

Direct-To-Consumer Prescription Drug Advertising: Trends, Impact, And Implications

Aiming drug ads at consumers means big business for drug companies, but its effect on clinical care is not yet known.

by Michael S. Wilkes, Robert A. Bell, and Richard L. Kravitz

PROLOGUE: Anyone who watches television or reads newspapers or magazines in modern-day America cannot help but notice the dramatic upsurge in the number of prescription drug ads. Drug companies spent \$905 million on direct-to-consumer (DTC) advertising in the first half of 1999 alone—a 43 percent increase over spending levels a year earlier, according to IMS Health. CBS HealthWatch reports that in 1998, 66 percent of drug consumers in the central United States recalled seeing a particular product advertised in print, and 61 percent of Southern consumers recalled seeing one advertised on TV.

The explosion in DTC drug advertising is fueling the trend toward better-informed consumers. Although this trend might appear benign, it is changing the physician/patient relationship. The authors of this study conclude that evidence is accumulating to suggest that clinical quality of care is harmed by DTC advertising.

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ABSTRACT: We provide an overview of what is known about the impact of direct-to-consumer (DTC) advertising of prescription drugs. Specifically, we explore the historical trends that led to the industry's increasing use of this form of promotion. Then, using the published literature to date, we review the impact of DTC advertising on the consumer, the medical profession, and the health care system. We conclude by offering policy suggestions for how the pharmaceutical industry can promote its products more responsibly, how the Food and Drug Administration (FDA) can regulate DTC advertising more effectively, and how the medical and public health communities can educate the public about drug therapies more constructively.

Doctor: Hello, Mr. Jones, nice to see you. What can I help you with today?

Patient: (*unfolding advertisement from his shirt pocket*) My wife saw this advertisement for this medicine for toenails in one of her magazines, and she thinks I might have this fungus.

Doctor: We can certainly take a look at your toenails, but you should know that the condition mentioned in the ad is not at all uncommon and is never serious. In fact, there are far more problems from the drug than have ever been reported from the toenail problem. All that occurs with this nail condition is that your nails get thicker than usual and often become discolored. (*Doctor examines feet and concludes that a large toe is infected with a benign toenail fungus.*) In fact, your wife is right, you do have the condition, but I do not recommend treating it. First, the mild infection will do you no harm. Second, the fungus will likely come back. Third, the drug is not completely safe, and fourth, using such a strong medicine can lead to resistant bugs that will be more difficult to treat in the future.

Patient: I understand your concerns, but my wife would feel better if I got rid of the condition. Would you mind writing me a prescription for the medicine?

DIRECT-TO-CONSUMER (DTC) ADVERTISING of prescription drugs is affecting patients, doctors, and health care organizations in profound but not always predictable ways. In a recent survey more than one-third of respondents reported asking their doctors for information about a drug they had seen or heard advertised, and nearly a quarter asked for the drug itself. Of those, three-quarters reported that their doctors provided the requested prescription.¹

As the number of drugs marketed directly to consumers has grown, patients such as "Mr. Jones" are an increasingly common, if not altogether welcome, presence in physicians' offices. Not only have the number of drugs advertised increased, but so have the drug companies' advertising budgets directed at consumers; the advertisements have also become far more sophisticated.² No longer is the consumer simply provided with information about a pharmaceutical product. Now advertisers enlist well-known personalities such as Maureen Reagan (Ronald Reagan's daughter), Terrell Davis (football player for the Denver Broncos), Joan Lunden (television personality), Karl Malone (basketball player for the Utah Jazz), and Bob Dole (former senator and Republican presidential candidate) to

endorse their products.³ This is happening at a time when people are taking more prescription drugs than ever before and per capita drug spending is more than \$300 per year—an all-time high.⁴ Of all prescriptions filled, 79 percent are paid for at least in part by some type of private or public insurance.⁵ Even given the push from managed care and other payers to increase the use of generic drugs, most prescriptions written are still for brand-name medicines.⁶

This year alone, drug companies will spend more than a billion dollars on marketing directly to the consumer, up from \$55 million in 1991 and representing a fivefold increase since 1994. The driving force for this rise has been the need for pharmaceutical manufacturers to stimulate consumer demand in an ever more competitive marketplace.⁷ Other forces that have propelled DTC advertising include a more proactive consumer; a strong, business-oriented, Republican-led U.S. Congress; the proliferation of restrictive drug formularies; and an increase in cosmetic medications with popular appeal.⁸

Several news sources have suggested that drug manufacturers' earnings have directly benefited from this new promotional strategy.⁹ For example, in 1998 Schering-Plough invested \$186 million in promoting its antihistamine Claritin (loratadine) and saw company profits soar.¹⁰ While this may be a coincidence, other examples abound: Bristol-Myers-Squibb's anticholesterol drug Pravachol (pravastatin sodium), Merck's osteoporosis agent Fosamax (alendronate sodium), and Pfizer's Viagra (sildenafil citrate).

In this paper we provide an overview of what is known about DTC advertising, defined as "any promotional effort by a pharmaceutical company to present prescription drug information to the general public in the lay media."¹¹ Specifically, we look at underlying reasons for the rapid growth in DTC advertising and then examine the impact of this advertising on the consumer, the medical profession, and the health care system.

Why The Increase In DTC Advertising?

In 1708 Boston's Nicholas Boone placed the first advertisement for a patent medicine in an American newspaper.¹² For the next 200 years patent medicines such as Bateman's Pectoral Drops, Turlington's Balsam of Life, and Dr. Benjamin Godfrey's Cordial promised to cure or treat dandruff, stomach ailments, rheumatism, baldness, and infidelity, through newspapers, magazines, and traveling medicine shows. By the early 1800s the press and the drug industry had developed a strong symbiotic relationship. Newspapers received their greatest income from advertising, and patent medicine advertisers spent more on it than any other group.¹³

By 1938, with the passage of the Food, Drug, and Cosmetic Act,

the U.S. Food and Drug Administration (FDA) was given authority over the labeling of pharmaceuticals (both prescription and over-the-counter); however, control over drug advertising remained with the Federal Trade Commission (FTC). In 1962 the Kefauver-Harris drug amendments changed the face of pharmaceutical promotion with a strong push for consumer protection by requiring that all drugs be proved both safe and effective and by transferring authority for prescription drug promotional material from the FTC to the FDA. Regulations for pharmaceutical advertising (section 502n) require such specifics as a summary of contraindications, side effects, and effectiveness; and “fair-balance” coverage of risks and benefits. In addition, the regulations contain specific guidelines for size of print and readability.¹⁴

For decades manufacturers promoted drugs and medical devices exclusively to physicians. Given the paternalism that was typical of physician/patient relationships in the middle decades of the twentieth century, promoting prescription drugs to the public was inconceivable. Not until 1981 did the pharmaceutical industry first propose changing its marketing approach to include consumers. The industry argued in its proposal to the FDA that consumer protection should no longer be seen as simply providing the public with access to accurate claims but rather as providing the public with knowledge that they would not have, were it not for the “educational” benefit of pharmaceutical advertising. At the same time, the political and regulatory climate was moving toward allowing consumers more choice and empowering them to share in medical decision making.¹⁵ Even so, researchers began to ask whether pharmaceutical advertisements could “serve two masters: the promotional interest of the pharmaceutical industry and the public’s health needs.”¹⁶ However, because companies are ultimately responsible to their shareholders, not to patients, and shareholders’ desires for increased sales are often at odds with patients’ needs for rational drug prescribing, there is an inherent conflict.¹⁷

FDA Commissioner Arthur Hull Hayes responded to the industry’s request by asking for a voluntary prohibition period during which time the FDA would study the proposal. In 1985 the FDA published a notice in the *Federal Register* stating that current regulations were sufficient to safeguard the consumer from false or misleading promotional material.¹⁸ The message to the pharmaceutical industry was clear: They could advertise to the public but had to abide by existing standards. The FDA requested that the manufacturers provide their DTC ads to the FDA for preliminary comments.

Still not satisfied, pharmaceutical manufacturers argued that the “brief summary” (of contraindications, side effects, and effective-

ness) often required them to produce one to three additional pages at considerable expense, which did not provide added value for consumers (it was either not read or not understood). Further, providing such detailed summaries via electronic media (radio and television) is unrealistic in ten, thirty, or even sixty seconds. In 1997, following a public hearing and debate, the FDA issued a draft proposal for new guidelines on broadcast DTC advertising. For the first time, manufacturers could give both the drug's name and the condition without disclosing all of the product's risks. However, advertisers were required to mention important risks and to provide a statement explaining that additional information is available from other sources, such as toll-free telephone numbers, World Wide Web sites, print advertising, and physicians and pharmacists.¹⁹ The FDA thereby ensured that persons with varying levels of education and technological savvy would have access to additional, detailed information. Thus, the increase in DTC advertising was driven in part by manufacturers' need to be more aggressive at marketing their products and by regulators' willingness to provide consumers with new information in the hopes of providing further education.

An Overview Of DTC Drug Advertisements

The current spectrum of drug advertisements aimed at consumers is broad; such ads fall into three categories, according to Lynette Bradley and Julie Zito.²⁰ (1) Health-seeking advertisements educate consumers about a disease or medical condition. The specific drug is not mentioned. An example would be a 1989 advertisement by Upjohn that encouraged men who were concerned about hair loss to talk with their physicians about the matter; Rogaine was never mentioned. (2) Reminder advertisements provide the name of the drug and other minimal information but say nothing about the drug's use, effectiveness, or safety. This type of advertisement is not required to provide a brief summary. (3) Product-specific advertisements mention a drug therapy by name, describe its therapeutic use(s), and make representations about its safety and effectiveness. The vast majority of advertisements fall within this latter category.

■ **A content analysis.** We recently conducted a content analysis of product-specific DTC prescription drug advertisements in an effort to describe trends in the prevalence of such advertising.²¹ In brief, we collected prescription drug advertisements appearing in each of eighteen diverse lay magazines from 1989 through 1998. Judges independently coded each advertisement based on written messages into categories pertaining to the promotion's target audience, use of inducements, and product benefits. We identified a total of 320 distinct advertisements, representing 101 brands and

fourteen categories of medical conditions (Exhibit 1).

New advertisements and brand introductions increased dramatically over the course of the decade (Exhibit 2). Advertisements for dermatological, human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS), and obstetrical/gynecological drugs were most common. Two-thirds of advertisements were for oral medications. Almost all advertisements were targeted to the potential user of the drug, not to third-party intermediaries, and women were more likely to be targeted than men.

The most common appeals used were claims of effectiveness, symptom control, innovativeness, and convenience. Since advertisers often use “new and improved” claims to sell consumer products, it is not surprising that 40 percent of ads used claims of “innovativeness” to market pharmaceuticals. In truth, when it comes to drugs,

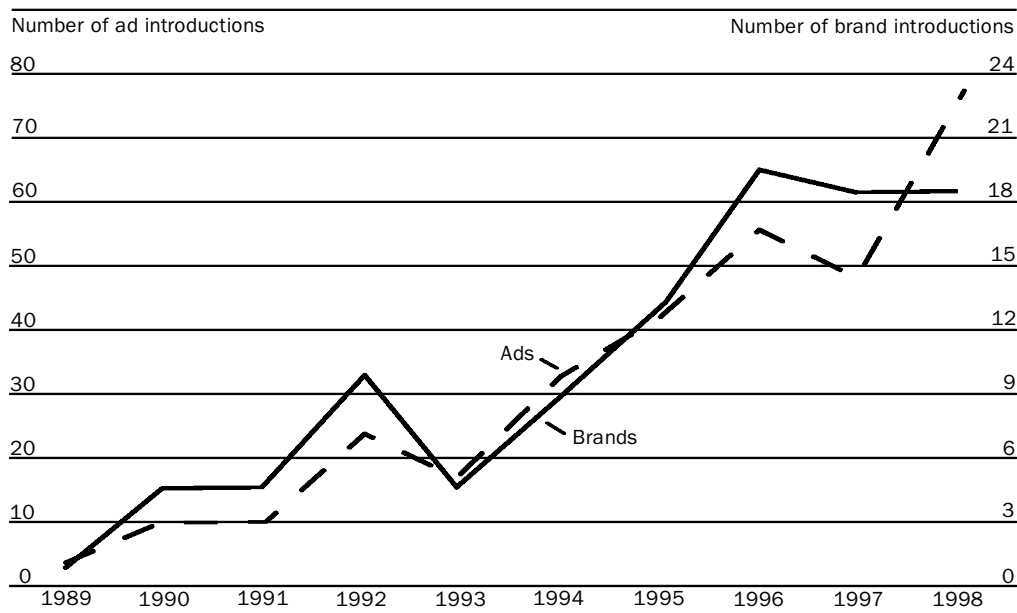
EXHIBIT 1 Prescription Drug Brands Advertised In Lay Magazines, By Medical Condition, 1989–1998

Medical condition	Brand	Number of ads
Allergies	Allegra, Claritin, Claritin-D, Flonase, Hismanal, Seldane, Seldane-D, Zyrtec	46
Obstetrical/gynecological	Climara, Depo-Provera, Estraderm, Monistat 5, Norplant, Ortho-Novum 777, Ortho Tri-Cyclen, Premarin, Prempro, Preven	45
Dermatological	Denavir, Differin, Dovonex, EMLA, Lamisil, Metrogel, Nizoral, Propecia, Renova, Retin-A, Rogaine, Sporanox	37
Cardiovascular	Adalat CC, Calan SR, Cardizem CD, Lotensin, Mevacor, Minitran, Nitrolingual, Pravachol, Procardia XL, Zocor	36
HIV/AIDS ^a	Combivir, Crixivan, Cytovene, Fortovase, Invirase, Norvir, ProCrit, Viracept, Viramune, Zerit, Ziagen	33
Tobacco addiction	Habitrol, Nicoderm, Nicorette, Nicotrol, Prostep, Zyban	23
Urological	Cardura, Caverject, Detrol, Hytrin, Muse, Proscar, Testoderm, Viagra	19
Gastrointestinal/nutritional	Actigall, Marinol, Nascobal, Oxandrin, Prilosec, Transderm-Scop, Zantac	17
Musculoskeletal	Daypro, Evista, Fosamax, Hyalgan, Lodine XL, Naprelan, Relafen	17
Psychiatric/neurological	Ambien, Aricept, BuSpar, Effexor, Felbatol, Imitrex, Prozac	17
Infectious (non-HIV)	Diflucan, Havrix, measles vaccine, Monural, Valtrex, Zithromax	16
Diabetes	Glucophage, Glucotrol XL, Humalog, Rezulin	9
Respiratory	Accolate, Atrovent, Serevent	3
Cancer	Eulexin, Nolvadex	2

SOURCE: Authors' content analysis.

^a HIV is human immunodeficiency virus; AIDS is acquired immunodeficiency syndrome.

EXHIBIT 2
Number Of New Drug Advertisement Introductions And New Drug Brand Introductions, 1989-1998



SOURCE: Authors' content analysis.

what is new is not necessarily better and could even be more risky.²² Many new drugs are “me-too” products that offer few advantages over older drugs and whose safety profiles are less well understood.²³ DTC ads tend to play up the positive features of a drug and downplay the negative or unknown aspects.²⁴ Side effects, for instance, are almost always discussed last. Headings and subheadings usually play up benefits; side effects are typically buried in the narrative.

■ **Public education or brazen marketeering?** There is increasing debate about the advantages and disadvantages of DTC advertising.²⁵ Proponents argue that it serves an educational mission. Others argue that it is contradictory to have a category of drugs called “prescription,” made available through those with specialized training, yet allow those same drugs to be marketed to persons who lack that specialized knowledge.

Ultimately, the argument that DTC promotions educate the public about medical conditions and their treatments hinges on the quality of drug information available to consumers through advertising. However, our analyses found that educational quality is highly variable.²⁶ Virtually all advertisements provide the name of the condition treated by the marketed drug, and most give information about the symptoms of that condition. However, other potentially valuable sources of information were rarely provided. For in-

stance, a cause or risk factor was identified in only 27 percent of advertisements, prevalence information in 12 percent, and clarifications of condition-related myths or misconceptions in 9 percent. Detailed information about treatments also was lacking. For example, the existence of competing treatments was acknowledged in only 29 percent of advertisements (although rarely by name), supportive behaviors through lifestyle changes that could augment treatment were reported in only 24 percent, and an estimate of the drug's success rate was given in only 9 percent.

Our content analyses revealed that 35 percent of advertisements invited the reader to learn more about the drug by obtaining information from the company. We did not study whether these materials provide high-quality education or simply try to sell a product. Increasingly, these advertisements offer additional information to consumers through the Internet. Fourteen percent of advertisements provided a Web site address in 1996; 57 percent did so in 1998. Future research should evaluate the accuracy and educational merit of these "secondary" sources of information.

Impact On The Consumer

To understand DTC advertising from the consumer's perspective, one must consider the recipient (consumer) as well as the message (ad) and the messenger (drug industry).²⁷ It has been suggested that few consumers have the clinical and pharmacologic background to properly understand and evaluate DTC advertisements.²⁸ These advertisements thus may lead to confusion and inaccurate perceptions of a drug's effectiveness and safety. In fact, miscomprehension of drug advertisements has been documented.²⁹ A recent experiment found that the inclusion of both promotional and risk-related information in the same broadcast advertisement adversely affected consumers' ability to understand each type of information.³⁰ Even so, as yet there is no evidence that miscomprehension rates exceed those for advertising in general. We also are unaware of any data comparing comprehension of advertisement-delivered drug information with that of physician-delivered information.

■ **Consumer awareness.** In a recent study we attempted to assess consumers' understanding of and exposure to DTC advertising. We conducted a telephone survey of 329 Sacramento County residents using standard random-selection procedures and a standardized interviewing protocol.³¹ First, we asked respondents whether they paid attention to DTC advertisements. Then we asked if they had seen an advertisement for each of ten drugs being extensively marketed at the time of the survey, as well as one bogus drug included to assess deception. On average, respondents were aware

of ads for 3.7 of the 10 drugs. Women were aware of ads for more drugs than men were. Awareness of DTC advertisements was very much associated with having been diagnosed with a condition for which a given drug was advertised. In addition, persons who were taking other medicines, who had more exposure to magazines, who were in poor health, and who had better health care coverage seemed more aware of DTC advertisements.

In another survey of consumers' receptivity to DTC advertising, Louis Morris and colleagues found that older patients were more accepting of such advertising than younger respondents were. They suggested that older patients may view the taking of prescription drugs as a sign of health, whereas younger ones may consider taking such drugs to be a sign of illness.³²

■ **Consumers' understanding of DTC advertising regulation.**

Few health professionals and even fewer members of the general public understand the regulations surrounding drug promotions. We therefore asked what assumptions consumers make about the regulation of DTC advertising. Half of respondents believed that DTC ads had to be submitted to the government for prior approval, 43 percent believed that only "completely safe" drugs could be advertised directly to consumers, 22 percent thought that advertising of drugs with serious side effects had been banned, and 21 percent believed that only "extremely effective" drugs could be marketed directly to consumers.³³ (All of these statements are untrue.) Thus, a large number of consumers believe that DTC ads carry the imprimatur of the federal government.

■ **Attitudes toward DTC advertising.** How do consumers feel about DTC advertising? The typical consumer in our Sacramento survey was decidedly neutral about the value of DTC advertising (a mean of 3.2 on a five-point scale). Respondents with the most positive attitudes tended to be misinformed about the rigor of government regulation. Our results are in line with earlier investigations. In a consumer survey carried out in the greater Baltimore area in the early 1990s, most respondents believed that DTC advertising could educate the public and would not be confusing to consumers. However, this study revealed skepticism over the claim that DTC advertising would bring down drug prices.³⁴ Stephen Everett found that consumers were open to the idea of making use of DTC advertisements as a source of drug information but were inclined to use these advertisements to supplement more traditional sources of information, including health care professionals.³⁵

■ **Consumers' behavior.** Do these advertisements affect behavior? Fifty-six percent of respondents in the Sacramento survey reported having read a DTC advertisement carefully and completely,

“DTC advertising is viewed as just one more rift in the physician’s cloak of influence and authority.”

35 percent said that they had asked their doctor for more information because of such an ad, and 19 percent reported that they had asked for an advertised drug. Approximately 17 percent claimed to have clipped a DTC ad for later reference, but only 9 percent reported that they had called a drug company for more information.³⁶

There are methodological limitations in asking people how they would behave in a hypothetical scenario. We nonetheless asked survey participants how they would respond if their physician turned down their request for an advertised drug. Nearly half (46 percent) thought that they would be disappointed, 25 percent anticipated that they would try to change their physician’s mind, 24 percent thought that they might attempt to obtain the prescription from a different doctor, and 15 percent thought that they might switch to a new doctor.³⁷ Such reactions were more likely to be reported by respondents who evaluated their relationship with their physician negatively, who held positive attitudes toward DTC advertising, and who overestimated the government’s efforts and ability to regulate it.

Impact On The Medical Profession

Physicians’ attitudes toward DTC advertising are neutral at best and more often quite negative. In a recent study of 454 U.S. family physicians, about four-fifths believed that DTC advertising was “not a good idea.”³⁸ The most common specific concern was that ads increase costs and promote a “misleading, biased view.” In another study involving a smaller but more diverse sample, mean attitudes toward DTC advertising were slightly positive (3.3 on a five-point scale), but there was significant interspecialty variation. For example, the mean scale score for internists was 2.4 (reflecting rather negative attitudes) and for dermatologists 3.5 (fairly positive).³⁹ Together, these two studies suggest that primary care physicians (who happen to treat the majority of conditions targeted by DTC advertising) hold the most negative opinions of such promotions.

What is behind the profession’s reluctance to embrace DTC advertising? One possibility is that they are distrustful of pharmaceutical promotions. To date, data on the accuracy, fairness, and balance of DTC advertisements suggest that information provided by drug companies to physicians is frequently biased, unbalanced, or unbalanced.⁴⁰ In one study, a panel of pharmacists judged that only

65 percent of DTC advertisements presented a fair balance of risk and benefit.⁴¹ They also found that most ads did not specify how the drug should be used.

Another explanation for physicians' resistance is that they do not like losing professional control or are afraid of appearing ignorant or poorly informed. In this view, DTC advertising is just one more rift in the physician's cloak of influence and authority. Ironically, while many physicians oppose DTC advertising, many are themselves regularly influenced by industry sources of information, which can lead to inappropriate prescribing.⁴² Despite these contradictions, physicians and other prescribing professionals may have legitimate reasons to question the proliferation of DTC advertising. Among the charges leveled by some physicians are that DTC advertising promotes inappropriate prescribing, strains the patient/provider relationship, increases the costs of care, and contorts the physician's professional role. In the following sections, we review the evidence for and against these charges.

■ **Effect on prescribing.** DTC advertising clearly increases the volume of prescribed drugs. The question is whether these additional prescriptions are appropriate. Using a well-established definition, a prescription is appropriate when "the health benefits of the drug so outweigh the health risks that the drug is worth taking."⁴³ While proponents of DTC advertising claim that such ads avert underuse of effective medicines without greatly increasing inappropriate use, many physicians are wary of this claim, for three reasons. First, as noted, a study from the early 1990s found substantial inaccuracies in advertisements directed at physicians.⁴⁴ Contrary to the beliefs of many consumers, DTC ads are not subject to mandatory FDA review or approval.⁴⁵ The market is no more likely to ensure the accuracy of DTC advertisements than of ads in medical journals. Thus, even in the absence of direct empirical evidence, physicians have reason to suspect that DTC ads may contain inaccuracies. Assuming that accurate information is a prerequisite for informed discussion, the specter of inaccuracy is a threat to optimal prescribing.

Second, DTC advertising may encourage patients to pressure their physicians to switch them from well-studied treatments to new drugs, for which knowledge about benefits and risks is more limited. In 1991 the American Academy of Pediatrics opposed DTC advertising because it felt that it would encourage demand for treatment not medically indicated and boost inappropriate requests for specific medications.⁴⁶

The third reason for physicians' skepticism is based on indirect evidence. A generation of geographic variations research has shown that it is very difficult to increase or decrease use of health care

services in a way that is clinically selective.⁴⁷ The net public health gain or loss over the long term will be determined by (1) the current prevalence of undertreatment (that is, the number of patients not receiving drug therapy who should be), (2) the amount of inappropriate (that is, harmful) prescribing that might be stimulated by DTC advertising, and (3) the degree of harm accruing to undertreated versus overtreated patients.

■ **Effect on the patient/provider relationship.** Even if the net effect of DTC advertising on the quality of prescribing were neutral or positive, many physicians would object to these promotional efforts based on their perception of how the ads affect the dynamics of the patient/provider relationship. As portrayed in the opening dialogue of this paper and as documented extensively elsewhere, DTC advertising clearly motivates discussions between patients and their physicians about pharmaceutical products. This often requires the physician to reeducate the patient so that expectations are realistic and the message is properly perceived as a promotion.

However, if ad-motivated discussions focus on specific brand-name drugs, trivial complaints, or procurement issues (such as which products are and are not available on formulary), the conversations could detract from more meaningful discussions concerning the basis of a patient's symptoms, the range of available treatments, and the context of a patient's illness. A major concern is that DTC advertising rarely mentions lifestyle changes or other nonpharmacological interventions, which often are as important as pharmacological therapy.⁴⁸ Patients may become angry when their physician insists on discussing a low-fat diet, stress management, or allergen avoidance rather than writing a prescription for Pravachol, BuSpar, or Flonase. In other words, DTC advertising may cultivate the belief among the public that there is a pill for every ill and contribute to medicalization of trivial ailments, leading to an even more "overmedicated" society.⁴⁹

Most of these concerns remain hypothetical, as no empirical study has directly addressed whether DTC ad-motivated discussions enhance or detract from visit efficiency, patient/physician trust, patient and provider satisfaction, or health outcomes. However, our own recent work has shown that physician visits in which patients ask more questions or make more requests are rated by physicians as more demanding (but not necessarily less satisfying).⁵⁰ It is likely that to many physicians, patients presenting a print ad are just one more element of the "hassle factor" that is a key feature of modern medical practice.⁵¹

■ **Effect on the costs of care.** The costs of DTC advertising are both direct and demand-related. Although the direct costs of print

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and broadcast DTC ads are substantial (nearly \$1 billion in 1998), they are dwarfed by demand-related expenditures. Increased consumer interest in advertised drugs and conditions leads to more office visits and tests. For example, IMS Health reported that one year after a DTC campaign for Fosamax, physician visits for osteoporosis evaluation nearly doubled.⁵² Increased consumer demand leads to more prescriptions. The policy question is whether the ad-induced prescriptions are cost-effective. Unfortunately, there is insufficient evidence to answer this question. On the one hand, a few very expensive pharmaceuticals have been shown to be cost-effective relative to their alternatives (for example, surgery). On the other hand, if ad-induced prescriptions are written mainly for low-risk persons with mild disease or cosmetic concerns, such prescriptions could have unfavorable cost-effectiveness ratios.

The tendency for advertising to reduce both mean prices and price variation in other sectors of the economy is unlikely to apply to prescription drugs.⁵³ One reason is that few DTC ads provide information on price. In addition, drug-purchasing decisions require a physician “agent” to interpret technical information, and consumers’ incentives are skewed by health insurance. In any case, the question, “Does advertising increase or decrease health care spending?” is not the right question to ask. First, advertising may increase drug costs to the consumer under certain circumstances but decrease costs in other circumstances. For instance, when there is a competing drug on the market, advertising may promote competition and lower prices. When no such competitor exists, advertising costs may simply be passed on to the consumer. Second, the question does not take drugs’ effectiveness into consideration. An inexpensive drug that is not needed or that treats a trivial condition adds to health spending, whereas a very expensive drug that prevents a costly disease could be a bargain. More research is needed on the kinds of patients who are receiving prescriptions as a result of DTC ads and on the cost-effectiveness of specific agents in these patients. In the meantime, some medical professionals will remain concerned that DTC advertising diverts resources from other critical priorities.

■ **Effect on professional role and morale.** In addition to its possible impact on clinical quality, doctor/patient relations, and health care costs, DTC advertising has the potential to fundamentally alter the roles of doctor and patient. Philosophically, DTC ad-

vertising accelerates the trend toward patient autonomy, which is supplanting beneficence as the guiding ethical principle of medical practice.⁵⁴ At best, this transformation will create better-informed patients, ready to take an active role in setting and reaching their own health goals. At worst, we will have a world of aggressive, distrustful, and only partially informed patients and cowed physicians.

Imagine, for example, a patient who sees an ad for an antidepressant and recognizes her symptoms as suggestive of major depression. As a result of the ad, she reveals these symptoms to Physician A. Physician A performs a careful history and physical exam and considers hypothyroidism a likely explanation for the patient's depression. Testing confirms the diagnosis, and the patient is successfully treated with thyroid hormone replacement therapy. In a different scenario, the patient waves the same ad in the face of Physician B and demands the drug. After taking a cursory history that suggests depressive symptoms, Physician B writes the prescription. Six months later the patient is hospitalized for severe hypothyroidism.

The difference between the two scenarios involves more than the difference between good and bad medicine. The difference is that in the first scenario the ad is a springboard to a thorough investigation of symptoms, development of a reasonable differential diagnosis, and prescription of appropriate therapy. Physician A remembers her professional responsibility to evaluate not just the patient's request but the patient's problem. In the second scenario, Physician B responds to the patient much as a waiter in a restaurant: If it's on the menu and you're not allergic to it, you can have it. The great unknown is whether DTC advertising will create enough demanding patients that more than a few physicians will prescribe drugs against their better judgment. The cost will be measured not only in lower quality of prescribing but also in reduced professionalism, impaired physician morale, and possibly even a sea change in the type of student who is attracted to medicine.

Policy Suggestions And Future Research Needs

Our suggestions for improving the quality of DTC advertising are directed toward the major participants: the industry, the government, and the medical community. We premise our suggestions on the belief that DTC advertising is here to stay. The political power of the industry, the desire of consumers to have access to health information, and technological developments (namely, the Internet) make it impossible for the nation to reverse course. As such, the objective of all parties involved should be to make this form of promotion as useful to consumers as possible.

■ **The industry.** To drug companies, we suggest that it is in the

industry's long-term interest to communicate openly, honestly, and accurately with customers. Price comparisons, detailed explanations of benefits and risks, and discussions of costs are encouraged. We hope that the drug industry will realize that responsible self-regulation and self-policing are the best defenses against unwanted government regulation. We also suggest that (1) product package inserts be written at an appropriate level for most readers; (2) promotions not use technical graphs and charts or pseudoscientific jargon; (3) promotions provide just as much attention to side effects as they do to treatment effects; (4) advertisements be less "drug-centric" and more "disease/medical condition-centric"; and (5) the industry enter into more nonproprietary partnerships with health communication researchers to develop a better understanding of how people process DTC advertising information and to devise strategies to communicate more effectively with consumers.

■ **The government.** The FDA can increase the likelihood of effective self-regulation through strong, well-funded, and aggressive oversight. The FDA also should take the lead in providing accurate, unbiased information to consumers. It is also necessary for the FDA to more fully communicate to the public the role of promotional materials, the role of drug evaluations, and the need for patients to partner with the medical community.

Congress should ensure that the FDA has at the resources it requires to effectively monitor and regulate DTC advertising. In particular, the FDA needs additional staff to ensure a level playing field and to monitor many of the new forms of media, most notably the Internet and other forms of electronic promotion.

The visual elements of advertisements need to be closely monitored. Powerful yet subtle product claims can be made visually. When DTC advertising misleads, it often does so through visual persuasion. Thus, the FDA should adopt the following rules: (1) All advertisements should be required to say that the physician or pharmacist is the single best source of information about whether a particular treatment is appropriate for a particular patient. (2) When data are available, ads must explicitly mention the success and failure rates of each drug and compare those rates with other common products and with "no treatment." (3) When alternative treatments are available, the advertisement should be required to mention these other treatments by name or at least by class. (4) Once independent sources of drug information are available—sources that do not receive any pharmaceutical industry funding—all advertisements should be required to refer consumers to these sources of information.

■ **The medical community.** The medical community needs to

respond vigorously to DTC advertising. Individual physicians and medical associations should monitor of the content of DTC advertisements for accuracy and balance. In addition, organized medicine needs to “counter-advertise” by suggesting the appropriate uses and limitations of medication. The public health community needs to create mechanisms for providing consumers with objective, independent information about available drug therapies, including their indications, risks, benefits, and alternatives. Such information must be placed in the context of education about medical conditions.

The medical community needs to develop a systematic, ongoing media literacy campaign to inform consumers of the promotional nature of DTC advertising, as well as the regulatory context in which it is designed. For example, clinic waiting areas, hospitals, and other health care locations can be used to disseminate reminders to consumers that advertisements in the media are promotional and do not necessarily represent the most objective advice. Similarly, when companies elect to promote products contrary to the advice of respected government agencies, the public should be notified.

The medical community also needs to lobby Congress for research funds to understand better the potential and pitfalls of consumer-targeted prescription drug promotions. In particular, physicians and health care organizations need to understand more clearly what effect DTC advertising is having on pharmaceutical costs and their impact on overall health care costs. Given the huge amounts spent on DTC marketing and the fact that a large part of this is supported indirectly via government drug purchases, it would also be in the public’s interest for policymakers to understand better the impact DTC marketing has on the quality of prescribing.

Each of these suggestions is geared toward assuring the accuracy of information conveyed to the consumer and balancing the legitimate profit motive of pharmaceutical companies with the public’s health. None of these suggestions is likely to stifle creative development of new drugs or disrupt the scientific process.

OVER THE PAST DECADE DTC ADVERTISING has become a major tool to promote pharmaceutical products. At its best, DTC advertising motivates consumers to pursue further information about a product or the disease it purports to cure or help. The few studies that have examined the impact of DTC advertising on the health care system indicate that these promotions are influencing consumers, but there is little research on the clinical consequences. The available empirical findings comport well with our own clinical experience. Patients like Mr. Jones are coming to physicians to request treatment for medical conditions for which they

have not yet been diagnosed or to ask about a change in treatment for established diagnoses. The long-term effects of DTC advertising on the health of patients and the well-being of the health care establishment will require extensive investigation, but such investments in research are worthwhile, given the enormous public health stakes as well as the huge sums of money involved.

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NOTES

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