

the accuracy of sources of information that physicians use to learn about new drugs or devices. There is evidence that many drug advertisements are not balanced or accurate,^{13,14} and duped gatekeepers may not adequately resist patients' exhortations to write a prescription.

Since a ban on the advertising of pharmaceutical agents is incompatible with the First Amendment, much stricter control by the FDA of misleading advertising is necessary. Although expenditures for the promotion of drugs increased from \$11 billion in 1997 to \$15.7 billion in 2000 (Fig. 1), there was a significant decrease in the number of actions taken by the FDA to enforce advertising regulations — from 139 letters of warning to companies or notices of violation in 1997 to 79 in 2000 and an estimated 73 in 2001. The FDA is grossly understaffed for this important oversight function: the entire Division of Drug Marketing, Advertising, and Communications has had only 28 to 30 employees since 1997 (Abrams T: personal communication). A further handicap for the FDA is that it lacks the legal authority to impose civil monetary penalties on companies, even when they repeatedly violate the law. An editorial in a December 2001 issue of *Business Week* commented that “pharmaceutical company advertising on TV promotes high-priced new drugs with marginal improvement over cheaper generic versions. The FDA should crack down harder on misleading ads.”¹⁶ In the realm of screening with the use of computed tomography, analyzed by Lee and Brennan,² enforcement is beginning to occur. The FDA recently sent a notice of violation to a company, CATscan2000, for illegally promoting screening for heart disease in asymptomatic people: this form of technology has not been approved for such screening.¹⁷

Beyond increased enforcement by the FDA, the issue of better information for patients must be addressed. The irritation felt by many physicians when patients approach them after seeing a direct-to-consumer advertisement may derive from the fact that such advertisements, with their powerful, emotion-arousing images and frequently unbalanced information on safety and effectiveness, mislead patients into believing that drugs are better than they actually are. There is a hollow ring to the statement by Pharmaceutical Research and Manufacturers of America president Alan Holmer that “direct-to-consumer advertising is an excellent way to meet the growing demand for medical information, empowering consumers by educating them about health conditions and possible treatments.”¹⁸

The education of patients — or physicians — is too important to be left to the pharmaceutical industry, with its pseudoeducational campaigns designed, first and foremost, to promote drugs. Public

Health Service agencies such as the National Institutes of Health and the FDA, along with medical educators in schools and residency programs, must move much more forcefully to replace tainted drug company “education” with scientifically based, useful information that will stimulate better conversations between doctors and patients and lead to true empowerment.

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REFERENCES

- Rosenthal MB, Berndt ER, Donohue JM, Frank RG, Epstein AM. Promotion of prescription drugs to consumers. *N Engl J Med* 2002;346:498-505.
- Lee TH, Brennan TA. Direct-to-consumer marketing of high-technology screening tests. *N Engl J Med* 2002;346:529-31.
- Mintzes B. Blurring the boundaries: new trends in drug promotion. Amsterdam: HAI-Europe, 1998. (Accessed January 25, 2002, at <http://www.haiweb.org/pubs/blurring/blurring.intro.html>.)
- Ingelfinger FJ. Advertising: informational but not educational. *N Engl J Med* 1972;286:1318-9.
- Understanding the effects of direct-to-consumer prescription drug advertising. Menlo Park, Calif.: The Henry J. Kaiser Family Foundation, November 2001.
- Bell RA, Wilkes MS, Kravitz RL. The educational value of consumer-targeted prescription drug print advertising. *J Fam Pract* 2000;49:1092-8.
- Leacock S. The garden of folly. New York: Dodd Mead, 1924:122-31.
- Wolfe S. Drug advertisements that go straight to the hippocampus. *Lancet* 1996;348:632.
- Why Rubin-Ehrenthal sticks exclusively to DTC accounts. *Medical Marketing and Media*. September 1999:136-46.
- Liebman M. Return on TV advertising isn't a clear picture. *Medical Marketing and Media*. November 2001:81-4.
- Bell RA, Kravitz RL, Wilkes MS. Direct-to-consumer prescription drug advertising and the public. *J Gen Intern Med* 1999;14:651-7.
- Davis JJ. Riskier than we think? The relationship between risk statement completeness and perceptions of direct to consumer advertised prescription drugs. *J Health Commun* 2000;5:349-69.
- Stryer D, Bero LA. Characteristics of materials distributed by drug companies: an evaluation of appropriateness. *J Gen Intern Med* 1996;11:575-83.
- Wilkes MS, Doblin BH, Shapiro ME. Pharmaceutical advertisements in leading medical journals: experts' assessments. *Ann Intern Med* 1992;116:912-9.
- Center for Drug Evaluation and Research. Compliance activities: warning letters and notice of violation letters to pharmaceutical companies. Rockville, Md.: Food and Drug Administration, 2002. (Accessed January 25, 2002, at <http://www.fda.gov/cder/warn/index.htm>.)
- How to control drug costs, simply. *Business Week*. December 10, 2001.
- Letter to CATscan 2000 President/CEO Gina Johnson. Rockville, Md.: Food and Drug Administration, January 3, 2002.
- Holmer AF. Direct-to-consumer prescription drug advertising builds bridges between patients and physicians. *JAMA* 1999;281:380-2.

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DIRECT-TO-CONSUMER ADVERTISING — STRENGTHENING OUR HEALTH CARE SYSTEM

IT has been almost five years since the Food and Drug Administration (FDA) issued guidelines clarifying the agency's broadcast requirements for the advertising of specific pharmaceutical agents directly to

consumers on television.¹ Previously, most direct-to-consumer advertising had been confined to newspapers and magazines. We think this expansion to television has been a positive step.

Does direct-to-consumer advertising strengthen or weaken the physician-patient relationship? Physicians should and do remain in control of prescribing medicines. As the article by Rosenthal et al. in this issue of the *Journal*² makes clear, pharmaceutical companies recognize this fact by directing a large proportion of their promotional activities toward physicians. Moreover, survey data consistently show that when patients ask a physician to prescribe a specific medicine that has been advertised directly to consumers, many receive a different medicine or an alternative, nonpharmaceutical treatment. Among respondents to an FDA survey who said advertisements had caused them to talk with a physician and ask for a particular drug, about half said their doctor recommended a nondrug therapy or a different medicine.³

We disagree with the assertion that direct-to-consumer advertising bypasses physicians. The purpose of this advertising is to encourage patients to talk to their physicians about their medical conditions and treatment options. In fact, every television advertisement for a prescription drug must include the message that viewers should ask their physician or pharmacist about the product. Such discussions are beneficial — to the patient, who gains a better understanding of the physician's recommendation for treatment, and to the physician, who gains a better understanding of the patient's needs. In the FDA survey, most patients who had been prompted by direct-to-consumer advertising to discuss a drug with their doctor stated that their doctor welcomed the question (81 percent), discussed the drug with them (79 percent), and reacted as if the question were an ordinary part of the visit (71 percent).

The physician-patient relationship is strengthened, not weakened, when, as surveys show, direct-to-consumer advertising prompts a patient to talk with a physician for the first time about a previously undiscussed condition. A 1999 survey by *Prevention* magazine found that since 1997, as many as 24 million Americans had been prompted by a direct-to-consumer advertisement to talk to a doctor about a medical condition they had previously not discussed.⁴ This type of advertising also adds to the information available to patients about the risks, side effects, and treatment profile of a particular drug. For example, 82 percent of the respondents to the FDA survey³ reported seeing information on risks or side effects in direct-to-consumer advertising, and 81 percent reported seeing information on who should not take a drug.

Moreover, direct-to-consumer advertising appears to encourage compliance with physician-prescribed

treatment regimens. Lack of compliance is a critical problem in achieving efficacious medical care. In the 2000 *Prevention* survey,⁵ 22 percent of consumers said direct-to-consumer advertising made it more likely — whereas only 3 percent said it made it less likely — that they would take their medicine regularly; 33 percent of respondents to the 1999 survey reported that such advertising had reminded them to refill a prescription.⁴ A study by Pfizer and RxRemedy from June 2001 found that the percentage of patients with diabetes, depression, elevated cholesterol levels, arthritis, or allergies who continued with therapy after six months was substantially higher when the patient asked for a medicine after being prompted by direct-to-consumer advertising than when the patient was given a prescription for a medicine without such prompting.⁶

Direct-to-consumer advertising is concentrated among a few therapeutic classes. These classes include agents for the treatment of conditions whose symptoms are easily recognized by consumers (such as arthritis, seasonal allergies, and obesity), agents for the treatment of chronic diseases that are often undiagnosed (such as high cholesterol, osteoporosis, and depression), and agents for the enhancement of the quality of life (such as those for skin conditions or hair loss). These advertisements may help consumers to recognize symptoms and encourage them to seek appropriate care.

What accounts for the emergence of direct-to-consumer advertising? Patients are turning to the growing volume of publicly accessible health care information. Dr. Nancy Ostrove, deputy director of the FDA's Division of Drug Marketing, Advertising, and Communications, Center for Drug Evaluation and Research, has argued that direct-to-consumer advertising of pharmaceuticals "is consistent with the whole trend toward consumer empowerment" and has asserted her belief that "there is a certain public health benefit associated with letting people know what's available."⁷ In keeping with this trend, direct-to-consumer advertising is used throughout our health care system: managed care organizations, hospitals, and doctors all advertise to consumers. Unlike other health care information, direct-to-consumer advertising of drugs is subject to intense scrutiny by FDA regulators, who evaluate it for accuracy and balance.

In today's health care marketplace, there are numerous financial factors that influence the delivery of medical care. There are payment incentives that are linked to patterns of prescribing and dispensing of medications, formularies that are typically structured at least partially on the basis of financial considerations, and variable cost-sharing arrangements with patients for certain types of medicines. In the light of these strategies designed to influence decisions about the med-

icines that patients receive, the provision of information to patients about their treatment options through direct-to-consumer advertising is a healthy development that helps balance the system. With so many parties using such financial incentives and encouraging patients to assume increased responsibility for their medical care, it is surprising that the transmission of FDA-regulated information to consumers has engendered controversy.

Direct-to-consumer advertising does not affect the prices of drugs⁸: price increases of drugs are the least important factor contributing to the increase in pharmaceutical spending. In 2000, price inflation accounted for approximately one fifth of the growth.⁹ Such advertising may increase the rate of use of prescription drugs by prompting the treatment of patients for previously untreated conditions and by improving compliance with treatment among those with known conditions. If so, this increase is a positive development. The proper use of prescription drugs is often the most effective and least expensive form of health care. Ostrove testified to a Senate subcommittee in July 2001 that there is no evidence that direct-to-consumer advertising is increasing inappropriate prescribing,¹⁰ and an unpublished industry-supported study on cholesterol-lowering statins, which are the subject of a substantial amount of direct-to-consumer advertising, found no tendency toward less appropriate prescribing as the rate of use increased.¹¹ As John Calfee of the American Enterprise Institute has observed, "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."¹²

Direct-to-consumer advertising is clearly here to stay. Given this reality, physicians must, as Rosenthal et al. note, "develop strategies for helping their patients evaluate this information and make appropriate and informed choices about treatment."² With

such a diversity of treatment options available for acute and chronic diseases, patients need the guidance that only a trusted health care professional can provide. The health care system is stronger as a consequence. Direct-to-consumer advertising does not replace the physician-patient relationship; its purpose is rather to encourage an informed discussion between patient and physician.

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REFERENCES

- Center for Drug Evaluation and Research. Guidance for Industry: consumer-directed broadcast advertisements. Rockville, Md.: Food and Drug Administration, August 1999. (Accessed January 25, 2002, at <http://www.fda.gov/cder/guidance/1804fnl.htm>.)
- Rosenthal MB, Berndt ER, Donohue JM, Frank RG, Epstein AM. Promotion of prescription drugs to consumers. *N Engl J Med* 2002;346:498-505.
- Center for Drug Evaluation and Research. Attitudes and behaviors associated with direct-to-consumer (DTC) promotion of prescription drugs: main survey results. Rockville, Md.: Food and Drug Administration, 1999. (Accessed January 25, 2002, at <http://www.fda.gov/cder/ddmac/dtcindex.htm>.)
- Year two: a national survey of consumer reactions to direct-to-consumer advertising. Emmaus, Pa.: Rodale, 1999.
- International survey on wellness and consumer reactions to DTC advertising of Rx drugs. Emmaus, Pa.: Rodale, 2000.
- Drug ads help people take their medicines. New York: Pfizer, November 29, 2001. (Accessed January 28, 2002, at <http://www.pfizer.com/pfizerinc/about/press/dtcads.html>.)
- Stolberg SG. The Nation: ads that circumvent doctors: want a new drug? Plenty to choose from on TV. *New York Times*. January 23, 2000.
- Manning R, Keith A. The economics of direct-to-consumer advertising of prescription drugs. *Economic Realities in Health Care Policy* 2001;2(1):3-9.
- Pharmaceutical industry profile 2001: a century of progress. Washington, D.C.: Pharmaceutical Research and Manufacturers of America, 2001.
- Teinowitz I. DTC regulation by FDA debated; agency says it has no evidence ads prompt unnecessary prescriptions. *Advertising Age*. July 30, 2001:6.
- Calfee J, Winston C, Stempski R. Statin drug advertising effects. Presented at the University of Chicago Conference on the Regulation of Medical Innovation and Pharmaceutical Markets, Chicago, April 20-21, 2001.
- Calfee JE. Public hearings on direct-to-consumer advertising of prescription drugs. Testimony before the Senate Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism, Committee on Commerce, Science and Transportation, Washington, D.C., July 24, 2001:2-3.

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