1997**

Policy-makers, drug marketers, and the FDA have had almost ten years to adjust to the new era of DTCA, and to respond to the data that have slowly accumulated about the effects of the practice and the opinions of various stakeholders. In 2004, the FDA released several new DTCA guidance documents, calling for brief summaries to be written in more consumer-friendly language, clarifying the difference between different categories of advertisements, and encouraging non-brand-specific help-seeking and disease-awareness advertisements. These guidance documents were drafted based on the results of the FDA’s own surveys, as well as the opinions expressed at an open meeting on DTCA held by FDA in September 2003.\(^6^4\) Since then, the FDA has held another round of public meetings to take comment on DTCA (held in November 2005), but has yet to signal any policy changes.

In response to reports of poor DTCA regulatory enforcement, however, federal legislators have indicated their intention to act if the situation does not improve. Over the past several years, multiple bills have been introduced to amend the tax code to deny deductions for DTCA expenses, and two bills were introduced proposing new statutory DTCA regulation: one in the Senate in 2004 by Senator John Edwards of North Carolina

---

(S. 2445), and one in the House of Representatives in 2005 by representative Rosa DeLauro of Connecticut (H.R.3950). 65

Both bills represent an attempt by legislators to step up FDA regulation of DTCA, largely in response to reports of misleading and/or unbalanced advertisements. The bill introduced in the House, however, represented a major backlash against pharmaceutical advertising in the wake of the Vioxx scandal. Unlike the Senate bill (which essentially would codify existing FDA guidelines on DTCA and implement stricter penalties for advertisements found to be in violation of those guidelines), the House bill proposes to prohibit advertising within the first three years of a drug’s approval. The bill would also require the Secretary of Health and Human Services to “conduct an education campaign to increase public awareness of risks that . . . may outweigh the benefits of using a particular drug,” and perhaps most importantly, calls for an extra $2.5 million per year to be appropriated to the FDA for the sole purpose of regulating DTCA.

This proposal—short of an outright ban, but nevertheless a substantial regulatory imposition—is the most radical policy reform that has been suggested since the Vioxx scandal, which brought the issue of DTCA (and questions about drug regulation more generally) to the forefront of the national consciousness for a brief moment. In July, 2005, Senate Majority Leader Bill Frist took the floor of the Senate to discuss his

---

concerns about prescription drug advertising. In his remarks, he suggested that “at a minimum” the pharmaceutical industry should voluntarily restrict DTCA of prescription drugs during their first two years on the market. He praised Bristol-Myers Squibb for committing to withholding advertisements for the first year a drug is on the market, and also warned “if [drug companies do not clean up their act with regard to direct-to-consumer advertising], I believe congress will need to act.”

So far, however, Congress has not implemented any DTCA policy changes; both the Senate and House bills were referred to committee and have yet to be addressed. Yet (perhaps in deference to Senator Frist’s threat of legislative action) PhRMA recently released voluntary “guiding principles” on DTCA. These fifteen principles, published in August 2005, were “premised on the recognition that DTC advertising of prescription medicines can benefit the public health by increasing awareness about diseases, educating patients about treatment options, motivating patients to . . . engage in a dialogue about health concerns, increasing the likelihood that patients will receive appropriate care for conditions that are frequently under-diagnosed and under-treated, and encouraging compliance with prescription drug treatment regimens.”66 Most of the specific action points merely reinforce the pharmaceutical’s commitment to adhering to existing FDA guidelines, asserting, for example, that “all DTC information . . . should reflect a balance between risks and benefits, and should consistent with FDA approved labeling.”67 Two of the “guiding principles” do, however, suggest a serious departure from current regulation: guideline six affirms that “companies should spend an appropriate amount of

67 PhRMA Guiding Principles: 2.
time to educate health professionals about a new medicine . . . before commencing the
first DTC advertising," and guideline 8 states that “companies should submit all new
DTC television advertisements to the FDA before releasing these advertisements for
broadcast.” PhRMA also committed to opening an advertising accountability office,
and to appoint an independent panel to review the process and issue a report on
compliance at the end of the year.69

Response to PhRMA’s “Guiding Principles” has been mixed, with some lauding the
pharmaceutical industry for taking the initiative on DTCA reform, and others accusing
PhRMA for making empty, unenforceable promises in attempt to fend off new statutory
or administrative regulation.70 Senator Bill Frist “applauded the industry’s plan” but said
the guidelines should have "gone farther."71 In any case, it seems that at this point, the
most meaningful policy reform enacted has been undertaken on a voluntary basis by the
pharmaceutical industry; whether legislative or administrative rule changes will follow
remains in doubt.

68 PhRMA Guiding Principles: 2, 3. My emphasis. Notice that a commitment to send in advertisements
before broadcast does not mean that companies will wait for approval from the FDA before broadcasting.
70 Burton Bob. US drug industry's guidelines on advertising too limited, say critics. BRITISH MEDICAL
71 Saul S.
III. Analysis: DTCA, Patient Autonomy, and the Role of the FDA

The broader debate around DTCA has focused on a number of key issues, including the educational value of DTCA, its impact on the doctor-patient relationship, its effect on prescription drug expenditures, and its capacity to empower patients. As I mentioned at the outset, it is only this final issue—the issue of patient autonomy and patient empowerment—that I will address in this paper.

Specifically, I would like to add a new perspective to the debate on how DTCA affects patient autonomy. In general, the debate tends to follow along these lines: critics argue that the effects of DTCA on prescribing practices and the patient-physician relationship are so harmful to patients that the practice must be abolished (or at least much more heavily regulated), while proponents assert that DTCA empowers patients to become more actively involved in their own health care, and that to oppose the practice is insupportably paternalistic.

For a number of reasons, however, it is important to also consider whether there are ways in which DTCA actually harms, rather than enhances, patient autonomy. The first reason is practical: we simply do not have conclusive empirical evidence about the effects of DTCA on health outcomes and spending.\(^{72}\) The second reason is theoretical: even if we did have conclusive evidence that DTCA leads to poor prescribing habits and inefficient health care spending, it is unclear that these effects would necessarily justify withholding drug information from consumers in the absence of arguments rebutting the principled

position in favor of DTCA. Who’s to say that we shouldn’t value a patient’s right to know over suboptimal clinical and cost-effectiveness outcomes? If we could try instead to understand the ways in which DTCA harms rather than enhances patient autonomy, however, perhaps we could likewise understand why so many remain opposed to the practice, and perhaps—even in the absence of conclusive empirical evidence—questions about how to regulate DTCA would become easier to answer.

The argument here is relatively simple: when an individual or entity in a position of authority and trust in health care makes a suggestion of treatment that is motivated by its own interests rather than the interests of patients, the patients’ autonomy suffers. For a variety of reasons—some of them less simple—this is precisely what occurs with DTCA.

The discussion begins with a discussion of the fiduciary duty owed by physicians to patients, and how patients’ autonomy suffers when a physician acts in accordance to her own goals instead of those of her patients. After examining precisely what it is about this case that makes it morally objectionable, I argue that DTCA manipulates patients by a similar mechanism. I then entertain the opposing view—that the case of DTCA has little in common with the case of the selfish physician, and that rather than inhibiting patients’ autonomy, DTCA actually enhances it. The remainder of this analysis is spent rebutting these counter-arguments, and briefly addressing the theoretical and practical limitations of the discussion.
Doctors' goals vs. patients' goals

It is generally accepted that physicians enter a unique fiduciary relationship with their patients, and they have an affirmative obligation—a duty—not just to protect and promote the health of those they care for, but also to foster autonomous decision-making. In addition to helping his or her patients to be as healthy as possible, a doctor must simultaneously consider and respect the patients' own values and goals with regard to their health and lifestyle. It is because of these special obligations, recognized by both medical case law and professional codes of ethics, that physicians are held to a higher standard of care—the professional standard—than are non-physicians.

In the context of this special relationship, patients have a reasonable expectation that their doctor is acting in their best interest when a diagnosis or treatment is suggested. Patients will trust, therefore, that the ultimate aim of the suggestion is to make them healthier, or at least to prevent a further decline in their health. Their decisions about how to proceed are based on this assumption. When a doctor fails to act in her patients' best interests, however, this turns out to be a false assumption. Even if that "selfish" physician does not actually lie, threaten, or coerce, she does take advantage of her position of authority and trust to motivate her patients to cooperate with her agenda. And when patients are treated

---


in accordance with the goals of the physician, and without regard to their own goals, they are being treated “merely as means, and their autonomy suffers.”

In this sense, part of the negative impact of the “selfish” physician has nothing to do with the fact that many patients may end up with suboptimal health outcomes. Rather, it is the doctor’s failure to consider and privilege her patients’ own goals and judgments that make her actions morally objectionable.

Furthermore, the ethical principle at issue is not limited to the case in question, and certainly can be extended to other scenarios. This principle might be generalized as follows: when an individual in a position of authority and trust in health care makes a suggestion that puts its own interests ahead of the interests of patients, patients’ autonomy suffers. For unless that individual’s agenda substantially accords with the patients’ own, the patients are being treated as means rather than as ends in themselves, and their ability to make autonomous decisions about their own health care is effectively undermined.

Comparing the case of DTCA to the case of the selfish physician

To the extent that consumers believe that prescription drug ads come from a source that is acting in their interest when in fact they do not, DTCA compromises consumers’ ability to act autonomously—regardless of whether they ultimately obtain prescriptions for the

---

75 Beauchamp and Childress: 71.
medications being advertised. As in the case of the physician who fails to privilege her patients' goals, consumers' trust—in this case in the authority of medical science, generally, and in the FDA, in particular—is manipulated by DTCA to further the interests of advertisers with little regard to the consumers' own goals.

It is immediately obvious, however, that the case of DTCA differs from the case of the physician in at least three very important respects:

a) **DTCA and the rule of caveat emptor**
The pharmaceutical industry cannot reasonably be said to be in the same position of authority and trust as the doctor. It does not have the same kind of special obligations to each individual consumer/patient, and any minimally savvy person must realize that. Because it is unreasonable for consumers to expect that pharmaceutical advertisers are acting in their best interests, DTCA is not morally equivalent to the case of the selfish physician, and does no more harm than any other form of advertising.

b) **DTCA offers many benefits to patients**
DTCA can, in many cases, serve a morally valuable purpose: it makes patients aware of new discoveries in medical research that they otherwise might never hear of, and it enables them to act on that knowledge. Even though drug companies' principal motivation in advertising is to increase sales of their products, DTCA also acts to empower patients to take a more active role in their own health care. In this respect, DTCA actually promotes rather than detracts from meaningful patient autonomy.

c) **Physician as "Learned Intermediary"**
Even if patients are acting according to promotional information in the first place, they still have the opportunity to receive unbiased information from their physician, someone who is specially trained and morally obligated to act in their interest. In fact, they cannot receive a prescription without the consent of their physician. DTCA empowers patients not to prescribe medications, but to seek further information from their doctors, and become more active agents in their own care.
In the following pages, I will elaborate on each of these points, exploring and rebutting the counter-arguments to my claim that DTCA unfairly manipulates patients in the same way as the selfish physician.

**DTCA and the rule of caveat emptor**

For-profit pharmaceutical companies are legitimate businesses that are legally obligated to generate the maximum revenue possible for their shareholders. Their job is to profit from the development and distribution of effective medications, *not to participate directly in patient care*. The pharmaceutical industry is not involved in a therapeutic relationship, or any relationship of special obligation, with the individual patients for whom their medications are intended. In fact, this lack of special obligation is formally recognized in pharmaceutical liability case law: unlike in other industries, where manufacturers can potentially be held liable for any adverse outcomes associated with their products, when it comes to pharmaceuticals, it is only the individual physician— "the learned intermediary"—who bears the positive obligation to inform his or her patients about the risks and benefits of a given therapy.\(^{76}\) The pharmaceutical companies are obligated simply to follow FDA guidelines, make sure that the doctors are adequately informed about the risks and benefits of their products, and to include a summary of that information in the package insert.\(^{77}\)

---


\(^{77}\) When a patient encounters DTCA, of course, there is no learned intermediary present to inform the consumer of the risks and benefits of the product being advertised. The FDA requires that any product-specific DTCA contain "adequate provision" of the major side effects associated with the medication, but
Therefore, because the pharmaceutical companies are not involved in a relationship of special obligation with patients, DTCA is no more manipulative than any other form of advertising. As long as it makes no overtly false claims about the definition of a specific disease or the benefits and indications of a given drug, DTCA merely brings consumers’ attention to the fact that certain symptoms may be biologically based, and that FDA-approved medications for these conditions are available. As with any advertising, it is the consumer’s responsibility to be appropriately sceptical about the claims the advertiser makes about its product. Any competent adult should be able to recognize that pharmaceutical companies spend billions of dollars on advertising not as a form of public service, but because they are attempting to increase product sales. In fact, it would be paternalistic to assume otherwise. As one proponent of DTCA puts it,

Certainly, all stakeholders have different agendas. Companies will want to increase the market for their medicines; doctors will want to guard professional territory; and the government will want to minimise the cost to the exchequer. But it seems condescending to assume that consumers have no consciousness of these mixed motives and that their scepticism will be dissolved in their anxieties about health and illness.\(^78\)

It is therefore up to individual consumers to be appropriately sceptical of DTCA, to weigh the evidence rationally, and to decide whether or not to seek treatment; it is up to their physicians to help guide them through their treatment options.

In other words, consumers can reasonably be expected to apply the rule of *caveat emptor* in the case of DTCA, while they cannot reasonably be expected to exercise similar skepticism when receiving advice from their own physicians. To the extent that consumers are manipulated by an advertisement, it is the fault of their own unreasonable expectations, and not any unreasonable action on the part of the advertiser.

*Rebuttal: the rule of caveat emptor does not apply in the case of DTCA*

It must be said, however, that even if consumers *shouldn’t* assume that DTCA is intended to promote their best interests, *they often do*. Furthermore, this misunderstanding does not occur because consumers are naïve. To the contrary; even if consumers realize fully that pharmaceutical companies are under no special obligation to them, and that they advertise primarily to boost sales of their products, those consumers still have a perfectly reasonable expectation that DTCA is being regulated by an entity that *does* have a special obligation to protect their interests: the FDA. Survey data show that consumers do in fact expect such regulation: according to one study, 50% of respondents thought advertisements had to be pre-approved by the government, and 43% thought only “completely safe” medications could be advertised.79 The survey also found that such “false faith” was strongly correlated with a positive attitude about DTCA.80

To many, the fact that consumers harbor false faith is not surprising, not only because the pharmaceutical industry is so heavily regulated in general, but because regulating the information that consumers receive about medications is explicitly part of the FDA’s

80 Bell, Kravitz, Wilkes.
mandate. According to the FDA mission statement, it is the agency’s responsibility to help the public get “the accurate, science-based information they need to use medicines and foods to improve their health.”

It is therefore perfectly logical for consumers to assume that pharmaceutical DTCA is meaningfully regulated by the FDA, just as they assume the medications they are prescribed by their physicians are approved by the FDA. In this sense, consumers might reasonably believe that drug advertisements have been vetted by an entity that safeguards patients’ interests—even though the drug companies themselves are recognized to be biased stakeholders. Based on this belief, consumers are likely to be less skeptical of prescription drug advertisements than they are of other sorts of advertisements (after all, there is no government agency devoted to ensuring the safety and efficacy of, say, pet supplies or footwear), and their decisions will be affected accordingly.

But because the FDA does not in fact pre-approve pharmaceutical advertisements before they are released to the public, and often fails to effectively enforce its own guidelines, this turns out to be a false assumption. In this sense, DTCA takes advantage of consumers’ trust in the FDA just as the selfish physician takes advantage of his patients’ trust in his professional integrity. Although this manipulation is not necessarily the fault of the drug manufacturers, it does mean that patients’ ability to act autonomously is effectively undermined.

82 Interestingly, the disclosure of side effects that comes at the end of product-specific drug advertisements may in fact reinforce this assumption of regulation.
DTCA offers many benefits to patients

DTCA, while advancing the interests of pharmaceutical manufacturers to increase the market for their medicines, also serves to increase public awareness of certain diseases and the treatments available. In this regard, unlike the case of the selfish physician, DTCA holds great potential to empower patients to take a more active role in their own health care. For if patients are better informed, they are better able to participate in medical decision-making with their physicians. This is desirable not only because increased patient involvement leads to better health outcomes, but also because patients have a right to be involved in their own health care, and truly informed decisions cannot be reached without access to comprehensive, comprehensible medical information. In other words, the patient’s ability to take a greater role in his or her own health care is a worthy end in itself. The selfish physician did not further this end; although she may have reached certain patients who actually could benefit from the suggested treatment, her intervention did not encourage their greater participation in their own health care in any way. In this respect, DTCA is indeed very different from the case outlined above: DTCA actually contributes to a more robust and meaningful patient autonomy.

Rebuttal: the potential benefits of DTCA depend largely on advertisement content

One can only agree that raising patient awareness about certain medical conditions and medical therapies is a worthy goal, and also that DTCA could potentially provide patients with the kind of accurate and balanced information that facilitates informed decision-

---

83 Bonaccorso and Sturchio JL: 910.
making. As noted above, however, even if DTCA could enhance patient autonomy in this manner, it is a separate question whether it actually does.

Another way to phrase that question is to ask, what information do patients need to engage in a meaningful discussion about prescription drug treatment with their doctor, and does DTCA provide that? Although there seems to be little consensus on what constitutes sufficient information from a normative perspective, numerous empirical studies have nevertheless endeavored to answer that question by examining DTCA content and consumer knowledge, attitudes, and behavior following exposure to DTCA. Several studies, for example, have demonstrated that DTCA succeeds in prompting patients to talk to their doctors about their health concerns. A survey by Prevention Magazine (co-sponsored by the American Pharmaceutical Association) found that an estimated 24.7 million Americans talked to their doctors about a medical condition they had never discussed with a physician before as a result of DTC advertising, and a 1999

---

84 There is great, debate, of course, about what constitutes “accurate and balanced information”, but that is not a question that will be addressed in this paper.

85 See Bell, Wilkes, Kravitz. The educational value of consumer-targeted prescription drug print advertising. JOURNAL OF FAMILY PRACTICE 49(12) (Dec. 2000): 1092-8. See also Cooper RJ, Sehrger DL, Wallace RC, Mikulich VJ, Wilkes MS. The quantity and quality of scientific graphs in pharmaceutical advertisements. JOURNAL OF GENERAL INTERNAL MEDICINE 18(4) (2003): 294-7, and Vilanueva P, Peiró S, Librero J, IPereiró I. Accuracy of pharmaceutical advertisements in medical journals. LANCET 361 (2003): 27-32. One of the first ethical questions that comes to mind about DTCA content is whether some information (i.e. information that is accurate but incomplete) is always better than no information when it comes to medical subject matter. It is also interesting to note that even if DTCA were sufficiently regulated to ensure unbiased content, the standard of disclosure in any mass advertising campaign is necessarily the “reasonable person” standard. In contrast, when a doctor informs a patient about the risks and benefits of a given therapy, he or she can tailor the discussion to meet that individual patient’s unique informational needs (this is the so-called “subjective standard” of disclosure). DTCA does not have the flexibility to tailor its content for each individual consumer, and therefore the determination about the kind and amount of information to be included in the advertisement must be based in reference to a hypothetical reasonable person. Again, the issue of whether or not this standard of disclosure is sufficient to protect informed consent is a topic best left for another paper, but it does remind us that there are questions about the relationship between DTCA and meaningful patient autonomy that go beyond the scope of this discussion. 86 Bonaccorso and Sturchio: 910.
survey by the FDA found that 27% of respondents who remembered seeing a DTC ad asked their doctors about a condition they had not discussed before.  

Other studies have shown, however, that although DTCA is successful in promoting awareness of the names of prescription drugs and the symptoms of the conditions they treat, it rarely provides specific information about important issues such as disease prevalence, drug efficacy, alternative treatments (including non-pharmacologic alternatives), and cost. One study published in the Journal of Family practice in 2000, for example, examined 320 print advertisements and found the following:

- Information about condition prevalence was provided in only 12% of advertisements.
- Clarifications about a condition-related misconception was provided in only 9% of advertisements.
- An acknowledgement of the existence of one or more competing treatments was offered in only 29% of the advertisements.
- Supportive behaviors such as changes in diet, physical activity, and sleeping patterns were reported in 24% of the advertisements.
- A success rate estimate was reported in only 9% of advertisements.

Another study in 2002 found that “70 percent [of the television advertisements reviewed] did not provide any information about about risk factors or symptoms that might raise awareness among undiagnosed people . . . [and] only 34 percent informed consumers that the drug might not work for everyone.” The authors (Kaphingst et. al.) also observed that although 80% of the ads told consumers to talk to their doctors about the advertised

---

89 Bell, Wilkes, Kravitz: 1092-1098.
drug, only one out of twenty-three advertisements directed consumers to seek information about the indication for treatment.⁹¹

A subsequent study by the same authors reported that in addition to suboptimal informational content of many DTC ads, DTC text materials are often not appropriately tailored for patient readers.⁹² Not only are the brief summary sections (the parts of the print advertisement that contains detailed risk information) printed in extremely small type, but they often include many medical terms and extensive research data lifted directly from the professional labeling, and have average reading difficulty scores well above the reading ability of the average American adult.⁹³ These factors may contribute to the fact that, according to a 2002 survey by the FDA, only 10% of patients read the brief summary in its entirety, and up to 41% read none of it at all.⁹⁴

Finally, research over the past decade has demonstrated that advertisements often fail to achieve the “fair balance” between risks and benefits (which the FDA nominally requires).⁹⁵ Television advertisements, for example, often spend less time presenting risk facts, and risk information is provided in one continuous segment, during which time positive or neutral visual images are shown.⁹⁶ Emotional appeals and other non-verbal

---

⁹¹ Kaphingst and Dejong: 144
⁹² Kaphingst and Dejong: 145.
⁹³ Kaphingst and Dejong: 146
⁹⁴ Aiken K. FDA has since issued a draft guidance which explicitly permits and encourages drug manufacturers to include a more consumer-friendly version of the brief summary instead of a verbatim copy of the approved professional labeling. See Food and Drug Admin. Guidance for Industry Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements (Draft Guidance). Jan 2004.
⁹⁶ Kaphingst and Dejong: 144.
cues only add to this confusion. It is no surprise to DTCA critics, therefore, that one study commissioned by the FDA to assess the effects of DTCA found that consumers retain more information about the advantages of products than about the risks.⁹⁷

Taken together, the existing empirical data suggest that while DTCA successfully raises patient awareness about specific conditions and pharmaceutical treatments, it often fails to provide the kind of details that would educate consumers, such as information about disease prevalence, treatment efficacy, and treatment alternatives. Moreover, the “fair balance” between risks and benefits—required by the FDA guidelines—is not consistently realized. Thus, even if DTCA succeeds in encouraging patients to initiate discussions with their physicians, it is unclear whether those same patients would do so if given better information. In other words, patients may be entertaining and acting on new health concerns precisely because of the information DTCA lacks. For this reason, there is no clear answer to the question of whether DTCA provides patients with the quality and quantity of information they need to make informed decisions about initiating treatment discussions with their physicians.

Furthermore, for the purposes of this analysis, the potential advantages—even the actual advantages—do not alter the problem with under-regulation of DTCA that I have described: patients are acting on DTCA under the false assumption that advertisements being regulated by the FDA in ways that in fact they are not. For this reason, when patients choose to act on DTCA, they are not making a truly informed decision to do so.

They are manipulated, albeit subtly, into putting more stock in the advertisements than they might if they knew they were not strictly regulated by the FDA.

**Physician as “Learned Intermediary”**

The outcome of the discussion initiated by patients depends, of course, on the individual patient-physician interaction. Unlike in the case of the physician who willfully manipulates her patients, DTCA has a very important safety net: the individual still has to go talk to their doctor.98 In this sense, DTCA does not (as critics often suggest) encourage self-diagnosis or inappropriate prescription decisions. After all, DTCA does not change the fact prescription drugs remain available only under a doctor’s supervision.

Direct-to-consumer advertising merely motivates patients to learn more about medical conditions and treatment options and to consult their physicians. Once the dialogue has started, the physician’s role is preeminent. The patient has been empowered with information, not prescribing authority. In the words of Harvard Medical School Professor Jerry Avorn: "... Ultimately, it isn’t the patient’s signature on the prescription—it’s the doctor’s."99

Indeed, among patients who are prompted by DTCA to seek further information about a specific prescription drug, 89% cite their own doctor as a source of such information, and 73% of patients survey disagree that DTCA makes it seem like a doctor is not needed to decide if a prescription drug is right for them.100 In this sense, DTCA empowers patients not to bypass the physician, but to actively engage with her in discussions about their own health concerns.

---

98 This fact is recognized in the legal doctrine of the “learned intermediary”, in which the legal “duty to warn” about drug risks falls not to drug manufacturers, but to individual physicians. See Garbutt BJ, Hofmann ME. Recent developments in pharmaceutical products liability law: failure to warn, the learned intermediary defense, and other issues in the new millennium. *Food Drug Law J.* 58(2)(2003):269-86.


100 Aiken K.
Moreover, limited data suggest that DTCA may be quite effective in addressing problems of underdiagnosis and undertreatment, especially of traditionally stigmatized conditions such as depression or sexual dysfunction. A recent, well-publicized randomized controlled trial by Kravitz et. al. found that physicians were significantly more likely to consider and record a diagnosis of depression and/or make a mental health referral if the patients made a request for medication compared with no request. 101 According to the authors, “these results underscore the idea that patients have substantial influence on physicians and can be active agents in the production of quality.” 102

Thus, DTCA, unlike a physician who acts in her own interest when suggesting a certain treatment, ultimately advances patient autonomy by expanding patients’ opportunities to initiate discussions with their physicians. Even if patients are presented with incomplete information in the first place, and even if they misunderstand how that information is regulated, when they go to the doctor and mention that drug ad they saw on television, there is a new opportunity for them to learn about and participate in their own care. By prompting important discussions between patients and their doctors, DTCA actually fosters greater patient participation, and greater patient autonomy.

**Rebuttal: The “Learned Intermediary” Doctrine Is Insufficient**

Although DTCA may in some cases initiate good conversations between patients and their doctors, and ultimately lead to more informed, healthier patients, this is not

---

101 Kravitz R et al.

102 Kravitz R et al.
necessarily what occurs. Remember, DTCA not only prompts patients to visit their doctor, but in many cases to also ask for the specific brand of drug they saw advertised. In a recent FDA survey, for example, 92% of the physicians surveyed reported that they could recall a recent patient who had initiated a discussion about a prescription drug they saw advertised, and 59% reported that the patient had made a request for a specific brand name drug.\textsuperscript{103} For this reason, DTCA may lead to situations in which the doctor and patient engage not in meaningful discussions about the patient’s health concerns and the broad range of treatment options available (including non-pharmacologic treatments), but rather in discussions about why a single, brand name medication may or may not be the most appropriate therapy.

There is also concern that patients might not accept their physician’s opinion, having already been “sold” on a certain treatment by its aggressive advertising. A 1999 study by Michael Wilkes et. al. found that “as many as half of patients would register disappointment, and 15% would consider switching physicians, if their physician refused a request for an advertised prescription medication.”\textsuperscript{104} Additionally, in one survey by the FDA, 62% of physicians reported that DTCA had “caused some tension” between them and their patients.\textsuperscript{105} Therefore, rather than being in a position to listen to a patient’s health concerns and offer a range of alternative approaches, doctors who are faced with requests for specific drugs may find themselves in a defensive position, in which they are

\textsuperscript{103} Aiken K. Of the 211 physicians who received a request for a specific brand name drug, 57% prescribed the requested drug.
\textsuperscript{105} Aiken K.
forced to balance the often competing goals of rational, holistic patient care and immediate patient satisfaction.\textsuperscript{106}

In the era of managed care, when physicians have less and less time to spend with each patient, that balance might be quite difficult to achieve.\textsuperscript{107} Physicians may simply not have time to help patients adequately interpret the content of drug advertisements and review the pros and cons of a specific drug and all its alternatives. In fact, to do so might take away from more important concerns, such as assessing the patient’s health status.

As Dr. Catherine DeAngelis, editor in chief of the Journal of the American Medical Association, described exactly this scenario in a recent radio program on drug safety:

And the point is you go into the doctor and of course you’ve got your little coupon here and the doctor can spend five minutes trying to convince you not to take it or he can use those five out of his average 11 minutes that he has with a patient talking about other important things and just say, ‘Look, all right, I’ll write you the prescription already.’

DTCA critics argue that by exerting such pressure on the doctor-patient relationship, DTCA will lead to poor prescribing practices, and there is preliminary evidence that supports such a concern. For example, a 1989 study found that patient request was the most common reason offered by physicians for inappropriate drug prescribing,\textsuperscript{108} and a more recent cross-sectional survey showed that not only did patients with higher exposure to advertising request more drugs, but that patients who requested drugs were 17 times as likely to receive 1 or more new prescriptions as patients who made no

\textsuperscript{106} Kravitz: 2244.
\textsuperscript{107} One should also consider that physicians may be biased toward patient satisfaction, since patient satisfaction is often used as a proxy measure for quality of care, and as such, may affect physician income. Murray E, Lo B. Direct-to-Consumer Advertising: Physicians' Views of Its Effects on Quality of Care and the Doctor-Patient Relationship. J AM BOARD FAM PRACT 16(6)(2003): 521.
requests. The same survey showed that physicians were more likely to judge patients as knowledgeable about a drug if they requested it, but at the same time, they considered 50% of prescriptions for requested drugs to be a "possible" or "unlikely" choice for similar patients.

These data call into question doctors' ability to consistently fulfill their role as gatekeeper in the prescription system, making sure that patients receive the very best medication available for their condition (or no medication if none is indicated). In the words of DTCA critic Matthew Hollon,

Some argue that physicians serve as the system's safety net, preventing the inappropriate use of prescription drugs. This argument, however, rests on a number of questionable assumptions. It assumes that physicians are always rational in prescribing. It assumes that such things as patients' demands do not influence physicians' prescribing practices. It assumes that, at a population level, physicians are nearly infallible. Available evidence casts doubt on these assumptions.

Ironically, this admission calls into question doctors' ability to make appropriate prescribing decision in general, a point that DTCA proponents often use to justify consumers' need to be educated and informed about their various treatment options. In the context of Hollon's argument against DTCA, however, this statement exposes an obvious and important weakness in industry's argument in favor of DTCA: their argument depends on physicians not only protecting patients from the dangers of self-diagnosis and inappropriate drug use, but also taking the time to educate their patients

---

111 Hollon: 382.
fully about the drug in question, and inform them of alternative treatments. In the face of overwhelming pressure, however, physicians may not be up to the task.

Furthermore, even if doctors could consistently “do the right thing” when faced with a DTCA-based drug request, that would not change the fact that patients may have been acting on a false assumption of DTCA regulation in the first place. From a normative perspective, it is unclear whether the chance of initiating meaningful conversations with physicians outweighs the fact that patients are functioning in a system with poor regulatory transparency. In fact, because the false assumption of strict regulation could be corrected so easily (and not necessarily by limiting patients’ access to drug information), it seems unacceptable that these arguments should be used to justify the current regulatory scheme.

The question of how to reform current DTCA policy to address the false assumption of strict regulation is discussed in the next section of this paper.
IV. **Policy Implications**

Thus far, the available empirical data show that DTCA has competing effects: it raises disease and treatment awareness, but can mislead in terms of risks and benefits; it encourages patients to seek care, but may rely too heavily on individual physicians to dispel misconceptions. Even if DTCA had only positive effects on patient knowledge and awareness of available drug treatments, however, these effects would not undo the subtle structural manipulation that occurs in DTCA. Patients are acting often under the false assumption of stricter FDA regulation, and therefore they are being misled.

Because the pharmaceutical company’s goal of increasing sales is not always in line with the consumer’s interest in receiving unbiased advice about pharmaceutical products, and because it is the FDA’s special obligation to help the public get “accurate, science-based information” about prescription medications, it seems clear that the FDA should actively regulate DTCA to ensure that consumers receive the kind of information they need to make truly informed decisions.

Faced with such an imperative, it becomes clear that whether restricting DTCA is permissibly paternalistic is not the only ethical issue at stake. If, as I have argued, loosely regulated DTCA is structurally manipulative, then the ethical conflict is not only between protecting patients’ autonomy and protecting patients’ well being, but also between patients’ right to unbiased, quality drug information and drug manufacturers’ right to promote their products. Although I have spent the bulk of this paper focusing on one way in which DTCA detracts from meaningful patient autonomy, when it comes to considering options for DTCA policy reform, it is useful to begin to attend to the other
interests at stake; although patient autonomy is an important goal, it is certainly not the only goal.

**DTCA is a Multiattribute Policy Challenge**

From a policy perspective, therefore, the challenge of DTCA regulation is that it is a “multiattribute problem”. That is to say, when faced with the question of how to regulate DTCA, one must attempt to achieve a balance between many different objectives. As discussed at length, one of the primary objectives put forward by industry, regulators, doctors and patients alike is the promotion of patient autonomy along with patient well-being. But we can also easily identify other goals, including the well-being of the community overall (i.e. the public health), promoting cost-effective prescription drug spending, and protecting the freedom of pharmaceutical companies (acting in the interest of their shareholders) to promote their products and compete for market share. The crux of the problem with DTCA regulation (as with all multiattribute problems) is that is impossible to optimize all variables simultaneously, or even to decide which objectives will be prioritized. The task at hand, then, is to determine which goals are most important, and how best to achieve them.

“The first step in thinking systematically about the multiattribute problem is to define the attributes of the problem.” As described above, patient autonomy is only one of the outcomes we value when it comes to DTCA regulation; health outcomes, efficient

---

113 Stokey and Zeckhauser: 117.
114 Stokey and Zeckhauser: 117.
prescription drug spending, and the rights of the pharmaceutical companies and their
shareholders are also at stake. These objectives can be discerned not only by thinking
about the perspectives of different “stakeholders”, but also from the rhetoric that has
emerged around the topic of DTCA.

This list of lofty objectives is helpful in recognizing and identifying the values at stake in
this arena. In terms of real policy-making, however, they are totally unmanageable, and
must be broken down into more specific, more actionable goals. 115

<table>
<thead>
<tr>
<th>Individual autonomy</th>
<th>Individual well-being</th>
<th>Public health</th>
<th>Cost-effective prescribing</th>
<th>Freedom of Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. maximize the amount of quality drug information available to patients.</td>
<td>1. ensure that when a medication is indicated, each individual receives the safest and most effective medication available.</td>
<td>1. minimize incidence and prevalence of adverse drug events (e.g. by using “tried and true” therapies instead of new, unproven ones).</td>
<td>1. encourage prescribing of lower-cost medications and generics where appropriate.</td>
<td>1. minimize infringement on commercial speech</td>
</tr>
<tr>
<td>2. minimize misleading, coercive, and manipulative drug advertising to which patients are exposed.</td>
<td>2. maximize the chance that when an individual would benefit from a medication, he or she will receive it.</td>
<td>2. prioritize diagnosis/treatment of prevalent, debilitating, and treatable illnesses.</td>
<td>2. minimize overprescribing.</td>
<td></td>
</tr>
<tr>
<td>3. encourage and empower patients to partner with their physicians in medical decision-making.</td>
<td>3. minimize the risk of individual patients receiving suboptimal or unnecessary medications.</td>
<td>3. minimize time spent by health care providers correcting false assumptions about prescription drugs so they may attend to other responsibilities.</td>
<td>3. encourage diet and lifestyle therapies instead of medication when appropriate.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. min. development of drug-resistant pathogens.</td>
<td>3. limit use of long-term, expensive medications when health benefit is marginal or unproven.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>5. promote development of safe, effective medications for prevalent and debilitating illnesses.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

115 Stokey and Zeckhauser: 117.
Examining the objectives in this way, it also becomes apparent that there is significant overlap between them: while empowering patients to participate in medical decision-making with their care providers clearly promotes patient autonomy (column 1), for example, we also know that so doing promotes better health outcomes (column 2). Likewise, minimizing adverse drug events not only aids the public health, but also clearly filters down to benefit individual patients and the overall cost of health care delivery.

Of course, the overlap between objectives is not only synergistic (i.e. one specific goal can advance more than one broader objective at once), but also antagonistic. Minimizing the amount of biased drug information to which patients are exposed, for example, will require greater infringement on pharmaceutical companies’ freedom of commercial speech. Or, in a classic example of weighing individual well-being against the greater good, we might limit access to a certain drug for public health or financial reasons, even though an individual might derive benefit from that medication. From these examples, then, it seems that the most accurate way to represent the broad principles and specific objectives of DTCA is as a complex web of attributes, rather than a simple list. In the model of the problem below, it is easier to see how the advancement of one objective will sometimes detract from another, and that there is no mechanism for reducing all the objectives to a common denominator.\textsuperscript{116} Additionally, we can see that determining how to achieve the best outcome depends on how one prioritizes the various objectives. Should more weight be given to public health than individual health, or vice versa? To what extent are we willing to curtail freedom of commercial speech in order to contain

\textsuperscript{116} Stokey and Zeckhauser: 123.
prescription drug spending? Is patient autonomy ultimately more important than patient well-being, or must we struggle always to balance the two?

**Concept Map** of DTCA Policy Goals and Actions: In this model of the problem, overarching values are arrayed on the periphery, and actionable goals are shown in between them. Representing the policy challenge in this way, it is easy to see how different goals may be related both synergistically and antagonistically. For example, limiting false and misleading drug information would positively affect the goals of public health, cost-effective prescribing, etc., but would negatively affect attempts to limit restrictions on commercial speech, and therefore freedom of information. In contrast, encouraging patients to become more involved in their own care has positive affects both on their autonomy and well-being.
Ultimately, how the various objectives of DTCA policy are prioritized depends entirely on the values of the society asking the questions. In nations where health care is treated as a responsibility of government, for example, there might be a stronger emphasis on public health and cost-containing objectives than on the goals of patient autonomy and freedom of commercial speech. [It is easy to speculate that this is why countries of the European Union and other developed nations have opted to ban DTCA altogether . . . to do otherwise would detract from the basic principles around which their health care systems are built.] In the United States, by contrast, where the health care system is much less centralized and there is strong constitutional protection for freedom of expression, the relative value placed on patient autonomy and freedom of commercial speech might be expected to be greater.

Indeed, it seems that in the United States at least, the goal of promoting patient autonomy is of paramount value, for this objective seems to be the fundamental premise of public discourse about DTCA. Not only does the FDA already identify “helping the public get the accurate, science-based information they need to use medicines to improve their health,” as part of their mission, but advocates and critics of DTCA agree that patients deserve such information.¹¹⁷ In the words of outspoken DTCA critic Barbara Mintzes, “the question is not whether consumers should obtain information about treatment options, the question is whether drug promotion—whose aim is to sell a product—can provide the type of information consumers need.”¹¹⁸ In other words, there is broad

¹¹⁸ Wolfe: 524.
consensus that in addition to patient well-being, patient autonomy ought to be maximized. The only question is how.\textsuperscript{119}

\textit{Do Voluntary Guidelines Succeed in Maximizing Patient Autonomy?}

Given my conclusion that DTCA is subtly but meaningfully manipulative in its current form, the logical question to ask is whether recent policy reforms will do enough to protect patients from being fundamentally misled. In other words, can and will PhARMA’s voluntary “guiding principles” address the problem that DTCA is assumed to be subject to FDA approval when in fact it is not? Should our legislators follow Bill Frist’s proposed model, waiting to see if the drug companies “clean up their act” independently and voluntarily before taking action on DTCA?\textsuperscript{120}

PhRMA’s “guiding principles” are clearly a step in the right direction; they represent an admission by industry that in addition to the benefits of DTCA, there are risks. Even while attempting to avoid further regulation by the FDA, they hint at the importance of such regulation, noting, “the innovative pharmaceutical industry takes its responsibilities to comply with FDA requirements seriously.”\textsuperscript{121} The guidelines also include important provisions that will significantly change the content of DTCA, committing adherents to include information about the availability of “other options such as diet and lifestyle changes” and effectively eliminating “reminder ads” that aren’t obligated to contain risk information. Finally, the “guiding principles” also commit companies to educating

\textsuperscript{119} It is worth noting that just because patient autonomy is bandied about in the public sphere as the goal of DTCA, that does not mean that it is truly the primary objective of each and every stakeholder.

\textsuperscript{120} Frist.

\textsuperscript{121} PhRMA Guiding Principles.
doctors about new medications before advertising to patients, and submitting ads to the FDA before releasing them for broadcast, just as pending legislation would require. Although they do not go so far as to voluntarily submit to FDA approval of ads before they are broadcast, the guidelines clearly take into account the concerns of regulators and policy-makers, and signal a desire to maximize the benefits of DTCA while minimizing the risks.

Yet the industry guidelines differ from government regulation in one very important respect: whereas pending legislation would make the FDA accountable for DTCA regulation, the PhRMA guidelines leave enforcement up to “internal processes” and a “PhRMA office of accountability.” Although the guidelines do allow for “an independent panel of credible individuals” to review the performance of the PhrMA office of accountability on a yearly basis, they do not outline what consequences the companies should face if they fail to meet their own guidelines. Therefore, although the PhRMA guidelines do represent an admission by industry of the public health risks of DTCA, they fail to address the structural problem with DTCA regulation that I identified earlier. Namely, self-regulation by industry—or even a “promise” by industry to voluntarily comply with more meaningful regulation by the FDA—does not change the fact that when it comes to drug promotion, it is the FDA that is obligated to ensure that consumers receive unbiased information, not the drug industry.

In a perfect world, pharmaceutical companies’ duty to maximize profits for their shareholders would always align with their social responsibility and voluntary
commitment to educate patients by providing complete and unbiased drug information.

In a perfect world, DTCA could serve those two masters: their own interests in promoting their products and the public’s health needs. In reality, however, those two masters often require conflicting actions, and when push comes to shove, industry is obligated to privilege profits over public health. If there were stricter penalties for violating FDA guidelines, or if drug companies faced a greater risk of being sued for misleading advertisements, it might be in their interest to be more careful about the balance of information provided in DTCA. Because they don’t face harsh penalties or expose themselves to great legal risk by emphasizing benefits over risks, however, why shouldn’t the drug companies chose to emphasize the positive aspects of their products? Persuasive DTCA promises to increase sales, and given the very minor negative consequences, companies would be foolish not to maximize the persuasiveness of their ads.

PhARMA’s guiding principles do not recognize or address the fact that it is the drug companies’ fiduciary duty to maximize the interests of their shareholders, whether or not those interests align with the interests of consumers and patients. Thus, even if these voluntary guidelines do lead to more balanced, better-reviewed advertisements (which they very well might), they do nothing to correct the false assumption by consumers that the FDA is meaningfully in charge. In this sense, such voluntary self-regulation threatens to exacerbate rather than dismantle the illusion that DTCA is neither pre-approved nor consistently regulated by a government agency with a fiduciary duty to ensure consumers receive unbiased information.
Policy Alternatives Addressing Lack of DTCA Pre-approval

There are three possible ways in which the government could act to remedy this particular misunderstanding:

1. Ban DTCA altogether
2. Mandate a disclaimer that “this ad has not been approved by the FDA”
3. Require that ads be pre-approved by the FDA.

In the following paragraphs, I will consider each of these policy alternatives in turn.

Banning DTCA Altogether

An outright ban on DTCA would certainly be the most radical way to protect patients from being exposed to biased drug information, or from being misled about how DTCA is regulated. A ban might also advance objectives other than protecting patients in this regard: it could potentially lead to more cost-effective prescribing by decreasing use of newer, unproven and expensive medications instead of safer, cheaper, and equally or more effective older medications; it could shift pharmaceutical manufacturers’ budgets away from marketing towards research and development; and it could free up resources at the FDA for other regulatory activities. In fact, considering the resources that would be required to review every ad before broadcast, an outright ban might be a fiscally attractive alternative.

Unfortunately, such a ban would also remove what has been—for better or worse—a principal source of drug information for patients for over a decade. Although “protecting” patients from being mislead is one way to “protect” their autonomy,
depriving them of the huge quantities of information about prescription drugs without providing them with an alternative source of equally accessible information would certainly hurt their ability to participate meaningfully in decisions about their own medical care. In other words, advancing patient autonomy not only requires limiting the potential for patients to be manipulated, but also providing them with access to as much quality drug information as possible. While a ban would succeed in the former, it would certainly fail in the latter, particularly if it were not accompanied by an aggressive initiative to fill the information void left by such a ban. In this sense, simply banning DTCA would be overly restrictive, minimizing the risks associated with DTCA by totally precluding the possibility of the benefits, both to patients’ health and to their ability to make more autonomous decisions about their own medical care.

Additionally, a comprehensive ban on DTCA would infringe significantly on drug companies’ freedom of commercial speech, as protected by the first amendment. As noted above, balancing patients’ right to unbiased drug information with drug companies’ right to promote their products is properly considered part of the ethical challenge of DTCA regulation. One needn’t be a legal expert to grasp the reasons we would care about protecting freedom of commercial speech, or to understand the standard by which the court evaluates restrictions on such expression. Although courts do recognize the “common sense” difference between commercial speech (aimed at advancing the economic interests of the speaker) and so-called “pure speech” (the expression of opinions and ideas), and although they afford lesser protection to the former than the
latter, commercial speech still merits a certain degree of protection under the first amendment.\textsuperscript{122, 123}

Commercial speech is protected from undue government restriction not as much because of the rights of the speaker, but because of the public’s right to free access of information (i.e. the “consumer’s right to know”).\textsuperscript{124} As Justice Blackmun wrote in 1976,

\textit{Advertising, however tasteless and excessive it may seem, is nonetheless dissemination of information as to who is producing and selling what product, for what reason, and at what price. So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well-informed. To this end, the free flow of information is indispensable.}\textsuperscript{125}

And in 1997, Judge Lambreth of the DC circuit wrote (citing an earlier Supreme Court decision),

\textit{If there is one fixed principle in the commercial speech arena, it is that “a State’s paternalistic assumption that the public will use truthful, non-misleading commercial information unwisely cannot justify a decision to suppress it.”}\textsuperscript{126}

Insofar as commercial speech is protected more because of the rights of potential listeners than because of the rights of the speaker, it does not matter whether the speaker is an individual or corporation. “The inherent worth of the speech in terms of its capacity for informing the public does not depend upon the identity of its source, whether corporation,

\textsuperscript{122} Commercial speech, as opposed to “pure speech”, is speech that is “authored and/or uttered directly by the commercial entity that wishes to financially benefit from the message.” See \textit{Washington Legal Foundation v. Friedman} (13 F. Supp.2d 51). It is generally undisputed that DTCA qualifies as commercial speech.


\textsuperscript{124} Crister: 39.


\textsuperscript{126} \textit{Washington Legal Foundation v. Friedman}.
association, union, or individual."¹²⁷ Thus, courts generally assume that the first amendment protects consumer’s right to hear, that government paternalism does not justify restricting such information, and that the identity of the speaker does not affect the utility of the speech. For these reasons, courts frown on government restriction of commercial speech—provided it is non-misleading—except under very special circumstances.

It turns out that those special circumstances have been fairly well-defined by the court in the last three decades. Generally speaking, when a government restriction on commercial speech is challenged in court, and it is determined that the speech in question is indeed commercial in nature, the court will apply the four-part Central Hudson test (based on a 1980 Supreme Court case on advertising by an electrical utility) to determine whether the restriction is constitutional:

- First, is the speech inherently or potentially misleading?
- Second, is the government interest in restricting the speech “substantial”?¹²⁸
- Third, does the regulation directly advance that governmental interest?
- Fourth, is the regulation no more extensive than is necessary to serve that interest?

If the court finds that the speech is inherently misleading, it is not entitled to protection and the restriction will stand. If it is only potentially misleading (or not misleading at

¹²⁸ “Substantial government interests, for purposes of this test, have been held to include protection of consumers from misleading, deceptive, or aggressive sales practices [and] ensuring the accuracy of commercial information.” Constitutional Law West’s Key Number Digest CJS Constlaw 815.
all), however, then the restriction must meet the remaining criteria in order to be legally permissible.

In the case of ban on DTCA, the court would probably determine DTCA to be potentially—i.e. not inherently—misleading, simply because the information in DTCA is not necessarily inaccurate or illegal. In other words, although there is potential for consumers to be mislead (both in terms of content, and, as I have argued, in terms of how DTCA is regulated), not each and every person will be mislead by each and every ad. Thus a ban on DTCA would certainly be subject to scrutiny under the remaining criteria. Although the government’s interest in the public health and prevention of consumer fraud would no doubt be regarded as substantial, and the ban would certainly be recognized as a direct way to protect those interests, it is likely that an outright ban on DTCA would be deemed impermissibly extensive. That is to say, a government-imposed moratorium on DTCA would probably not withstand legal scrutiny, because there are a variety of obvious, less-burdensome alternatives the government could employ to advance its interests with regard to DTCA.

*Mandatory Disclaimer on all DTCA*

In contrast to an outright ban, a government mandate that all DTCA contain a disclaimer (e.g. “this ad has not been pre-approved by the FDA”) would permit companies to continue advertising, and patients to continue receiving a high volume of information about prescription drugs, while ensuring that patients are accurately informed about the extent to which the information is government regulated. In other words, a mandated
disclaimer would alert patients to the fact that DTCA is not in fact pre-approved by a government agency obligated to act in their interest, allowing them to exercise the proper amount of skepticism about the content of the ads, but it would do so without being overly-restrictive in terms of the amount of information available to patients. Indeed, in a case in the late 1990's regarding FDA regulation of “health claims” labeling on dietary supplements, the court suggested the use of disclaimers would be a more appropriate way to regulate such information than an outright ban, providing a perfect model for use of a disclaimer on DTCA.\(^{129}\)

Despite the advantages of a mandatory disclaimer, however, there are significant drawbacks. One obvious disadvantage is that merely notifying patients that the ads are not pre-approved does not give the FDA the opportunity to require content changes that would provide consumers with better quality information about prescription drugs. In other words, even though it would help prevent patients from making the false assumption that ads are pre-approved by the FDA, it would not help to optimize the content of the drug ads that are released. Moreover, faced with “unapproved” messages, consumers might have difficulty finding independent, objective, and consumer-friendly information to verify the claims, even if they tried to do so.\(^{130}\) Therefore, although informing patients that drug ads are not necessarily vetted by the FDA is certainly preferable to having them mistakenly presume otherwise, it fails to guarantee patients access to higher quality information about prescription drugs, which would enhance both


\(^{130}\) Although consumers can always access the complete labeling of a drug, the technical description is often difficult to interpret.
their health and their ability to participate more meaningfully in medical decision-making.

Requiring DTCA to be pre-approved by the FDA

Requiring that the FDA approve all advertisements before they are released to the public would not only help ensure better ad content (e.g. more objective balancing between risk and benefit information), but perhaps more importantly, it would ensure that drug ads be regulated in the way that consumers assume they already are. Unlike a ban on DTCA or a mandatory disclaimer, requiring pre-approval is not a particularly radical solution. It merely would help ensure that drug advertisements comply with existing FDA guidelines, and the guidelines that the pharmaceutical companies have already pledged to follow (albeit voluntarily). In this sense, mandatory pre-approval would allow the FDA to fulfill its obligation to police drug information while not restricting the information patients receive, or the pharmaceutical companies’ promotional activities.

Of course, the substantive difference between having the FDA police DTCA instead of the drug companies policing themselves is the difference in enforcement. Although the voluntary guidelines promulgated by the pharmaceutical industry do provide for internal review (as described above), they do not outline how violators of the guidelines would be held accountable. Since the guidelines are voluntary and presumably not legally binding, it is difficult to see how PhRMA could ensure compliance. It is also easy to imagine reasons why they would not want to publicize violations or punish them harshly. In contrast, regulation by the FDA could be enforced by penalties. These penalties would
need to be significant enough to deter violations or the pre-approval requirement, such that potential profits gained by violating the regulation would not outweigh the risk of penalty. Finally, violations of the process could be made public knowledge so that the violating drug company’s image would suffer if it failed to comply.

Because part of the justification for permitting DTCA in the first place was concern about the FDA’s legal authority to restrict it, it seems likely that the FDA would not enact a pre-approval policy without a clear mandate from congress. Indeed, although the FDA recently completed another round of public hearings on DTCA, it remains unclear whether the FDA will revise existing guidelines.\textsuperscript{131} A statute that required the FDA to enact such a policy would not only avoid the necessity of a prolonged administrative review process, but could also guarantee the FDA the additional resources necessary to carry it out.

Making pre-approval a matter of statute rather than simply an administrative rule is important because just like a ban or a mandatory disclaimer, mandatory pre-approval also raises free speech issues. Ultimately, the constitutionality of a pre-approval requirement would probably be determined in court according to the Central Hudson criteria. If the government can successfully argue that requiring pre-approval is the least restrictive and most effective way to crack down on misleading advertising, the restriction will stand, but recent cases suggest that this may be a difficult task.\textsuperscript{132} The government will have to argue, as I have, that the current laissez-faire approach is inadequate, and that pre-

\textsuperscript{131} Saul.
approval is the best and only way to strike the proper balance between the drug companies’ right to advertise and the FDA’s obligation to promote patient autonomy and public health.

Other Policy Recommendations
Requiring drug companies to submit DTCA to the FDA for pre-approval is not the only means by which the government can act to improve the quality of drug information available to patients. The government could also change the guidelines for advertisements, provide incentives for pharmaceutical companies to run more public health oriented consumer campaigns, and engage directly in the provision of drug information to consumers more actively than it already does. These reforms would go beyond preventing consumers’ false belief in DTCA regulation; they would actually improve the drug information to which consumers have access, thereby meaningfully enhancing patient autonomy rather than simply preventing consumers from being misled.

For example, Congress could act to explicitly authorize the FDA to impose monetary penalties for advertisements in violation of FDA guidelines, such that it has the capacity to deter false and misleading advertisements in the first place, not only prompt their removal once they have been found to be in violation. And even without Congressional mandate, the FDA could devise more specific guidelines for what constitutes “fair balance,” prohibiting, for example, the use of positive visual cues to undermine the conveyance of risk information. In keeping with this commitment to fair disclosures of risk, the FDA could require that risk information be presented in every

133 Sugarman Brozan.
promotional piece that mentions a specific brand, whether the piece mentions the indication or not. This action would cut down on the problem of reminder advertisements, coupons, and health-seeking pieces that promote a specific drug without disclosing risk information.

Additionally, because data suggest that the advantages offered by DTCA are not dependent on advertisements being brand-specific, the FDA could act to discourage the use of reminder and product-specific advertisements (i.e. brand-specific advertisements). Based on their randomized controlled trial on the effects of DTCA on prescribing, Kravitz et. al. reported that “non–commercially driven (general) requests were at least as effective at promoting antidepressant prescribing in major depression as brand-specific requests prompted by DTC advertising.” The authors also noted that based on the differences in physician reactions to brand-specific requests and general requests, one could infer that “more neutrally couched requests, generated from noncommercial sources, might not produce so furious a rush to comply in clinically equivocal situations.” In other words, advertisements that don’t mention a specific brand are just as effective in stimulating new prescriptions, and may not lead physicians to make questionable prescribing decisions as often as brand-specific requests.

Based on these data one can make a strong argument that product-specific and reminder advertisements should be banned, even if general disease awareness advertisements are allowed to continue. This would allow more advertising time to be spent providing

134 Kravitz et al.
135 Kravitz et al.
information about the indication and whole range of treatment options. No product-specific advertisements would also mean that doctors, faced with DTCA-based drug requests, would not need to spend as much time talking about one particular drug, and could spend it instead educating about the medical condition in question, life-style changes that could help, and the range of pharmacologic treatments available.

One can easily imagine, however, the public health and cultural consequences that could ensue if the pharmaceutical industry were to put as much zeal into advertising disease as they’ve put into advertising their cures, and with as little regulation. Any shift towards disease awareness advertisements, therefore, would have to be accompanied by better FDA regulation of disease awareness advertisements, in order to prevent drug companies from slanting information to their advantage. Such restrictions would certainly raise first amendment questions, if not further complicate consumers’ position in “the sea of unregulated drug information”. Rather than prohibiting the dissemination of brand-specific advertisements, therefore, the government might do better if the simply provided incentives to industry for spending less of their marketing budgets on brand-specific advertisements (if not DTCA in general), and tried to provide better drug information to consumers directly.

As discussed in the background section above, there are several bills pending in congress that attempt to remedy the shortcomings of current DTCA regulation: House Resolution 575 proposes to amend the tax code to deny any deduction for DTCA, and House Resolution 3950 would require the Secretary of Health and Human Services to conduct a
education campaign to increase public awareness about the balance between the risks and benefits of certain prescription drugs.

It is easy to see the benefits that would follow from denying deductions for DTCA expenses, and indeed, the current bill proposing such reform is hardly the first to do so.\textsuperscript{136} The idea behind these legislative initiatives is to take away incentives for pharmaceutical manufacturers to spend as much on DTCA as they have been. In the words of Representative Nadler (democrat from New York), "our bill wouldn't forbid the ads, but it would make the drug companies run them on their own dime."\textsuperscript{137} That is, given the government interest in minimizing the amount of misleading drug information to which patients are exposed (not to mention containing growing drug expenditures), it makes sense to remove tax breaks that help underwrite DTCA in the first place.\textsuperscript{138}

An additional benefit of denying tax deductions for DTCA expenses might be an innovative use of the extra revenues collected. Specifically, they could be funneled into funding DTCA regulation and public campaigns to educate and inform patients about prescription drugs. The idea of the government actively participating in educating


\textsuperscript{138} Healy M. Although there have been no formal proposals to do so, it is also conceivable that the government could choose to levy additional taxes on DTCA. For example, the government could decide to tax money spent on airtime for television advertisements. While denying deductions removes incentives to advertise, special taxes would provide incentives \textit{not} to advertise, and would probably have a more "chilling" effect on DTCA spending.
patients about prescription drugs is hardly a new idea—not only has it been proposed in congress, but it is already the status quo in some countries where DTCA is not permitted. In the United Kingdom, for example, citizens have access to the website www.besttreatments.co.uk, where they can access consumer-friendly, evidence-based information on health conditions and the pharmaceutical products available to treat them. In the United States, a similar site can be accessed by members of consumer reports, but only by paying for a subscription. Imagine if instead of its new “drug information index”\textsuperscript{139} which is relatively difficult to access and contains only very basic information about individual drugs, the FDA supported access for every American to a resource like besttreatments.co.uk. Imagine if the agency used some of the money collected from duties on DTCA to advertise that website and its content on television, using the same sleek, consumer-friendly manner that pharmaceutical companies currently employ to promote their products? In the words of Matthew Hollon, outspoken critic of DTCA,

> Concise, coherent, evidence-based messages, delivered using the most sophisticated techniques of Madison Avenue, unbiased by the motivation to turn a profit, and funded either by a tax on DTCA \ldots will benefit the public’s health. These public service messages could supplement the haphazard approach to health promotion that relies on occasionally helpful and intermittently harmful advertisements \ldots advertisements that, first and foremost, sell prescription drugs.\textsuperscript{140}

In other words, rather than trusting pharmaceutical companies, motivated to turn a profit rather than promote the public health or patient autonomy, the government could actively invest in educating patients, empowering them with information to play a more powerful role in their own care. As health policy expert Tom Bodenheimer muses, what if instead of being prompted to ask their doctors why about the latest me-too drug, “millions of

\textsuperscript{139} See FDA Index to Drug Specific Information at www.fda.gov/cder/drug/DrugSafety/DrugIndex.htm \textsuperscript{140} Hollon: 2030-2033.
parents were prompted by a TV spot to ask their physicians about asthma action plans to help in the self-management of their children’s asthma."  

Policy Summary

I have argued the current regulatory and enforcement framework governing DTCA is fundamentally inadequate, and that stricter regulation of DTCA by the FDA is a moral imperative. When considering how best to reform this framework, it becomes clear that the challenge of DTCA regulation is that it is a multiattribute problem—that is, there are many different goals one must take into account when deciding how and to what extent DTCA should be restricted. Based on the current debate, and general consensus regarding the value of advancing patient autonomy, however, it is useful to isolate patient autonomy for a moment and ask, *what would a policy that actually privileged patient autonomy look like?*

In answering this question, I have made the following suggestions:

1. Voluntary guidelines are insufficient because they do not require compliance and have no mechanism of enforcement.

2. The FDA should be formally granted the authority to impose harsher penalties on companies whose consumer marketing is found to be in violation of federal guidelines.

3. Risk information should be communicated in all promotional material that mentions a specific brand.

4. All DTCA should be subject to pre-approval by the FDA to ensure compliance with existing guidelines and fulfill the expectation of regulation of DTCA by an agency with a fiduciary duty to patients.

---

5. The tax code should be amended to deny deductions for DTCA expenses to remove financial incentives that encourage companies to spend more on advertising, and to provide revenue to fund regulatory and education activities by the government.

6. The government should engage directly in educating the public about the risks and benefits of prescription drugs by making a more consumer-friendly website and running public health awareness advertisements on television and in consumer publications.

Implementing these changes would effectively enhance patient autonomy by minimizing misleading, coercive, and manipulative drug advertising to which patients are exposed, maximizing the amount of quality drug information available to patients, and empowering patients to partner with their physicians in medical decision-making.
V. Conclusions

In 2001, the Institute of Medicine proclaimed that the sharing of knowledge with patients is of paramount importance to providing quality care in the 21st century. "Information is not inert;" the report declared, "rather the transfer of knowledge is care."\footnote{Committee on Quality of Health Care in America, Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century.* Washington, D.C.: National Academy Press (2001): 72.} If that is indeed the case, then all of us have a duty to ensure that the quality of information provided by DTCA is the very best, not simply (as on FDA official put it) "in compliance."

Thus far, the story of DTCA—from the under-enforcement of DTCA guidelines by the FDA to the debut of voluntary guiding principles from PhRMA—shows that we depend too much on the pharmaceutical industry to provide us with the kind of drug information that we need to make informed decisions. But this story is not unique to prescription drug advertising. Indeed, this is the very same argument that Jerry Avorn has articulated with regard to the prescription drug research agenda.\footnote{Pitts PJ. Turning Point or Tipping Point: New FDA Draft Guidelines and The Future of DTC Advertising. *HEALTH AFFAIRS.* 28 April 2004. W4: 260.} Just as Avorn argues that "the nation requires studies that will meet the needs of evidence-based prescribing and not just the needs of the pharmaceutical industry," so I would argue that the nation requires drug information that truly empowers patients, and that goes beyond serving the bottom line of pharmaceutical manufacturers.

\footnote{Avorn, J. Torcetrapib and Atorvastatin—Should Marketing Drive the Research Agenda? *NEJM* 352(25) (June 23, 2005): 2573-2576.}
It is not fair to anyone—to patients, to doctors, even to pharmaceutical manufacturers—to leave the task of ensuring the quality of drug information in the hands of industry alone. Indeed, any pharmaceutical executive who puts the needs of patients first in marketing decisions “might be accused of compromising his or her fiduciary duty to the company’s shareholders.”\textsuperscript{145} It is in recognition of this conflict of interest that we require drug manufacturers to jump through so many hoops when bringing a drug to market in the first place. If information about treatments is left up to “voluntary guidelines” and lax oversight by the FDA, patients suffer. As Dr. Bill Frist acknowledged on the floor of the Senate this past summer “unbalanced and misleading prescription drug information hurts the American people.”\textsuperscript{146}

Thus, when it comes to drug information, we must shift the balance of responsibility away from industry and back towards the government, because prescription drugs are unlike any other consumer product. Unlike televisions and pet food, pharmaceuticals affect our health in a very direct way; “\textit{these products actually change our bodies.}”\textsuperscript{147}

Sometimes, we even need them to stay alive. Moreover, the consumer does not make decisions about drugs alone, but rather partners with someone with special medical expertise: her physician. In fact, we have long recognized the “complexity and uniqueness of the pharmaceutical marketplace”, as reflected by the high degree of pharmaceutical regulation the public has come to expect and depend on.\textsuperscript{148} It is why we

\textsuperscript{145} Avorn: 2573-2576.
\textsuperscript{146} Frist.
\textsuperscript{147} Crister: 133. Original emphasis
\textsuperscript{148} Chockley N. Testimony on the Emerging Impact of Direct-to-Consumer Prescription Drug Advertising before the Senate subcommittee on consumer affairs, foreign commerce and tourism (July 24, 2001).
require that certain drugs be available only by prescription; it is why we have the FDA in the first place.

Many consumers assume that the FDA regulates DTCA more strictly than it does. When they act on this false assumption, their autonomy suffers. The FDA’s enforcement failures also lead to high volumes of suboptimal information, further compromising consumers’ ability to make informed decisions about their own care. Relying on physicians to remedy this situation does not adequately protect consumers from manipulation in the first place. It’s time to recognize that when it comes to prescription drugs, more informed does not necessarily equal better-informed. The FDA should take immediate action not only to deter false and misleading advertisements, but also to improve consumers’ access to high-quality, unbiased drug information.
**APPENDIX A: Chronology of selected issues relevant to DTCA.** Adapted from Lyles A. Direct marketing of pharmaceuticals to consumers. Annu Rev Public Health 2002; 23: 73-91.

<table>
<thead>
<tr>
<th>Year</th>
<th>Event/Issue</th>
<th>Relevance to drug Marketing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1906</td>
<td>Federal Food and Drug Act</td>
<td>Prohibited interstate commerce of misbranded drugs</td>
</tr>
<tr>
<td>1938</td>
<td>Federal Food Drug &amp; Cosmetic Act</td>
<td>Required evidence of safety prior to marketing approval</td>
</tr>
<tr>
<td>1951</td>
<td>Durham-Humphrey Amendment</td>
<td>Defined separate classes for prescription and OTC drugs</td>
</tr>
<tr>
<td>1962</td>
<td>Kefauver-Harris Amendment</td>
<td>Required evidence of safety and efficacy prior to marketing; required risk and benefit information for advertisements in medical journals; gave FDA jurisdiction for prescription drug advertising</td>
</tr>
<tr>
<td>1968</td>
<td>Caution on isoproterenol inhalers</td>
<td>First FDA labeling directed at patients (patient package insert)</td>
</tr>
<tr>
<td>1970</td>
<td>Information for patients on oral contraceptive’s risks and benefits</td>
<td>First PPI required by FDA</td>
</tr>
<tr>
<td>1981-1982</td>
<td>First product-specific promotions of prescription drugs to consumers</td>
<td>FDA’s reliance on voluntary initiatives for patient information</td>
</tr>
<tr>
<td>1982</td>
<td>Cancellation of PPI program</td>
<td>Time to evaluate risks and benefits of DTCA</td>
</tr>
<tr>
<td>1983</td>
<td>Voluntary moratorium on DTCA</td>
<td>Same marketing regulations for physician and consumer audiences</td>
</tr>
<tr>
<td>1985</td>
<td>Withdrawal of moratorium on DTCA</td>
<td>Required manufacturer’s fees to support hiring additional FDA reviewers, expedited pre-marketing product reviews, increased new product competition</td>
</tr>
<tr>
<td>1992</td>
<td>Prescription Drug User Fee Act</td>
<td>Allowed broadcast DTCA to contain limited risk and benefit information, required adequate provision for alternate sources of complete labeling information</td>
</tr>
<tr>
<td>1997</td>
<td>Draft guidance for industry on broadcast DTCA</td>
<td>Retained features of draft guidance, FDA committed to reevaluate in two years</td>
</tr>
<tr>
<td>1999</td>
<td>Final guidance for industry on broadcast DTCA</td>
<td>Focused attention on need for empiric evidence of DTCA’s effects</td>
</tr>
<tr>
<td>2001</td>
<td>Conference on the effects of DTCA on health care use, costs, outcomes</td>
<td></td>
</tr>
<tr>
<td>2005</td>
<td>PhRMA’s Publishes Guiding Principles</td>
<td></td>
</tr>
<tr>
<td>2005</td>
<td>Latest FDA hearings</td>
<td></td>
</tr>
</tbody>
</table>

FIGURE 4
2000 Direct-to-Consumer Spending
(Drugs Ranked in Terms of Year 2000 DTC Spending)

<table>
<thead>
<tr>
<th>Rank</th>
<th>Name</th>
<th>Type of Drug</th>
<th>DTC Spending in 2000 ($millions)</th>
<th>DTC Share of Spending</th>
<th>Cumulative Share of DTC Spending</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Vexx</td>
<td>Antihistamine</td>
<td>$160.8</td>
<td>7.1%</td>
<td>7.1%</td>
</tr>
<tr>
<td>2</td>
<td>Priosec</td>
<td>Antibacterial</td>
<td>$107.5</td>
<td>4.6%</td>
<td>11.7%</td>
</tr>
<tr>
<td>3</td>
<td>Claritin</td>
<td>Oral Antihistamine</td>
<td>$99.7</td>
<td>4.4%</td>
<td>16.1%</td>
</tr>
<tr>
<td>4</td>
<td>Paxil</td>
<td>Antidepressant</td>
<td>$91.8</td>
<td>4.1%</td>
<td>20.2%</td>
</tr>
<tr>
<td>5</td>
<td>Zocor</td>
<td>Cholesterol Reducer</td>
<td>$91.2</td>
<td>4.0%</td>
<td>24.2%</td>
</tr>
<tr>
<td>6</td>
<td>Viovia</td>
<td>Sex Function Disorder</td>
<td>$89.5</td>
<td>4.0%</td>
<td>28.2%</td>
</tr>
<tr>
<td>7</td>
<td>Celebrex</td>
<td>Antihistamine</td>
<td>$78.3</td>
<td>3.5%</td>
<td>31.8%</td>
</tr>
<tr>
<td>8</td>
<td>Flonase</td>
<td>Respiratory Steroids (inhaled)</td>
<td>$73.5</td>
<td>3.3%</td>
<td>35.1%</td>
</tr>
<tr>
<td>9</td>
<td>Allegra</td>
<td>Oral Antihistamine</td>
<td>$67.0</td>
<td>3.0%</td>
<td>38.0%</td>
</tr>
<tr>
<td>10</td>
<td>Merida</td>
<td>Antibiotics</td>
<td>$65.0</td>
<td>2.9%</td>
<td>40.9%</td>
</tr>
<tr>
<td>11</td>
<td>Flovent</td>
<td>Respiratory Steroids</td>
<td>$62.9</td>
<td>2.8%</td>
<td>43.7%</td>
</tr>
<tr>
<td>12</td>
<td>Pravachol</td>
<td>Cholesterol Reducer</td>
<td>$62.0</td>
<td>2.7%</td>
<td>46.5%</td>
</tr>
<tr>
<td>13</td>
<td>Zyrtec</td>
<td>Oral Antihistamine</td>
<td>$60.2</td>
<td>2.7%</td>
<td>49.1%</td>
</tr>
<tr>
<td>14</td>
<td>Singular</td>
<td>Asthma Treatment</td>
<td>$59.3</td>
<td>2.6%</td>
<td>51.7%</td>
</tr>
<tr>
<td>15</td>
<td>Lipitor</td>
<td>Cholesterol Reducer</td>
<td>$58.2</td>
<td>2.6%</td>
<td>54.3%</td>
</tr>
<tr>
<td>16</td>
<td>Nasonex</td>
<td>Respiratory Steroids (inhaled)</td>
<td>$53.2</td>
<td>2.4%</td>
<td>56.7%</td>
</tr>
<tr>
<td>17</td>
<td>Ortho Tri-Cyclen</td>
<td>Oral Contraceptive</td>
<td>$47.0</td>
<td>2.1%</td>
<td>58.8%</td>
</tr>
<tr>
<td>18</td>
<td>Wytevix</td>
<td>Antiviral</td>
<td>$39.7</td>
<td>1.8%</td>
<td>60.5%</td>
</tr>
<tr>
<td>19</td>
<td>Lamisil</td>
<td>Antifungal</td>
<td>$39.3</td>
<td>1.7%</td>
<td>62.2%</td>
</tr>
<tr>
<td>20</td>
<td>Prenpro</td>
<td>Sex Hormones</td>
<td>$37.9</td>
<td>1.7%</td>
<td>64.9%</td>
</tr>
<tr>
<td>21</td>
<td>Sonata</td>
<td>Non-Bariumulute Sedative</td>
<td>$37.5</td>
<td>1.7%</td>
<td>66.6%</td>
</tr>
<tr>
<td>22</td>
<td>Imilite</td>
<td>Non-narcotic Painkiller</td>
<td>$37.1</td>
<td>1.6%</td>
<td>68.2%</td>
</tr>
<tr>
<td>23</td>
<td>Xemical</td>
<td>Anticoagulant</td>
<td>$35.5</td>
<td>1.6%</td>
<td>69.8%</td>
</tr>
<tr>
<td>24</td>
<td>Prevacid</td>
<td>Antiviral</td>
<td>$34.4</td>
<td>1.5%</td>
<td>71.3%</td>
</tr>
<tr>
<td>25</td>
<td>Avandia</td>
<td>Oral Diabetes</td>
<td>$33.9</td>
<td>1.5%</td>
<td>73.8%</td>
</tr>
<tr>
<td>26</td>
<td>Detrol</td>
<td>Bladder Control</td>
<td>$33.8</td>
<td>1.5%</td>
<td>75.3%</td>
</tr>
<tr>
<td>27</td>
<td>Zyban</td>
<td>Smoking Cessation</td>
<td>$30.9</td>
<td>1.4%</td>
<td>76.7%</td>
</tr>
<tr>
<td>28</td>
<td>Diffucen</td>
<td>Antifungal</td>
<td>$29.9</td>
<td>1.3%</td>
<td>78.0%</td>
</tr>
<tr>
<td>29</td>
<td>Reprin</td>
<td>Crohn Disease</td>
<td>$29.0</td>
<td>1.3%</td>
<td>79.3%</td>
</tr>
<tr>
<td>30</td>
<td>Buspar</td>
<td>Antianxiety</td>
<td>$28.7</td>
<td>1.3%</td>
<td>80.6%</td>
</tr>
<tr>
<td>31</td>
<td>Tamiflu</td>
<td>Influenza</td>
<td>$28.4</td>
<td>1.3%</td>
<td>82.9%</td>
</tr>
<tr>
<td>32</td>
<td>Synmax</td>
<td>Antihistamine</td>
<td>$25.6</td>
<td>1.1%</td>
<td>84.0%</td>
</tr>
<tr>
<td>33</td>
<td>Glucophage</td>
<td>Oral Diabetes</td>
<td>$25.8</td>
<td>1.1%</td>
<td>85.1%</td>
</tr>
<tr>
<td>34</td>
<td>Procrit</td>
<td>Aminol</td>
<td>$25.5</td>
<td>1.1%</td>
<td>86.2%</td>
</tr>
<tr>
<td>35</td>
<td>Petanol</td>
<td>Allergic Conjunctivitis</td>
<td>$25.1</td>
<td>1.1%</td>
<td>87.3%</td>
</tr>
<tr>
<td>36</td>
<td>Prozac</td>
<td>Antidepressant</td>
<td>$23.3</td>
<td>1.0%</td>
<td>88.4%</td>
</tr>
<tr>
<td>37</td>
<td>Relpena</td>
<td>Influenza</td>
<td>$22.5</td>
<td>1.0%</td>
<td>89.4%</td>
</tr>
<tr>
<td>38</td>
<td>Ancept</td>
<td>Antidepressant</td>
<td>$20.6</td>
<td>0.9%</td>
<td>90.3%</td>
</tr>
<tr>
<td>39</td>
<td>Daravir</td>
<td>Hepes Treatment</td>
<td>$19.9</td>
<td>0.9%</td>
<td>91.2%</td>
</tr>
<tr>
<td>40</td>
<td>Rhiinocor Aqua</td>
<td>Respiratory Steroids (inhaled)</td>
<td>$19.3</td>
<td>0.9%</td>
<td>92.1%</td>
</tr>
<tr>
<td>41</td>
<td>Propedia</td>
<td>Hair Treatment</td>
<td>$18.0</td>
<td>0.8%</td>
<td>92.9%</td>
</tr>
<tr>
<td>42</td>
<td>Glucovee</td>
<td>Oral Diabetes</td>
<td>$16.4</td>
<td>0.7%</td>
<td>93.6%</td>
</tr>
<tr>
<td>43</td>
<td>Suralum</td>
<td>Premenstrual Syndrome</td>
<td>$14.4</td>
<td>0.6%</td>
<td>94.2%</td>
</tr>
<tr>
<td>44</td>
<td>Clarins D</td>
<td>Oral Cold Preparation</td>
<td>$14.2</td>
<td>0.6%</td>
<td>95.8%</td>
</tr>
<tr>
<td>45</td>
<td>Flomax</td>
<td>Benign Prostate Disease</td>
<td>$12.5</td>
<td>0.6%</td>
<td>96.4%</td>
</tr>
<tr>
<td>46</td>
<td>Diferin</td>
<td>Acne Treatment</td>
<td>$12.1</td>
<td>0.5%</td>
<td>97.9%</td>
</tr>
<tr>
<td>47</td>
<td>Prevner</td>
<td>Pneumococcal Vaccine</td>
<td>$11.2</td>
<td>0.5%</td>
<td>98.4%</td>
</tr>
<tr>
<td>48</td>
<td>Ambien</td>
<td>Non-Bariumulute Sedative</td>
<td>$11.1</td>
<td>0.5%</td>
<td>99.9%</td>
</tr>
<tr>
<td>49</td>
<td>Ditropan Xl</td>
<td>Bladder Control</td>
<td>$11.0</td>
<td>0.5%</td>
<td>99.4%</td>
</tr>
<tr>
<td>50</td>
<td>Zithromax</td>
<td>Broad Antibiotic</td>
<td>$9.8</td>
<td>0.4%</td>
<td>94.8%</td>
</tr>
</tbody>
</table>

Rest of Market $117.1 5.2% 5.2%
Total market $2,258.4 100.0% 100.0%

Works Cited


Chockley N. Testimony on the Emerging Impact of Direct-to-Consumer Prescription Drug Advertising before the Senate subcommittee on consumer affairs, foreign commerce and tourism (July 24, 2001).


Garbutt BJ, Hofmann ME. Recent developments in pharmaceutical products liability law: failure to warn, the learned intermediary defense, and other issues in the new millennium. FOOD DRUG LAW J. 58(2)(2003):269-86.


Lyles A. Direct Marketing of Pharmaceuticals to Consumers. ANNUAL REVIEW OF PUBLIC HEALTH 23 (2002): 76.


Schultz S. Mr. Outside moves inside: Daniel Troy fought the FDA for years; now he's helping to run it. *US News* (March 24, 2003). Available at www.usnews.com/usnews/health/articles/030324/24fda.htm

Stanek S. Debate persists over drug advertising’s side effects. *Chicago Tribune* (Mar 9 2004). Quoting Peter Pitts, associate commissioner for external relations at the FDA.


Sugarman-Brozan A. Testimony before the FDA Public Hearing on Direct to Consumer Advertising (November 2, 2005).


