DIRECT-TO-CONSUMER PRESCRIPTION DRUG ADVERTISING

A Position Paper

of the

American College of Physicians

13 March 1984

INTRODUCTION

Traditionally, the promotion of prescription drugs by pharmaceutical manufacturers has been limited to physicians and other health professionals who prescribe, dispense, or administer medicines. Recently, several pharmaceutical companies (Pfizer Pharmaceuticals; Eli Lilly & Co.; Merck, Sharp & Dohme; the Burroughs Wellcome Company; and Boots Pharmaceuticals, Inc.) have experimented with advertising prescription drugs directly to consumers. In 1982, Merck, Sharp & Dohme advertised a vaccine, Pneumovax, as effective against pneumococcal pneumonia. On 19 May 1983, Boots Pharmaceuticals, Inc., launched the first television advertising campaign (in Florida) claiming its brand of ibuprofen (Rufen) was available at a lower price than other brands.

Direct-to-consumer prescription drug advertising has generated active debate among physicians, other health care professionals, consumer groups, and pharmaceutical firms. The problems of providing patients appropriate information about prescription drugs, how this information should be presented, who should present it, and federal regulation of this process are issues being debated. The Food and Drug Administration (FDA) is responding to these debates with a comprehensive study on the effect of advertisements on consumers.

POSITION

The American College of Physicians supports the patient's right to know information about prescription drugs that allows their safe and effective use. The College does not, however, favor direct-to-consumer prescription drug advertising; promotion of commercial products does not constitute appropriate patient education about therapeutics.

RATIONALE

Some pharmaceutical manufacturers, attempting to respond to some consumer and medical organizations' concerns about the need for increased patient education about pharmaceuticals, have proposed direct-to-consumer advertising of prescription drugs. Although advertising would add to the quantity of information consumers have about prescription drugs, the issue is whether the information provided through advertising would be the type (accurate and appropriate) that is most useful to patients. Advertising, by its nature, consists of both information and promotion. It not only presents information intended to educate; it is also calculated to encourage increased consumption of the advertised product.
For example, Merck, Sharp & Dohme in 1982 advertised its pneumococcal pneumonia vaccine by promoting its availability for Medicare reimbursement. Print advertisements in newspapers and national publications described the vaccine (Pneumovax) and touted its use for all people over age 65, promising that it "may provide protection for as long as five years against the most common causes of pneumococcal pneumonia in the United States." Although presented as fact, advertising claims regarding the necessity for immunization against pneumococcal pneumonia are at odds with medical recommendations about the effectiveness of this vaccine. The College, through its Clinical Efficacy Assessment Project, has endorsed pneumococcal vaccine only for people considered at high risk of developing pneumococcal pneumonia and has stated that "a strong recommendation for the universal use of the vaccine in healthy elderly patients cannot be made at this time (1982)" (1). The College recommendation is consistent with that made by the Centers for Disease Control in 1981 (2).

Proponents of direct-to-consumer prescription drug advertising have suggested that consumer advertising could have some positive effects on the public health. Advertising could help satisfy the consumer's desire to know more about prescription drugs, and thus help to ensure that drugs are used appropriately. Advertising could reduce the number of people who do not seek medical treatment because they are not aware they suffer a condition for which effective treatment exists. Advertising could speed the adoption and utilization of important medical advances. Opponents of direct-to-consumer prescription drug advertising note that at $14 billion per year, the market for prescription drug advertising is even now huge (3). New advertising would be an add-on cost for the industry, and would have to be passed on to patients. Consumers now spend an average of $60 per year on prescription drugs. Advertising would undoubtedly increase that cost.

Advertising also could encourage the use of unnecessary or deleterious treatments and could speed the acceptance of drugs that are not cost-effective. Consumer groups, such as the American Association of Retired Persons (AARP), have warned that direct-to-consumer prescription drug advertising might increase unnecessary drug consumption. The AARP has stated that good medical practice, including patient education by physicians, is the most appropriate way to decrease unnecessary drug consumption (4). The Consumer Federation of America also has stated that consumer advertising of prescription drugs would generate excessive demand for drugs by enhancing the belief that "there is a pill for every ill" (3). Some physicians have expressed concern that promotion of prescription drugs would result in patients beseeching their physicians with requests for specific products. In a survey conducted in 1982 by American Medical News, nearly two-thirds of the physicians polled said they were opposed to direct-to-consumer prescription drug advertising (5).

The American College of Physicians believes that direct-to-consumer prescription drug advertising may do real harm. Advertising could lead patients to solicit physicians to prescribe unnecessary drugs; it could confuse patients by leading them to believe that a minor difference in drugs represents a major therapeutic advance; and it could foster increased drug taking in a society that may be already overmedicated.

There are additional concerns among physicians about the promotional nature of advertising. Chief among these is the concern that advertising might be
misleading to the lay public. There are, for example, cases of easily mis-interpreted advertisements for prescription products aimed at the comparatively sophisticated physician audience. Advertisers are skilled at communicating complicated, unresolved, controversial information as solid fact. They also have learned to demonstrate "facts" with pictures, charts, and graphs, while explaining the "facts" in small print; for example, one advertisement for an analgesic published in many national medical journals assigned to small print at the bottom of the page the explanation for the graph showing a blood level twice that of other analgesics: the dosage (20 grains) also was twice that of the other analgesics.

This type of physician-directed advertisement has been permitted by the FDA in accordance with its "fair balance" doctrine (balancing promotional aspects of the message with required warnings and precautions). As part of this doctrine, the FDA requires that "brief summary of prescription information" statements accompany prescription drug advertisements. These "brief summaries" are lengthy, somewhat difficult to read, and often not on the same page as the promotional part of the advertisement. It is unclear how this fair balance doctrine could be met adequately in direct-to-consumer advertising, especially electronic media advertisements.

It has been suggested that advertisements aimed at patients not contain such brief summaries of factual scientific data and warnings; the American Association of Advertising Agencies (AAAA) has suggested that a "layman's" code of language be developed and used for full disclosure in print media. The AAAA also has suggested the following language for use in electronic media as a replacement for the present full disclosure:

This pharmaceutical product can be prescribed by a registered physician. Almost all medicines have side effects and limits of use, and only a physician knowledgeable of your particular case can determine the correctness of your use of this product. Follow his advice and his counsel, and be careful to take any medicine he prescribes only as his instructions indicate (6).

The FDA has suggested that presenting specific precautionary and risk information may not ensure that the consumers' impressions about a drug are fairly balanced and that, if this is true, prescription drug advertising to consumers should not be permitted because of its inherent danger (7). In order to ascertain the validity of this supposition, the FDA has begun a study of the effect of advertisements on consumers (7). The study involves 1600 consumers in four cities who will review television and print ads on drugs for arthritis and hypertension. There will be 20 television commercials with brief summaries that vary from those that give no risk information to those giving full disclosure within the actual commercial. The study focuses on what use, if any, the brief summary would serve in an advertisement directed at consumers, and hypothesizes several possible answers to this question: (1) brief summaries are not relevant at all to consumer advertising, (2) brief summaries may reinforce the physician as the only individual capable of making proper prescribing decisions, or (3) the brief summary is needed to provide broader context for consumers to understand the promotional message.
CONCLUSION

The American College of Physicians favors the approach of the Food and Drug Administration to the issue of direct-to-consumer prescription drug advertising in carefully evaluating its potential effects, but nevertheless advises that such advertising not be permitted. Promotion of prescription drugs—even as regulated by the FDA and Federal Trade Commission—has the potential, not merely for usefulness, but for harm. Advertising, by its promotional nature, is not solely informational or educational. Direct-to-consumer prescription drug advertising is likely to be carried out for the principal reason of enhancing brand name identification and loyalty. It exists to present a positive image of a product—not a balanced, scientific, objective perspective.

NOTES


5. MDs, pharmacists polled on drug ads. AM News. 5 November 1982; 3 (col 2-4), 19(col 1-4).
