

Potential Effects of a Ban on Direct-to-Consumer Advertising of New Prescription Drugs

Summary and Introduction

Direct-to-consumer (DTC) advertising of prescription drugs has elicited various concerns. One concern is that DTC advertising may add to spending on drugs by consumers, insurers, and the federal government without providing enough benefits to justify that spending; specifically, some observers worry that DTC advertising encourages broader use of certain drugs than their health benefits warrant. Another concern is that DTC advertising for newly approved drugs may lead people to use drugs whose potential risks were not fully discovered during the drug approval process. Those concerns have spurred recent proposals for a moratorium on advertising brand-name prescription drugs to consumers during the first two years following a drug's approval by the Food and Drug Administration (FDA). Although such a moratorium would allow more time for safety concerns about a new drug to be revealed, it would entail health risks of its own, because some individuals who would benefit from a new drug might be unaware of its availability in the absence of consumer advertising.

A moratorium on direct-to-consumer advertising might affect other marketing strategies used by drug manufacturers and the quantities and prices of drugs sold. To highlight some of those effects, this Congressional Budget Office (CBO) issue brief draws on data documenting DTC advertising and other promotional activities used by pharmaceutical producers as well as academic analyses of how advertising has affected the market for drugs. The expected effects of a moratorium include the following:

- Drug manufacturers would probably expand their marketing to physicians to substitute for at least some of the banned advertising to consumers.
- The number of prescriptions filled would probably decrease for some drugs. For other drugs, the number of prescriptions might be little changed, owing both to the likely substitution of other types of promotions

and to the various other factors that influence a drug's reach in the prescription drug market.

- Any change in prescription drug prices would depend on changes in demand; to the extent that the effects on demand are likely to be limited, so too are the effects on prices.

In addition, a moratorium could affect public health. That impact is uncertain, depending on whether the benefits of fewer unexpected adverse health events were larger than the health costs of possibly reduced use of new and effective drugs.

Use of and Concerns About DTC Advertising

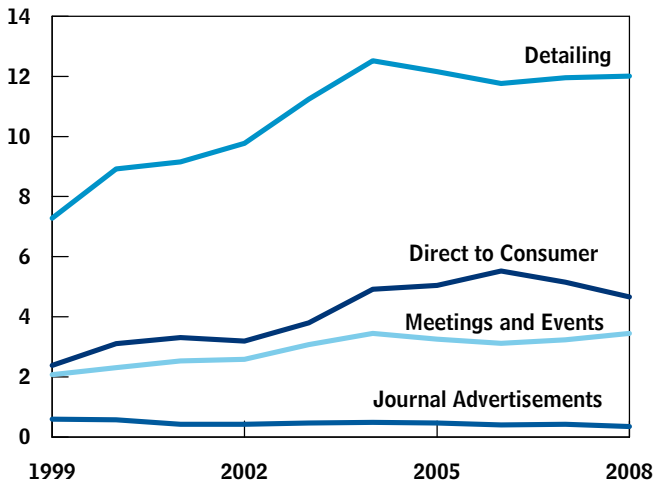
Consumer advertising of prescription drugs and the economic and health concerns that surround it have been an issue since at least the late 1990s, when pharmaceutical manufacturers intensified their efforts to promote prescription drugs directly to consumers. Until then, drug makers had focused their marketing efforts on physicians and other health care providers.

That change came about as a result of new guidelines issued by the FDA. In 1997, the agency issued draft regulatory guidance (which was finalized two years later) that clarified the rules about the way DTC advertisements in the broadcast media present drug information. Since then, many prescription drug manufacturers have increased their purchases of television and radio air time, as well as newspaper and magazine advertising space, to make consumers aware of drug makers' products and to encourage consumers to visit their doctors for more information.

In 2008, spending on DTC advertising totaled \$4.7 billion, nearly one-fourth of pharmaceutical manufacturers' expenditures for all promotional activities (see Figure 1).

Figure 1.**Marketing Expenditures, by Type, for Prescription Drugs**

(Billions of 2008 dollars)



Source: Congressional Budget Office based on data from SDI's promotional audits.

Note: 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.

The rest of the \$20.5 billion that pharmaceutical manufacturers spent on promotional activities in 2008 was directed at physicians and other health care professionals.¹ In a practice called “detailing,” drug makers send representatives to visit physicians, nurse practitioners, and physicians’ assistants to discuss their products and to provide samples and reprints of academic literature on their company’s products. Pharmaceutical manufacturers also target physicians by advertising their drugs in medical journals and by sponsoring professional meetings and events, both in person and online. Except in rare cases, promotional spending directed at either consumers or physicians is on behalf of brand-name drugs that do not yet face competition from generic drugs.

Policymakers have expressed concerns about pharmaceutical manufacturers’ efforts and expenditures to promote their prescription drugs. One set of concerns centers around whether those promotions may lead to higher prices for prescription drugs or to expanded use of advertised prescription drugs—in particular, expanded use of drugs that may provide relatively little benefit from that

additional use. Another set of concerns centers around public health and whether expanded use of new drugs might expose consumers to unnecessary risk.

Concerns about manufacturers’ efforts to market their drugs led an Institute of Medicine committee to recommend in 2007 that the FDA require pharmaceutical manufacturers to refrain from advertising drugs to consumers during the first two years following a drug’s approval.² Although all prescription drugs must undergo testing for safety and efficacy before receiving approval from the FDA, the expanded patient population that consumes a drug once it is released on the market may bring to light safety problems that smaller, preapproval clinical trials did not reveal. The newest drugs on the market tend to be among the most heavily promoted, raising the risk that more people will be adversely affected before steps can be taken to identify and address such potential safety problems.

The Congress has considered, but has not adopted, several bills in recent years that would limit DTC advertising of prescription drugs. Some bills would grant the FDA the authority to prohibit DTC advertising of a prescription drug for the first two or three years after the drug is approved for sale.³

A moratorium on DTC advertising for newly approved drugs could have various effects on the marketing of prescription drugs, their demand and supply, and public health. To study the potential effects of such a ban, CBO analyzed data from SDI and IMS Health (two companies that collect and sell information on the pharmaceutical industry) and reviewed academic research on advertising in prescription drug markets. CBO examined data from

2. The committee also recommended that the FDA require manufacturers to mark the packaging of new drugs with a special symbol that would alert patients that the product is new and may have unknown health risks. See Institute of Medicine, Committee on the Assessment of the US Drug Safety System, *The Future of Drug Safety: Promoting and Protecting the Health of the Public* (2007), p. 171.
3. See Responsibility in Drug and Device Advertising Act of 2008, H.R. 6151, 110th Cong., 2nd sess. (2008); and Food and Drug Administration Revitalization Act, S. 1082, 110th Cong., 1st sess. (2007). Other proposed legislation would change the effective price of DTC promotions for pharmaceutical companies by denying them the ability to deduct their spending on DTC advertising as a business expense on their tax returns. See Say No to Drug Ads Act, H.R. 722, 112th Cong., 1st sess. (2011); Protecting Americans from Drug Marketing Act, S. 1763, 111th Cong., 1st sess. (2009); and Fair Balance Prescription Drug Advertisement Act of 2007, H.R. 2823, 110th Cong., 1st sess. (2007).

1. Congressional Budget Office, *Promotional Spending for Prescription Drugs*, Issue Brief (December 2009).

SDI on promotional activities from 1999 to 2008 and on prescription drug sales from 2004 to 2008.

From IMS Health, CBO received data on prescription drug sales from 1999 to 2004. All of the data cover brand-name and generic drugs in the classes of medications that include most outpatient drugs that were produced in tablet or capsule form and were among the top-selling drugs in 2003.⁴

The Role of Prescription Drug Promotion

Selling a prescription drug is a multistage process. The first step in that process is typically for a person to perceive that there is some benefit in visiting a doctor to seek treatment for a health problem. 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. (In many cases, the individual's insurer can influence prescription drug purchases by determining whether to include a drug on the formulary—or list of drugs it covers—and by deciding how large a copayment to assign to it.)⁵

Advertising for most products is intended to make consumers aware that such a product exists, inform them of its purpose, and, in some cases, persuade them that the advertised product is better than its rivals. The ultimate aim of the advertising is to encourage a consumer to choose a product and purchase it through whatever retail channel is available (typically in a store, by telephone, or through a Web site).

Prescription drug advertising cannot prompt consumers to take such independent action because they must receive a prescription before obtaining a drug; however, that advertising can lead them to consult a doctor about their condition and to ask about the advertised medication as a treatment option. Only physicians and other

4. CBO's data set includes promotional and sales data for 93 drug classes as defined by the IMS Uniform System of Classification. It 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.

5. Pharmaceutical manufacturers promote their products to health insurers and pharmacy benefit managers 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 Care" (press release, Plymouth Meeting, Pa., August 31, 2009).

Table 1.

Promotional Spending for Newly Approved Drugs, 1999 to 2008

Type of Promotional Spending	Two-Year Spending per Drug (Millions of 2008 dollars)	Number of Drugs
Direct to Consumer	71	73
Detailing	46	335
Meetings and Events	14	242
Journal Advertisements	3	260
Any Type	68	366

Source: Congressional Budget Office based on data from SDI's promotional audits.

Notes: Drugs included in one type of spending may also be included in other types. For example, the drugs with direct-to-consumer advertising expenditures in their first two years also had detailing expenditures in those years, so the spending on detailing for those drugs in their first two years is included in the calculation of per-drug detailing expenditures.

For this analysis, drugs are considered newly approved during the first two years following approval by the Food and Drug Administration.

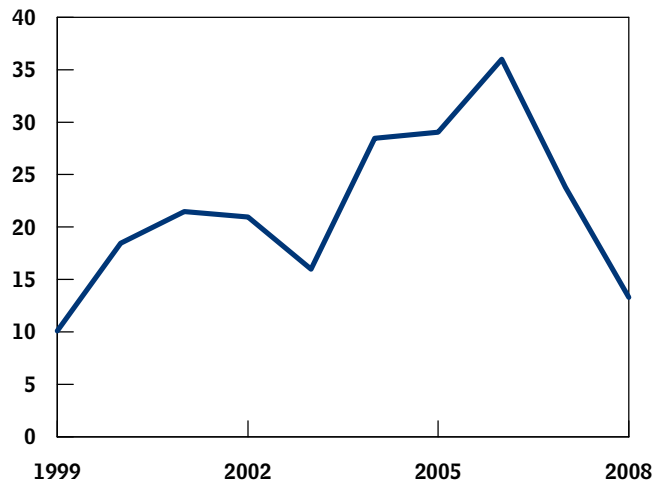
health care professionals can write prescriptions, which explains why drug manufacturers target them with most of their promotional spending.

Although pharmaceutical manufacturers use DTC advertising to promote only a small set of specific drugs, they spend heavily on such advertising for those drugs. From 1999 to 2008, CBO's data set included 366 brand-name drugs that were promoted to physicians and other health care professionals—through detailing, journal advertisements, professional meetings, or some combination of the three approaches—during the first two years following approval by the FDA. Of those 366 drugs, 73 were also advertised directly to consumers. For those 73 drugs, pharmaceutical manufacturers spent an average of \$71 million per drug on DTC advertising during the two-year period that would correspond to a moratorium (see Table 1). To promote the larger set of drugs to physicians, manufacturers spent an average of \$54 million per drug over the two-year period, of which \$46 million was for detailing. Thus, the average amount spent on advertising to physicians was less than the average amount spent on advertising to consumers for those drugs for which advertising to consumers occurred.

Figure 2.

DTC Advertising Expenditures for Newly Approved Drugs as a Share of All Promotional Expenditures for Those Drugs

(Percent)



Source: Congressional Budget Office based on data from SDI's promotional audits.

Notes: For this analysis, drugs are considered newly approved during the first two years following approval by the Food and Drug Administration.

DTC = direct to consumer.

Over the 1999–2008 period, manufacturers varied their emphasis on consumers in their promotional spending for drugs during their first two years on the market (see Figure 2). That variation may have resulted in part from the relative newness of DTC advertising in the early part of that period because the FDA did not finalize its regulatory guidance on broadcast advertising for prescription drugs until August 1999.⁶ The changing characteristics of the new drugs approved by the FDA over the decade probably also contributed to the variation in the emphasis on DTC advertising over time. Between 2004 and 2006, when DTC advertising peaked as a share of promotional spending for new drugs, a large portion of the drugs in CBO's data set that were less than two years old were counted among the top-selling drugs in the country. DTC advertising's share of promotional spending for new drugs has declined since then because drugs approved more recently have not had such broad potential markets.

6. Department of Health and Human Services, Food and Drug Administration, *Guidance for Industry: Consumer-Directed Broadcast Advertisements* (August 1999).

Advertising to consumers is frequently used to make the public familiar with treatments for common conditions that affect a large portion of the population (such as high cholesterol, insomnia, or depression), for drugs that address chronic conditions, and for medications for widely untreated diseases. The top-selling drugs in any given year are frequently among the drugs with the largest expenditures for DTC advertising.⁷ The total dollar value of retail sales and the total number of retail prescriptions filled for drugs in CBO's data set that were advertised to consumers generally exceeded the retail sales and prescriptions for brand-name drugs without such advertising. Between 2004 and 2008, the average annual number of prescriptions for brand-name drugs in CBO's data set with DTC advertising was nearly 14 times the average annual number of prescriptions for brand-name drugs without such advertising. Distinguishing cause and effect between advertising and sales is difficult, however. For drugs that have large potential markets, pharmaceutical manufacturers may be more likely to spend more on advertising to consumers because a substantial share of the advertising audience may be candidates to take the drug.

In 2007 and 2008, there were fewer newly approved drugs in CBO's data set than in the preceding few years, and an even smaller number that were top sellers. Manufacturers submitted and the FDA approved fewer applications for new brand-name drugs than they had a decade earlier, and fewer still with large potential markets like a number of the drugs that obtained FDA approval in the 1990s.⁸ As a result, among the drug classes in CBO's data set, new brand-name drugs made up a small and shrinking share of all retail sales of brand-name drugs, falling from nearly 10 percent in 1999 to less than 2 percent in 2008.⁹

The share of brand-name prescriptions attributed to drugs within their first two years after FDA approval exhibited a similar pattern, suggesting that lower sales, rather than declining drug prices, caused the drop in the

7. For a more detailed discussion of drugs' characteristics and promotional spending, see Congressional Budget Office, *Promotional Spending for Prescription Drugs*.

8. Congressional Budget Office, *Pharmaceutical R&D and the Evolving Market for Drugs*, Issue Brief (October 2009).

9. Over the same period, a qualitatively similar decline in the sales of new brand-name drugs as a share of all brand-name drugs occurred for drugs purchased through the Medicaid program, which includes a broader set of drugs than those in CBO's data set.

share of retail sales for new drugs. New drugs accounted for 7 percent of brand-name prescriptions in 2004, but that share fell to less than 2 percent in 2008. The total number of brand-name prescriptions in CBO's data set was dropping at the same time, from roughly 1 billion in 2004 to roughly 700 million in 2008, while the total number of prescriptions for generic drugs increased at a double-digit pace; during that period, patents expired for a number of older brand-name drugs, and prescriptions shifted to new generic versions of those drugs. The combination of a declining number of brand-name prescriptions and a declining share of those prescriptions representing new drugs meant that the number of prescriptions for new brand-name drugs plummeted. The number of prescriptions for newly approved brand-name drugs without DTC advertising fell from 19 million in 2004 to 5 million in 2008, and the number of prescriptions for newly approved brand-name drugs with DTC advertising dropped from 61 million in 2004 to 7 million in 2008 (see Figure 3).

Potential Effects of a Moratorium on DTC Advertising in a Drug's First Two Years

In the context of overall sales and use of prescription drugs, the magnitude of any effects of limiting direct-to-consumer advertising for newly approved drugs would probably be small because such a small share of drugs would be affected. Nevertheless, the impact on sales and use of individual drugs could be substantial because a number of changes could occur in response to a moratorium on advertising to consumers.

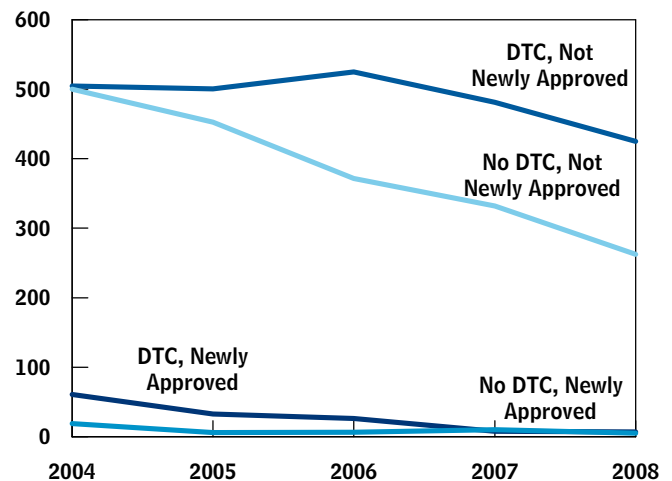
Promotional Spending Patterns

A moratorium that forced pharmaceutical manufacturers to discontinue DTC advertising for drugs in their first two years following FDA approval would probably alter the timing and the amount of promotional spending in general, and would certainly alter spending on DTC advertising in particular, for some drugs. Pharmaceutical manufacturers' promotional spending patterns—their choices about how much to advertise a drug and how to balance those advertisements between consumers and physicians—depend on a number of different factors, including the drug's characteristics, the intended population of patients, the competitive environment in which that drug is sold, and the drug's historical sales. Moreover, once a drug has been on the market for a time, its sales history may yield further information about how well known it is to patients and physicians, the brand loyalty

Figure 3.

Number of Retail Prescriptions of Brand-Name Drugs, by DTC Advertising Use and Age of Drug

(Millions)



Source: Congressional Budget Office based on data from SDI's promotional audits.

Notes: For this analysis, drugs are considered newly approved during the first two years following approval by the Food and Drug Administration.

DTC = direct to consumer.

of the patients taking it, and whether it is preferred over its therapeutic substitutes. In light of all of the factors that affect promotional spending and all of the alternative options for that spending, a moratorium on DTC advertising for the first two years following FDA approval could have a variety of effects on the timing, amount, and patterns of drug makers' spending on marketing.

Pharmaceutical manufacturers faced with a moratorium on DTC advertisements for new drugs could substitute other types of promotion for the banned activities while the moratorium was in effect. In many cases, drug makers would probably expand their promotions to physicians by spending more on detailing, professional meetings, and journal advertisements. An expanded effort to market the drugs affected by a DTC moratorium to physicians would be a reasonable, but not perfect, substitute for DTC advertising for many drugs. For some drugs, however, a moratorium might so significantly reduce the ability of physician-oriented marketing to increase sales that drug companies would spend less on marketing those drugs to physicians under such a moratorium.

Substituting promotions to physicians for banned advertising to consumers could be especially important for brand-name drugs that have close competitors. Physicians consider competing drugs when determining which to prescribe to patients, so they could be an important audience for manufacturers trying to improve—or at least maintain—their competitive positions. Alternatively, if a ban on DTC advertising addressed only product-specific advertising, drug makers might shift their efforts toward disease advertising to consumers that omitted any mention of a specific product and instead described the condition a drug is approved to treat and encouraged patients to contact their doctors to discuss treatment options.¹⁰ That strategy would be likely to work best for drugs without close competitors, because they have no clear substitutes that could benefit from any increase in demand from the advertisement.

When the period of the moratorium expired for a drug, its manufacturer could compare the drug's sales to the size of the market for that drug. If there was a substantial gap, the drug company might look to DTC advertising to help close it in the years remaining before generic competitors entered the market. To quickly improve sales before patent protection expires, drug makers could even spend more on DTC advertising over the life of a drug than they would have spent in the absence of a moratorium.

On the other hand, the literature on the effects of DTC advertising on drug sales suggests that sales of some drugs that pharmaceutical manufacturers would otherwise advertise to consumers might not be substantially affected by a moratorium on advertising in the first two years of a drug's life. For those drugs, the sales volume during the moratorium might lead a pharmaceutical firm to advertise at a lower level than it would have without the moratorium or to forgo DTC advertising altogether in later years.

Demand, Supply, Prescriptions, and Prices

Pharmaceutical manufacturers advertise their products directly to consumers in an attempt to boost demand for their products and thereby raise the price that consumers are willing to pay, increase the quantity of drugs sold, or

achieve some combination of the two. For prescription drugs, that task may be more difficult than for other products because the decision to purchase a prescription drug is not entirely the individual's; rather, it depends also on his or her physician's decisions about what to prescribe and, in many cases, his or her health insurer's choices about what to cover. As a result, even if an advertisement increases an individual's demand for a drug, it may not translate into more prescriptions or higher prices for the advertised drug.

Although the expense of DTC advertising may contribute significantly to the total cost to produce and sell a drug, that expense does not vary automatically with the amount of a drug that the manufacturer produces or distributes.¹¹ DTC advertising is therefore not likely to be a factor in determining a firm's supply of a drug in the short term, but it may have an effect on long-run decisions about new drug development.

Prescriptions. Among the drugs in CBO's data set, the average number of prescriptions written for newly approved brand-name drugs with DTC advertising was nine times greater than the average number of prescriptions written for newly approved brand-name drugs without DTC advertising. However, the drugs that pharmaceutical manufacturers advertise to consumers are not generally equivalent to the drugs that they do not advertise. Treatments for common conditions that affect a large portion of the population are a primary focus of DTC advertising. Drug makers are less likely to heavily advertise products that treat rare illnesses because they would have to spend considerable amounts to reach the relatively few individuals who have those conditions.¹² That factor and others make it difficult to attribute differences in the average number of prescriptions written to the DTC advertising itself: Doctors are likely to write

10. Neither the Institute of Medicine nor the legislation the Congress has considered specifies whether the intended moratorium would affect all advertisements for a newly approved drug equally or whether advertising that mentions diseases and symptoms without naming a particular drug would be permitted.

11. Ernst R. Berndt, "Pharmaceuticals in U.S. Health Care: Determinants of Quantity and Price," *Journal of Economic Perspectives*, vol. 16, no. 4 (Fall 2002), pp. 45–66.

12. Although drugs that address rare conditions are not likely to be the subject of television or print advertising that reaches a broad audience, they may be promoted in a more targeted way online through search and banner advertisements or social networking sites such as Facebook or Twitter. Data on Internet advertising expenditures do not extend beyond banner advertising, however, making analysis difficult. The FDA has issued warnings about the incompleteness of risk information in pharmaceutical advertising in online searches and is studying advertising in social media platforms.

more prescriptions for drugs that can treat a large number of patients than they are for drugs with a much more limited patient population, regardless of the types of promotional efforts for each drug.

A moratorium on DTC advertising in the first two years would probably result in a smaller number of prescriptions for some drugs that would have been advertised. Several studies have found that DTC advertising spurs individuals to visit their doctors, although physicians do not always prescribe the drug whose advertisement prompted the visit.¹³ Another study of drugs in five therapeutic classes showed that DTC advertising for a drug increased sales of that drug and other drugs in the same therapeutic class but did not change each drug's share of the market.¹⁴ In two other studies, researchers limited their investigations to two or three drugs and found that DTC advertising increased prescriptions for some advertised drugs but not for others.¹⁵

Another drug characteristic that may factor into the effect of DTC advertising on prescriptions is whether a drug is a first-in-class treatment or a new competitor in an established market. Without the possibility of DTC advertising, pharmaceutical manufacturers may see their opportunity to create a market for a first-in-class drug and to benefit from its monopoly status delayed or diminished. That outcome could, in turn, reduce their incentive to research and develop new breakthrough therapies. (However, if permitted, the use of advertisements that mention diseases and symptoms but do not mention a product name could mitigate some or all of the effects of a moratorium on DTC advertising for drugs without close competitors.)

13. Toshiaki Iizuka and Ginger Zhe Jin, "The Effect of Prescription Drug Advertising on Doctor Visits," *Journal of Economics & Management Strategy*, vol. 14, no. 3 (September 2005), pp. 701–727; John E. Calfee, Clifford Winston, and Randolph Stempfski, "Direct-to-Consumer Advertising and the Demand for Cholesterol-Reducing Drugs," *Journal of Law and Economics*, vol. 45, no. S2, pt. 2 (October 2002), pp. 673–690; 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), pp. 1371–1377; and Joel S. Weissman and others, "Physicians Report on Patient Encounters Involving Direct-to-Consumer Advertising," *Health Affairs*, Web exclusive (April 28, 2004).

14. Meredith B. Rosenthal and others, *Demand Effects of Recent Changes in Prescription Drug Promotion* (Menlo Park, Calif.: Henry J. Kaiser Family Foundation, June 2003).

For new drugs entering an established market, the number of prescriptions written may be relatively unaffected by a moratorium on advertising new drugs to consumers because drug manufacturers could expand their promotions to physicians in that case. Pharmaceutical companies already spend less, on average, on consumer advertising for drugs in classes with more competitors because patients for those drugs already know that treatments are available for their condition.¹⁶ Gaining sales for a new entrant in those cases may depend more on physicians' deciding to switch patients to the new drug than on patients' being made aware that a new medication exists and seeking treatment they otherwise would not have looked for.

For older drugs, the moratorium on advertising to consumers for their newly approved competitors would probably have two competing effects on the number of prescriptions for the older drugs. To the extent that the DTC advertising for a new drug would have drawn new patients to seek treatment and doctors would have prescribed the older drugs to some of those new patients, fewer prescriptions would be written for those older drugs than would have been written in the absence of the moratorium. However, those older drugs could also benefit from a moratorium on advertising new drugs to the extent that it caused them to lose fewer sales to the new entrant than they would have otherwise. That latter effect would be more likely to dominate the former effect if drug companies' expanded marketing to physicians was less successful in boosting market share than DTC advertising would have been.

Prices. Analysis of pricing practices in the pharmaceutical industry suggests that a moratorium on DTC advertising for new drugs would affect the prices of prescription drugs for which it changed the demand. For example, the price of a drug that would have been advertised to consumers in the absence of the moratorium would generally be lower than it would have been if demand was smaller as a result of the moratorium. In many cases, however,

15. 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," *British Medical Journal*, vol. 337, no. 7669 (September 6, 2008); and Bradford and others, "How Direct-to-Consumer Television Advertising for Osteoarthritis Drugs Affects Physicians' Prescribing Behavior."

16. For more details, see Congressional Budget Office, *Promotional Spending for Prescription Drugs*.

pharmaceutical manufacturers would probably respond to a moratorium on DTC advertising by substituting other types of promotional activities that would mitigate the drop in demand, so a ban on advertising new drugs could have little effect on the prices of some drugs subject to the ban.

Insurance coverage for prescription drugs may also limit the effect that a moratorium on consumer advertising of new drugs has on demand for those drugs and therefore on drug prices. Insurers decide which drugs to include on their formularies (the lists of prescription drugs whose purchase is covered, at least to some extent, by the insurance) partly on the basis of the prices, rebates, and discounts they are able to negotiate with drug manufacturers.¹⁷ To encourage their subscribers to choose certain drugs, insurers set lower copayment or coinsurance amounts for those drugs. As a result, individuals' demand for certain drugs can depend as much on insurers' actions as on drug makers' promotional activities, including DTC advertising.

Older drugs not directly subject to a moratorium on consumer advertising could still see their prices affected by a ban on DTC advertising for newly approved drugs. To the extent that those older drugs would have benefited from new competitors' advertising pushing up demand for all the products in the market, a moratorium on that advertising would result in lower demand and thus lower prices for those incumbent drugs. However, to the extent that advertising for the new drug would have drawn demand away from older drugs, drug makers might face higher demand and be able to charge higher prices for the older drugs than they would have in the absence of a moratorium.

Public Health

Concerns about large numbers of patients taking drugs whose safety and possible side effects might not be fully understood underpin proposals to impose a two-year moratorium on DTC advertising for newly approved prescription drugs. Indeed, researchers have found a link between the promotional activities that pharmaceutical manufacturers use to expand the market for their drugs and increased reporting to the FDA of adverse events

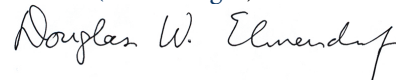
from a greater number of people taking those drugs.¹⁸ A moratorium on consumer advertising would provide more time for possible safety problems with some drugs to be uncovered and to become widely known.

However, a moratorium on DTC advertising that delayed the widespread use of new drugs could also worsen—rather than enhance—public health in some ways. Positive effects on health from DTC advertising could be lost or delayed: Some studies have found that DTC advertising spurs individuals to seek treatment when they otherwise might not and improves patients' compliance with prescribed drug regimens.¹⁹ Therefore, for drugs whose health benefits outweigh their safety and other concerns, a moratorium might reduce their use by a portion of the population who would benefit from the drugs. Moreover, in some cases, a moratorium on consumer advertising could postpone the realization of a drug's true risks—if, for example, the number of people taking the drug was reduced enough by a moratorium that the full risks were not discovered as quickly.

18. Guy David, Sara Markowitz, and Seth Richards, *The Effects of Pharmaceutical Marketing and Promotion on Adverse Drug Events and Regulation*, Working Paper 14634 (Cambridge, Mass.: National Bureau of Economic Research, January 2009).

19. Iizuka and Jin, "The Effect of Prescription Drug Advertising on Doctor Visits"; and Marta Wosinska, "Direct-to-Consumer Advertising and Drug Therapy Compliance," *Journal of Marketing Research*, vol. 42, no. 3 (August 2005).

This brief was prepared by Sheila Campbell. It and other CBO publications are available at the agency's Web site (www.cbo.gov).



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17. For more details, see Congressional Budget Office, *Prescription Drug Pricing in the Private Sector* (January 2007).