

reassurance are thin. Even more troubling are the excess invasive diagnostic procedures that must be performed to prove that an incidental lesion discovered by such screening is not malignant. I am sure that there will be anecdotes about people who believe that their lives were saved by the early discovery of such lesions, but these stories will be counterbalanced by untold stories about those who suffer from the inevitable complications of diagnostic procedures that are required in order to prove that an incidentally discovered lesion was benign.

The issue of direct-to-consumer advertising in health care is emotionally and economically charged. In order to provide balance, we solicited two editorials, both of which appear in this issue, on the subject of direct-to-consumer marketing. The first, by Sidney Wolfe of Public Citizen Health Research Group, a consumer watchdog group, lays out arguments against this approach to marketing.³ The companion piece, by Alan Holmer of Pharmaceutical Research and Manufacturers of America, a consortium of major pharmaceutical manufacturers, argues that direct-to-consumer advertising provides benefits for patients and physicians.⁴ These marketing methods are not likely to go away; as health care professionals, we need to understand such new approaches to marketing medical services. Most important, we need to remind our patients that what they see and hear in the mass media is simply advertising. Although advertising does inform patients, it should not be confused with medical advice given in the best interest of the patient by a learned intermediary.

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DIRECT-TO-CONSUMER ADVERTISING — EDUCATION OR EMOTION PROMOTION?

DURING the past two decades, there has been an irreversible change in the nature of the doctor-patient relationship. Patients are seeking much more medical information and are actively participating in decisions affecting their health. Intruding into this

trend has been the rise of direct-to-consumer promotion, which, in its initial thrust, bypasses primary care doctors and other physicians. Although increased access by patients to accurate, objective information about tests to diagnose and drugs to treat illnesses is an important advance, confusion arises when commercially driven promotional information is represented as educational. Two articles in this issue of the *Journal* address the direct-to-consumer promotion of medical products and services. Rosenthal et al.¹ describe the resources allocated to direct-to-consumer advertising of prescription drugs, as compared with other forms of promotion. Lee and Brennan² examine issues arising from the direct-to-consumer marketing of high-technology medical screening tests. These articles raise several questions. Is direct-to-consumer advertising educational or emotional? How often is it misleading? Is enforcement by the Food and Drug Administration (FDA) of advertising regulations adequate? What can be done to neutralize the negative effect of this type of advertising?

In an excellent review of direct-to-consumer promotion, Mintzes stated that “the question is not whether consumers should obtain information about treatment options; the question is whether drug promotion — whose aim is to sell a product — can provide the type of information consumers need.”³ Addressing the issue of pharmaceutical advertising more generally 30 years ago in the *Journal*, Ingelfinger⁴ argued that “advertisements should be overtly recognized for what they are — an unabashed attempt to get someone to buy something, although some useful information may be provided in the process.” He suggested that such advertising should be divested of its “pseudo-educational character.”

Serious deficiencies have been documented in the educational value of advertising for over-the-counter drugs. In a survey of 1872 viewers of television advertisements, 70 percent thought they had learned little or nothing more about the health condition requiring treatment, and 59 percent thought they knew little or nothing more about the drug being advertised.⁵ Another study found that whereas many advertisements provided information about the name and symptoms of the disease for which the drug was being promoted, few educated patients about the success rate of the drug, the necessary duration of use, alternative treatments (including behavioral changes) that could improve their health, or misconceptions about the disease to be treated. The average number of “educational codes” (i.e., specific learning points relating to a medical condition or a treatment) present in the advertisements was only 3.2 out of a possible 11.⁶

None of these deficiencies should be surprising in the light of the characterization of advertising by the Canadian economist Stephen Leacock as “the science

of arresting the human intelligence long enough to get money from it.” Leacock also thought that, for the purpose of selling, advertising “is superior to reality.”⁷ An advertisement, aimed at the marketers of pharmaceutical products, from an agency that creates drug advertisements provides some revealing insights about how the process works. The promotional material describes the hippocampus as the “prescription-writing center of the brain” — the part that “processes information by connecting new concepts with the parts of the brain where gut instincts are formed, areas that influence emotional behavior and form memories.” The advertising agency asserts that its “communications are focused on making the hippocampus respond positively to your product . . . [by demonstrating] how your product is superior and unique.”⁸ An executive of a company that focuses on direct-to-consumer advertising commented that “consumers react emotionally, so you want to know how they feel about your message and what emotional triggers will get them to act. . . . We want to identify the emotions we can tap into to get that customer to take the desired course of action.”⁹ Another article, describing problems the drug industry has had in adapting to direct-to-consumer marketing, said that

companies “are overly focused on communicating rational attributes to customers. But consumers often choose a product on [the basis of] emotional attributes. . . . How an emotional appeal fits into fair balance in advertising prescription drugs under the requirements and approval process of FDA is not clear.”¹⁰

Patients have dangerous misperceptions about direct-to-consumer advertising. According to one study, a substantial proportion of people incorrectly believed that only the safest and most effective drugs could be advertised directly to consumers and that the FDA required that it be allowed to review advertisements before they were published.¹¹ According to another study, consumers rated the safety and appeal of drugs described with an incomplete statement of risks more positively than similar drugs described with a more complete statement of risks.¹²

Defenses of direct-to-consumer advertising by the pharmaceutical industry inevitably mention that the real gatekeeper is the doctor, since only the doctor can write a prescription. Even Rosenthal et al. state that doctors will only write a prescription for a drug when they are “familiar with it and comfortable prescribing it.”¹ Although it is beyond the scope of this editorial, it is important to examine studies assessing

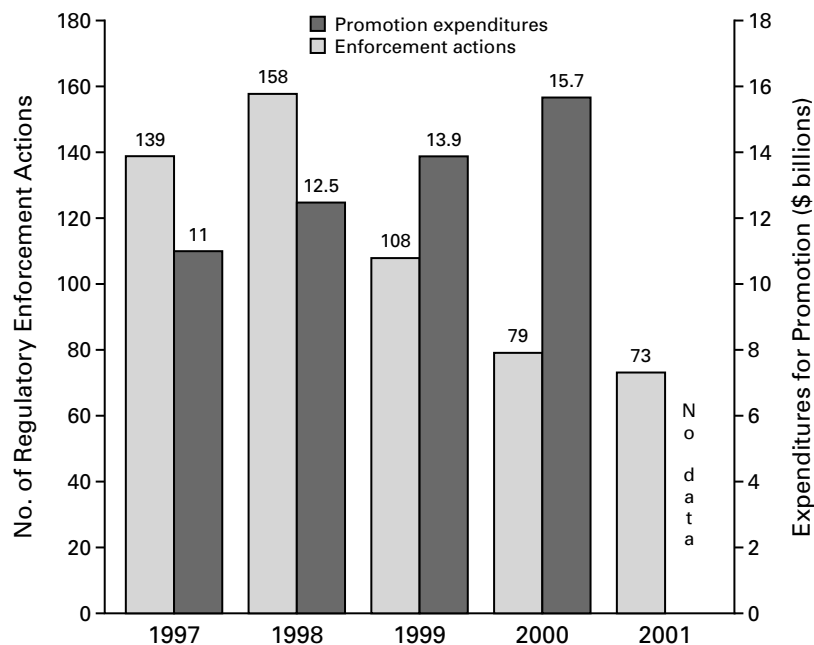


Figure 1. FDA Actions Enforcing Drug Advertising Regulations and Drug-Industry Expenditures for Promotion.

Data on promotion are as reported by Rosenthal et al.¹ Data on enforcement actions (warning letters and notices of violation) are from the FDA Web site.¹⁵ FDA enforcement data for 2001 were extrapolated from data for the first 11 months.

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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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