

Direct-to-Consumer Pharmaceutical Advertising Therapeutic or Toxic?

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Introduction

Direct-to-consumer pharmaceutical advertising (DTCPA) has grown rapidly during the past several decades and is now the most prominent type of health communication that the public encounters.¹⁻³ The FDA regulates DTCPA, but critics say that the rules are too relaxed and inadequately enforced.⁴⁻⁶ Although only limited data exist, research suggests that DTCPA is both beneficial and detrimental to the public health.^{4,6,7} The number of arguments that favor or oppose DTCPA is fairly evenly balanced, and viewpoints presented by both sides can be supported with evidence.⁸ Although there have been calls to ban or severely curtail consumer drug advertising, remedies to maximize the benefits and minimize the risks of DTCPA are more frequently suggested.^{7,9}

What Is Direct-to-Consumer Drug Advertising?

DTCPA can be defined as an effort (usually via popular media) made by a pharmaceutical company to promote its prescription products directly to patients.⁴ The U.S. and New Zealand are the only countries that allow DTCPA that includes product claims.⁴ Most other countries don't allow DTCPA at all; however, Canada does allow ads that mention either the product or the indication, but not both.^{10,11} The pharmaceutical industry and lobby groups have tried unsuccessfully to overturn bans against DTCPA in Canada and other countries or regions, such as in the European Union (EU).^{12,13} Notably, in 2008, 22 of the 27 EU member states voted against proposed legislation that would have allowed even limited "information to patients" to be provided.¹³

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Types of Advertisements

There are currently several types of DTC drug advertisements (Table 1).^{5,11} One type is the "help-seeking ad," which provides only information about a medical condition and encourages patients to contact their physician but doesn't mention a product.^{5,11} Another category is the "reminder ad," which includes the product name; this type may provide information about strength, dosage form, or price, but it doesn't mention the indication or make any claims.^{5,11} The third and most common type is the "product claim ad," which mentions the product and its indication and includes efficacy or safety claims.^{4,5} Each category of ads is subject to different FDA regulatory restrictions (see Table 1).¹⁴

Media That Distribute Direct-to-Consumer Drug Ads

Channels used to distribute DTCPA most commonly include television, print (magazines, newspapers), radio, the Internet, and other forms of mass media (billboards and direct mailings).^{4,5} Promotional brochures that are supplied to health care professionals to distribute to patients can also be considered DTCPA, even though they aren't provided directly to the consumer by the manufacturer.⁴

Many marketers are also beginning to recognize the enormous potential of online DTCPA, which reaches millions of potential consumers globally.^{15,16} Though the vast majority of DTCPA budgets are still allocated to traditional media (television, newspaper, magazine, radio), marketers are beginning to shift some of their promotional spending to digital promotion, such as product Web sites, online display advertising, search engine marketing, social media campaigns, and mobile advertising.^{15,16}

Table 1 Types of Direct-to-Consumer Drug Advertisements and FDA Regulatory Requirements

Type of Ad	Requirement
Product claim ad: Names a drug and the indication(s); makes claims regarding safety and efficacy	Product claims are made, so "fair balance" does apply and risks are required to be included in a "brief summary." or (for broadcast ads only) Risks must be included in "major statement," and "adequate provision" for access to a "brief summary" is required.
Reminder ad: Names a drug, dosage form, and possibly cost, but not its uses	No product claims are made, so "fair balance" doesn't apply and mention of risks in "brief summary," "major statement," or "adequate provision" is not required. However, the FDA does not allow this type of ad for drugs with serious risks (i.e., a boxed warning).
Help-seeking ad: Describes a disease or condition but doesn't mention a specific drug that treats it	No product is mentioned, nor are any claims made, so "fair balance" doesn't apply; inclusion of risks in "brief summary," "major statement," or "adequate provision" is not required.
From FDA. Basics of drug ads. ¹⁴	

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History and Regulation Of Direct-to-Consumer Drug Advertising

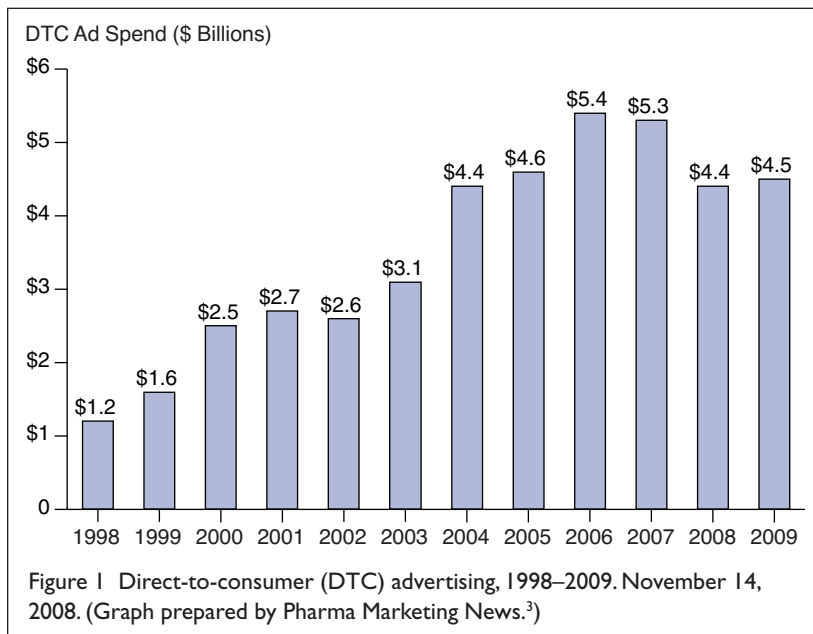
The FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) is responsible for the regulation of DTCPA.⁵ The FDA was given the authority to approve pharmaceutical products for marketing in the U.S. as a result of the Federal Food, Drug, and Cosmetic Act, passed in 1938.¹⁷ In 1962, Congress specifically granted the FDA statutory authority to regulate prescription drug labeling and advertising.¹⁷ In 1969, the agency issued final regulations for prescription drug advertising, which stipulated that these ads must (1) not be false or misleading, (2) present a "fair balance" of information describing both the risks and benefits of a drug, (3) include facts that are "material" to the product's advertised uses, and (4) include a "brief summary" that mentions every risk described in the product's labeling.¹⁷

During the 1980s, the political climate in the U.S. became more favorable to the pharmaceutical industry.⁴ In addition, a cultural shift occurred that caused patients to start actively participating in medical decision-making with their health care providers.^{18,19} In response to both of these changes, an increase in DTCPA occurred.^{19,20} In 1981, Merck ran the first direct-to-consumer (DTC) print advertisement for its new antipneumococcal vaccine, Pneumovax (pneumococcal vaccine polyvalent) in *Reader's Digest*.^{2,4} Shortly afterward, Boots Pharmaceuticals ran the first DTC broadcast advertisement, which promoted the lower price of its prescription brand of ibuprofen (Rufen), compared with Motrin (McNeil Consumer), in 1983.²

With this introduction of DTCPA, the FDA had to consider new questions about how consumer drug advertising should be regulated. In 1983, FDA Commissioner Arthur Hayes asked the pharmaceutical industry to observe a voluntary moratorium while the agency studied the issue.^{2,20} In 1985, the FDA published a notice in the *Federal Register* claiming regulatory jurisdiction over DTCPA and stating that prior standards of "fair balance" and "brief summary" that had been established for advertising to health care providers were sufficient to protect American consumers against deceptive or misleading claims.^{2,4}

This ruling triggered an onslaught of widespread print, but not broadcast, DTCPA.⁴ The need to include complete information about risks from the package insert to satisfy the "fair balance" and "brief summary" regulatory requirements could be satisfied with small type in a product claim print ad.⁴ However, the cost of purchasing enough time to include this information in product claim broadcast ads was prohibitive.² Therefore, the only types of DTCPA that pharmaceutical companies broadcast on the radio and television were reminder, or help-seeking, ads, which do not make product claims, and so "fair balance" doesn't apply and a brief summary doesn't need to be included (see Table 1).^{4,5}

In 1995, the FDA held a hearing to discuss easing broadcast DTCPA regulations in recognition of the prohibitive time and



expense that the rules then required.² In 1997, the FDA issued draft guidance on this topic (and final regulations in 1999) that allowed broadcast DTC product claim ads to include a "major statement" and "adequate provision" to satisfy the "fair balance" requirement, rather than the lengthier "brief summary," which listed all product risks.^{2,4} Now, advertisers had to include only "major risks" and provide an "adequate provision" that would direct viewers elsewhere to access complete "brief summary" information (from a toll-free number, a health care provider, a Web site, or a print ad).⁴

In 2004, the FDA further relaxed regulations concerning DTCPA, eliminating the need to reprint complete prescribing information in print product claim ads and allowing the inclusion of a "simplified brief summary" instead.^{20,21} This change allowed pharmaceutical companies to present information on only the "major risks" and in simplified language that would be easier for the average consumer to understand.^{4,20,21}

Rapid Growth of Direct-to-Consumer Ads After FDA Regulations Were Relaxed

Many believe that the relaxation of the rules for DTC broadcast advertising in 1997 was responsible for the deluge of DTCPA that we experience today; however, there is evidence that this trend began much earlier.^{2,4} For example, in 1980, total spending on DTCPA was \$12 million; in 1990, it was \$47 million; and in 1995, it was \$340 million, representing a nearly 3,000% increase in expenditures during a 15-year period before broadcast ad regulations had even been relaxed.² In 1997, after the FDA issued revised draft guidelines for broadcast DTCPA, the budgets for consumer drug advertising more than tripled to \$1.2 billion in 1998 (Figure 1).³ Spending on DTCPA nearly quadrupled again during the following decade, topping \$5 billion in 2006 and 2007, before dropping to \$4.5 billion in 2009.^{2,3} In 2008, spending decreased because of the financial crisis and subsequent economic slowdown—this was the first substantial reduction in DTCPA since the late 1990s.²²

Prior to 2005, the Government Accountability Office (GAO)

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had estimated that DTCPA was growing at approximately 20% per year, or twice as fast as spending on pharmaceutical direct-to-physician (DTP) advertising or on drug research and development.²³ The growth in DTC advertising expenditures was not without reason, being that it was estimated that every dollar spent on DTCPA would increase sales of the advertised drug by an estimated \$2.20 to \$4.20.²⁴⁻²⁶ Still, in 2005, DTCPA accounted for only 14% of industry expenditures, whereas DTP advertising totaled 24%.^{6,26}

Although the relaxation of FDA rules in 1997 might not have been totally responsible for the rapid growth of DTC drug advertising, it did have an impact on the most preferred media for DTCPA.^{15,17} Most of the budget for DTCPA is now spent on television commercials.^{26,27} The average American television viewer watches as many as nine drug ads a day, totaling 16 hours per year, which far exceeds the amount of time the average individual spends with a primary care physician.^{5,23,27}

In recent years, drug marketers have also increased their expenditures for marketing efforts on the Internet, as searching for health-related information has become the third most com-

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mon activity for online users.^{22,26} In 2003, the pharmaceutical industry spent \$59 million on DTC promotion on the Internet, and spending is now estimated to have grown to \$1 billion.^{15,26} This channel of promotion also promises to be lucrative; data show a 5:1 return on investment for online DTCPA, which is much better targeted than print or television ads in reaching the intended audience.²²

Difficulty Enforcing FDA Regulations

The FDA has the authority to enforce regulations and take action against companies that do not abide by DTCPA rules.^{4,5} However, the FDA's capacity to enforce drug advertising regulations seems to have substantially weakened.⁶ In recent years, the number of regulatory actions taken by the FDA against DTCPA violations has fallen off dramatically, which could reflect better industry compliance but could also be a result of a decline in FDA oversight.⁶

Several factors may be responsible for the apparent weakening of the FDA oversight of DTCPA. In 2002, the Secretary of Health and Human Services (HHS) began requiring that all draft regulatory warning letters be reviewed and approved by the FDA's Office of Chief Counsel before they are issued.⁶ A GAO report noted that this required legal review seems to have resulted in a reduced number of warning letters to be issued as well as in delays that frequently caused them to be sent long after an advertising campaign ended.⁶ This conclusion was based on the fact that more than twice the number of regulatory letters (68 vs. 28) were sent by the FDA in 2001, compared with 2002, the year the legal review requirement was implemented (Figure 2).⁶ This decline in regulatory letters has continued, since in 2006, the FDA issued only 21 citations, in con-

trast to 142 that were sent in 1997.^{6,24} Interestingly, during the same time period, the proportion of regulatory letters citing problems with DTCPA increased from 15.5% to 33.3%.⁶

Difficulties are also encountered because the number of FDA staff members dedicated to reviewing drug ads has remained relatively constant.⁶ In 2009, only 59 full-time employees were reportedly responsible for reviewing 71,759 industry submissions of both DTCPA and DTP promotional material, and they could cope with only a fraction of them.²⁸ With respect to DTCPA, in September 2006, fewer than half a dozen people were assigned to review more than 15,000 DTC advertisements and brochures.²⁰ In 2008, only 35% of broadcast DTCPA materials had been reviewed as a result of staff shortages.²⁰

This difficulty of keeping up with pharmaceutical ad review, including DTCPA, seems to be due to the disproportionately low funding of the FDA, in comparison to the pharmaceutical industry's expenditures on advertising.²⁴ In 2010, the industry's budget for DTCPA alone was reportedly nearly twice the entire budget for the FDA.²

Need for Regulations Regarding Online Direct-to-Consumer Ads

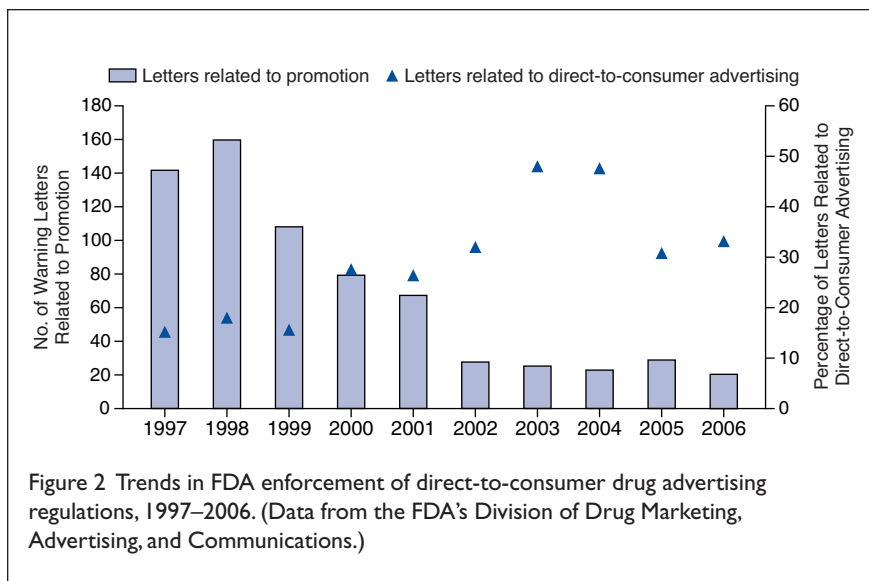
The FDA has not yet issued formal guidelines regarding online DTCPA.^{15,28} However, in April 2009, the FDA did send warning letters to more than a dozen pharmaceutical manufacturers regarding company-sponsored search engine links that failed to mention product risks.¹ The ads typically contained the product name, the disease or condition it treats, the potential benefits, and a link to a product's Web site.¹ The FDA stated that because the links mentioned the product name and its use (and sometimes even other product claims), risk information also had to be provided.¹² In response, drug company-sponsored links now include the indication *or* the name of the drug—but not both.²⁸

In the absence of formal guidelines regarding online media, drug companies have asked the FDA for guidance about what is acceptable, particularly in the context of social media. In response, in November 2009, an FDA hearing on online drug marketing was held, during which pharmaceutical companies argued in favor of allowing the use of space-limited online media for DTCPA.¹ Many companies also requested that the FDA rule on whether companies or their surrogates could directly interact with patients or physicians via online chat rooms or social media Web sites.¹ Participants at the hearing also debated whether companies were responsible for identifying reports of adverse reactions made online by individuals as well as the need for transparency regarding company-sponsored content.¹

Calls for Banning Direct-to-Consumer Drug Ads

There have periodically been calls for the FDA to severely curtail or ban DTCPA.⁹ However, free speech arguments regarding the right of a manufacturer to market its products, for the most part, prevent this.⁵ In a series of cases dating back to the 1970s, the courts had ruled that product advertisements were a form of "commercial speech."⁹ Banning or restricting commercial advertising therefore violates the First Amendment protections of freedom of speech.⁹ By 1980, the Court had

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sumers. The results of a 2005 study of more than 6,000 adults indicated that although the physician was still the most trusted source of information, 48.6% of the subjects went online first and then consulted their physician, whereas only 10.9% talked to their physician first.³¹ Online DTCPA or other pharmaceutical company-sponsored Web sites can also be used to inform patients by communicating safety risks and public health information, public and private health warnings about topics such as online drug purchasing, and adverse reactions.¹⁵

Encourages patients to contact a clinician. A common claim is that DTCPA prompts patients to consult a health care provider to seek medical advice.¹⁷ A 2004 FDA consumer survey found that exposure to DTCPA

prompted 27% of Americans to make an appointment with their doctor to talk about a condition they had not previously discussed.³² Another study found that the small print in a drug ad was strongly associated with patients contacting their health care providers.¹⁷ The effect of DTCPA in increasing patient contact with health care providers could also be beneficial by promoting dialogue about lifestyle changes that improve patients' health, whether or not a drug is prescribed.¹⁷

Promotes patient dialogue with health care providers. Most health care professionals seem to agree that DTCPA is beneficial because it promotes dialogue with patients.³² In the 2004 FDA survey, 53% of physicians said DTCPA led to better discussion with patients and 73% believed that consumer drug advertising helped patients ask more thoughtful questions.³² In addition, in a survey of 221 American oncology nurse practitioners (ONPs), 63% of participants felt that DTCPA promoted dialogue with patients.⁴ DTCPA may also benefit

Exposure to DTCPA prompted 27% of Americans to make an appointment with their doctor to talk about a condition they had not previously discussed.

patients by promoting heightened awareness and detection of adverse reactions, which also may lead to a discussion with a health care provider.¹⁹

There is evidence that dialogue inspired by DTCPA doesn't always benefit the manufacturer of the advertised drug, because physicians do not usually prescribe a medication simply because it is requested by a patient.³⁴ In a November 2006 report from the GAO, only 2% to 7% of patients who requested a drug in response to DTCPA ultimately received a prescription for it.^{12,33,34} In another study, DTCPA increased the likelihood that a patient would initiate a dialogue with a physician to request an advertised drug.³⁵ However, in this study, doctors usually prescribed requested drugs only for patients who had been advised by other health care providers, such as phar-

developed a set of criteria, the Central Hudson test, which is still used today for determining whether a ban on commercial speech is permissible.⁹ This test examines whether the advertising is misleading, whether banning it directly advances a substantial government interest (e.g., preserving public health), and whether the government's interest could be achieved through a less restrictive route, such as by adding a special label.⁹ Some scholars object to this test, but nonetheless, the Court has repeatedly referred to it when overruling prohibitions on the advertising of alcohol, tobacco, and medications.⁹ Legal scholars therefore believe that the courts would overturn a complete ban on DTCPA on the basis that it is unconstitutional.^{9,18,29}

However, some experts suggest that increased regulation of DTCPA, rather than a ban, could satisfy the Central Hudson test and survive constitutional scrutiny.¹² Other measures have also been proposed, such as the Say No To Drug Ads Act, first introduced by Representative Jerrold Nadler (D-N.Y.) in 2002, and reintroduced most recently in February 2011.^{5,30} This Act would amend the Internal Revenue Code to prevent drug manufacturers from claiming the cost of DTCPA as a tax deduction.⁵ Other representatives have introduced or supported legislation similar to Mr. Nadler's.⁵

Arguments in Support of Direct-to-Consumer Drug Ads

Although one might think that positions against DTCPA would predominate, the debate is actually quite balanced. Opinions and data in support of DTCPA are as follows. DTCPA:

Informs, educates, and empowers patients. Proponents claim that DTCPA educates patients and allows them to take charge of their health.⁵ In the U.S., it is thought that informing consumers will benefit the drive for health care reform.¹⁹ Consumers can also benefit from having access to multiple information sources about drugs and other treatment options rather than relying solely on health care providers.¹⁹

The Internet, including online DTC ads, has become an increasingly popular source of medical information for con-

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macists and other physicians, not by the mass media.³⁵

Data also show that patients who discuss a prescription medication with their doctor after seeing DTCPA often receive a different recommendation or treatment.³¹ According to a 2006 survey conducted by *Prevention Magazine*, of the patients who had a discussion with their doctors after seeing DTCPA, 77% reported that their doctors suggested health and lifestyle changes instead; 55% said they were prescribed a generic prescription; and 51% said their doctor suggested nonprescription treatments, such as over-the-counter medicines.³¹

Strengthens a patient's relationship with a clinician.

Studies generally agree that participation of an informed patient in clinical decision-making benefits the patient-clinician relationship.¹⁹ One research study of print DTCPA suggested that DTC ads reinforced the patient-clinician relationship: 83% of the ads focused on physician-patient communication, 76% explicitly promoted dialogue with health care providers, and 54% clearly placed the doctor in control.³¹ Another study showed that the small print in DTCPA encouraged patients to seek the advice of their doctor, whom they described as their most preferred and trusted source of information.¹⁵

Encourages patient compliance. The data consistently show that small, but statistically significant, improvements in adherence occur among patients exposed to DTCPA.¹ This increased compliance is believed to be due to drug ads serving as a reminder about a patient's medical conditions and prescriptions.¹⁸ DTCPA is also thought to reinforce physician recommendations and make patients more likely to follow treatment instructions.⁷

The beneficial effect of DTCPA on patient adherence has been detected in several research studies.³¹ In the 2004 FDA study, 33% of physicians reported that DTCPA increased patient adherence.³² In another study by Harvard University/Massachusetts General Hospital and Harris Interactive, 46% of physicians said that they felt DTCPA increased patient compliance.³¹ In addition, a study utilizing the Rx Remedy database (which follows drug utilization by 25,000 monthly diary panel participants) found that patients who requested a prescription after seeing DTCPA were the most compliant of any group tested.³¹

Reduces underdiagnosis and undertreatment of conditions. DTCPA has been credited with decreasing the underdiagnosis and undertreatment of medical conditions.¹⁸ Drug ads enhance patient perceptions about conditions that could be medically treatable and encourage dialogue with health care providers.¹⁸ The 2004 FDA survey also found that DTCPA improved the underdiagnosis of illnesses, since 88% of patients who had inquired about a medication in response to a drug ad had a condition that the drug treated.³² The 2003 Harvard University/Massachusetts General Hospital/Harris Interactive study also found that 25% of patients who visited their doctor after seeing DTCPA received a new diagnosis; of these, 43% were considered to have a high-priority health condition.³¹ DTCPA has also been shown to increase class-wide (rather than product-specific) sales, thereby helping to improve the underuse of drugs that might not be promoted but are available to treat chronic conditions.⁶

Epoetin alpha (Procrit, Ortho Biotech) provides an interesting example of how DTCPA can have a positive impact on

Patients who requested a prescription after seeing DTCPA were the most compliant of any group tested.

the underdiagnosis and undertreatment of a condition.⁴ Procrit is used to treat anemia by stimulating the production of hemoglobin-containing red blood cells, which can counteract fatigue.⁴ This drug was rarely prescribed before a DTC advertising campaign was conducted, partly because chemotherapy patients were not telling their doctors that they were fatigued.⁴ The ads for Procrit suggested that chemotherapy patients who were experiencing fatigue should discuss possible treatments with their physicians.⁴ This DTC advertising campaign spurred patient awareness and dialogue with their health care providers about chemotherapy-associated fatigue.⁴ This led to a dramatic increase in the use of Procrit to treat anemic chemotherapy patients.⁴

Removes the stigma associated with certain diseases.

Consumer drug advertising for health problems that could be embarrassing to a patient, such as depression or erectile dysfunction (ED), can reduce the stigma associated with these conditions.⁵ For example, an advertising campaign for finasteride (Proscar, Merck), a treatment for benign prostatic hyperplasia, is widely regarded as having successfully raised awareness of a medical condition that men had been reluctant to discuss with their doctors.³¹ A poll of people who called a toll-free number in response to a 1997 DTC campaign for a genital herpes treatment was also conducted.⁵ The poll revealed that 45% of callers had been prompted to make an appointment to discuss the problem with a doctor within three months after seeing an ad.⁵

Encourages product competition and lower prices.

DTCPA is often assumed to be a major driver of rising pharmaceutical costs; however, economic theory and evidence suggest that pharmaceutical prices are instead largely influenced by consumer, physician, and payer perceptions of product value rather than advertising costs.^{6,36} Consumer drug ads may spur manufacturer price increases because of demand, but the evidence for this is mixed.⁶

Supporters of DTCPA also claim that drug advertisements stimulate increased competition, which leads to lower prescription drug prices.^{5,25} They argue that DTCPA also encourages early pharmacological management, resulting in cost-savings from avoiding more expensive surgical interventions.¹³ Unfortunately, these claims are not verifiable, because data available regarding the effect of DTCPA on drug costs are limited.¹³

Arguments Opposing Direct-to-Consumer Ads

Critics also commonly voice arguments against DTCPA. Opinions and data opposing DTCPA are as follows. DTCPA:

Misinform patients. Although DTC advertising may educate patients, it also has the ability to misinform them.⁴ A common complaint is that DTCPA omits important information.^{7,27} For example, in one study, 82% of DTCPA ads made some factual claims and rational arguments for use of the advertised drug; however, only 26% of the ads described risk

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factors or causes of the condition, and only 25% mentioned prevalence.²⁷ DTCPA also tends to suggest that health improvement comes from a medication, perhaps in combination with healthy activities, but never from behavior modification alone.²⁵

For example, one study found that although 19% of DTC ads mentioned lifestyle changes as an adjunct to medication, none mentioned them as an alternative to drug treatment.²⁷ By promoting a drug as the solution to a health problem, these advertisements may lead viewers to believe that adopting healthy behaviors, such as a good diet and exercise, are ineffective or unnecessary.²⁵ Because DTCPA rarely focuses on public health messages about diet, exercise, addictions, social issues, and other treatments, it can also cause people to falsely believe that they are well informed, reducing their motivation to search for more reliable information.⁷

Patients may also lack the skills needed to evaluate comprehensive medical information, even if it has been provided.⁴ This is because the content in DTCPA often exceeds the eighth-grade reading level, which is typically recommended for information distributed to the general public.¹⁸ In addition, few laypeople have the advanced skills that are required to evaluate the psychology, logic, economics, and semiotics behind DTCPA.⁷

Consumers have also been found to place unwarranted trust in DTC ads.⁵ One survey of consumers found that 50% of respondents thought that the ads were approved by the government, 43% thought that a medication had to be completely safe for it to be advertised; and 22% thought that a drug known to have serious side effects could not be advertised.⁵

Paradoxically, the inclusion of information about risks and adverse events in DTCPA may also promote an unnecessary fear of side effects.^{1,18} This concern has been expressed by physicians as well as by proponents of DTCPA, who request further deregulation. They say that the required risk warnings are so extreme that they cause consumers undue concern about drug safety and may cause noncompliance.^{1,18,19}

Overemphasizes drug benefits. Opponents to DTCPA warn that ads for drugs overemphasize potential benefits.¹ In support of this view, content analytic studies have found that most DTC ads emphasize drug benefits over risks.¹⁸ A 2007 study in the *Journal of Health Communication* also found that the average DTC television commercial devotes more time to benefits than to risks.²⁵ Disciplinary action by the FDA during 1997 to 2006 also confirmed that this has been a common problem.⁶ During this time, nearly 84% of the regulatory letters for DTCPA cited ads for either minimizing risks (e.g., omitting information about side effects) or exaggerating a drug's effectiveness (e.g., portraying the indication too broadly or making unsubstantiated claims of superiority over other drugs), or both.⁶

Physicians also report that most patients who initiate a request for a new drug understand the benefits much better than they understand its risks.³⁷ Studies have found that when a claim presents a drug as being very efficacious, consumers do not make much effort to process the rest of the information within the message.¹⁹ Information about risks is also typically presented in often-ignored smaller print or as part of a large, undifferentiated block of text or audio.³⁷ In addition, ads often show a mismatch between visual imagery and verbal mes-

sages when risk information is presented.¹⁸ For example, a person may be seen enjoying a walk in a park while the narrator lists serious side effects.¹⁸ Research has shown that when visual and verbal messages are discordant, visual messages tend to predominate, which can result in insufficient processing of verbally presented risk information.¹⁸

Current FDA regulations may contribute to this problem by permitting a variety of approaches to risk communication that may confuse consumers and reduce their understanding of drug-associated risks.³⁷ DTCPA regulations allow advertisers to select the "major risks" to be included, determine the order in which adverse effects are presented, and decide whether to include quantitative data or results in comparison to those of a placebo group.³⁷

FDA regulations also don't address the use of qualifying language in DTCPA.³⁷ Opponents complain that information in DTC ads is often described in vague, qualitative terms that exaggerate the magnitude of drug benefits.¹⁸ Qualifying language with respect to side effects may therefore be misleading and open to multiple interpretations because of the use of words such as "mild," "usually," "short time," "if," and "may."³⁷ It has been found that statements that use qualifying language to communicate side effects actually contribute to the benefit, not the risk, side of the "fair balance" equation, because they reduce the risk potential that a patient perceives as being associated with a drug.³⁷ Risk information is also often missing quantitative data regarding the incidence of adverse events, which studies have shown would assist consumers in evaluating drug risks.³⁷

Promotes new drugs before safety profiles are fully known. New drugs have been associated with previously unknown serious adverse events after they have been introduced to the market and a substantial amount of use has occurred.⁹ This is particularly true for "first-in class" drugs.⁹ Clinical trials required for FDA approval are typically not designed to detect rare adverse effects, and current methods of postmarketing surveillance often fail to connect adverse events that have a high rate of background prevalence with the use of a particular drug.⁶ Drugs that are expected to be "blockbuster" sellers are also most heavily promoted early in the product's life cycle, which can present a public health risk because the drug's safety profile is not fully known at that point.¹⁵

The safety problems with rofecoxib (Vioxx, Merck) are perhaps the most frequently cited example regarding this issue.⁹ Vioxx was among the most heavily promoted drugs in the U.S. from 1999 to 2004.⁹ During that time, Merck spent over \$100 million per year to build the drug into a blockbuster seller, with annual sales of more than \$1 billion in the U.S.⁹ Patients requesting Vioxx thought that they were advocating for themselves by asking for a drug that they thought was better than its competitors, not knowing that it could lead to stroke or myocardial infarction.^{4,9} On September 30, 2004, Merck voluntarily withdrew Vioxx from the market.^{4,9}

Other drugs that were heavily promoted to consumers have also been linked to safety advisories, FDA black-box warnings, and withdrawals from the market.^{15,18} These include benoxaprofen (Oraflex, Eli Lilly) for arthritis, troglitazone (Rezulin, Parke-Davis) for diabetes, cisapride (Propulsid, Janssen) for gastric reflux, cerivastatin (Baycol, Bayer) for high cholesterol, and

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tegaserod (Zelnorm, Novartis) for irritable bowel syndrome in women.^{15,18}

Manufactures disease and encourages drug overutilization. DTCPA has been criticized as contributing to the “medicalization” of natural conditions, cosmetic issues, or trivial ailments, resulting in an overmedicated society.^{5,12,25} For this reason, some commentators have even referred to DTCPA as a threat to public health.⁵

One often-cited example is DTC ads for ED drugs, which seem to target men who may be experiencing normal variations in sexual performance.²⁵ Studies show that only 10% of American men experience a total inability to achieve an erection.⁵ Therefore, many requests for ED drugs seem to be for occasional problems, which may actually be “normal.”⁵ Similarly, DTC drug ads have also been criticized for redefining menopause as a hormone-deficiency disease rather than a normal midlife experience.^{5,12}

Opponents also complain that DTCPA exacerbates unhappiness about normal experiences and also creates heightened expectations of drug benefits.⁷ These effects can cause severe distress when a drug is unaffordable or when the response to a medication is disappointing.⁷ A survey of men who used sildenafil (Viagra, Pfizer) for ED found that DTCPA raised expectations and therefore had an adverse effect on the morale of the patients for whom it didn't work.⁷

Leads to inappropriate prescribing. If a patient's request for an advertised drug is clinically inappropriate and the health care provider is unable or unwilling to correct the patient's perception that it is a good choice, this situation may lead to unnecessary or harmful prescribing.¹⁸ An additional problem mentioned by critics is that patients may withhold information to fit a particular profile that they saw in DTC ads in an attempt to get the doctor to prescribe a drug they want but that might not be appropriate for them.⁵

Data regarding whether DTCPA leads to inappropriate prescribing have been mixed. Although studies have shown that only 2% to 7% of drug requests by patients are successful, one study reported that such requests were made during about 40% of doctor visits and were successful more than half the time.^{12,34,35} Furthermore, more than half of the physicians in this study said that they prescribed the drug in order to accommodate the patient's request.³⁵ Similarly, 94% of ONPs (n = 221) reported having had a patient request for an advertised drug, and 40% said they experienced one to five requests per week.⁴ Alarming, 74% of the ONPs said patients asked for an inappropriate drug, which 43% said they sometimes felt pressured to prescribe.⁴

A 2005 randomized clinical trial using “patient-actors” also reported interesting results.^{4,38} The participants (n = 18) were randomly assigned to one of six roles—a patient with major depression or an adjustment disorder who requested a brand-specific drug, a generic drug, or no medication.⁴ The study participants were assigned to make a total of 298 visits to the offices of primary care physicians (n = 152) over a one-year period.⁴ After explaining that they had seen a television program about depression, the subjects requested paroxetine (Paxil, GlaxoSmithKline), a nonspecific antidepressant, or no medication.⁴ Results showed that prescribing rates for patients with depression were 53%, 76%, and 31%, respectively (*P* <

0.001, for rate differences).⁴ In contrast, for patients who said they had an adjustment disorder (which is usually treated without medication), prescribing rates were 55%, 39%, and 10% (*P* < 0.001), respectively.⁴

These results suggest that brand-specific requests were more powerful for a questionable, rather than “standard,” indication.⁴ These findings also demonstrate that patients who made either a general or brand-specific request for a prescription were much more likely to receive it compared with those who didn't.⁷

Strains relationships with health care providers. DTCPA is often criticized for its potential impact on the patient-clinician relationship.⁴ Drug ads can have an influence in diminishing a patient's trust in their health care provider's clinical decisions.^{5,39} Clinicians may also find themselves challenged with increased work and frustration when a patient questions their clinical authority with a piece of “evidence” obtained from an advertisement or Web site.^{4,19}

One study that surveyed primary care physicians (n = 1,080) and physician assistants (n = 704) in Arizona listed several hypothetical patient scenarios.⁴ Clinician responses to the described scenarios showed that if patients asked a question inspired by DTCPA, clinicians were more likely to become annoyed (*P* = 0.03), compared with those who were asked a question inspired by the *Physicians' Desk Reference*.⁴ Clinicians were also less likely to answer the patient's questions (*P* = 0.03) and to provide a prescription (*P* < 0.001) for drugs seen in DTCPA.⁴ In a national survey, 39% of physicians and 30% of patients felt that DTCPA interfered with the physician-patient relationship.¹⁸

The negative impact that denying a prescription request can have on the therapeutic relationship has been well documented.¹⁸ More specifically, denial of a prescription request has been shown to decrease patient satisfaction and increase physician switching.¹⁸ In one study, nearly half of the patients reported feeling disappointed about not receiving a requested medication.¹⁸ One-quarter of the patients said they would try to change their physician's mind or get the drug elsewhere, and 15% said they were considering switching physicians.^{18,35}

Wastes appointment time. Supporters of DTCPA argue that doctors should act as learned intermediaries and should educate consumers about prescription drug indications, benefits, and alternatives.¹⁸ However, many physicians oppose DTCPA because they feel it is difficult and time-consuming to have to convince patients that a requested drug is inappropriate.⁵ Data suggest that the average patient-doctor visit lasts between 16 and 21 minutes.¹⁸ If discussion of an inappropriate prescription request needs to occur, this leaves little time for a doctor to address other more important issues.¹⁸ Discussions about advertised drugs can affect patient goals, divert time away from disease screening or examinations, or pre-empt dialogue about healthy lifestyle changes or mental health issues.³⁹ Many clinicians also resent being put in the role of a gatekeeper for an advertised commodity rather than being able to focus strictly on evidence-based medicine.³⁹

Is not rigorously regulated. Some critics argue that FDA regulations concerning DTCPA are too relaxed.⁵ They complain that FDA rules don't prevent DTCPA violations, because drug manufacturers are held liable only after a violation has

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been identified.⁵ Because drug companies are not required to obtain clearance for DTCPA prior to dissemination (“pre-clearance”), a misleading advertisement could complete its run by the time the DDMAC issues a letter.²⁰ The FDA can request that a DTC ad be amended in response to a violation; however, critics say that this won’t make consumers forget the misleading information they saw in the original ad.⁵ Even if pharmaceutical manufacturers voluntarily submitted more DTC ads to the FDA for pre-clearance, the agency has stated that “current FDA resourcing for this work would probably result in delayed reviews and discourage [manufacturers] from submitting the materials.”⁶

The lack of FDA regulations that mandate a DTCPA waiting period for newly approved drugs is also criticized.⁵ The pharmaceutical manufacturers trade group, Pharmaceutical Research and Manufacturers of America (PhRMA), has issued suggested guidelines regarding submission of DTCPA to the FDA for clearance as well as waiting periods for consumer ads for new drugs.⁵ However, these guidelines are criticized as being highly discretionary, voluntary, and unenforceable.⁵

Increases costs. Another common complaint is that manufacturers often use DTCPA to promote expensive “me-too” or “copycat” drugs that might not offer any significant benefits over older and cheaper medications.^{5,25} For example, two heavily promoted diabetes treatments, rosiglitazone (Avandia, GlaxoSmithKline) and pioglitazone (Actos, Takeda), were found to be no more effective—or safe—than older drugs, even though they were much more expensive.²⁵ In another study, older drugs for the treatment of schizophrenia were found to be equally effective and to cost as much as \$600 per month less than olanzapine (Zyprexa, Eli Lilly), quetiapine (Seroquel, AstraZeneca), or risperidone (Risperdal, Janssen).²⁵

Critics say that cost information that could benefit consumers is rarely included in DTCPA.¹⁸ They suggest that, at a minimum, ads should note whether generic drugs that might be a less expensive alternative are available.¹⁸ Patients also don’t know that they might not be able to obtain a new drug that they saw advertised, because it costs 10 times more than an older, equally effective drug and is not on formulary.⁴ Some opponents also suggest that DTCPA increases health care costs because visits to the physician prompted by a drug ad can be a waste of time and money.¹⁹

Industry analysts have suggested that increased drug sales resulting from DTCPA allow companies to spread fixed overhead expenditures over a greater number of units, making drugs more affordable for the population as a whole.³⁶ However, studies have found that long-term prescribing practices for several drugs (clopidogrel, mometasone, etanercept, and tegaserod) were not increased by DTCPA, and an increase in units sold doesn’t always result in price declines.³⁶

Suggested Remedies

Both supporters and opponents of DTCPA agree that even though it might not be possible to severely curtail or ban DTC ads, measures should at least be undertaken to maximize the benefits and minimize the risks of consumer drug advertisements.

Some measures that have been suggested to achieve those goals are summarized as follows.

Manufacturers often use DTCPA to promote expensive “me-too” or “copycat” drugs that might not offer any significant benefits over older and cheaper medications.

Delay Advertising for New Products

After Vioxx was withdrawn from the market in 2004, there were widespread calls for the FDA to institute a mandatory waiting period for new drug DTCPA.^{4,9} In July 2005, Senator Bill Frist, a former practicing physician, called for a two-year ban on DTCPA and asked for the GAO to study the issue.⁴ The Institute of Medicine (IOM) also concluded that DTCPA contributes to early widespread use of new drugs and recommended a two-year advertising moratorium to conduct adequate postmarketing safety surveillance.⁹ The IOM recommended that a special symbol appear on packaging for the first two years that a new drug is on the market.⁹ Despite endorsement of the delay in DTCPA by many sources, governmental regulations for such a moratorium have not been established.⁹

In response to the Vioxx recall, PhRMA also issued guidelines recommending that new drug DTCPA be delayed until the drug’s safety profile is fully established and health care professionals are educated as to the drug’s proper use.¹² In response, several drug companies announced a voluntary, time-limited moratorium on DTCPA for new products.¹⁸ However, it is unclear how well companies are adhering to these voluntary moratoriums for new drug DTCPA. In 2007, tracking by TNS Media Intelligence, a marketing information service, found that companies waited an average of 15 months from the time a new drug was approved before initiating DTCPA.⁹ However, for some new drugs, DTCPA began within one year of approval.^{9,12}

Ban Product-Specific Ads

DTCPA is said to be designed to instill product preferences in people who often don’t have the information, training, or incentive to compare risks, benefits, and costs of available treatment options.^{5,11} It has therefore been proposed that DTCPA be replaced with non-branded informational campaigns, which would have comparable educational benefits but would be safer, more effective, and more economical than DTCPA.⁵ Rather than invest so much money in DTCPA, it has been proposed that drug manufacturers could sponsor an informational advertisement that lists the benefits of a drug class and encourages patients to see their doctors to discuss treatment choices.⁴ It has also been suggested that the tax system be used to create incentives for public and private mass media campaigns aimed at educating patients about common, serious medical conditions and encouraging them to discuss evidence-based therapies with their health care providers.⁷

Require Pre-clearance by the FDA

The FDA has also been urged to establish a mandatory pre-clearance procedure for DTCPA, particularly for television commercials.⁵ Pharmaceutical companies could also conduct consumer pre-tests to demonstrate to the FDA that the ads comply with regulations and that any flagged issues have been

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addressed before an ad is aired to the public.^{1,18} Because the FDA already lacks the staff to review DTCPA, many commentators agree that the pharmaceutical industry will need to pay user fees to foot the bill for a pre-clearance procedure.²⁸ Many proposals made by both industry and consumer groups to increase the personnel resources at the FDA are in agreement that user fees should be created to defray the costs of more proactive monitoring.¹ In 2008, however, the FDA announced that the planned user-fee program for industry promotional material monitoring would not commence because of inadequate funding by Congress.²⁰

Establish Regulations for Online Advertising

The establishment of regulations for online DTCPA has also been urged. These regulations could include mandatory public notification when online content is sponsored by a pharmaceutical company.¹⁵ It has also been recommended that drug companies be made responsible for correcting user-generated content that makes unverified, negative, or clinically inappropriate comments.¹⁵ Proposals for drug manufacturers to use the Internet to collect adverse-event reports from consumers have also been presented.¹⁵

Include Quantitative Information

It has been suggested that the FDA establish regulations that eliminate qualifying statements and require the inclusion of quantitative data in DTCPA.³⁷ Ads could provide specific quantitative information about potential benefits and risks of advertised drugs instead of the current qualitative and often emotionally driven messages.^{1,18,37} It has been shown that exaggerated perceptions of drug benefits can be easily corrected by including quantitative data in DTCPA ads.¹⁸ A series of studies found that the addition of a table displaying quantitative data to DTCPA led to a more realistic appraisal of a drug's benefits relative to a standard print ad that lacked this information, even for participants with little formal education.¹⁸

Improve Patient Comprehension

All information included in DTCPA, including product risk, could be presented at an eighth-grade literacy level to ensure comprehension by a larger segment of the population.¹⁸ Health centers with computers should include user-friendly interfaces, such as touch screens, voice recognition, and hand-held remote controls, to reach patients who lack computer skills or have low literacy levels.²¹

Include Drug Cost Information

Consumers would also benefit from being provided with drug cost information. However, price comparisons of different drugs are difficult because this information is rarely publicly accessible.¹⁸ Until such data are disclosed, ads could, at a minimum, note when a generic alternative is available.¹⁸

Conclusion

Current available evidence, although limited, indicates that the effect of DTCPA on consumers is both positive and negative.⁸ An increased understanding of the effects of DTCPA will have important implications for public health in the U.S. and New Zealand as well in other countries and regions where

the ban on such advertising is being challenged.⁶ Although a ban or severe curtailment of DTCPA has occasionally been called for in the U.S., remedies that will maximize the benefits and minimize the risks of DTCPA are more frequently proposed.⁷ It is hoped that these measures will allow this controversial, but powerful, medium to be better utilized for the improvement of public health.⁷

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