ECONOMIC AND BUDGET ISSUE BRIEF

CBO

A series of issue summaries from the Congressional Budget Office

DECEMBER 2, 2009

Promotional Spending for Prescription Drugs

Pharmaceutical companies' efforts to promote prescription drugs have attracted the attention of policymakers because such activities may affect the rate at which different drugs are prescribed and consumed, the total amount spent on health care, and, ultimately, health outcomes. Those promotional activities—usually undertaken on behalf of brand-name, rather than generic, drugs—may influence consumers and health care professionals through a variety of channels. For example, advertisements for prescription drugs that are aimed at consumers may prompt individuals to seek medical treatment they might otherwise have delayed. Such advertisements may also influence individuals to request a specific drug that is higher or lower in price or that is more or less effective than one they had previously used. Promotional efforts aimed at physicians may help them keep abreast of the latest drug therapies and improve their ability to treat patients. Those efforts may also lead doctors to prescribe brand-name medications that are more expensive than alternatives.

The way that pharmaceutical manufacturers promote prescription drugs has changed significantly in the past decade. Until the late 1990s, pharmaceutical manufacturers confined their marketing efforts largely to physicians and other health care providers. In the late 1990s, however, drugmakers began marketing directly to consumers—a practice known as direct-to-consumer (DTC) advertising. The Food and Drug Administration (FDA) issued draft regulatory guidance in 1997 (which was finalized two years later) that clarified the agency's expectations about the way information in DTC advertisements should be presented in the broadcast media. Since then, the manufacturers of many prescription drugs have increased their purchases of air time on television and of advertising space in newspapers and magazines in an effort to make consumers aware of their products and to encourage them to visit their doctors to request a prescription. In 2008, spending on DTC advertising totaled $4.7 billion, nearly one-fourth of pharmaceutical manufacturers' expenditures for all promotional activities. Those developments may be having an impact on the functioning, cost, and effectiveness of the nation's health

Marketing to Physicians and Consumers

Drug companies use advertising and promotions in much the same way that producers of other goods do: to inform consumers about an advertised product's existence and uses and, if alternatives are available, to persuade consumers that the advertised product is better than competing products. If successful, advertising can spur demand for the good and therefore boost its producer's sales and profits. Pharmaceutical manufacturers incur most of the costs of producing a drug during the research and development phases and during the process of gaining the FDA's approval to put the drug on the market. Any additional sales that advertising generates can be highly profitable because the prices that manufacturers receive for their products generally exceed the cost to manufacture and distribute those additional units.

Drug companies face a different task in making sales than do the producers of most consumer goods, however, because several separate actors must be persuaded that a prescription drug merits purchasing. First, a consumer must perceive that visiting a doctor to seek diagnosis and treatment offers a benefit. Then, following an examination to diagnose the patient's condition, the doctor must determine an appropriate treatment and, when warranted, write a prescription. Finally, the consumer must fill that prescription for the manufacturer to make a sale. (In many cases, the individual's insurer can also influence prescription drug purchases by determining whether or not to include a drug on the formulary of drugs it covers and by deciding how large a copayment to assign to it.[1])

Recognizing that both consumers and physicians take part in the decision to purchase a drug, pharmaceutical manufacturers adopt different marketing strategies for reaching

1. Pharmaceutical manufacturers promote their products to health insurers and pharmacy benefit managers (PBMs) to encourage them to include their products on plans' formularies and to assign those products a low copayment. See, for example, SDI, "SDI Reports: Takeda Touts New Drugs to Managed

each group. Direct-to-consumer advertising appears in magazines and newspapers, on television and radio, on outdoor billboards, and increasingly online. Drug companies also promote their products to physicians in a variety of ways. They send sales representatives to meet with physicians, nurse practitioners, and physicians' assistants in a practice called detailing. During those sales calls, the representatives discuss drugs manufactured by their company that are relevant to the physician's specialties, and they may provide product samples and reprints of academic literature that discuss their company's products. In addition to detailing, pharmaceutical manufacturers purchase advertisements for their drugs in medical journals. They also sponsor professional meetings and events, both in person and online, including some that offer physicians credit for continuing medical education.[2]

Overall Marketing Trends

Pharmaceutical manufacturers spent at least $20.5 billion on promotional activities in 2008.[3] Detailing to physicians, nurse practitioners, and physicians' assistants cost $12 billion, accounting for more than half of that promotional spending (see Figure 1). Drug companies spent another $3.4 billion sponsoring professional meetings and events and about $0.4 billion placing advertisements in professional journals. Pharmaceutical manufacturers spent the rest of their promotional budgets, $4.7 billion in 2008, on direct-to-consumer advertising. To place those figures in context, the Pharmaceutical Research and Manufacturers of America (PhRMA) estimated that, among its members, domestic sales of pharmaceuticals and medicines totaled $189 billion in 2008 and domestic spending on research and development totaled $38 billion.[4] In 2008, promotional expenditures equaled 10.8 percent of the U.S. sales reported by PhRMA, in line with most years since the early 1990s, during which time that share has remained between 10 percent and 12 percent.

The growth of pharmaceutical manufacturers' overall promotional spending has slowed from a double-digit annual pace in 2003 and 2004 to a rate that is close to zero. That slowdown is probably related, at least in part, to the decline in the number of new drugs that have received FDA approval since 2000. In the second half of the 1990s, the FDA approved an unusually large number of drugs, some of which were the first on the market to treat certain conditions and a number of which treat widespread conditions. Not only are fewer new drugs being approved of late, but more drugs also face competition from generic versions. Those factors may be particularly important in explaining declining spending on DTC advertising, which peaked at $5.2 billion in 2006, because pharmaceutical manufacturers tend to use more DTC advertising for drugs that have especially broad potential markets, drugs with few or no substitutes, or drugs with some combination of those characteristics.

To study the potential effects of promotional spending for prescription drugs, the Congressional Budget Office (CBO) analyzed data from SDI, a company that collects and sells information about the pharmaceutical industry. CBO examined data on promotional activities from 1989 to 2008 for drugs in the classes of medications that include most outpatient drugs that were produced in tablets or capsules and were among the top-selling drugs in 2003.[5]

Direct-to-Consumer Marketing

Until the late 1990s, the use of DTC advertising was limited, consisting mainly of print advertisements that presented the required disclosure of the risks associated with the advertised product in a manner similar to the

2. In several recent cases, the appropriateness of certain promotional activities undertaken by pharmaceutical companies has been called into question and some companies have come under scrutiny for promoting products for uses not approved by the FDA. See, for example, Department of Justice, "Justice Department Announces Largest Health Care Fraud Settlement in Its History" (press release, Washington, D.C., September 2, 2009).

3. That amount (obtained from SDI Promotional Audits) does not include the expense of the free samples that pharmaceutical manufacturers distribute to physicians, which one study estimated to have a retail value of $18.4 billion in 2005. See Julie M.Donohue, Marisa Cevasco, and Meredith B. Rosenthal, "A Decade of Direct-to-Consumer Advertising of Prescription Drugs," *New England Journal of Medicine*, vol. 357, no. 7 (August 16, 2007), pp. 673–681. It also excludes other activities that may have promotional value, such as efforts targeting PBMs and research grants that encourage studies and publications about products.

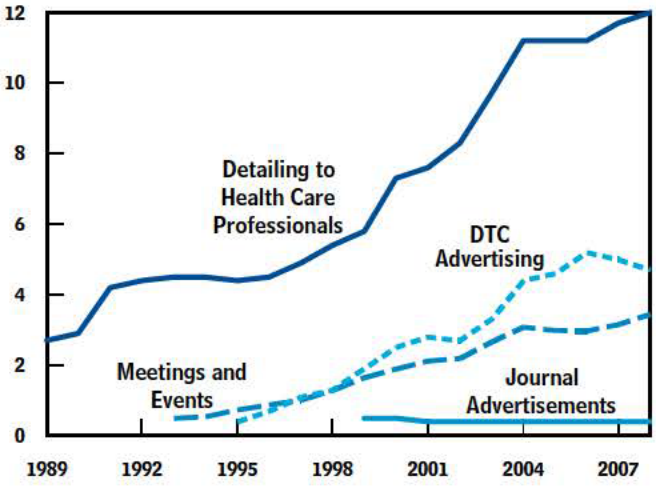
4. Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile 2009* (Washington, D.C.: PhRMA, April 2009).

5. CBO's data set was constructed using information from SDI's Promotional Audit Suite. The data set includes 111 drug classes as defined by the IMS Uniform System of Classification and covers a majority of the top 200 (in dollar sales) outpatient brand-name drugs sold in solid form (for oral administration) in 2003 and their closely related therapeutic substitutes. Other dosage forms are not included in the data set. The starting date for each type of promotional spending varies, as SDI has expanded its data collection to include other types of promotional spending.

Figure 1.

Promotional Spending by Type of Marketing Activity, 1989 to 2008

(Billions of dollars)



Source: Congressional Budget Office based on data from SDI Promotional Audits.

Notes: The starting date for each type of marketing reflects the date at which SDI began including the series in its collection of data.

Detailing refers to the practice in which pharmaceutical representatives make sales calls to physicians and other health care professionals to discuss the uses of a particular prescription drug and its benefits for patients.

DTC = direct to consumer.

summaries offered in advertisements directed to physicians. Television advertising was less popular, however, because presenting the labeling information required by the FDA in a 30- or 60-second commercial proved impractical.[6] A guidance document issued by the FDA in draft form in August 1997 and finalized two years later laid out an approach for pharmaceutical manufacturers to use in radio and television commercials that would comply with the risk-disclosure requirement. Instead of presenting all of the potential adverse effects as they appear in the package labeling, drugmakers could provide a brief summary and refer viewers to a toll-free number, Web site, physician, or print advertisement that would provide more-detailed information about potential risks and side-effects.[7] Subsequent guidance documents from the FDA focused on similar issues in print advertisements.

Since the FDA published its draft guidance document on DTC advertising in the broadcast media, drug companies have spent most of their DTC budgets on television commercials. However, some observers have questioned how carefully DTC advertising—especially television commercials—balances the presentation of a drug's potential benefits and risks, as well as whether such advertising plays a useful role in the nation's health care system.[8]

In 2008, pharmaceutical manufacturers spent $2.6 billion on DTC advertising for the drugs in CBO's data set, equal to about 55 percent of the industry total for that year. Television commercials, including those broadcast on cable stations, accounted for $1.6 billion of those outlays, while expenditures for print advertising totaled about $900 million. The newest outlet for direct-to-consumer advertising—the Internet—still represents a small share of such advertising. Drug companies spent $93 million in 2008 on online banner and display ads and for ad time in streaming video presentations for the drugs in CBO's data set. In addition to that amount, drug companies also purchased sponsored links on search engines and hosted their own product- or disease-specific Web sites. Regulators have begun issuing warnings to manufacturers to ensure that the presentation of risks and benefits in Internet advertisements complies with the law.[9]

Different Marketing Strategies for Different Drugs

Pharmaceutical manufacturers use different marketing strategies for the drugs they produce. Many drugs are promoted solely to physicians, with no attempt to reach

6. See statement of Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, Food and Drug Administration, before the Senate Special Committee on Aging, *Regulating Prescription Drug Promotion* (July 22, 2003).

7. For the final version of the draft guidance document, see Department of Health and Human Services, Food and Drug Administration, *Guidance for Industry: Consumer-Directed Broadcast Advertisements* (August 1999).

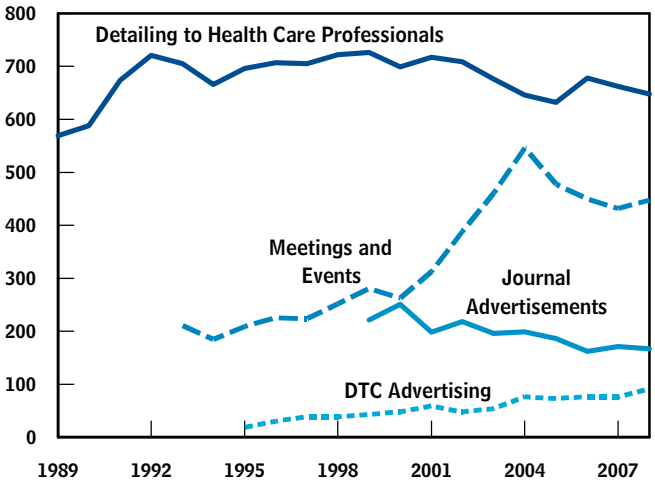
8. See, for example, *Direct-to-Consumer Advertising: Marketing, Education, or Deception?,* hearing before the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce (May 8, 2008); and *The Impact of Direct-to-Consumer Advertising on Seniors' Health and Health Care Costs,* hearing before the Senate Special Committee on Aging, Serial No. 109-14 (September 29, 2005).

9. See, for example, Department of Health and Human Services, Food and Drug Administration, Warning Letter to Johnson & Johnson regarding a Webcast video promoting Ultram ER, May 12, 2009; and Warning Letter to Bayer Healthcare Pharmaceuticals, Inc., regarding sponsored links on Internet search engines for Levitra, Yaz, and Mirena, March 26, 2009.

Figure 2.

Promotional Activity for Prescription Drugs in CBO's Data Set, 1989 to 2008

(Number of drugs)



Source: Congressional Budget Office based on data from SDI Promotional Audits.

Notes: The starting date for each type of marketing reflects the date at which SDI began including the series in its collection of data.

Detailing refers to the practice in which pharmaceutical representatives make sales calls to physicians and other health care professionals to discuss the uses of a particular prescription drug and its benefits for patients.

DTC = direct to consumer.

consumers. Others are heavily promoted to consumers and, in varying degrees, to physicians as well.

That different marketing strategies are used for different drugs is not surprising because there is no consensus among experts about the effects of such strategies on the sales or prices of prescription drugs. For DTC advertising, studies that have analyzed the effects for a few specific drugs or classes of drugs have shown mixed results; the writing and filling of prescriptions increased for some advertised drugs but not for others.[10] For detailing, some analyses have found positive effects on the number of prescriptions written for the targeted drug, but others suggest that detailing's effects are unclear.[11]

Of the more than 2,000 drugs included in CBO's data set, 700 to 800 have some promotional spending reported in any given year. For nearly all of those drugs, some spending on detailing was recorded. However, manufacturers purchased DTC advertisements for fewer than 100 of those drugs in each of the years since 1995, the year the data set begins to encompass DTC advertising, making DTC advertising the least frequently used form of drug promotion (see Figure 2). Journal ads and professional meetings are used to promote fewer drugs than detailing but more drugs than DTC advertising.

Though pharmaceutical manufacturers use DTC advertising for only a small set of drugs, they spend heavily on DTC advertising for those drugs. For those drugs in the data set that were promoted using DTC advertising, average expenditures for such advertising peaked at $41.8 million in 2006. The average detailing expenditure for drugs promoted through detailing that year was $10.4 million. Drug companies spend far less per drug to promote drugs through advertisements in medical journals or by sponsoring professional meetings and events. In 2008, for the drugs in CBO's data set with such expenditures, they spent about $1 million per drug on journal advertisements and $3.6 million per drug on meetings and events.

Drugs promoted using DTC advertising are, on average, newer to the market than drugs promoted through detailing, but the difference in the average expenditures for DTC advertising and detailing seems largely a result of the distribution of the two types of spending. Drug companies spend similarly large annual amounts on detailing and DTC advertising for a few drugs (in some cases, more than $200 million a year on each); but they spend small amounts on detailing for many more drugs. Among the

10. See W. David Bradford and others, "How Direct-to-Consumer Television Advertising for Osteoarthritis Drugs Affects Physicians' Prescribing Behavior," *Health Affairs,* vol. 25, no. 5 (September/October 2006); and Michael R. Law, Sumit R. Majumdar, and Stephen B. Soumerai, "Effect of Illicit Direct to Consumer Advertising on Use of Etanercept, Mometasone, and Tegaserod in Canada: Controlled Longitudinal Study," *BMJ*, vol. 337

11. Some studies suggest that detailing may have positive effects on the number of prescriptions written for a given drug. See Natalie Mizik and Robert Jacobson, "Are Physicians 'Easy Marks'? Quantifying the Effects of Detailing and Sampling on New Prescriptions," *Management Science*, vol. 50, no. 12 (December 2004), pp. 1704–1715; Puneet Manchanda and Pradeep K. Chintagunta, "Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis," *Marketing Letters*, vol. 15, no. 2-3 (2004), pp. 129–145; and Michael A. Steinman and others, "Characteristics and Impact of Drug Detailing for Gabapentin," *PLoS Medicine,* vol. 4, no. 4 (April 2007). Other studies find no clear effects from detailing. See Meredith B. Rosenthal and others, *Demand Effects of Recent Changes in Prescription Drug Promotion* (Menlo Park, Calif.: Kaiser Family Foundation

drugs in CBO's data set, the 10 with the highest DTC expenditures in 2008 accounted for 30 percent of expenditures for DTC advertising industrywide. That concentration is nearly twice what was observed for detailing, where the 10 drugs with the highest expenditures totaled 16 percent of the industry's detailing expenditures. That difference may be explained, in part, by the fact that detailing visits can include discussions of more than one product while each DTC advertisement typically focuses on only one drug.

According to CBO's analysis, when pharmaceutical manufacturers promoted drugs to consumers, they also spent more, on average, promoting those drugs to physicians. For those drugs in CBO's data set with reported spending on DTC advertising, their manufacturers spent an average of $40.5 million per drug in 2008 on promotional activities directed to physicians—14 times the average amount they spent when promoting drugs exclusively to physicians. That difference may indicate that manufacturers use promotional activities directed to physicians and DTC advertising to reinforce each other. Although DTC advertising might spur a consumer to visit his or her doctor, the physician must prescribe the drug; therefore, manufacturers would seek to ensure that physicians were also informed about the drugs they advertised to consumers. Alternatively, pharmaceutical manufacturers could have spent extensively to promote to physicians those drugs marketed with DTC advertising even if advertising to consumers was not permitted, perhaps because of the size of the potential market for those drugs.

DTC advertising is almost never used in isolation. Detailing is far more likely to be the exclusive promotional outlet for a drug. Even if manufacturers find that it is not useful to promote certain drugs directly to consumers—for example, because the condition they treat is relatively rare—drug companies would still want to ensure that doctors know about their product and any advantages it has over its competitors.

Market Characteristics That Influence Promotional Strategies

A pharmaceutical manufacturer's decision to use DTC advertising or other types of marketing tools depends on the potential size of the market for a given prescription drug, the current competition in that market, and the amount of time that has elapsed since the drug received FDA approval. Manufacturers may also choose to alter their marketing mix over time, especially as new competitors enter the market, the manufacturer faces the end of a drug's patent protection and the entry of generic versions on the market, or the manufacturer introduces new dosage forms, extended-release versions of a drug, or new combination drugs. The balance of this brief focuses on those issues for the two largest components of pharmaceutical manufacturers' promotional expenditures—detailing and DTC advertising.

Market Size

Treatments for common conditions that affect a large portion of the population—such as high cholesterol, insomnia, or reduced bone density—are a primary focus of direct-to-consumer advertising. Many top-selling drugs have some of the highest DTC advertising expenditures. Drugs that have large potential markets are likely candidates for direct-to-consumer advertising because a substantial share of the intended audience may benefit from the treatment and may seek out and receive a prescription for the advertised drug. That effect may be even more important if that large potential market includes many individuals whose condition is undiagnosed or untreated. Drugs that treat rare illnesses are less likely to be the subject of DTC advertising because manufacturers would have to spend considerable amounts to reach the few individuals suffering from such illnesses.[12]

If a drug has both a large potential market and is approved to treat chronic or long-term conditions, its manufacturer may be even more likely to embrace DTC advertising.[13] For those drugs, individuals who receive a prescription may continue with the advertised drug for a long time, producing a steady stream of sales for the pharmaceutical company if it succeeds in building brand loyalty. For patients already taking an advertised drug, DTC advertisements may serve as a reminder to refill the prescription. DTC advertising is less common for drugs (such as antibiotics) that address acute conditions (such as an infection)—perhaps because individuals are more likely to seek care for an acute condition without being prompted

12. Internet advertising may offer a more targeted approach for manufacturers whose products treat rare conditions. To date, however, there are no apparent differences between drugs advertised online and those advertised in more traditional media.

13. See General Accounting Office, *Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations,* GAO-03-177 (October 2002), p. 13.

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