

**Written testimony of**

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**Before the  
Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism,  
Committee on Commerce, Science, and Transportation  
United States Senate**

**In Public Hearings on Direct-to-consumer Advertising  
of Prescription Drugs**

**Tuesday, July 24, 2001**

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Mr. Chairman, I wish to thank you for inviting me to testify today on the effects of direct-to-consumer (DTC) advertising of prescription drugs. I am an economist who has devoted considerable attention to advertising, health care markets, and the pharmaceutical industry. During 1980-1986, I served in the Bureau of Economics at the Federal Trade Commission, where I specialized on consumer protection, including advertising regulation. Some of what I say today is drawn from my recently published book, *Prices, Markets and the Pharmaceutical Revolution* (AEI Press, 2000). That book is available from the publisher, AEI Press, and is also downloadable from the American Enterprise Institute website ([www.aei.org](http://www.aei.org)). Earlier, I wrote a book on advertising, *Fear of Persuasion: A New Perspective on Advertising and Regulation* (London: Agora; North American distribution by the American Enterprise Institute). I have also written numerous articles and book chapters on pharmaceutical advertising and related topics, and recently presented the results of a new empirical study of the effects DTC advertising for the statin class of cholesterol-reducing drugs (Calfee, Winston, and Stempski 2001). Much of this testimony is based on a recently released paper on what we can learn from consumer surveys on DTC advertising (Calfee 2001).

This statement addresses four topics: (1) the relationship between DTC advertising and prescription drug prices; (2) the relationship between DTC advertising and prescription utilization and costs; (3) why DTC advertising is likely to help consumers and patients; and (4) what consumer research can tell us about the impact of DTC advertising.

## **DTC Advertising and Prescription Drug Prices**

Expenditures for out-patient prescription drugs have been increasing at about 15% annually (Berndt 2000; NIHCM 2001). Several studies have found that about three-fourths of these increases have been caused by expanded usage and switching to newer and more effective drugs, while price increases have accounted for only about one-fourth (Berndt 2000; Dubois et al. 2000; RxHealth Value 2001). Even this modest role for price increases is overstated, because standard measures of pharmaceutical prices fail to take into account improvements in the quality and value of new drugs or drugs that have found expanded uses (Triplett 1999).

These facts suggest that even if DTC advertising increases prices, such an effect has been quite limited simply because overall price increases have been small. But there is little reason to expect DTC advertising to significantly increase prices at all. Research has generally found that advertising tends to reduce prices, rather than increase them, primarily because advertising makes markets more competitive (Calfee 1997, p. 10-11, and citations therein).

A current example of the separation between DTC advertising and prescription drug prices can be found in the market for the statin class of cholesterol-reducing drugs such as Pravachol, Zocor, and Lipitor. Total expenditures for statin drugs have increased rapidly, making this one of the largest therapeutic categories in terms of total sales (NIHCM 2001). Statin drugs have also been among the leaders in DTC advertising (NIHCM 2001). Yet average statin drug prices have been stable or even slightly declining, according to data from the widely respected market research firm, IMS Health (proprietary data supplied to author, summarized in Calfee, Winston, and Stempski 2001). Moreover, the oldest statin drug, Mevacor, is about to go off patent. Hence average statin drug prices may substantially decline in the future.

## **DTC Advertising and Prescription Drug Expenditures and Utilization**

DTC advertising totaled approximately \$2.6 billion in 2000 (Adams 2001). This is about 2% of total prescription drug expenditures, which were recently estimated at \$132 billion (NIHCM 2001). Clearly, even the total elimination of DTC advertising would have a negligible direct effect on total pharmaceutical costs.

The real question, however, is whether DTC advertising pushes expenditures upward and if so, whether it increases expenditures inappropriately. There is little evidence that recent increases in drug expenditures have been caused by inappropriate prescriptions. For example, a recent unpublished study of the rapidly growing statin drug market found no tendency toward less appropriate prescribing in this rapidly growing market (Dubois, et al., 2001). On the whole, increases in drug utilization seem to be driven primarily by the fact that health care organizations, physicians, and patients find many of the newer drugs to be extremely valuable.

In fact, there is strong evidence that many of the most effective drugs are underused, rather than overused (see citations in the next section). Hence public debate has focussed on how to pay for more extensive drug therapy, rather than on how to curtail it.

Whether DTC advertising is actually increasing usage has apparently been the subject of very little systematic research. In an attempt to fill this gap, I and two co-authors undertook a study of the statin drug market (Calfee, Winston, and Stempski 2001). Using proprietary data on DTC advertising, other forms of promotion, statin prescriptions, statin sales, and cholesterol-related office visits, plus other data, were found no detectable influence from DTC advertising or other forms of promotion on the volume of statin prescriptions, which simply increased steadily throughout the study period regardless of large fluctuations in DTC advertising. One reason for the apparent lack of a short-term connection between advertising and prescriptions is the fact that several steps must take place between the time when a consumer reacts to an ad and when that consumer receives a prescription (initial physician visit, cholesterol check, advice for life-style changes, etc.) -- if a prescription is written at all.

This is not to say that DTC advertising does not increase sales for advertised brands. But the evidence suggests that prescribing decisions are dominated by the physician's advice, which may involve non-drug therapy, a generic prescription, or an over-the-counter drug recommendation, as alternatives to prescribing the advertised brand.

### **Why DTC Advertising Is Likely to Help Consumers and Patients**

Decades of research have established that advertising makes markets work better by providing information and enhancing competition (Calfee 1997). Advertising is especially useful for providing consumers with essential information that they would otherwise ignore, fail to receive, or receive too late. The Federal Trade Commission, which regulates most advertising, has emphasized that advertising plays an essential role in improving consumer information and otherwise improving markets (FTC 1996).

There are compelling reasons to expect DTC advertising to improve the prescription drug market. Some of the most important medical information -- especially relatively new information -- often fails to reach physicians or patients in a timely manner. This situation is reflected in the proliferation of practice guidelines for physicians, and also in published findings that medical practice often falls well short of what can be achieved by following even the least controversial aspects of consensus guidelines (Calfee 2000, p. 24-26). Consumers and patients, of course, tend to be even less well informed than their doctors.

Many of the most valuable new drugs involve conditions or illnesses that require consumers to take the initiative in seeking medical advice for dealing with depression, for example, or to learn whether one is at risk for heart disease and if so, what can be done to reduce that risk. A number of studies and consensus statements from the medical community have documented the existence of large numbers of under-diagnosed and undertreated

consumers who suffer from serious, yet treatable medical conditions such as elevated cholesterol, depression, obesity, diabetes, and hypertension (Calfee 2000, p. 24-26).

A new report from the National Cholesterol Education Program at the National Institutes of Health illustrates these trends. That report concluded that elevated cholesterol should be treated much more aggressively than in the past, even as earlier studies have found that most persons who should have been treated under the previous guidelines were in fact not treated and often, not even identified (NIH 2001).

These circumstances dictate that patients and consumers must play an active role in their own health care. In particular, consumers need to acquire information about medical therapies, talk to their physicians about medical symptoms and conditions, and decide with their doctors how to deal with illnesses and conditions.

Both the FTC (1996) and the FDA have noted the potential value of DTC advertising in addressing these problems. The Food and Drug Administration, in particular, has stated, "It [DTC advertising] is consistent with the whole trend toward consumer empowerment. We believe there is a certain public health benefit associated with letting people know what's available." (Stolberg 2000). Even the American Medical Association, whose constituency has traditionally opposed prescription drug advertising to consumers, recently issued a statement that concluded, "If used appropriately, direct-to-consumer (DTC) advertising has the potential to increase patient awareness about treatment options and enhance patient-physician communication. Advertising directly to the public educates patients, enabling them to better understand and participate in medical care." (AMA 2000). In 1998, *Lancet*, a leading British medical journal, ran an editorial arguing that DTC advertising would benefit European consumers.

### **What Consumer Research Can Tell Us about the Impact of DTC Advertising**

In August 1997, the FDA relaxed its regulatory requirements for DTC advertising on broadcast media including television (Calfee 2001, FDA 1997). This decision triggered large increases in the volume of television DTC advertising while also prompting a shift from print to broadcast media. In August 1999, after a two-year review, the FDA reaffirmed its new policy, while also announcing its intention to review DTC advertising again in 2001 (FDA 1999a). This past March, the FDA announced the beginning of its latest review, which will include commissioning surveys of both consumers and physicians (FDA 2001).

In the meantime, several studies have appeared on the impact of DTC advertising. These consist primarily of a number of nationally representative surveys of consumers. The most notable examples include a 1999 survey commissioned by the FDA itself (FDA 1999b,

1999c), and a series of surveys commissioned by *Prevention Magazine* (1999, 2000). Other more limited, but nonetheless useful research includes national consumer surveys by AARP, the National Consumers League, and NewsHour with Jim Lehrer (with the Kaiser Family Foundation and the Harvard School of Public Health); a survey of California consumers (Bell, et al. 2000), and content analyses of individual DTC ads (Wilkes 2000). I focus here on the findings from national surveys, especially those by the FDA and *Prevention Magazine*.

## **DTC Advertising and Consumer Information**

The national consumer surveys have provided a number of useful findings on the relationship between DTC advertising and consumer knowledge about prescription drugs. One finding is that DTC ads provide a reasonable balance of information about both benefits and risks. In the FDA survey, for example, there was little difference in the prominence of benefits vs risks or warnings, and 70% disagreed with the statement that DTC ads “make it seem like a doctor is not needed to decide whether a drug is right for me.” In a response to a 1999 *Prevention* survey question about whether advertising made respondents feel more or less confident about drug safety, 70% said “no difference” or “less confident.”

The surveys also supply direct and indirect evidence that DTC advertising provides valuable information to consumers. Responses revealed very high levels of awareness and attention to DTC ads, as the proportion of respondents recalling DTC ads ranged between 72% (FDA survey) and 95% (aided recall in the 1999 *Prevention* survey). Such high awareness levels strongly suggest that consumers gained information about the core topics of DTC ads: details on a variety of medical conditions, potential therapies, alternative dosages, and other important topics, in addition to risk information. The potential value of making so much information available through advertising is clear from the AARP survey results, in which 27% of respondents said their doctors seldom or never discussed pharmaceutical risks, and another 18% said physicians did so only sometimes, while 27% said their doctors rarely or never discussed alternative drug therapies.

The bulk of respondents (on the order of 80% in the FDA survey) noticed information on benefits, risks, and warnings. Substantial proportions read some or all of the fine-print risk information in print ads, and readership was much higher for those who had a special interest in the advertised drug. In particular, the FDA survey found remarkably high levels of readership of the fine-print risk information in print ads: 40% said they read half or more of that information, another 26% said they read a little of it, and 85% said they would read all or almost all of the information if they were especially interested in the drug. The *Prevention* survey obtained roughly similar results, also finding high levels of attention to detailed risk information.

The surveys also suggest that DTC ads motivated consumers to seek additional information from numerous sources, including, of course, their own doctors. Of special importance is the finding that DTC ads opened up new topics for consumers to investigate.

Twenty-seven percent of respondents in the FDA survey were prompted by ads to talk to their doctors about medical conditions they had never previously discussed. These results are consistent with the fact that many of the most heavily advertised drugs treat conditions that are widely believed by the medical community to be undertreated, such as elevated cholesterol, depression, obesity, diabetes, and hypertension.

Of special interest in the FDA survey was the balance of information on risks and benefits in DTC ads. A series of detailed questions revealed a remarkably balanced assessment. Asked what kinds of information they saw in ads, 87% of respondents said, “the benefits of the drug,” while 82% said, “risks or side effects,” and 81%, “who should not take the drug.” The proportion of respondents who thought ads lacked information on benefits (49%) was nearly as large as the proportion who thought ads lack information on risks (59%). The *Prevention* surveys provided similar results.

### **DTC Advertising and Patient-Doctor Relationships**

Both the FDA and *Prevention* surveys document that large majorities of consumers agree that DTC ads provided sufficient information to prepare to talk to their doctors -- 70% in the FDA survey. But advertising was far from a dominant influence. In the FDA survey, respondents said the main reasons for expecting a new prescription were: past prescription history, information from friends or relatives, and previous discussions with physicians, with advertising far down the list.

Large majorities of respondents to the FDA survey reported favorable assessments of their talks with their doctors, and encountered no resentment or other unfavorable reaction. This is apparent from the numbers in Table 1. Most respondents said their doctor welcomed their questions (81%), reacted as if those questions were an ordinary part of a visit (71%), and proceeded to discuss the drugs with the patient (79%). Only 4% said their physician “seemed angry or upset.” Equally important, of those who had not asked such questions of their physicians, only 3% expected to encounter an adverse reaction if they were to ask such a question in the future. Eighty-five percent of respondents were satisfied or very satisfied with their discussions with physicians about advertised drugs, with only 7% unsatisfied or very unsatisfied. Finally, 62% agreed or strongly agreed that DTC ads helped them have better discussions with their physicians.

**Table 1. Physician Reactions When Asked About  
an Advertised Drug**

	Question 28: "Which, if any, of these possible reactions did your doctor have when you asked about the [advertised] drug?"	Question 33: "Which, if any, of these possible reactions do you think your doctor <u>would</u> have if you asked about a prescription drug you had seen advertised?" (May say "Yes" to more than one.)
Welcomed question	81%	69%
Discussed drug	79%	82%
Reacted as if the question were ordinary part of visit	71%	56%
Got angry or upset	4%	3%
None of the above	2%	1%
Don't know/refused	1%	2%
Sample size	220	607

Adapted from: Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications. Attitudes and behaviors associated with direct-to-consumer (DTC) promotion of prescription drugs: main survey results. Available at: <http://www.fda.gov/cder/ddmac/dtcindex.htm>. Accessed May 1, 2001.

In 26% of the discussions motivated by advertising, according to the *Prevention* survey, patients said they requested prescriptions for specific brands, and they usually got one. We do not know, however, the extent to which these requests arose from discussions in which physicians had already made clear that the decision was up to the patient, perhaps because the choice was obvious or because any of several alternatives was acceptable. In the FDA survey only about half of physicians wrote a prescription when asked about a specific drug. These surveys provide no reason to suggest that these requests and questions about specific advertised drugs tended to yield inappropriate prescriptions.

### **Overall Consumer Attitudes Toward DTC Advertising**

Consumers generally like DTC ads and find them useful. In the FDA survey, those who liked DTC ads outnumbered those who did not by nearly two to one. Eighty-six percent said the ads "help make me aware of new drugs," and 62% said DTC ads help them have better discussions with their physician about their health. In the 1999 *Prevention* survey, 76% thought that ads "allow people to be more involved with their health care," 72% said that DTC ads "educate people about the risks and benefits of prescription medicines," and 63% said that DTC ads "help people make their own decisions about prescription medicines." Finally, 76% of respondents to the National Consumers League survey agreed that prescription drug ads "increase consumer knowledge about medicines," and 78% agreed that prescription drug ads

“increase consumer knowledge about disease.”

### **Positive Spillovers from DTC advertising**

Survey research also provides something that may be surprising to most observers: evidence that DTC advertising provides spillover benefits to consumers, beyond any gains realized by the manufacturers who pay for the ads. One spillover benefit, for example, is increased consumer awareness of the simple fact that virtually all prescription drugs are risky and have side effects. This must be clear to anyone who has perused a few of the “brief summaries” in print ads or noticed the staccato list of warnings in TV ad voice-overs. In addition, the 1999 *Prevention* survey found that physicians tend to provide more risk information to those patients who ask about advertised drugs.

A second category of spillover benefits is the dissemination of information about new, previously undiscussed conditions. Advertising about elevated cholesterol, obesity treatments, and the like do not invariably lead to prescriptions for the advertised drugs. On the contrary, when ads induce patients to talk to their doctor, most patients do not actually ask for or about the brand whose advertising sparked the discussion, and when they do, the result is a mixture of prescriptions for the advertised drug, prescriptions for a competing drug, recommendations for OTC drugs, and advice to change life-styles or behavior. Ads can raise awareness of the need for a particular type of drug to treat a particular condition, but the benefits of that consciousness-raising may go to the patient and to competitors rather than to the advertiser.

A third spillover benefit is to call consumers’ attention to nondrug approaches to improved health. Many ads start out by mentioning the value of dietary changes and exercise. When DTC ads succeed in getting consumers to talk to their doctors about obesity, diabetes, depression, and cholesterol levels, those consumers probably learn that behavioral and life-style changes are the first line of treatment. In response to a 2000 *Prevention* survey question asked of respondents who said that ads had caused them to talk to their physician, 53% said their doctor had mentioned a nondrug therapy for their condition. The proportions were much higher for certain conditions: diabetes (77%), high cholesterol (92%), and obesity (84%).

Finally, a fourth example of spillover benefits is inducing compliance with drug therapies. Research has shown that inadequate compliance with physician instructions when taking prescription drugs is an extremely common and dangerous problem (Calfee 2000, p. 19). Advertising is an excellent vehicle for inducing better compliance because consumers tend to pay attention to advertising for brands they use. It is no surprise, therefore, that the FDA survey found that consumers pay special attention to ads for drugs they are taking or in which they have a special interest.

In 2000 *Prevention* survey, about half of those respondents taking a prescription drug recalled seeing an ad for a drug they were using. Thirty-six percent said the ads made them feel

better about the safety of their prescriptions, while only 3% said the ads made them feel worse. In response to a crucial question -- "Do ads make you more or less likely to take your medicine regularly?" -- "more likely" outscored "less likely" by 22% to 3%. In addition, 33% in the 1999 survey said that prescription drug ads reminded them to have their prescriptions refilled.

There is no reason to expect the reminder powers of DTC advertising to be restricted to the advertised brand. Although no research appears to have been done on the topic, these survey results strongly suggest that by reminding patients to take their medicine and refill their prescriptions, DTC ads tend to encourage patients to persist in their drug therapy.

### **Conclusions**

There are good reasons to expect DTC advertising to provide valuable information to consumers and otherwise improve the health care market. The emerging evidence on DTC advertising effects, particularly the results of consumer surveys by the FDA, *Prevention Magazine*, and others, indicates that DTC ads are in fact providing substantial benefits while avoiding most or all of the problems that some analysts have suggested DTC ads could bring.

This evidence goes far toward explaining why the FDA reaffirmed its policy of permitting DTC advertising in August 1999. Indeed, the agency noted at the time that "FDA is unaware of any data supporting the assertion that the public health or animal health is being harmed, or is likely to be harmed, by the Agency's actions in facilitating consumer-directed broadcast advertising" (FDA 1999b). The FDA is to be congratulated for persisting in its policy toward DTC advertising in the face of criticism and opposition from diverse segments of the health care community. Equally worthy of praise is the fact that the FDA commissioned a well-designed consumer survey that could easily have uncovered severe problems with its new policy, rather than providing support for the policy (which it did, of course).

We have learned at least six things from the leading consumer surveys and other evidence on DTC advertising. First, we can largely rule out the possibility that DTC advertising is causing systematic consumer deception, including the inappropriate downplaying of risks and side effects. The FDA and *Prevention* surveys, in particular, addressed this topic in so many ways that it is very unlikely that widespread consumer deception has escaped detection by the FDA regulators.

Second, DTC advertising provides valuable information, and not just on obvious topics such as potential treatments and dosages, but also on risks and side effects. On the whole, DTC advertising appears to increase the salience of both risks and benefits from drug therapy. Third, the information in DTC advertising motivates consumers to seek additional information from many sources, but especially from physicians and pharmacists. Many of these consumers ask about conditions they had not previously discussed with their doctors.

A fourth finding is that from the patient's perspective at least, DTC advertising is causing almost no tension in the doctor's office. Very few respondents -- usually well under 5% -- encountered resentment or resistance when they brought up what they had seen in advertising, or asked about specific drugs. Fifth, consumers like DTC advertising. They think it helps them in making decisions and in talking to their doctors.

Sixth, DTC advertising yields significant spillover benefits that go to consumers rather than to advertisers. Such benefits range from heightened awareness of the inherently risky nature of prescription drugs to better compliance with drug therapies and even motivation to pursue life-style and behavioral changes that may obviate the need to use pharmaceuticals. In particular, ads reminded consumers to take their medications and to refill their prescriptions. Overall, DTC ads appear to make patients more comfortable with the risks and benefits of the medicines they take.

Overall, these survey results are strongly supportive of a situation in which consumers are motivated by advertising first to seek additional information -- specially from physicians, and particularly for previously untreated or inadequately treated conditions -- and then to work with their doctor to reach a decision about what if any prescription drug to use.

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