

Special Article

PROMOTION OF PRESCRIPTION DRUGS TO CONSUMERS

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ABSTRACT

Background Spending on prescription drugs is the fastest growing component of the health care budget. There is public concern about the possibility that direct-to-consumer advertising of prescription drugs will result in inappropriate prescribing and higher costs of care. Guidelines issued in 1997 by the Food and Drug Administration (FDA) regarding advertising to consumers through electronic media are considered by some to be responsible for unleashing a flood of direct-to-consumer advertising.

Methods Using data on spending for promotional purposes and sales of prescription drugs, we examined industrywide trends for various types of promotion. We also tracked the relation between promotional efforts and sales over time. Finally, we documented the variation in direct-to-consumer advertising among and within five therapeutic classes of drugs and compared the variation in the intensity of such advertising with variation in the intensity of promotion to health care professionals.

Results Annual spending on direct-to-consumer advertising for prescription drugs tripled between 1996 and 2000, when it reached nearly \$2.5 billion. Despite this increase, such advertising accounts for only 15 percent of the money spent on drug promotion and is highly concentrated on a subgroup of products. Within a therapeutic class, there is marked variation in the intensity of direct-to-consumer advertising, and the amount of such advertising for specific products fluctuates over time. The initial surge in direct-to-consumer advertising preceded the 1997 FDA guidelines that clarified the rules for electronic direct-to-consumer advertising, and thus the 1997 guidelines may not have been the most important reason for the overall increase.

Conclusions Although the use of direct-to-consumer advertising has grown disproportionately to other forms of promotion, it continues to account for a small proportion of total promotional efforts. Nevertheless, physicians must assist patients in evaluating health-related information obtained through direct advertising. (N Engl J Med 2002;346:498-505.)

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SPENDING on pharmaceuticals has accelerated greatly in recent years and is now the fastest growing component of the health care budget.¹ Part of the growth in pharmaceutical spending is almost surely the result of an increase in the number of highly effective medications. There is widespread concern, however, that increased expenditures too often result from more advertising of drugs that do not provide more effective or efficient care.²

Direct-to-consumer advertising of prescription drugs has become controversial. Proponents argue that such communication by the pharmaceutical industry leads to better-informed consumers and improved quality of care. Critics despair that direct-to-consumer advertising causes physicians to waste valuable time during encounters with patients and encourages the use of expensive and sometimes unnecessary medications, which leads to waste and excessive profits for pharmaceutical companies. A survey found that 71 percent of family physicians believe that direct-to-consumer advertising pressures physicians into prescribing drugs that they would not ordinarily prescribe.³

Guidelines for broadcast advertising promulgated by the Food and Drug Administration (FDA) in 1997 may have facilitated the increased use of direct-to-consumer advertising. Technically, direct-to-consumer advertising through electronic media had been legal for many years, as long as major risks were disclosed and "adequate provision" was made for "information in brief summary relating to side effects, contraindications, and effectiveness" that is included in package labeling.⁴ Confusion arose, however, about what constituted adequate provision. Primarily to clarify the requirement for such adequate provision and requirements for nonmisleading and balanced content, the FDA issued guidelines in August 1997 for the broadcast advertising of prescription drugs di-

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rectly to consumers. The guidelines indicated that an acceptable approach to fulfilling the requirement for adequate provision was to refer in the broadcast to four sources from which consumers could obtain further information: their doctor, a toll-free number, a print advertisement, and a Web site. In addition to changes in the regulatory environment, other factors such as the spread of managed care and changes in consumer attitudes and behavior may have contributed to the increase in direct-to-consumer advertising.

Despite the controversy over this type of advertising, published research remains limited. Most recent studies have focused on the perceptions of such advertising by consumers and health care providers. We know of no analyses of the patterns of direct-to-consumer advertising before and after the release of the FDA guidelines in 1997.^{2,3} We provide data on the use of direct-to-consumer advertising for pharmaceuticals over time and in various categories of products in the contexts of promotional strategies that target physicians and sales trends in the pharmaceutical industry.

METHODS

Collection of Data

We obtained industrywide annual data on the promotion and sales of prescription drugs for the years 1994 through 2000. Data on spending on direct-to-consumer advertising were obtained from IMS Health and Competitive Media Reporting. IMS Health is an independent consulting company that provides data and analysis to the pharmaceutical industry, researchers, the FDA, and numerous state and federal agencies. Competitive Media Reporting tracks local and national advertising campaigns in major media such as television and radio. Advertisements that promote specific products and those that focus on diseases or symptoms without naming a product are both included in the estimates of spending on direct-to-consumer advertising. Competitive Media Reporting does not track Internet advertising or statements of program sponsorship such as those that appear on public television. Other published reports indicate that the expenditures on these types of advertising represent a small portion of total expenditures for direct-to-consumer advertising.⁵

Industrywide data on promotion to health care professionals were collected from IMS Health. Four major components of spending on promotion to professionals are reported here: detailing (providing information on a product in a face-to-face meeting) to office-based physicians, detailing to hospital-based physicians, free samples left with physicians, and advertising in professional journals. Because IMS Health does not track spending on meetings and events, this element of promotion to professionals does not appear in our analysis. Other published data indicate that such activities account for 12 to 15 percent of promotional efforts targeted at health care professionals.⁶

IMS Health estimates spending on detailing on the basis of information provided by a national panel of 6443 office-based physicians and hospital directors of pharmacy who track their contacts with pharmaceutical sales representatives. Data on the retail value of free samples provided by pharmaceutical companies were also obtained from IMS Health, which uses a panel of 1265 members of the front-office staff in medical practices (sampled from the practices of the office-based physicians who are on the panel involved in collecting the data on detailing) to monitor the quan-

tity of the drugs provided by sales representatives in the form of samples. The stratified random sample of physicians who record the information on promotion-related contacts is representative, in terms of detailing activity, of the universe of hospital- and office-based physicians in the continental United States; the data on free samples are representative of samples given to office-based physicians only.

IMS Health also collects data on advertising spending and the number of advertisements placed in roughly 400 medical journals. Estimates of the printing costs for journal advertisements were added to the publisher's charge for advertisements to obtain estimates of total spending on journal advertising. Industrywide sales data were obtained from published reports based on the annual survey conducted by Pharmaceutical Research and Manufacturers of America; this survey, in turn, relies on sales data from IMS Health.⁷

Data on promotion to health care professionals and sales of specific products (e.g., Claritin) were obtained from Scott-Levin, an independent consulting company. Scott-Levin's detailing projections were obtained from a panel of more than 11,000 office- and hospital-based physicians in 31 specialties, accounting for 2 percent of the physicians in the United States. Data on sales of prescription drugs were collected by means of an audit of more than 36,000 retail pharmacies, accounting for approximately 65 percent of the retail pharmacies in the United States.

Statistical Analysis

Our analyses are descriptive. Using data on promotion-related spending and sales, we examined industrywide trends for various types of promotion. Our principal comparison was between direct-to-consumer advertising and all promotion to health care professionals. Advertising is the principal method the industry uses to reach consumers; it accounts for approximately 95 percent of expenditures on promotion targeted at consumers. The four methods of promotion to professionals that we included account for 85 to 88 percent of the dollars spent by pharmaceutical companies to reach physicians. We also tracked the relation between promotional efforts and sales over time.

Finally, we documented the variation in direct-to-consumer advertising among and within five therapeutic classes of drugs and compared the distribution of the intensity of direct-to-consumer advertising with that of promotion to professionals. The five therapeutic classes (antidepressants, antihistamines, antihyperlipidemics, nasal sprays, and proton-pump inhibitors) were selected because they rank among the top 20 therapeutic classes in terms of sales and contain at least one product for which there is substantial spending on direct-to-consumer advertising. Within each class of drugs, we show product-specific promotional spending patterns for the leading brands and compare the variation in the intensity of direct-to-consumer advertising with the variation in the intensity of promotion to professionals.

RESULTS

Industrywide Trends in Promotion

There has been an upward and accelerating trend in spending on direct-to-consumer advertising for prescription drugs in recent years (Fig. 1). Spending on direct-to-consumer advertising increased by 212 percent between 1996 and 2000 (Table 1). In 1996, direct-to-consumer advertising accounted for 9 percent of total spending on promotion, whereas in 2000 it accounted for just under 16 percent. Nevertheless, promotion to health care professionals still accounts for more than 80 percent of the money spent on the promotion of prescription drugs. While

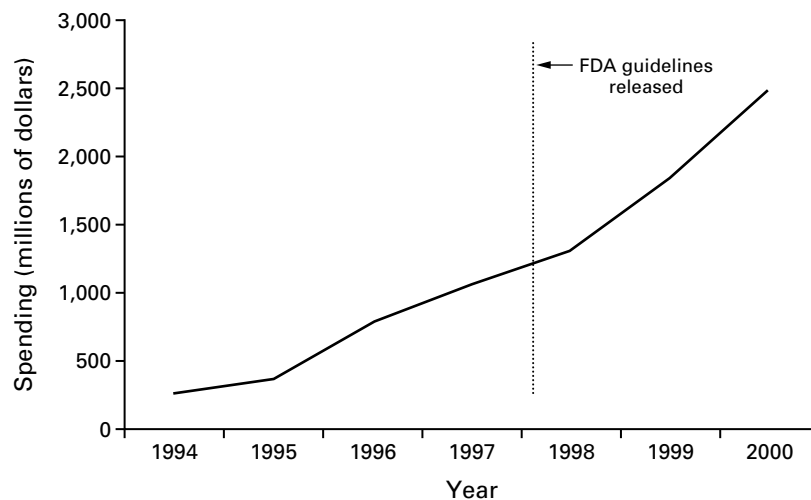


Figure 1. Trend in Spending on Direct-to-Consumer Advertising between 1994 and 2000.

TABLE 1. SPENDING ON DIRECT-TO-CONSUMER ADVERTISING AND PROMOTION TO HEALTH CARE PROFESSIONALS, 1996 THROUGH 2000.*

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

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

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

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

spending on direct-to-consumer advertising increased by \$1.7 billion between 1996 and 2000, spending on the promotion of prescription drugs to physicians (including the retail value of free samples) increased by nearly \$5 billion.

The greatest percentage increase in spending on

direct-to-consumer advertising occurred in spending on television advertising, which increased by a factor of more than seven between 1996 and 2000 (Table 1). Other forms of promotion, particularly advertising in professional journals and hospital-based promotion, have declined in importance relative to total

promotional efforts. In 2000, nearly twice as much money was spent on print advertising targeted at consumers as on advertising in professional journals.

Since 1996, total spending on promotion for prescription drugs has grown by approximately 70 percent (Table 1). Relative to product sales, however, total spending on promotion has remained fairly constant at 14 to 15 percent and has, in fact, fallen very slightly since 1998. This relatively constant relation may reflect the fact that recent increases in spending on promotion, particularly for high-priced drugs, are driving the growth of spending, about one third of which, some have argued, is attributable to the increasing numbers of high-priced drugs on the market.⁸

Variation in Direct-to-Consumer Advertising

Direct-to-consumer advertising has not been adopted as a marketing strategy for every pharmaceutical product. Unlike promotion to professionals, which is used for nearly all brand-name drugs, spending on

direct-to-consumer advertising is concentrated on a few products. In 2000, the 20 prescription drugs for which spending on direct-to-consumer advertising was greatest accounted for about 60 percent of the total industry spending on such advertising (Table 2). Prescription drugs for which spending on direct-to-consumer advertising is high are sold by many different drug companies and belong to a wide variety of therapeutic classes, including antidepressants, antihistamines, antihyperlipidemics, and antiinflammatory agents.

When we compared the direct-to-consumer advertising efforts for selected classes of drugs, we found substantial variation in the intensity of spending on such advertising: the ratio of expenditures to sales for the class with the highest expenditures was 23 times as high as the ratio for the class with the lowest expenditures (Table 3). By contrast, spending on promotion to professionals as a percent of sales varied by a factor of only three among the five classes.

TABLE 2. TOP 20 DRUGS IN TERMS OF SPENDING ON DIRECT-TO-CONSUMER ADVERTISING IN 2000.*

RANKING	TRADE NAME OF DRUG	TYPE OF DRUG	SPENDING ON DIRECT-TO-CONSUMER ADVERTISING
			millions of dollars
1	Vioxx	Antiinflammatory	161
2	Prilosec	Antiulcer	108
3	Claritin	Antihistamine	100
4	Paxil	Antidepressant	92
5	Zocor	Antihyperlipidemic	91
6	Viagra	Erectile-dysfunction therapy	90
7	Celebrex	Antiinflammatory	79
8	Flonase	Antiinflammatory for nasal allergies	78
9	Allegra	Antihistamine	67
10	Meridia	Weight loss	65
11	Flovent	Antiasthmatic	63
12	Pravachol	Antihyperlipidemic	62
13	Zyrtec	Antihistamine	60
14	Singulair	Antiasthmatic	59
15	Lipitor	Antihyperlipidemic	59
16	Nasonex	Topical corticosteroid for nasal allergies	53
17	Ortho Tri-Cyclen	Oral contraceptive	47
18	Valtrex	Antiviral for genital herpes	40
19	Lamisil	Antifungal for toenail fungus	39
20	Prempro	Hormone	38
All 20 combined			1,451
Total percentage of industry spending on direct-to-consumer advertising			58.8

*Data are from Competitive Media Reporting.

TABLE 3. DIRECT-TO-CONSUMER ADVERTISING FOR SELECTED CLASSES OF DRUGS IN 1999.*

CLASS OF DRUGS	SPENDING ON DIRECT-TO-CONSUMER ADVERTISING		SPENDING ON PROMOTION TO HEALTH CARE PROFESSIONALS	
	MILLIONS OF DOLLARS	PERCENTAGE OF SALES	MILLIONS OF DOLLARS	PERCENTAGE OF SALES
Antidepressants	32	0.5	985	14.4
Antihistamines	237	6.1	481	12.4
Antihyperlipidemics	92	1.5	525	8.7
Nasal sprays	115	11.6	245	24.7
Proton-pump inhibitors	80	1.4	644	11.2
Variation in intensity of promotion†		23.2		2.8

*Data on direct-to-consumer advertising are from Competitive Media Reporting; data on sales and promotion to health care professionals are from Scott-Levin.

†The variation was calculated by dividing the highest ratio of expenditures to sales by the lowest ratio of expenditures to sales.

Within a given therapeutic class of drugs, pharmaceutical companies make a substantial investment in direct-to-consumer advertising for some products but a much smaller investment for others (Table 4). For example, whereas most of the non-sedating antihistamines were advertised to consumers in 1999, among proton-pump inhibitors, only Prilosec was advertised to consumers during 1999. Similarly, Paxil was the only antidepressant for which substantial investments were made in direct-to-consumer advertising in 1999, despite the existence of a number of competitors in the market.

Spending on direct-to-consumer advertising for a specific product and for entire therapeutic classes fluctuated substantially over time (Fig. 2). Some of these patterns could have resulted in part from seasonal variation in the symptoms of the conditions treated by the drugs being advertised. For instance, spending on advertising for non-sedating antihistamines used to treat seasonal allergies dropped substantially in December and January, when persons with such allergies typically do not have symptoms. Temporal patterns in the spending on advertising for antidepressants were even more varied than those for antihistamines: first, a direct-to-consumer advertising campaign was launched for Effexor, followed, with little temporal overlap, by campaigns for Prozac, Serzone, and Paxil.

DISCUSSION

Over the past decade, the pharmaceutical industry has altered its marketing strategies, dramatically increasing the flow of dollars into advertising that tar-

gets consumers. Total spending on direct-to-consumer advertising for prescription drugs has been increasing since the early 1990s and has more than doubled since 1996. Despite this rapid growth, such advertising still accounts for only 15 percent of the promotion-related budgets of pharmaceutical companies. The continued importance of promotion to health care professionals reinforces the conventional wisdom that physicians are unlikely to prescribe a drug unless they are familiar with it and are comfortable prescribing it. It may thus be accurate to characterize direct-to-consumer advertising as a marketing strategy that complements rather than displaces promotional efforts targeted at professionals, especially in the case of indications for which alternative therapies exist.

The ratio of overall spending on promotional efforts to sales has changed little over time; the increase in spending on direct-to-consumer advertising represents a shift in the particular combination of marketing tools used rather than an increase in the intensity of the total promotional effort. This constancy, however, may reflect the success of direct-to-consumer advertising in generating increasing sales, especially of high-priced drugs.

The relatively moderate emphasis on direct-to-consumer advertising by the pharmaceutical industry contrasts with the apparent degree of concern about it among physicians and policy makers. There are a number of possible reasons for the furor over such advertising. First, there has been a high rate of growth in spending for direct-to-consumer advertis-

TABLE 4. DIRECT-TO-CONSUMER ADVERTISING AND SALES FOR SELECTED PRODUCTS IN 1999.*

DRUG	SPENDING ON DIRECT-TO-CONSUMER ADVERTISING		SALES	SPENDING ON DIRECT-TO-CONSUMER ADVERTISING AS A PERCENTAGE OF SALES
	millions of dollars			
Antidepressants	32		6,843	0.5
Celexa	0		358	
Effexor	0		639	
Paxil	32		1,452	2.2
Prozac	0		2,447	
Serzone	0		291	
Zoloft	0		1,656	
Antihistamines	226		3,879	5.8
Allegra	43		738	5.8
Astelin	0		52	
Claritin	126		2,526	5.0
Semprex-D	0		12	
Zyrtec	57		552	10.4
Antihyperlipidemics	92		6,045	1.5
Lescol	1		255	0.4
Lipitor	56		2,660	2.1
Mevacor	0		286	
Pravachol	0		1,037	
Zocor	35		1,807	2.0
Nasal sprays	114		990	11.6
Beconase	0		20	
Flonase	53		490	10.9
Nasacort	9		78	12.0
Nasonex	52		264	19.8
Rhinocort	0		94	
Vancenase	0		44	
Proton-pump inhibitors	80		5,731	1.4
Aciphex	0		23	
Prevacid	0		2,059	
Prilosec	80		3,649	2.2

*Data are from Competitive Media Reporting and Scott-Levin. Percentages were calculated from unrounded numbers.

ing, and because nearly all of the recent increase in spending has gone to television advertising, it is highly visible. Second, pharmaceutical costs are now the fastest growing component of the health care budget, and some worry that direct-to-consumer advertising leads to inappropriate and wasteful prescribing. This concern may be justified by previous findings that demand by patients is the most common reason offered by physicians for inappropriate prescribing.⁹ Third, advertising targeted at consumers almost surely adds to physicians' workloads by requiring them to help patients interpret the information presented by advertisers. In bypassing the physician, pharmaceutical companies have disrupted long-standing conventions governing the doctor-patient relationship.

The reasons for the dramatic acceleration in direct-to-consumer advertising of prescription drugs are complex and not fully understood. Since increases in direct-to-consumer advertising preceded 1997, the data are more consistent with the argument that the regulatory guidelines of the FDA were issued partly in response to increased interest in consumer promotion on the part of pharmaceutical companies and were not the sole inspiration for such interest. The growing desire of patients to be involved in decisions about their health care, driven in part by the plethora of health-related information available on the Internet, may have motivated pharmaceutical companies to reach out to consumers. In addition, the spread of managed care and the use of formularies may be increasing the awareness of prices on the part of physicians and hospitals so that some forms of promotion to professionals are not as productive relative to direct-to-consumer advertising as they might once have been.

There is considerable variability among and within classes of drugs in the use of direct-to-consumer advertising as a marketing strategy. Moreover, in contrast to spending on detailing, spending on direct-to-consumer advertising is highly concentrated on a few products; for most drugs, no money is spent on such advertising. Our data cannot reveal what drives the decision to invest in direct-to-consumer advertising. There appear to be high levels of spending on such advertising for prescription drugs used to treat chronic conditions and drugs associated with a low incidence of mild side effects. In general, spending on such advertising also seems to be high for newer products or products that have no generic competitors. Products whose patents are expiring have less to gain from advertising, since they will soon face heightened price competition. There are a few instances, however, in which manufacturers may advertise heavily drugs approaching the end of their patent protection. For example, companies may launch advertising campaigns for products when they are approved for a new indication, in an attempt to differentiate them from other products in their class (e.g., Paxil for social anxiety disorder in 1999) or in order to build brand loyalty in anticipation of a switch to over-the-counter status (e.g., histamine H₂-receptor antagonists such as Pepcid).¹⁰ Although particular events in the life cycles of products and other characteristics of the products may reasonably explain some of the patterns we observed in spending on direct-to-consumer advertising, it is also likely that manufacturers are engaging in a substantial amount of experimentation with this relatively new marketing tool.

The implications of the increase in direct-to-consumer advertising for prescription drugs depend on how consumers perceive and act on the information

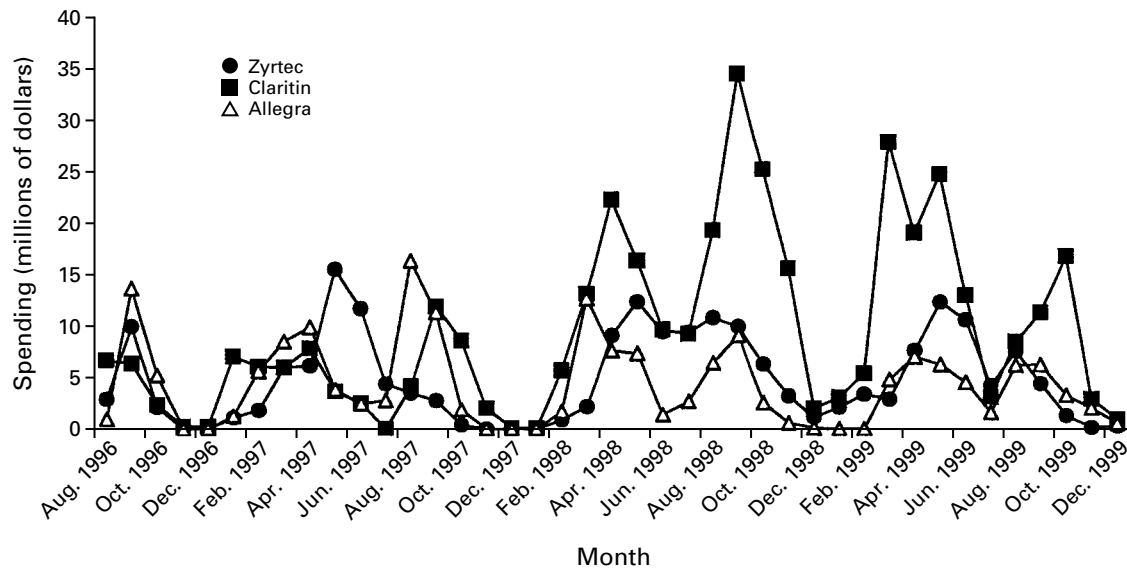


Figure 2. Spending on Direct-to-Consumer Advertising for Major Brands of Nonsedating Antihistamines between August 1996 and December 1999.

made available through advertising. Surveys of consumers support two preliminary conclusions.¹¹ First, people have a general awareness of advertising for prescription drugs (80 percent of those surveyed had seen an advertisement for a prescription drug), and this awareness has grown substantially over time. Second, many patients have initiated conversations with their doctors about a drug they saw on television (25 percent of those surveyed). Relatively few people surveyed (less than 6 percent), however, actually received a prescription for the advertised drug after being prompted by direct-to-consumer advertising to ask their doctor about the drug. Although these data suggest that direct-to-consumer advertising may be having a moderate effect on the market, whether the use that stems from such advertising is appropriate or inappropriate is not known.

Our findings should be interpreted in the light of the strengths and weaknesses of our data. The data we used were collected by independent consulting companies and do not rely on the reports of pharmaceutical manufacturers. As we have noted, several elements of the budgets for promotion were not available for our analyses, including spending on meetings and events and spending on Internet advertisements. There may be other kinds of efforts engaged in by pharmaceutical companies in addition to explicit promotion, such as so-called studies that have a substantial promotional component, whose magnitude

we cannot estimate. Despite this limitation, it is unlikely that our qualitative conclusions, which relate to the rate of change in spending on direct-to-consumer advertising and its importance relative to promotion to health care professionals, would be changed by the availability of more comprehensive data.

The majority of promotional efforts in the pharmaceutical industry continue to focus on the physician. Although direct-to-consumer advertising is unlikely to replace physician-oriented promotion of prescription drugs, it is likely to continue at current or higher levels. In some sense, direct-to-consumer advertising is a part of the growing store of health-related information available to consumers through electronic media that is transforming the physician-patient relationship. Consumers' access to both commercial and independent information about health has both benefits and costs that must be recognized. Some potential benefits are improved diagnosis, better matching of therapy to the needs and preferences of patients, and possibly enhanced compliance. The potential costs are inappropriate prescribing driven by the demands of misinformed patients and time wasted by physicians in explaining why a particular therapy or product is not appropriate. In this context, it is particularly important for physicians to develop strategies for helping their patients evaluate this information and make appropriate and informed choices about treatments. The challenge, then, is to

create mechanisms for facilitating the efficient exchange of information between doctors and patients.

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