

Economic Realities in Health Care Policy

VOLUME 2, ISSUE 1

IN THIS ISSUE:

Prescription Drug Advertising: Empowering Consumers Through Information



LETTER FROM THE EDITORS

Direct-to-consumer (DTC) advertising of pharmaceuticals has become a controversial topic in the current health care debate, and is the subject of this issue of *Economic Realities in Health Care Policy*.

Some critics of DTC advertising have expressed concern that recent growth in drug spending is a direct result of increased consumer advertising. In August 1997, the FDA issued new guidelines on DTC advertising; since then, spending on DTC ads has indeed increased severalfold. While much of the debate in broadcast media has focused on the potential impact of advertising on drug prices—and we present here clear evidence that such a connection does not exist—few have focused on the empowering benefits to consumers provided by DTC ads. This issue of *Economic Realities* addresses both the economic and consumer issues head-on.

The first essay, “The Economics of DTC Advertising of Prescription Drugs,” provides an economic analysis of the benefits of advertising and a perspective on how DTC affects the price and utilization of pharmaceutical products. Most importantly, the evidence examined here shows no direct relationship between DTC advertising and prescription drug prices.

In the second essay, “What the FDA Survey Showed About DTC Prescription Drug Advertising,” guest contributor John Calfee of the American Enterprise Institute analyzes the results of an important FDA survey. The survey shows that undiagnosed, untreated, and undertreated diseases often get attention and appropriate treatment as a result of DTC ads.

The final essay, “Information Matters: The Consumer as the Integrated Health Care System,” explores a broader question—how can the consumer become the central figure in the management of his or her own health? One key component of that transformation is information that enables consumers to participate fully in dialogues with their health providers. DTC ads are proving to be one of the most effective means available to communicate such information, and are thus a valuable resource to all participants in the health care system.

We hope this issue will help illuminate the debate on DTC advertising and bring consumers—most of whom enjoy and benefit from these ads—to the forefront of the discussion. Future issues of *Economic Realities in Health Care Policy* will address the value of medicines and pharmaceutical innovation to society, the role of intellectual property rights in drug development, and other issues of interest to the health policy community. As always, we appreciate the many comments we get from you and encourage you to share your thoughts and suggestions with us.

Richard L. Manning, PhD

Neal A. Masia, PhD

Pfizer Inc

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SECTION I

The Economics of Direct-to-Consumer Advertising of Prescription Drugs

By Richard Manning, PhD and Alison Keith, PhD
Pfizer Inc

Anyone in this country who has watched television or read magazines and newspapers in the past five years has witnessed the evolution of the advertising of prescription medicines. Indeed, since the FDA issued new guidelines in 1997, direct-to-consumer (DTC) advertising of pharmaceuticals has become one of the most visible and controversial developments in health care. Among other things, DTC advertising has been credited with driving the recent growth in drug expenditures, with causing patients to pressure doctors for unnecessary prescriptions, and sometimes with pushing drug prices higher. While at first blush it may seem logical to connect recent increases in DTC advertising with trends in drug spending and prices, a closer look at the importance of such advertising relative to other factors influencing the cost and utilization of prescription drugs in the United States suggests a different explanation.

One of the primary economic principles underlying all advertising is the value of information. Advertising serves to inform consumers of opportunities about which they might otherwise remain unaware. Whether the advertising is about eyeglasses, a clothing sale, or a job opening, informing

people about new opportunities has great potential value. Having been informed, people are in a position to act on the information either by choosing to try a new product or by seeking additional information. Without the information that advertising provides, consumers would not learn as quickly about things like lower prices or new product opportunities that might make them better off. The role of information is particularly important with prescription drugs, as advertising encourages patients to explore and discuss with a physician health concerns that might otherwise be ignored.

The aim of this brief essay is to review some of the principles underlying the advertising of prescription drugs and to touch on the evidence of its impact. We will first consider the impact of advertising on the rise in prescription drug use and then turn to the potential impact of advertising on drug prices. Finally, we will address the question of the impact of advertising on the quality of health care. We hope to highlight some interesting evidence and viewpoints and thereby, to offer balance to a debate that at times has been rather one-sided.

DTC Advertising and Rising Drug Expenditures

It is important to make clear at the outset the distinction between the concepts of cost and price. Unfortunately, this distinction is often blurred in public discussions related to prescription drugs. Often, changes in pharmaceutical expenditures are referred to as changes in drug cost, while the concepts of cost and price are used interchangeably. Expenditure, or the cost to the payer, is the product of price and quantity. Expenditures can rise or fall owing to changes in either price or quantity or both.

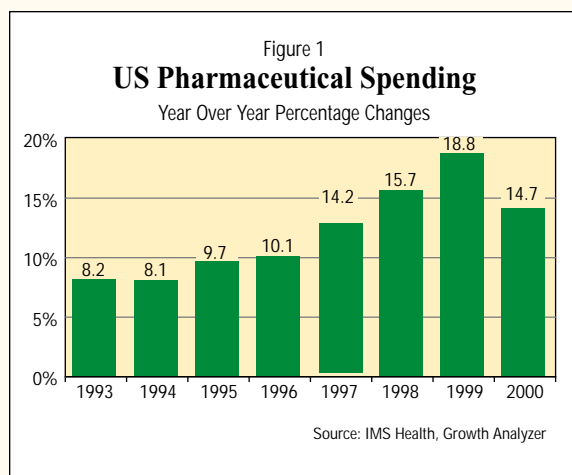
Prescription drug expenditures have risen substantially in the United States. Figure 1 shows the double-digit percentage increases in spending that have occurred over each of the past five years. It is also important to recognize that despite this recent growth, pharmaceuticals still account for less than nine cents out of every health care dollar in the United States.¹ Moreover, as discussed in the previous issue in this series, the vast majority of recent growth in spending has been driven by increases in the volume of use and not by price changes.^{2,3} Beyond advertising, a number of factors have contributed to the growth in prescription drug volume.

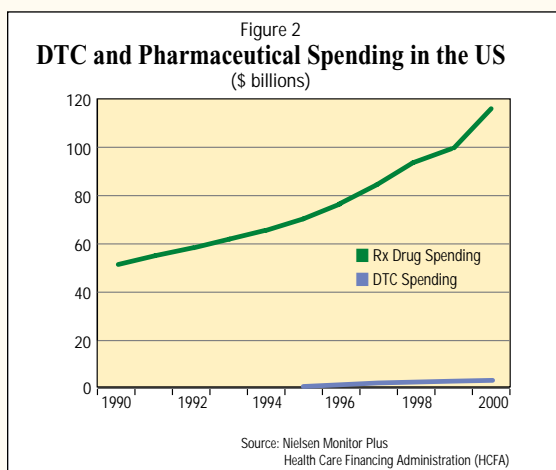
Among these are an aging population, advances in science that bring to market new treatments with improved efficacy or reduced side effects, changes in treatment protocols and clinical practice standards, and an increased appreciation for the value of medicine.

DTC advertising certainly plays a role in increasing pharmaceutical use. Informing and reminding people about new treatment options naturally leads some people to get and fill prescriptions that they otherwise would not. An assessment of advertising's impact on spending, however, requires consideration of the other factors that drive pharmaceutical use and the appropriateness of prescription drug use that is encouraged through advertising.

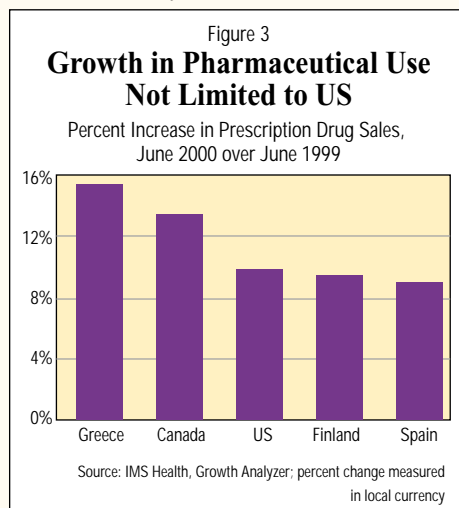
Many studies have demonstrated the value of new and existing pharmaceuticals in terms of health improvement and avoidance of more costly treatments.^{4,5,6} These discoveries, which have been heralded by medical institutions and the media, have generated enormous interest in drug therapies on the part of both physicians and patients and have led to greater pharmaceutical utilization. In addition, national health campaigns targeting conditions such as high cholesterol,

heart disease, and diabetes have also added to the increased use of pharmaceuticals. The new, well-publicized National Institutes of Health cholesterol treatment guidelines present a case in point.⁷ If the guidelines are followed, the number of patients on cholesterol-lowering statin drugs will nearly triple. Such changes increase drug utilization (and spending) to the benefit of consumers and public health.





To date, no one has done the kind of extensive study that would be necessary to establish the exact impact of advertising on pharmaceutical sales. Short of that, however, there are a few key facts that can put the relative importance of advertising into perspective. Figure 2, for example, illustrates the relative magnitude of prescription drug sales and DTC advertising in this country. With such advertising currently accounting for only about 2% of total sales, it seems highly unlikely that the former is the key driver of the latter.⁸



In addition, as illustrated in Figure 3, in the year ending with the second quarter of 2000, the volume of pharmaceutical sales rose by about 10% in this country, by more than 15%

in Greece, by 14% in Canada, and by nearly 10% in Finland and Spain. Clearly, the demographic and technological trends have led to spending growth worldwide. It is interesting to note that among these countries, DTC advertising is legal only in the United States.

These facts call into question the claims by some that advertising is a primary driving force for pharmaceutical spending, and provide perspective on the calls for restrictions

on such advertising. One source to which advertising critics have turned for evidence is a recent research brief, "Prescription Drugs and Mass Media Advertising," published by the National Institute for Health Care Management Foundation (NIHCM). This report briefly examines spending and advertising trends to assess the impact of advertising on sales and concludes, "A cause-and-effect relationship between DTC ads and the rise in drug prescriptions and pharmaceutical spending has not been firmly established." However, the report goes on to say, "But many observers infer it and the circumstantial evidence is strong."⁹ But is it? The data presented by NIHCM clearly show only the slightest relationship between DTC advertising and utilization-based spending increases. In fact, the NIHCM study indicates that some products experienced strong sales growth without intensive DTC ads, and, conversely, some heavily advertised products did not contribute much to overall spending increases.

Separating Price and Quantity Effects on Spending

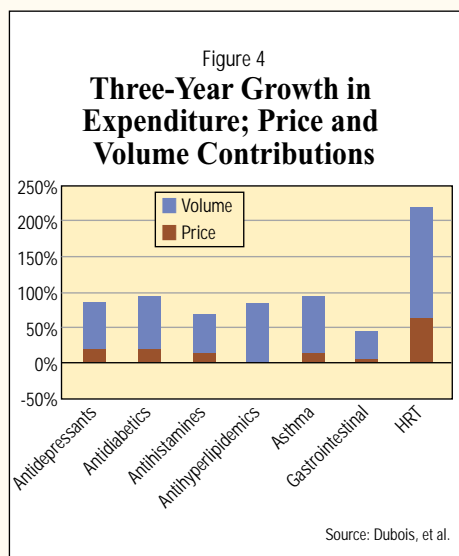
A comprehensive examination of spending trends was performed by Dubois, et al, in an article published recently in *Health*

Affairs, “Explaining Drug Spending Trends: Does Perception Match Reality?” The authors took a careful look at the forces behind rising drug expenditures by analyzing changes across seven therapeutic categories. Key to the analysis was the separation of price effects (factors impacting the price per day of therapy) and volume effects (factors such as the number of prescriptions per person and the duration of therapy). Using national standards for drug and consumer price indicators, Dubois found that, “...although the average transaction price rose in every case but one, the impact [of price] on the rise in drug spending was greatly exceeded by that of growth in medication volume.”¹⁰ (See Figure 4.)

A more detailed analysis provided by Dubois for anticholesterol drugs is especially interesting, because while overall spending in that category for the three-year period under study increased by 80%, the price actually went down over that time. Figure 5 details the real drivers of higher expenditure on these drugs—mainly an increase in disease prevalence and higher prescription length and frequency.

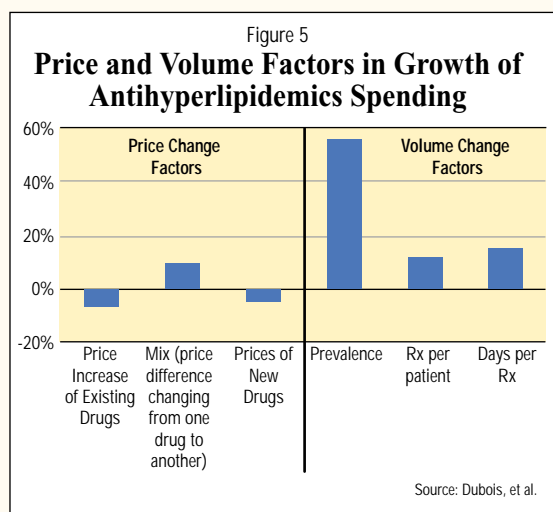
DTC Advertising and Volume Increases: A Tenuous Connection

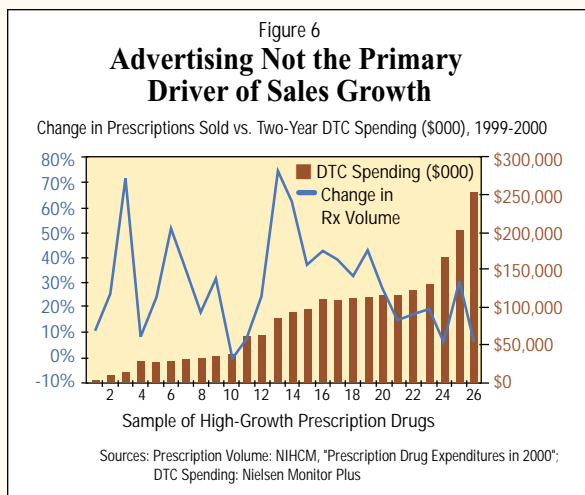
Another recent report from the NIHCM provides data that allow for drug-by-drug comparisons of changes in price and quantity.¹¹ Combining those data with information from Nielsen Monitor Plus on DTC advertising dollars for each drug suggests that factors other than advertising are responsible for the bulk of the change in sales of these products. Figure 6 provides an illustration. For 26 of the drugs



from the NIHCM report with the most rapid sales growth that were launched before 1999 and had significant DTC ad spending in 1999 and 2000, one observes no systematic relationship between quantity growth and DTC spending.

The fact that in this sample the amount spent on advertising is not positively related to increased sales does not imply that DTC spending is not productive for drug companies—it simply indicates that the impact of such spending is overwhelmed by other important market dynamics.





considers DTC advertising to be a positive influence on drug pricing and the industry as a whole, stating:

“Advertising is an important catalyst for price and quality competition. Advertising can put downward pressure on prices by spurring competition among alternative therapies. To the extent that prescription drugs compete with OTC drugs, prescription drug advertising

DTC Advertising and Rising Drug Prices: A Spurious Link

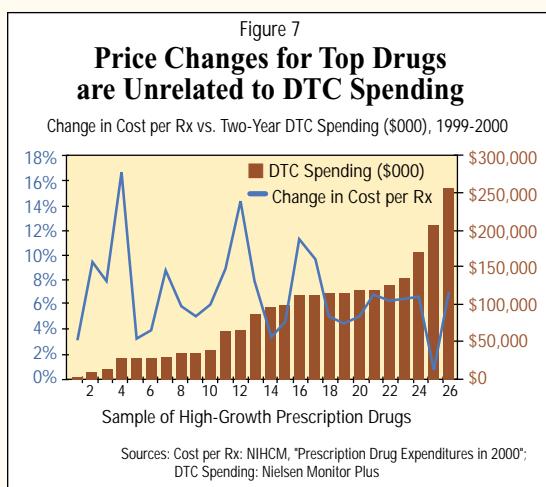
potentially can lead to lower average prices for both product categories.”¹²

We next turn to the impact of DTC advertising on drug prices. It is important to bear in mind that there is no theoretical reason to expect that advertising will cause higher prices. While advertising presumably will increase demand for a product, the cost of that advertising would usually be recouped through increased sales volume rather than through higher prices.

Advertising in any form is costly, but no clear connection has been made between higher levels of advertising and increased product prices. On the contrary, strong economic literature exists to demonstrate that in a variety of markets, the introduction of advertising (including nonprice advertising) has led to lower prices by intensifying competition. Moreover, national advertising specifically intensifies competition among retailers, leading to a compression of retail margins and therefore to lower consumer prices.¹³

The empirical evidence on drug prices and advertising bears out the theoretical ambiguity. Figure 7 takes the individual product data from Figure 6 and replaces changes in quantity sold with changes in price per prescription between 1999 and 2000 as reported by NIHCM. When compared to total DTC advertising dollars spent, it is clear that there is no relationship between ad dollars and price changes, calling into question the simplistic assumption that advertising drives price increases.

Beyond this evidence, the Federal Trade Commission (FTC), after carefully considering industry data, reported to the FDA that it



DTC Advertising and Quality of Care

By informing consumers of new products and treatment breakthroughs, DTC advertising enhances consumer awareness of the symptoms of disease and available therapies. In its report to the FDA, the FTC outlined the findings of a careful review of numerous studies on DTC advertising. The following excerpts from that report illustrate DTC advertising's positive role in enhancing the quality of health care in the United States:

"We believe that truthful and non-deceptive DTC advertising can contribute to consumers' health information environment and consumer welfare. A review of some recent DTC advertising suggests beneficial outcomes are likely, because many advertisements focus on the types of claims that we would expect to help consumers, such as, for example, improved convenience and cost advantages. In addition, recent consumer research evidence suggests that DTC advertisements are likely to encourage people to seek advice from their doctors, which may result in improved health care."¹⁴

"Advertising may encourage consumers to see a doctor for advice about conditions they might have previously ignored or for further information about conditions already being treated. Advertising may cause consumers to inquire about diagnostic tests that might not otherwise be performed. Better-informed consumers will be better able to understand and discuss their individual needs with their doctors and pharmacists. Thus, advertising can help consumers make decisions about their health care and health care costs."¹⁵

The FTC went on to report,

"Quality competition can also be motivated by advertising. Advertising can help foster

product improvements by delivering information to consumers on quality variables that they may not otherwise know about. If consumers prefer products with the advertised qualities and receive prescriptions for these products after consulting their doctors, then their demand for the advertised products is reflected in sales and the market reflects consumer preferences."¹⁶

There is also evidence to suggest that DTC advertising improves patient compliance with chronic-use medications. A two-year study by Express Scripts that monitored drug utilization rates for enrollees in health plans observed "uncommonly high rates of . . . compliance for chronic medications with heavy DTC advertising." According to the study, data from two health plans showed compliance rates of 76-85% for estrogens, ACE inhibitors/angiotensin II receptor blockers, and antilipids, whereas previous research had suggested across-the-board compliance rates of about 50%.¹⁷

Linking Greater Utilization With Better Health

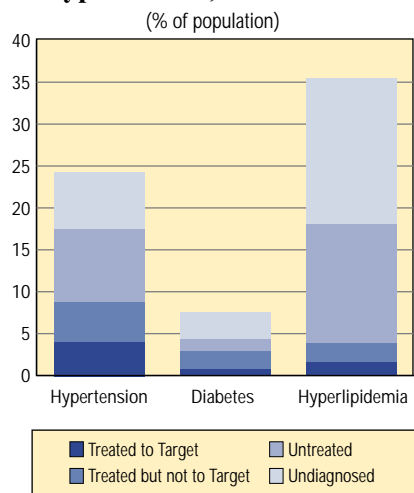
Physicians, institutions, and patients are clamoring for better quality of care, including more extensive treatment. Adding to this are millions of Americans with conditions treatable with drug therapy who have yet to be diagnosed and/or adequately treated. As these individuals do seek help, the demand for drug therapies will continue to grow. The Third National Health and Nutrition Examination Survey (NHANES III) provided numerous examples of the massive underdiagnosis and undertreatment present in today's workforce, especially for the common conditions of hyperlipidemia, hypertension, and diabetes (Figure 8).¹⁸

Today, 37 million American workers have hyperlipidemia. Of those 37 million, 41%

have not yet been diagnosed, and overall, 67% of affected workers do not have their cholesterol under control.¹⁹ Similarly, of the 18 million American workers who have hypertension, 35% have yet to be diagnosed and 14 million have uncontrolled conditions.²⁰ Furthermore, nearly half of the 5 million American workers with diabetes are not aware that they have the disease.²¹ One of the most effective ways to get people to address this enormous personal and public health risk is via direct advertising by the manufacturers of products that can save their lives.

Mental health treatment is another important contributor to past and possible future rises in prescription drug spending. Depression alone affects 19 million Americans, over 7 million between the ages of 18 and 39 (or 8% of the population).²² Emphasizing the importance of addressing depression in the workforce, *Healthy People 2010* (the U.S. government's health goals for the nation) lists one of its goals as increasing the treatment rate for adults diagnosed with depression from 23% to 50%.²³ Drugs are often an essential part of the treatment of depression. In fact, one new study published in the *New England Journal of Medicine* (Keller, et al) has found that, for cases of severe and chronic depression, the best treatment is a combination of psychotherapy and drugs.²⁴

Figure 8
Rate of Untreated and Undiagnosed Employed Persons with Hyperlipidemia, Hypertension, and Diabetes



Source: NHANES III

In view of these clinical drivers, scientific advances, and demographic trends, it is clear that increased pharmaceutical use and improved quality of health care will continue into the future. How quickly this advance in treatment and quality takes place depends, in part, on how well-informed consumers are about the choices available to them. DTC advertising can play an important role by providing the necessary information.

SECTION II

What the FDA Survey Showed About Direct-to-Consumer Prescription Drug Advertising

By John E. Calfee, PhD
American Enterprise Institute

Prescription drugs, unlike over-the-counter drugs such as aspirin or Tylenol®, may only be purchased by obtaining a prescription from a doctor. With few exceptions, prescription drugs were once advertised only to physicians and health care organizations, but that has changed in recent years with the advent of DTC drug advertising. Spending on DTC advertising has increased severalfold since August 1997, when the FDA changed some of its rules on television ads for prescription drugs, and is now running at over \$2 billion per year. This is certainly a striking development in the advertising world.

DTC advertising tends to generate controversy. It costs money, it is designed to increase pharmaceutical sales (which account for a relatively small but increasing proportion of all health care spending), it touches upon some of the most important and intimate aspects of our lives (ranging from heart disease and stroke to depression and erectile dysfunction), and it affects relationships between patients and their physicians. The United States and New Zealand are the only Westernized nations that permit DTC advertising, but DTC advertising is

also part of a larger and more important trend toward greater consumer involvement in making decisions about their own care. That trend promises to grow as consumers use the Internet and other patient-oriented tools in a medical marketplace dominated by managed care.

It is only natural to want to know more about how DTC advertising actually works in the medical marketplace. A number of large consumer surveys have been published to considerable acclaim—notably a series of surveys conducted on behalf of *Prevention* magazine, *Time* magazine, and the National Consumers League (all with FDA assistance), the *Wall Street Journal*, and AARP (formerly the American Association of Retired Persons).¹

Remarkably little attention has been paid, however, to arguably the most important effort of all: a 1999 survey by the Food and Drug Administration.

FDA Context and Survey Design

The FDA has an intense interest in direct-to-consumer advertising. It is the agency designated by Congress to regulate all pre-

scription drug advertising, and it has done so with a level of rigor seldom achieved for any other form of advertising. The FDA also monitors a pharmaceutical's safety and side-effect profile after FDA approval. The FDA is therefore deeply concerned with the accuracy and balance of direct-to-consumer advertising's effects on consumers, particularly with respect to information about potential side effects and other harms from prescription drugs, as well as its effects on relationships among patients and physicians.

On the other hand, the FDA is very cognizant of today's trend toward patient empowerment. The 1999 edition of the FDA's popular report, *From Test Tube to Patient: Improving Health Through Human Drugs*, notes in the first chapter that, "There is a growing trend for Americans to participate more actively in their healthcare decisions." Consumers have gained direct control over their use of more than 600 over-the-counter drugs in the past two decades, including such potent treatments as nicotine patches, strong anti-inflammatories, and treatments for yeast infections. Increased freedom for DTC advertising must be viewed squarely in the context of the consumer's increased role in ensuring his or her own health and welfare. That enhanced role requires both greater freedom—in this case, freedom to receive information—and greater responsibility.

In keeping with that context, the FDA performed a random survey of 1,081

interviewees in 1999 to gauge their attitudes toward and experiences with DTC advertising. Because the FDA was especially interested in how advertising affects patient-physician communications, the sample was constructed so that 80% of the respondents had seen a doctor within the previous 3 months. In fact, two-thirds of the sample had been to the doctor within the previous 4 weeks, and 20% had seen a doctor within the week before the survey. The FDA survey was therefore exceptional in its ability to assess patients' relatively fresh memories of interactions with their doctors, and is thus helpful in assessing the impact of DTC advertising on the patient-doctor relationship.²

The FDA survey
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Findings

What did the survey find? Not surprisingly, consumers are very much aware of DTC ads. Seventy-two percent recalled seeing a prescription drug ad in the past three months, mostly on television, and most respondents recalled seeing several ads.

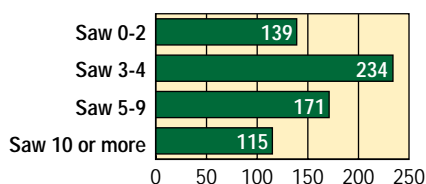
Half of the respondents who recalled seeing an ad said that DTC ads caused them to seek additional information from other sources, usually from a physician or pharmacist. Twenty-seven percent said that ads caused them to talk to their doctor about a medical condition or illness for the very first time. This is a spectacular result, because a fundamental reason for permitting DTC ads in the first place is to improve consumers' health by providing

them with essential information they are not receiving from other sources.

The survey also asked whether respondents had gone to their physicians with a specific question, and if so, why. In this respect, DTC ads ranked approximately equally with friends, news stories, and other sources that suggest health matters worthy of professional attention. Thus, in the space of a few years, DTC advertising has become an important component of the overall environment that prompts patients to ask questions of their doctors. The survey then turned to what actually

How Many Ads for Different Drugs Were Seen?

Those who have seen a doctor and seen a prescription drug ad in the last 3 months asked how many ads for different drugs have seen



Source: www.fda.gov/cder/ddmac/dtcindex.htm

happened in the doctor's office. Two-thirds of respondents were already on prescription medications at the time of their visit, but only half of those expected to continue taking the same medication after visiting their doctor. Another 6% were not taking any drug but thought they might be prescribed one on their next visit.

So a lot of patients thought they might get a new or changed prescription when they saw their physicians. When asked why, most respondents mentioned their own past prescription history, information from friends or relatives, news items, and other sources. Rather few, however, said ads

were a reason: responses citing broadcast ads ranged from 4% to 12%, and for print ads, from 3% to 6% (respondents could give multiple reasons, and there were several variants of the question).

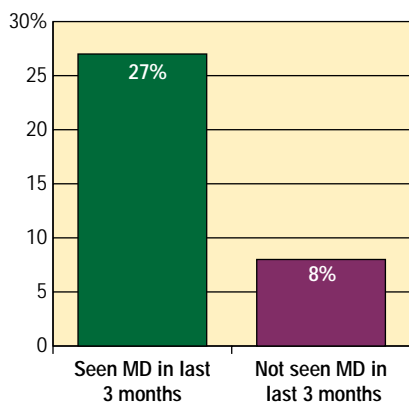
Nonetheless, a substantial proportion were prepared to ask for a prescription drug. About one-third of those who did not expect to continue their medication said they asked their doctor whether there was a prescription drug for their condition. Thirteen percent asked about a specific brand (amounting to about 9% of the entire group who had seen physicians in the past three months). Eight percent mentioned a specific ad, and 4% brought some kind of information with them (not necessarily an ad, however).

Next came a series of questions that considered many people's concerns about how DTC advertising works. Respondents reported that their doctors responded very favorably when patients mentioned ads or asked about specific brands. About 80% said their doctor welcomed their questions, reacted as if those questions were an ordinary part of a visit, and discussed the drugs with their patients. Eighty-five percent of respondents were satisfied or very satisfied with this discussion, with only 7% unsatisfied or very unsatisfied. In fact, only 3% thought their doctor would be likely to get upset at being asked about an advertised prescription drug. Finally, and most important in view of the widespread fear that DTC advertising creates a barrier to good communication, 62% agreed or strongly agreed that DTC ads helped them have better discussions with their physicians.

The FDA study clearly suggests that contrary to the opinion of some critics, if any-

Asking About Condition Not Previously Discussed

Has an ad ever caused you to ask a doctor about a medical condition or illness you hadn't previously talked about? (Percent answering "Yes")



Source: www.fda.gov/cder/ddmac/dtcindex.htm

thing, DTC improves patient-doctor interactions. Perhaps even more interesting, doctors tend to respond to the condition rather than the particular drug advertised—while half of respondents' doctors wrote prescriptions for the advertised drug, another one-third wrote for a different brand, 14% recommended an over-the-counter drug, and 15% recommended no drug at all. Meanwhile, 29% of respondents received advice to change their lifestyle or behavior. Most importantly, advertising seems to serve an important educational role, the benefits of which accrue first and foremost to patients. This is a striking example of a basic finding in the economics of advertising—that brand promotion often provides basic information that consumers need to know, but that no one has an incentive to provide to consumers unless the missing information is promoted with a branded product. When manufacturers of cholesterol-reducing drugs advertise their products, all they can do

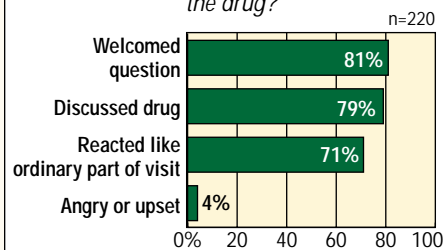
is get the patients to their doctors—who then in turn may promote healthy lifestyles or competing brands rather than the manufacturer's own product. That aspect of DTC advertising is usually ignored in public discussions. The FDA survey tells us that DTC advertising, rather than being an exception to the rule, is part of the general phenomenon of advertising improving consumer information.

What do consumers think they gain from DTC ads? Asked whether they liked seeing DTC ads, those who liked seeing them outnumbered those who did not by nearly two to one. Eighty-six percent said the ads "help make me aware of new drugs," thus validating what is surely one of the basic goals of DTC ads as well as an important justification for permitting the ads to take place.

Equally important, and perhaps more surprising, is the mix of information that respondents saw in DTC ads. A natural question is whether DTC ads emphasize the benefits of prescription drugs while downplaying the risks. Decades of surveys have shown that about 70% of consumers expect ads to be strongly biased in favor of the product being advertised.

How Did Doctor React?

Which of the these possible reactions did your doctor have when you asked about the drug?



Source: www.fda.gov/cder/ddmac/dtcindex.htm

In other words, consumers expect ads to make extravagant claims and to put products in an extremely favorable light. The result has been pervasive consumer skepticism of advertising. This reasoning also appears to apply to DTC ads, but with somewhat less force: 58% agreed that ads make drugs seem better than they really are.

The more detailed questions, on the other hand, reveal a strikingly balanced assessment. When asked what kinds of information they saw in ads, 87% of the FDA's respondents said, "the benefits of the drug"—while 82% said, "risks or side effects," and 81%, "who should not take the drug." Respondents were also asked what kinds of information the ads did not provide enough of: 59% said ads do not give enough information on the risks of drugs, but almost as many—49%—said ads do not give enough information on the benefits of drugs.

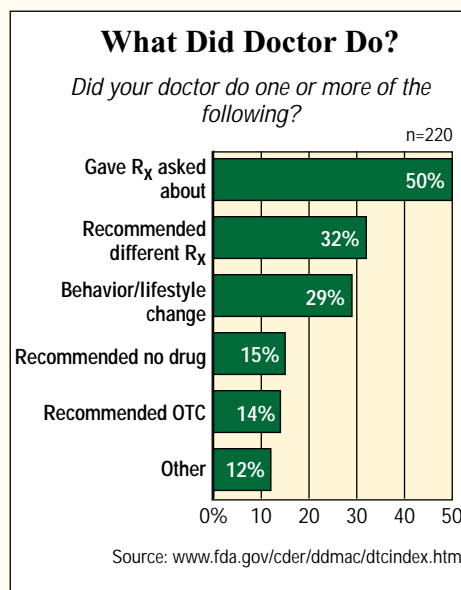
Finally, the survey addressed some broader issues. Asked whether DTC ads "make it seem like the doctor is not needed to decide whether a drug is right for me," 70% disagreed. Responding to a question that went straight to the heart of many debates over DTC advertising, only 29% agreed that ads are allowed only for the "safest" prescription drugs. The FDA survey thus gave voice to respondents who want a strong role in prescription drug usage even when there might be substantial risks that accompany the potential benefits.

The FDA's DTC Survey in Perspective

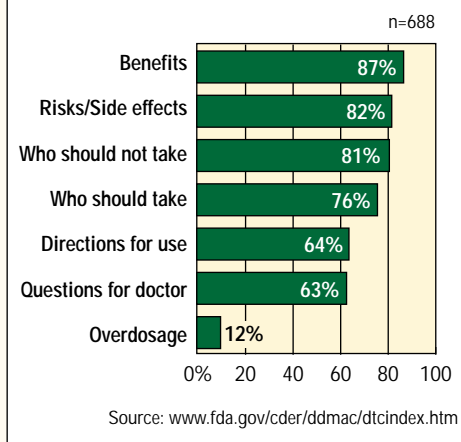
When the FDA issued its August 1999 notification that reaffirmed the 1997

guidelines for DTC advertising, it did so in the face of considerable criticism and opposition from segments of the physician community, managed care, consumer groups, and health care analysts. The FDA reiterated its traditional requirements that in addition to being nondeceptive, prescription drug advertising must meet a rigorous set of informational requirements to:

- present a fair balance between information about effectiveness and information about risk.
- include a thorough major statement conveying all of the product's most important risk information in consumer-friendly language.
- communicate all information relevant to the product's indication (including limitations to use) in consumer-friendly language.
- certain drugs (e.g., those with "black-box" warning labels) may not be advertised directly to consumers.



What Information is Recalled in TV Ads?



The FDA had at hand a number of DTC surveys in August 1999, and it must have had at least preliminary results from its own survey. The FDA clearly believed that the available evidence indicated that DTC advertising meets these standards.

The FDA also said it would continue to review its policies, continue to closely scrutinize DTC ads, and seek additional information on the effects of DTC ads. An important part of that additional information consists of the final results from the FDA's own survey. As we have seen, those results provide powerful evidence that on the whole, DTC ads tend to satisfy the FDA's standards for prescription drug advertising, as well as support for the FDA's willingness to permit DTC advertising despite the misgivings of foreign regulators and others. The survey is all the more persuasive because it was well-designed, straightforward, and

expertly administered.

Equally important is what the FDA's survey tells us about DTC advertising as a phenomenon. Despite widespread anxiety over the possibility of undue patient pressure for unwise prescribing, the survey documented friendly patient-doctor discussions and reasonable medical decisions that often strayed far from simply prescribing what patients heard about through advertising. In addition, it is apparent that advertising supplied important information that was new to patients, and motivated them to seek medical attention for problems they had not previously asked their doctors about.

Asked whether DTC ads "make it seem like the doctor is not needed to decide whether a drug is right for me," 70% disagreed.

DTC advertising is far more than a striking phenomenon in pharmaceutical marketing. It is an emerging story validating, once again, the consumer benefits of advertising and marketing. And it has already assumed a central role in increasing the scope of consumer initiative and decision-making in their own health care.

John Calfee is a Resident Scholar at the American Enterprise Institute in Washington, DC, and the author of *Prices, Markets, and the Pharmaceutical Revolution* (AEI Press, 2000). He can be reached at The American Enterprise Institute, 1150 17th St., NW, Washington, DC, 202-862-7175; fax: 202-862-7177; e-mail: calfeej@aei.org.

SECTION III

Information Matters: The Consumer as the Integrated Health Care System

Alison Keith, PhD

The future of health care is the consumer.

In a very real sense, the consumer has always been at the heart of health care: the consumer is the ultimate payer, through taxes, insurance premiums, foregone wages, or out-of-pocket expenditures. At the same time, the consumer is the ultimate beneficiary, from enjoying improved health-related quality of life and from escaping premature mortality.

Most health care systems seem to have the patient at the center. But in fact, the patient has been the relatively powerless recipient of well-intentioned care rather than a powerful center from which the criteria for the patient's own health care and the shape of the overall system radiate, with decisions made as full partners with health care professionals. For the new century, it is an easy prediction that consumers will assume greater control of their health and health care. Just think of the power of the Internet. It will be our challenge to respond to, but also, to foster increasingly empowered consumers.

With complex products ("health" and "health care") and complex systems (e.g., government-provided health care), it is especially

difficult to ensure that the system is efficient. An efficient system provides the array of goods and services consumers would most want and be willing to pay for, reflecting the tradeoffs in terms of what must be given up in order to have these. The "right" tradeoffs are those that suit people's preferences and values, and those best positioned to recognize and translate those preferences are the people affected—consumers themselves.

Given sufficient and accurate information about the options—information greatly enhanced by DTC advertising—a consumer knows better than anyone else whether he or she would prefer a product with fewer unpleasant side effects even at a slightly higher risk of some serious event. Consumers who are not professionally trained in health care are not so foolish as to discard the expert advice of medical professionals. Valuing and using technical experts is not the same, however, as electing to abdicate decision making to them. Rather, the ideal—and the emerging model—is a full partnership between patient and health care professional.

In fact, it would be pure illusion to suppose that medical decisions have been made primarily by health professionals even in the

past. Patients and their families are the primary health care providers. Consumers shape their own health through diet and exercise and prudent (and occasionally not-so-prudent) risk-taking and a panoply of other behaviors. They elect and implement over-the-counter and homeopathic and herbal remedies. They decide whether and when to approach the formal health care system. They have a great deal of information about themselves—symptoms, experiences, behaviors, preferences. They share or withhold this information from health care practitioners. Actually, the consumer may be the best, or even only, integrator of care received across various elements of the health care system.

The single common element of a series of visits to various medical specialists is the patient, and the only person who has knowledge of the combined effects of self-care and professional care is the person choosing and experiencing both. Finally, upon receipt of a physician's prescription for therapy, patients follow through on the therapeutic regimen or do not. (It is estimated that perhaps one-third of patients fail to "comply" with the physician's prescription.)

What then is meant by the "increasing activism of consumers in health care?" In addition to their traditional patterns of self-care, consumers have recently begun taking an increasingly visible, vocal, and proactive role in their dealings with health care professionals and with the formal health care system. They are seeking out and finding and using more, and more sophisticated,

information about health and health care in general and about their own personal health care needs and options. Individual consumers are feeling more confident because they are more competent in raising questions and discussing options with their personal physicians and in making explicit decisions about their own health care.

The role of consumers in determining their own health care will be even more pivotal in coming decades. Continuing growth in health care utilization, accelerated by growing proportions of the elderly, and ever more clear budgetary constraints will increase the tension between patient desires and institutional controls. Cost containment strategies abound, but do not universally fulfill the promise of containing costs. At the same time, they do not necessarily get the resource tradeoffs "right," in terms of health care consumers' preferences.

Meanwhile, scientific advances in genetics point toward customized medicine. Further, the increasing health care sophistication of patients makes their full partnership in decisions yet more productive. The broader acceptance of how much of the practice of medicine must be tailored to each individual reaffirms the appropriateness of each patient's full participation in health care decisions.

How can we help health care consumers be even more informed and effective in driving the health care system and their own personal care? Consider just a few tools to help health consumers perform at their best.

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Even the very basics must not be overlooked, such as literacy, both “literal” literacy (ability to read), but also health care “literacy,” e.g., how to read and understand medicine labels, how to interpret and implement a physician’s explanations and directions. Consumers are eagerly searching out information on diseases and therapeutic options. Rather than limit the sources or types of information available to them, via the Internet, for example, how much better it would be to provide tools to help them evaluate the content and the credibility of information they find there. For example, direct-to-consumer advertising can prompt consumers to volunteer information to a physician about symptoms, about behaviors and about preferences—information that may otherwise not emerge during a consultation, yet improves the physician’s prescribing match of drug to patient.

Equipping patients with more information, and probably more questions, may encourage a more active dialogue with the physician, which in turn can nurture the growing health care competence of an individual patient. (Of course, just because there is open discussion does not mean, and should not mean, that a physician will feel compelled to prescribe the product the patient asks about.) It can also promote adherence to the desired therapeutic regimen. (How much better is patient “adherence” to an agreed-upon regimen than patient “compliance” with a paternalistically imposed regimen!) Another new tool to facilitate shared decision making is a videotape, viewed by the patient, that explains a condition and therapeutic options and includes videotaped reports from patients describing their experience after choosing one option or another.

Such a tool fosters a true patient-physician partnership and, in turn, raises the likelihood that the care the patient receives is both appropriate and desired.

A strong consumer voice in health care is both predictable and desirable. From the vantage point of the innovative pharmaceutical industry, I would suggest that it is consumers—well able to recognize therapeutic options with promise and characteristics of special importance to them—who will be the champions for pharmaceutical innovations. They know how much they value improved quality of life. They know they want to be able to be productive at work and in their family and community, and they want to feel good and enjoy their lives. They know how much they appreciate convenient dosing regimens and freedom from unpleasant side effects. They do not believe that better pharmaceutical care can come for free. Consumers recognize the reality that new and better options may cost more. They will see that short-sighted efforts to cut costs may also limit future opportunities for healthier and better lives for themselves and their children. And they will understand that this brighter future is possible only through sustained searching for innovative therapies.

Alison Keith, PhD, retired as Director, *Economic and Science Policy Analysis at Pfizer Inc in 2001.*

REFERENCES

The Economics of Direct-to-Consumer Advertising of Prescription Drugs

1. Health Care Financing Administration. National Health Expenditures Projections: 2000-2010. Available at: www.hcfa.gov/stats/nhe-proj/proj2000/proj200. Accessed July 3, 2001.
2. IMS Health. *Pharmaceutical Pricing Update*. Plymouth Meeting, Pa; March 2000:3-7.
3. Bureau of Labor Statistics. Available at: <http://stats.bls.gov/datahome.htm>. Accessed July 3, 2001.
4. Fagan SC, et al. Cost-effectiveness of tissue plasminogen activator for acute ischemic stroke. *Neurology*. 1998; 50:883-889.
5. Legg RF, et al. Cost benefit of sumatriptan to an employer. *Journal of Occupational and Environmental Medicine*. 1997;39:652-657.
6. Soumerai SB, et al. Effects of limiting Medicaid drug-reimbursement benefits on the use of psychotropic agents and acute mental health services by patients with schizophrenia. *New England Journal of Medicine*. 1994; 331:650-655.
7. NCEP issues major new cholesterol guidelines [press release]. National Institutes of Health; May 15, 2001.
8. DTC spending data from Nielsen Monitor Plus; overall spending data from Health Care Financing Administration. (See note 1 above.)
9. *Prescription Drugs and Mass Media Advertising*. National Institute for Health Care Management; September 2000.
10. Dubois R, et al. Explaining drug spending trends: does perception match reality? *Health Affairs*. 2000;19:231-239.
11. *Prescription Drug Expenditures in 2000: The Upward Trend Continues*. National Institute for Health Care Management; May 2001.
12. In the Matter of Direct-to-Consumer Promotion; Public Hearing. Docket no. 95N-0227. Views of the staff of the Bureaus of Consumer Protection and Economics of the Federal Trade Commission, presented before the Department of Health and Human Services and Food and Drug Administration; January 11, 1996.
13. Beales JH, Muris TJ. *State and Federal Regulation of National Advertising*. Washington, DC: AEI Press, 1993.
14. Federal Trade Commission, op. cit., page 4.
15. *Ibid.*, page 3.
16. *Ibid.*, page 4.
17. DTC ads may boost chronic medication compliance, Express Scripts says. F-D-C Reports *Pink Sheet*; March 5, 2001.
18. *The Health and Status of the United States Workforce*. Report prepared by Pfizer Inc based upon data from NHANES III. Available at: www.Pfizer.com. Accessed July 3, 2001.
19. *Ibid.*, page 10.
20. *Ibid.*, page 13.
21. *Ibid.*, page 23.
22. *Ibid.*, page 10.
23. U.S. Department of Health and Human Services. *Healthy People 2010: Understanding and Improving Health*. 2nd ed. Washington, DC: U.S. Government Printing Office, November 2000. Available at: www.health.gov/healthypeople/publications. Accessed July 3, 2001.
24. Keller M, et al. A comparison of nefazodone, the cognitive behavioral analysis system of psychotherapy, and their combination for the treatment of chronic depression. *New England Journal of Medicine*. 2000; 342:1462-1470.

What the FDA Survey Showed About Direct-to-Consumer Prescription Drug Advertising

1. See Calfee J. What consumer surveys show about direct-to-consumer advertising of prescription drugs. 2001. Available at: www.aei.org.
2. US Food and Drug Administration Center for Drug Administration and Research. Attitudes and behaviors associated with direct-to-consumer (DTC) promotion of prescription drugs. Available at: www.fda.gov/cder/ddmac/dtcindex.htm. Accessed July 3, 2001.



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