

# Direct-to-Consumer Advertising of Prescription Drugs: The Evidence Says No

Joel Lexchin and Barbara Mintzes

*There is little rationale for direct-to-consumer advertising of prescription drugs. Most new drugs offer little if any therapeutic advantage over existing products. Direct-to-consumer advertisements frequently downplay safety information. Physicians are highly ambivalent about prescribing advertised drugs requested by patients. There is no evidence that direct-to-consumer advertising results in any improvement in health outcomes.*

John Calfee (2002) argues in favor of direct-to-consumer (DTC) advertising primarily by citing data from surveys conducted by the Food and Drug Administration and *Prevention Magazine* about consumers' opinions, attitudes, beliefs, and recall of past behaviors. This focus on survey data means that he omits any detailed discussion of work that has directly analyzed the content of DTC advertisements and the relationship between promotion and physician prescribing. In doing so, he leaves key questions unasked.

These questions include the following: Which drugs are advertised to the U.S. public? What is the likelihood that stimulating increased use of these products will lead to health improvements? What is the quality of content of the DTC advertisements? How do DTC advertising and promotion influence prescribing behavior? and What are the effects of DTC advertising on drug costs—not just individual product prices, but also the average price per prescription and volume of use? By avoiding these questions, Calfee presents a selective view of the costs and benefits of DTC advertising.

## How Valuable Are New Drugs?

Calfee (2002) asserts that “health care organizations, physicians, and patients [find] many of the newer drugs to be extremely valuable” (p. 180) and there is “strong evidence that some of the most important pharmaceutical information—especially relatively new information—often fails to reach physicians or patients in a timely manner” (p. 178). Underlying these statements is a series of unchallenged assumptions: Most new drugs offer significant therapeutic advantages, the function of DTC advertising is to bring these major advances to the attention of the public, and

drugs subject to DTC advertising have favorable benefit/harm ratios. Significant challenges to each of these assumptions can be raised.

Prior to 1992, the Food and Drug Administration (FDA) assigned new chemical entities to one of three categories: 1-A (important therapeutic gain), 1-B (modest gain), or 1-C (little or no gain). In the period 1978–91, of 312 new chemical entities, 166 were rated 1-C, 106 were 1-B, and only 50 were 1-A (Drake and Uhlman 1993; Kaitin et al. 1991).

Although the FDA no longer uses this rating system, similar evaluations are available elsewhere. The Canadian Patented Medicine Prices Review Board puts new patented medications into one of three categories for the purpose of determining whether the introductory price is excessive. Between 1996 and 2000, a total of 415 new patented drug products, mostly prescription-only products, were marketed in Canada for human use. Only 25, or just over 6%, were either “breakthrough” medications or substantial improvements over existing therapies, and the rest were line extensions (40%) or products that provided moderate, little, or no therapeutic improvement (54%) (Patented Medicine Prices Review Board 2000). The French drug bulletin, *Prescrire International* (2001), has recently published summary statistics on more than 2200 new preparations or new indications for existing drugs that it evaluated between 1981 and 2000. In that time period, it rated just 74 as major or important therapeutic gains, whereas it assessed more than 1400 as being superfluous because they did not offer treatment advantages over previously available products; 58 were found to be worse than existing treatments, that is, less effective and/or riskier. The striking observation from these numbers from three different countries spanning over two decades is that new, important medications are relatively rare, as judged in terms of evidence of therapeutic advantages over treatments that are already available. Does this level of innovation justify the extent of DTC advertising that is being aired in the United States and its projected rapid growth?

Actual DTC advertising spending does not match the rhetoric that it is intended to alert consumers to new innovative therapies. Expenditures for DTC advertising are highly concentrated on a small subset of new drugs. The decision to advertise a specific product to the public does not necessarily reflect superior safety or efficacy; it is a marketing decision made on the basis of likely returns on investment,

---

JOEL LEXCHIN is an associate professor, School of Health Policy and Management, York University, an associate professor, Department of Family and Community Medicine, University of Toronto, and an emergency physician, Department of Emergency Medicine, University Health Network. BARBARA MINTZES is a doctoral candidate, Health Policy Research Unit, Centre for Health Services & Policy Research, University of British Columbia. Barbara Mintzes was funded by Health Canada, as part of a project to assess the potential impacts of direct-to-consumer prescription drug advertising on the Canadian health system.

---

**Table 1: Products with Top DTC Advertising Budgets in 2000**

Drug	Condition	DTC Spending (Millions of U.S. Dollars)	Sales (Millions of U.S. Dollars)
Vioxx (rofecoxib)	Arthritis	\$160.8	\$1,518.0
Prilosec (omeprazole)	Ulcer/reflux	\$107.5	\$4,102.2
Claritin (loratadine)	Allergy	\$99.7	\$2,035.4
Paxil (paroxetine)	Anxiety/depression	\$91.8	\$1,808.0
Zocor (simvastatin)	High cholesterol	\$91.2	\$2,207.0
Viagra (sildenafil)	Impotence	\$89.5	\$ 809.4
Celebrex (celecoxib)	Arthritis	\$78.3	\$2,015.5
Flonase (fluticasone)	Allergy	\$73.5	\$ 618.7
Allegra (fexofenadine)	Allergy	\$67.0	\$1,120.4
Meridia (sibutramine)	Obesity	\$65.0	\$ 113.2
Total		\$924.3	\$16,347.8

Source: Findlay 2001.

and many of the alleged benefits and/or safety advantages become muted within a short period of time.

Table 1 presents the ten drugs with the highest DTC advertising budgets in 2000, representing 40% of advertising spending in that year and \$16 billion in sales. What is the likely health benefit to U.S. consumers from most of these products? Meridia (sibutramine) was withdrawn from the Italian market in 2002 following reports of two deaths and more than 50 serious adverse reactions (*Reuters Health* 2002). Initial optimism about potential important safety advantages with Vioxx (rofecoxib) and Celebrex (celecoxib) appears unfounded, on the basis of the full reports of the results of large-scale safety trials (Juni, Rutjes, and Dieppe 2002; Therapeutics Initiative 2001/2002), and there is no evidence of superior efficacy in relieving the symptoms of arthritis than that offered by other nonsteroidal anti-inflammatory drugs. Despite DTC advertisements that claim that paroxetine is “non-habit forming,” withdrawal reactions have been reported following its use, including in infants exposed prenatally (Vallis 2002). Consumers in the United States have started a class-action lawsuit against Schering Plough, alleging that the company overstated the efficacy of Claritin (loratadine) in DTC advertising (Lyles 2002).

Some drugs with significant levels of advertising to the U.S. public have been withdrawn for safety reasons, including Oraflex (benoxaprofen), Rezulin (troglitazone), Propulsid (cisapride), and Baycol (cerivastatin). These withdrawals call into question the assumption that new drugs will invariably have favorable benefit/harm ratios and that consumers will benefit from hearing about them.

Moreover, given this experience, why does Calfee (2002, p. 184) believe that it is reassuring that “just 29% [of respondents to the FDA survey] agreed that advertisements are allowed only for the ‘safest’ prescription drugs?” Similarly, a California survey found that 43% of respondents believed that only completely safe drugs could be advertised to the public (Bell, Kravitz, and Wilkes 1999). In both cases, a substantial minority of the U.S. public wrongly believed that they were protected against harm from advertised products.

A recent U.S. study on drug safety withdrawals adds to the evidence that rapid widespread use of new drugs may be ill-advised in the absence of solid evidence of an advantage over existing alternatives. Of the 548 new drugs introduced between 1975 and 1999, 2.9% were withdrawn for safety reasons, and 8.2% acquired one or more black-box warnings. The latter is the strongest type of warning required by the FDA, used to alert physicians to serious and/or life-threatening drug risks. More than half of withdrawals for safety reasons occurred within the first two years after market launch, and more than half of black-box warnings occurred within seven years (Lasser et al. 2002). Although only a small minority of drugs are withdrawn for safety reasons, considerable populations may be exposed, particularly if the drug’s use is heavily promoted soon after launch, before risks are fully known. Nearly 20 million Americans took one or more of the five drugs that were withdrawn from the market between September 1997 and September 1998 (Wood 1999).

## The Quality of DTC Advertising

### FDA Regulation

Calfee (2002, p. 175) claims that “the FDA regulation of prescription drug advertising is exceptionally stringent,” and though he does say that “the FDA also routinely challenges implied claims,” he leaves the distinct impression that because of this regulation most advertisements that appear are in compliance with the required standards. The actual situation is markedly different. From late 1997, when the FDA relaxed its broadcast advertising regulations, until early 1999, 33 products were fully advertised on U.S. radio or television—that is, with product name and one or more health claims (Koerner 1999). Of the 33 (52%) products, 17 were found to violate the Federal Food, Drug, and Cosmetic (FD&C) Act (1962, P. Law No. 87-781). In most cases, the FDA sent “untitled letters,” which document an actual violation of the provisions of the FD&C Act. These letters are the first stage of the regulatory response, asking the company to stop running the advertisement immediately. In two

cases, the agency issued a “warning letter,” the next step in regulatory response, which indicates a lack of compliance with an untitled letter or a more serious offense requiring immediate corrective actions.

The most common violations were inadequate communication of risks, overstatement of benefits, and a lack of fair balance between presentation of benefit and risk information (Melillo 1999). An FDA presentation at the Drug Information Association, “What’s New in the Regulation of DTC Promotion?” in June 2000 described the current trend as an increase in submissions of questionable quality occurring across the board, but also in broadcast advertisements, and asked whether outrageous overstatements of efficacy had become the norm (Ostrove 2000).

A report in *Pharmaceutical Executive* (Smith 1998) stated that in 1998, the FDA sent more than 100 notices of violation and warning letters to 50 pharmaceutical companies regarding both print and broadcast DTC advertising. The main reason these advertisements were found to violate the FD&C Act was that they lacked fair balance between risk and benefit information; the risk information was insufficient, was omitted, or was not readable or prominent enough (e.g., presented in small type against a dark background). In addition, safety and efficacy claims were not always backed by proper scientific studies, and confusing language or technical terms were used that were unlikely to be understood by the general public. Violations have continued to be common; more than 90 DTC advertising campaigns were found to violate FDA regulations by May 2001 (Wolfe 2001). Repeat violations are also common; Schering-Plough’s advertising of Claritin (loratadine) was found to violate FDA regulations 11 times from 1997 to January 2001, and Glaxo Wellcome 14 times for its advertising of Flovent and Flonase, two forms of fluticasone, a corticosteroid (Adams 2001).

### **Systematic Evaluations of the Risk and Benefit Information in DTC Advertisements**

Assessments of the quality of print DTC advertisements make it difficult to accept Calfee’s (2002, p. 183) statement that there is “evidence on the balance of risk and benefit information conveyed by DTC advertisements” and that there is “a remarkably balanced assessment.” The evidence from two systematic evaluations of information in DTC advertisements is that balance is frequently missing; advertisements often omit significant safety information.

*Consumer Reports* (1996) examined the accuracy and usefulness of 28 advertisements that appeared in top U.S. magazines in 1996, asking a panel of 32 medical specialists to assess accuracy, information content, and the potential usefulness of the information in the advertisements to consumers. Two to three doctors specializing in the relevant field reviewed each advertisement. Overall, they judged two-thirds of the advertisements factually accurate and to contain statements backed by scientific evidence in what they said. However, only half conveyed important information on side effects in the main promotional text, and only 40% were honest about efficacy and fairly described the benefits and risks in the main section. Eleven advertisements (39%) were considered “more harmful than helpful” by at least one reviewer. This report provides only sketchy

information about the way the advertisements were selected and the criteria used for review. Expert assessments do not always reflect the latest scientific evidence. However, the researchers did not consider a result valid unless two or more reviewers agreed, which lends additional weight to the results. Most of the findings also involved major inaccuracies and failure to provide needed information.

Roth (1996) collected 39 distinct print advertisements, which represented approximately 90% of all full DTC drug advertisements (advertisements mentioning both the drug name and indication) placed in consumer media from January 1993 to mid-1995. Two specially trained pharmacists assessed these advertisements in terms of the FDA’s criteria for fair balance of risk and benefit information. Just over one-third did not contain a fair balance of benefit and risk information in the main body of the advertisement, and 15% made no mention of risks in the advertising copy. Only 12% gave information about potential misuse, and more than half lacked directions for use. Roth’s study used a systematic approach to evaluating information quality, based on FDA regulatory standards. This study provides an independent assessment of how well the FDA was able to regulate print DTC advertising. It is appropriate to use pharmacists as judges of information quality, given their professional expertise, access to independent information sources, and knowledge of drug risks and benefits, and there was a high degree of interrater reliability. However, pharmacist reviewers cannot assess how members of the public understand and interpret the information in the advertisements. In addition, this study did not assess the images and emotive content of the advertisements.

Another criticism leveled at these and similar studies is that evaluators were not FDA-trained. However, the aim of the authors of these studies was to assess systematically the quality of information reaching the public, not regulatory action. Regulatory evaluations and research on information quality both include comparisons of advertising messages with approved product information and thus have much in common despite their different aims. It would be useful to compare FDA assessments to other systematic studies of advertising quality, given that the FDA does not require pre-screening and some advertisements found to be of poor quality may have escaped regulatory attention. No such studies have been published to date.

Calfee’s (2002, p. 183) argument is that it does not matter if there is a “disproportionate emphasis on benefits” in DTC advertisements, because consumers “assume that information in advertisements is biased in favor of the advertiser.” However, this assertion, in addition to the survey data he cites showing that for consumers advertising is the least trusted source of information about prescription drugs, should not provide any reassurance. Although U.S. doctors claimed that they found promotion an unreliable source of information about prescription drugs, the reality is that their prescribing habits were strongly influenced by information in commercial literature though they were not aware of this influence (Avorn, Chen, and Hartley 1982). Consumers in the United States are just as likely to underestimate the power of promotion as are U.S. physicians.

The studies described previously all focused on print advertising. The only published analysis of U.S. television

DTC advertising examined how often older people were portrayed and whether they were portrayed negatively or positively (Lill and Peterson 2001). This study did not assess the quality of information about the advertised product.

### Educational Value of DTC Advertisements

Calfee (2002, p. 187) uses data from FDA and *Prevention Magazine* surveys to assert that “DTC advertising provides valuable information to consumers,” but again he ignores evidence on what information is actually presented and how it relates to consumer information needs for shared informed health care decisions. Bell, Wilkes, and Kravitz (2000a) analyzed print DTC advertising in 18 U.S. consumer magazines over a ten-year period, 1989–98 inclusive. They chose magazines that represented a broad range of target audiences and were market leaders in their category. The authors identified six key types of information about a drug treatment and five key types of information about the health condition it treats that patients need to know to participate in informed decision making. Two coders measured the presence or absence of this information in 320 advertisements. Reliability was nearly perfect (.91, range .88–1.0).

The authors used a low bar for educational content: whether specific types of information were present or absent, not their accuracy, completeness, relevance to the target audience, or readability. However, most advertisements did not contain the basic elements of information a person might need to judge the usefulness of a treatment, such as how a drug works (missing in 64%) or the likelihood of treatment success (missing in 91%). Only 29% of advertisements mentioned any treatment alternatives, despite Calfee’s (2002, p. 186) claim that “another spillover benefit from DTC advertisements involves calling consumers’ attention to nondrug approaches to improved health.” Few advertisements provided educational content on the treated health condition beyond its name and, in 60% of advertisements, one or more symptoms. Of the advertisements, 91% did not discuss any myths or misconceptions about the disease the drug was designed to treat.

One of Calfee’s (2002) justifications for DTC advertising is that consumers are prompted to seek additional information about their medical problems and various treatment options, with the unstated implication that educational material will be supplied by doctors. However, this position raises the question whether this is the best use of the limited time doctors have to spend with patients. Using a portion of that time supplying information missing in DTC advertisements means that doctors have less time to discuss other issues related to the patients’ conditions. As Wilkes, Bell, and Kravitz (2000) argue, if discussions initiated by DTC advertisements focus on specific brand-name drugs, trivial complaints, or the way to best access the drug, the dialogue could distract from more important issues, such as the significance of the patients’ symptoms or alternative treatment options. Conversations initiated by DTC advertisements may require physicians to reeducate their patients so that expectations are realistic and the message in the advertisement is properly understood as having a commercial, as opposed to informative, function. The attitude that it does not matter what goes into the advertisement because the

doctor will fix it is fundamentally at odds with the concept of patient education.

Whether these concerns have a factual basis remains to be determined, because there has not yet been any objective study of the quality and quantity of information that results from DTC advertising–initiated interactions or of whether these discussions enhance or distract from visit efficiency, patient–physician trust, patient and provider satisfaction, or health outcomes (Wilkes, Bell, and Kravitz 2000). Until such evidence is forthcoming, any arguments that DTC advertising is educational are mere speculation.

### Other Content in DTC Advertisements

Bell, Wilkes, and Kravitz (2000b) performed a separate analysis on the 320 advertisements mentioned previously to examine inducements and appeals that were used. Slightly less than one in five advertisements offered a monetary incentive to the reader for using the promoted drug. Bell, Wilkes, and Kravitz also found that two-fifths of the advertisements made claims of innovativeness, although as the previous data show, when it comes to drugs, newer is not necessarily better.

The finding on financial incentives warrants additional comment. The World Health Organization’s (1988) *Ethical Criteria for Medicinal Drug Promotion*, a set of internationally agreed guidelines governing drug promotion, specifically recommend against the offer of incentives to physicians to prescribe specific products. Similarly, the provision of financial incentives to users of contraceptive services in developing countries has been decried as a form of coercion (Hardon and Hayes 1997). Bell, Wilkes, and Kravitz (2000b) raise similar concerns that incentives in DTC advertising may interfere with free, informed choice of health care treatments. A related concern is over privacy, as most offers require patients to provide their names and addresses to the company.

The most recent study of the content of DTC advertisements examined 67 advertisements that appeared between July 1998 and July 1999 in ten popular U.S. magazines in three categories (men’s, women’s, and general interest) (Woloshin et al. 2001). Two investigators independently coded 21 elements of the content of every advertisement. Few advertisements presented any quantitative data to support claims of benefits; 87% described the benefits of medications with vague, qualitative terms; and just 13% used data. As the authors point out, lack of data is a major concern for products meant to treat established disease, such as diabetes. Because the relevant outcomes are rare and occur in the distant future, patients have no way to judge a medication’s effectiveness for themselves. None of the advertisements mentioned cost. Calfee (2002) claims that one of the benefits of DTC advertising is to make markets more competitive and thereby reduce prices. However, as Calfee points out in his introduction, the market for prescription drugs differs from other consumer markets, because the person seeing the advertisements cannot buy the product without a prescription and most drugs are paid for by third parties. The latter may explain the paucity of price-related advertising: It would be expected to dampen consumer price-sensitivity, because the person using the product does not directly pay for it or often pays only a fixed copayment.

Calfee (2002) discusses potential effects of DTC advertising on prices. Advertising campaigns may not lead to a higher price for a specific product, but if advertisements lead to substitution of newer, more expensive products for cheaper alternatives and to increased overall pharmaceutical use, spending can grow substantially. Calfee touches briefly on this issue of overall prescription drug costs when he states that 75% of the increase in expenditures for outpatient prescription drugs is due to expanded use and switching to newer drugs. This observation is true, but his implied claim that these newer drugs are also invariably more effective is not. As we have pointed out, the majority of new drugs do not represent a substantial or even moderate therapeutic benefit.

In a series of analyses of the relationship between annual increases in U.S. retail drug spending and DTC advertising, the National Institute of Health Care Management (NIHCM) found that the most heavily advertised drugs were contributing disproportionately to annual increases in retail drug costs. The 50 top drugs promoted with DTC advertising represented more than 95% of spending in 2000 and were responsible for US\$9.94 billion of the \$20.8 billion increase in U.S. retail prescription drug spending from 1999 to 2000, or nearly half of the total (Findlay 2001).

Calfee (2002) dismisses the NIHCM analysis as not establishing causality, presumably because these products were also heavily promoted to physicians. Although the most likely explanation is a joint effect, in which some proportion of this increase was caused by DTC advertising, Calfee is right that it is not possible to know the proportion attributable to DTC advertising. However, the NIHCM analysis rightly differentiates between product-specific price increases and increases in the average price per prescription as well as overall prescribing volume. The role of DTC advertising as a cost driver is related chiefly to these latter two effects rather than to increases in product-specific price, which in many countries is subject to regulatory controls.

## How Does Promotion Affect the Quality of Prescribing?

### DTC Advertising

Calfee (2002) limits his discussion on the effects of DTC advertising to the question of whether medically unwise prescriptions have been driving increases in drug expenditures. However, recent evidence suggests that prescribing in response to requests generated through DTC advertising may be of questionable quality. In an article published in February 2002, Mintzes and colleagues used a cross-sectional survey to examine the relationship between patients' requests for medications and physicians' prescribing decisions. To assess physicians' confidence in their prescribing decisions, the authors asked doctors, "If you were treating another similar patient with the same condition, would you prescribe this drug?" An answer of "very likely" indicated confidence in choice, and "possibly" or "unlikely" indicated some degree of ambivalence. Physicians were ambivalent about the choice of treatment in approximately half the cases when patients had requested advertised drugs

compared with 12% when patients had not requested the drugs. The authors concluded that if physicians prescribe requested drugs despite personal reservations, sales may increase but appropriateness of prescribing may suffer.

If a physician is more ambivalent about a product he or she has prescribed following a patient request, does it necessarily suggest that prescribing appropriateness is compromised? This study did not involve review of medical records or long-term follow-up of patient health outcomes. It relied on a proxy measure, the physicians' confidence or ambivalence. The conclusions are suggestive but do not establish causality. However, physicians prescribed three-fourths of the advertised drugs that patients either initiated a conversation about or directly requested. Given this high prescribing rate combined with a high rate of ambivalence about treatment choice, concerns about prescribing appropriateness appear well founded.

The request and reporting rates in Mintzes and colleagues' (2002) survey were based on physician reports about each new prescription provided during individual patient consultations. As physicians filled in questionnaires following each patient consultation, these findings are unlikely to be affected by recall bias, a concern Calfee (2002) correctly identifies for the FDA and *Prevention* surveys. However, the rate of honored requests in this survey (74%) was similar to those reported by the FDA (69%) and *Prevention* (71%) for specific requested brands, lending additional credence to these findings. Taken together, these surveys suggest that if DTC advertising opens up a discussion between a patient and his or her physician, that discussion appears to be likely to end with a prescription for the advertised product.

For the prescription for the requested brand-name drug to be the most appropriate response to patients' problems, it must be assumed that patients have accurately self-diagnosed and chosen the best of available treatment options, in terms of efficacy, safety, convenience, cost, and relevance to their individual situation (including, e.g., comorbidities, other treatments). Because many prescription drugs treat conditions that are difficult to self-diagnose and advertising provides little information on alternative treatment choices, it is highly unlikely that patients' treatment choices will be correct 70%–75% of the time, which is how often they receive the requested product.

In 1999, General Motors, which manages its own employee health plan, hired pharmacists to examine the appropriateness of prescriptions for a heavily advertised drug for ulcer/reflux, Prilosec (omeprazole), among its employees (Silversides 2001). In 1999, Prilosec ranked second in DTC advertising spending. General Motors found that 92% of the employee plan members who received a prescription for Prilosec had not received a previous prescription or even consulted a doctor previously for gastrointestinal problems. Most received Prilosec as a first-line drug, though it is not an appropriate first choice for mild heartburn or reflux, which is often effectively treated with less intensive and expensive therapy. The 92% rate of first prescriptions with Prilosec suggests that DTC advertising may have contributed both to a shift in product choice and increased drug costs.

### Promotion Directed at Physicians

Although little is known about how DTC advertising affects the appropriateness of the therapy patients ultimately receive, there is research evidence on how promotion directed at doctors affects the quality of their prescribing. Between 1972 and 1998, there have been 11 studies in Belgium, the Netherlands, the United Kingdom, and the United States that have examined the correlation between what sources physicians use for their knowledge about drugs and prescribing and the appropriateness of their prescribing (Becker et al. 1972; Berings, Blondeel, and Habraken 1994; Blondeel et al. 1987; Bower and Burkett 1987; Caudill et al. 1996; Cormack and Howells 1992; Ferry, Lamy, and Becker 1985; Haayer 1982; Linn and Davis 1972; Mapes 1977; Powers et al. 1998). Although there were methodological concerns such as the validity of measures of the quality of prescriptions, the striking observation is that every study assessed reported that the physicians' approximations of their use of or reliance on the pharmaceutical industry for information were associated with some aspect of poorer prescribing. The measures used to assess prescription level varied between studies from measures of caution and rationality of drug prescriptions to the cost of prescriptions to prescriptions for dangerous drugs. The finding that many different measures of poorer physician prescription behavior are related to the use of pharmaceutical industry information, along with the consistency of the results over a 26-year period and from four different countries, strengthens the observation that increased reliance on drug promotion leads to less appropriate prescribing.

A more recent systematic review further supports these results. Wazana (2000) identified 29 empirical studies on the impact of interactions between the medical profession and the pharmaceutical industry published in the 1980s and 1990s. Most of these studies found an association between interactions with the industry and negative outcomes. These included

- An inability to identify inaccurate claims about medications,
- Rapid adoption and prescription of new drugs,
- Formulary requests for medications without important advantages over existing listed medicines,
- Nonrational prescribing behavior,
- Increased prescribing rate, and
- Prescribing of fewer generics and more expensive new medications at no demonstrated advantage.

One positive outcome was identified in one of the 29 studies. Residents who attended lunchtime rounds by pharmaceutical representatives were better at identifying treatment protocols for complicated illnesses. However, they were also more likely to prescribe inappropriately for milder forms of the same illness (Spingarn, Berlin, and Strom 1996).

If physicians, who are more knowledgeable about drugs and have easier access to objective sources of information than consumers, are negatively influenced by promotion, how realistic is it to believe that consumers will be positively affected?

### Does DTC Advertising Lead to Improved Health Outcomes?

Calfee (2002) claims, on the basis of the *Prevention* survey results, that DTC advertising is likely to improve treatment compliance and therefore health outcomes of drug treatment. The evidence he quotes is extremely weak. Approximately one-third of the *Prevention* survey respondents who were taking advertised drugs said that they were reminded to take the product or refill a prescription; the majority, two-thirds, did not. As this survey did not measure behaviors, it was unable to examine whether patients in either group had changed what they did in response to advertising. *Prevention* did not report what drugs these patients were taking and whether increased compliance would be expected to improve the patients' health. This would be expected for cardiac drugs, for example, but not for symptomatic allergy treatments or for anti-inflammatory drugs for arthritis. In the latter case, better compliance is associated not with health benefits but with a higher risk of serious adverse effects (Herxheimer 1998). Calfee's hypothesis that advertising improves health through better treatment adherence is interesting. It would be straightforward to plan and carry out empirical research to test this hypothesis, but to our knowledge this has not been done, and the *Prevention* survey did not use the type of design that could measure such an effect.

Another hypothesized positive effect of DTC advertising is that patients will obtain needed drug treatment sooner, which may lead to fewer complications and hospitalizations and therefore to lower overall health care costs (Bonaccorso and Sturchio 2002). In the absence of evidence, however, such a claim remains as speculative as the possibility of increased hospitalizations due to harmful effects of unnecessary additional drug use among healthier population groups.

### Conclusion

It seems to be an article of faith on Calfee's (2002) part that DTC advertising is bound to be beneficial to patients. He seeks to prove his thesis through survey data on patients' attitudes, perceptions, beliefs, and recall of past events, by citing the opinions of organizations such as the National Medical Association and by speculating about the relationship between DTC advertising and drug expenditures. All these approaches to formulating conclusions about DTC advertising have value, but they need to be validated against objective information, and here Calfee has failed.

For DTC advertising to have positive effects, such advertising would need to be shown to provide patients with accurate information about important new drugs, which would lead to improved knowledge on the patients' part and ultimately to appropriate drug therapy that they would not have obtained in the absence of DTC advertising. In some of these areas, the data are missing or limited, but what there is does not support Calfee's case. Most new drugs offer limited, if any, benefits over existing medications. Many DTC advertisements leave out important safety information and exaggerate the product's benefits, as witnessed by the frequency with which the FDA has found fault with them and the content of the letters that document the reasons for the

FDA's objections. Most DTC advertisements lack the key elements to be of educational value, and few, if any, mention costs. Finally, given what is known about how promotion affects physician prescribing, it is difficult, if not impossible, to conclude that DTC advertising will lead to more appropriate drug therapy.

Calfee attributes the lack of empirical research on the effects of DTC advertising to the fact that it became of obvious interest to the public policy community only in 1997, after the FDA relaxed its restrictions on broadcast advertising. However, the first print U.S. DTC advertising campaigns occurred in the early 1980s, and by 1993 pharmaceutical companies were spending \$130 million on DTC advertising (Mertens 1998). Spending that sum of money must have stimulated research by the companies into the effects of DTC advertising. The lack of published studies showing any improvement in prescribing or in health outcomes is remarkable, after more than 8 years of rapidly increased spending and 20 years after the first print DTC advertising campaigns. Could it be that the industry has been unable to prove such a proposition? Until clear evidence of benefit, as well as evidence allowing us to confidently exclude the possibility of harm, is available, proposals such as Calfee's to further loosen restrictions on DTC advertising must be resisted.

---



---

## References

- Adams, C. (2001), "FDA Scrambles to Police Truthfulness of Ads," *The Wall Street Journal*, (January 2), A24.
- Avorn, J., M. Chen, and R. Hartley (1982), "Scientific Versus Commercial Sources of Influence on the Prescribing Behavior of Physicians," *American Journal of Medicine*, 73 (1), 4–8.
- Becker, M.H., P.D. Stolley, L. Lasagna, J.D. McEvilla, and L.M. Sloane (1972), "Differential Education Concerning Therapeutics and Resultant Physician Prescribing Patterns," *Journal of Medical Education*, 47 (2), 118–27.
- Bell, Robert A., Richard L. Kravitz, and Michael S. Wilkes (1999), "Direct-to-Consumer Prescription Drug Advertising and the Public," *Journal of General Internal Medicine*, 14 (11), 651–57.
- , Michael S. Wilkes, and Richard L. Kravitz (2000a), "The Educational Value of Consumer-Targeted Prescription Drug Print Advertising," *Journal of Family Practice*, 49 (12), 1092–98.
- , ———, and ——— (2000b), "Direct-to-Consumer Prescription Drug Advertising, 1989–1998: A Content Analysis of Conditions, Targets, Inducements, and Appeals," *Journal of Family Practice*, 49 (4), 329–35.
- Berings, D., L. Blondeel, and H. Habraken (1994), "The Effect of Industry-Independent Drug Information on the Prescribing of Benzodiazepines in General Practice," *European Journal of Clinical Pharmacology*, 46 (6), 501–505.
- Blondeel, L., L. Cannoodt, M. DeMeyere, and H. Proesmans (1987), "Prescription Behaviour of 358 Flemish General Practitioners," paper presented at International Society of General Medicine, Prague (Spring).
- Bonaccorso, S.N. and J.L. Sturchio (2002), "Direct to Consumer Advertising Is Medicalising Normal Human Experience: Against," *British Medical Journal*, 324 (7342), 910–11.
- Bower, A.D. and G.L. Burkett (1987), "Family Physicians and Generic Drugs: A Study of Recognition, Information Sources, Prescribing Attitudes, and Practices," *Journal of Family Practice*, 24 (6), 612–16.
- Calfee, John E. (2002), "Public Policy Issues in Direct-to-Consumer Advertising of Prescription Drugs," *Journal of Public Policy & Marketing*, 21 (Fall), 174–93.
- Caudill, T.S., M.S. Johnson, E.C. Rich, and W.P. McKinney (1996), "Physicians, Pharmaceutical Sales Representatives, and the Cost of Prescribing," *Archives of Family Medicine*, 5 (4), 201–206.
- Consumer Reports* (1996), "Drug Advertising: Is This Good Medicine?" (June), 62–63.
- Cormack, M.A. and E. Howells (1992), "Factors Linked to the Prescribing of Benzodiazepines by General Practice Principals and Trainees," *Family Practice*, 9 (4), 466–71.
- Drake, Donald and Marian Uhlman (1993), *Making Medicine, Making Money*. Kansas City, MO: Andrews and McMeel.
- Ferry, M.E., P.P. Lamy, and L.A. Becker (1985), "Physicians' Knowledge of Prescribing for the Elderly: A Study of Primary Care Physicians in Pennsylvania," *Journal of the American Geriatric Society*, 33 (9), 616–21.
- Findlay, Steven (2001), *Prescription Drugs and Mass Media Advertising, 2000*. Washington DC: National Institute of Health Care Management, (accessed June 15), [available at [www.nihcm.org](http://www.nihcm.org)].
- Haayer, Flora (1982), "Rational Prescribing and Sources of Information," *Social Science & Medicine*, 16 (23), 2017–23.
- Hardon, Anita and Elizabeth Hayes, eds. (1997), *Reproductive Rights in Practice: A Feminist Report on Quality of Care*. London: Zed Books.
- Herxheimer, Andrew (1998), "Many NSAID Users Who Bleed Don't Know When to Stop," *British Medical Journal*, 316 (7130), 492.
- Juni, P., A. Rutjes, and P.A. Dieppe (2002), "Are Selective COX 2 Inhibitors Superior to Traditional Non Steroidal Anti-inflammatory Drugs?" *British Medical Journal*, 324 (7349), 1287–88.
- Kaitin, K.I., N.R. Phelan, D. Raiford, and B. Morris (1991), "Therapeutic Ratings and End-of-Phase II Conferences: Initiatives to Accelerate the Availability of Important New Drugs," *Journal of Clinical Pharmacology*, 31 (1), 17–24.
- Koerner, C. (1999), "The Regulation of Direct-to-Consumer Promotion of Prescription Drugs," paper presented at Health Canada Multi-stakeholders' Consultation on Direct-to-Consumer Advertising, Aylmer, Québec (April 14).
- Lasser, K.E., P.D. Allen, S.J. Woolhandler, D.U. Himmelstein, S.M. Wolfe, and D.H. Bor (2002), "Timing of New Black Box Warnings and Withdrawals for Prescription Medications," *Journal of the American Medical Association*, 287 (17), 2215–20.
- Lill, D.J. and R.T. Peterson (2001), "Older Adult Portrayal in Television Commercials by Pharmaceutical Manufacturers: An Analysis," *Journal of Pharmaceutical Marketing & Management*, 14 (1), 1–96.
- Linn, L.S. and M.S. Davis (1972), "Physicians' Orientation Toward the Legitimacy of Drug Use and their Preferred Source of New Drug Information," *Social Science & Medicine*, 6 (2), 199–203.
- Lyles, A. (2002), "Direct Marketing of Pharmaceuticals to Consumers," *Annual Review of Public Health*, 23 (1), 73–91.
- Mapes, P. (1977), "Aspects of British General Practitioners' Prescribing," *Medical Care*, 15 (5), 371–81.

- Melillo, W. (1999), "FDA Cites Most DTC Drug Spots," *Adweek*, 40 (7), 4.
- Mertens, G. (1998), "Direct to Consumer Advertising: Global Drug Promotion," in *Healthcare*. London: *Financial Times*, 16.
- Mintzes, Barbara, Morris L. Barer, Richard L. Kravitz, Arminée Kazanjian, Ken Bassett, Joel Lexchin et al. (2002), "Influence of Direct to Consumer Pharmaceutical Advertising and Patients' Requests on Prescribing Decisions: Two Site Cross Sectional Survey," *British Medical Journal*, 324 (7332), 278–79.
- Ostrove, N. (2000), "What's New in the Regulation of DTC Promotion?" (posted June 14), (accessed May 17, 2002), [available at [www.fda.gov/cder/ddmac/nodia260/index.htm](http://www.fda.gov/cder/ddmac/nodia260/index.htm)].
- Patented Medicine Prices Review Board (2000), *Annual Report 2000*. Ottawa, Canada: Supply and Services Canada.
- Powers, R.L., K.A. Halbritter, J.G. Arbogast, J.L. Neely, and A.J. Williams (1998), "Do Interactions with Pharmaceutical Representatives Influence Antihypertensive Medication Prescribing Practices of Family Medicine and General Internal Medicine Physicians?" *Journal of General Internal Medicine*, 13 (supplement), 13.
- Prescribe International* (2001), "A Look Back at 2000: Overabundance and Deregulation," 10 (February), 52–54.
- Reuters Health* (2002), "Italy: Prosecutor Opens Weight-Loss Drug Inquiry," (March 11), (accessed September 5), [available at [www.heartcenteronline.com/myheartdr/news\\_about\\_the\\_heart/Italy\\_Prosecutor\\_opens\\_weight-loss\\_drug\\_inquiry.html](http://www.heartcenteronline.com/myheartdr/news_about_the_heart/Italy_Prosecutor_opens_weight-loss_drug_inquiry.html)].
- Roth, Martin S. (1996), "Patterns in Direct-to-Consumer Prescription Drug Print Advertising and Their Public Policy Implications," *Journal of Public Policy & Marketing* 15 (1), 63–75.
- Silversides, Ann (2001), "Looser Ad Rules a Headache for Drug Plans. Direct-to-Consumer Advertising Will Send Costs Soaring, Employers Warn," *Globe and Mail*, (September 18), H1.
- Smith, D. (1998), "DTC: One Year Later," *Pharmaceutical Executive*, 18 (11), DTC18, DTC20.
- Spingarn, R.W., J.A. Berlin, and B.L. Strom (1996), "When Pharmaceutical Manufacturers' Employees Present Grand Rounds, What Do Residents Remember?" *Academic Medicine*, 71 (1), 86–88.
- Therapeutics Initiative (2001/2002), "Cox-2 Inhibitors Update: Do Journal Articles Tell the Full Story?" *Therapeutics Letter*, 43, (accessed June 15, 2002), [available at [www.ti.ubc.ca/PDF/43pdf](http://www.ti.ubc.ca/PDF/43pdf)].
- Vallis, M. (2002), "Antidepressant Puts Newborns at Risk, Study Says," *National Post*, (May 7), A2.
- Wazana, A. (2000), "Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?" *Journal of the American Medical Association*, 283 (3), 373–80.
- Wilkes, Michael S., Robert A. Bell, and Richard L. Kravitz (2000), "Direct-to-Consumer Prescription Drug Advertising: Trends, Impact, and Implications," *Health Affairs*, 19 (2), 110–28.
- Wolfe, Sidney (2001), "Testimony Before the Subcommittee on Consumer Affairs Hearing, Senate Commerce Committee Hearing on Direct-to-Consumer (DTC) Advertising," Washington, DC, (posted July 24), (accessed June 10, 2002), [available at <http://www.citizen.org/publications/release.cfm?ID=6785>].
- Woloshin, Steven, Lisa M. Schwartz, Jennifer Tremmel, and H. Gilbert Welch (2001), "Direct-to-Consumer Advertisements for Prescription Drugs: What Are Americans Being Sold?" *Lancet*, 358 (9288), 1141–46.
- Wood, A (1999), "The Safety of New Medicines: The Importance of Asking the Right Questions," *Journal of the American Medical Association*, 281 (18), 1753–54.
- World Health Organization (1988), *Ethical Criteria for Medicinal Drug Promotion*. Geneva, Switzerland: World Health Organization.

