UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

BEFORE THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

In the Matter of
Direct-to-Consumer Promotion; Public Hearing
Docket No. 95N-0227

Comments of the Staff of the Bureau of Consumer Protection and the Bureau of Economics of the Federal Trade Commission

January 11, 1996(1)

I. Introduction.

The Food and Drug Administration (FDA) has requested comments regarding the promotion of prescription drug products directly to consumers (DTC) through print, broadcast, and other media. Among other things, the agency announced that it "is particularly interested in exploring whether, and, if so, how, the agency's current regulatory approach should be modified.(1) The staffs of the Bureau of Consumer Protection and the Bureau of Economics of the Federal Trade Commission (FTC) offer the following comments to assist the FDA in its deliberations,(2) based on

likelihood of deception would therefore depend on a case by case evaluation. The FTC staff believes that the Commission's Deception Policy Statement and its Statement on Advertising Substantiation(10) may assist the FDA in evaluating prescription drug advertisements.

II. The Potential Effects of DTC Advertising on Consumers and the Marketplace.

Assessments of DTC regulatory options are likely to depend on one's understanding of DTC advertising's effects on consumers and the marketplace. In this section we consider this issue. First, we consider the incentives to provide consumers with information about drug therapies. Second, we describe the unique role of advertising, in general, and of DTC prescription drug advertising, in particular, in the consumer information environment. Third, we describe the potential effects of DTC advertising on competition. Finally, we consider how regulations can be designed to encourage the potentially beneficial effects of advertising while discouraging its potentially harmful effects.

A. Incentives to Provide Consumers with Information About Alternative Drug Therapies.

We believe this is a particularly good time to examine the potential value of DTC advertising. With the growth of managed care organizations, consumers are expected to become more actively involved in their health care decisions and to demand more information on alternative therapies.(11) The recent growth of DTC pharmaceutical advertising expenditures(12) is consistent with the view that consumers are demanding more product information.

Substantial information about drug therapies is provided to consumers by independent parties. Newspapers report on new drugs,(13) books describe drug options,(14) magazines discuss alternative therapies,(15) and public health organizations provide a wealth of information.(16)

Prescription drug advertising, like any type of advertising, represents only one component of the total consumer information environment, which includes the media, package inserts, reference books, doctors, and pharmacists. Advertising, like any of these components, is better at some tasks than

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,(26) which may result in improved health care.

In a regulatory scheme for DTC advertising, therefore, we would encourage balancing the benefits and the risks of allowing pharmaceutical manufacturers greater latitude in their advertising. In particular, it is important to protect consumers from deceptive information but not to stifle truthful information that could benefit consumers. As discussed below, we believe that the net benefits of DTC advertisements can be increased by limiting current disclosure requirements and by adjusting disclosure requirements according to the characteristics of different advertising venues.

III. The FTC's Approach to Advertising.

During the FDA's public hearings on October 18 and 19, 1995, regarding DTC prescription drug advertising, many commentators suggested that the FDA consider adopting an approach similar to that used by the FTC.(27) In light of these suggestions, it may be helpful for us to describe the framework used by the FTC concerning deceptive advertising.

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The FDA in its Federal Register Notice asked whether, and if so, how, the “brief summary” disclosure requirements for prescription drug advertising should be modified in the context of consumer directed advertising for prescription drugs.

The FDA has also requested comments regarding the regulation of new advertising technologies, such as the Internet. Although developing information technologies present new possibilities for the innovative delivery of valuable information to consumers, these technologies can be used to deceive consumers.(46) Although new media such as the Internet clearly present new challenges(47) with respect to monitoring and enforcing laws against deception, we believe that the core principles underlying the FTC's deception policy apply as well to these developing technologies as to more traditional advertising media.

C. Identifying the Source of an Advertisement.

The FDA also seeks comment concerning infomercials and manufacturer-supported DTC promotions that appear to be sponsored by independent third-party services.

Consumers' evaluation of information may be affected by an inaccurate perception regarding its sponsorship. A potential for deception therefore exists when consumers do not know that what appears to be a news broadcast or other programming is really an infomercial, or that what appears to be independently supplied information is really supplied by a product's manufacturer.

This concern about infomercials underlies numerous actions in recent years by the FTC, challenging the formats used as deceptive.(48) In these cases, the FTC typically barred advertisers from misrepresenting the nature of the "program" and required them to disclose, at the beginning of an infomercial and immediately before any product ordering information, that what consumers are watching is a paid commercial.(49)

The FTC also has addressed the third-party endorsement issue, both in its Guides Concerning the Use of

connections between an endorser and a seller of an advertised product that "might materially affect the weight or credibility of the endorsement (i.e., the connection is not ?reasonably expected by the audience')," should be disings if 9 -q13(s)-3(r)4(epr)4(e)13()13(pp)4(l)-1(i)113(d t)2(h)1 (ges)11(t7(and)3(ard-1(s)1d)4(e)13(s) [(c)-34.)[(di)be and id th(l)-1(

(9) See A. Masson & R. Steiner, Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws (1985); Drug Product Selection, FTC Staff Report (1979); R. Bond & D. Lean, Sales, Promotion and Product Differentiation in Two Prescription Drug Markets (1977); and Prescription Drug Price Disclosures, FTC Staff Report (1976).

(10) See infra notes 28 and 29.

(11) See H. W. Singer, Direct-to-Consumer Advertising, 14 Med. Ad News 10, 30 (October 1995); W. Borow, The AMA Explains Its About-Face on Direct-to-Consumer Advertising, Med. Marketing & Media, at 68, September 1993.

(22) Manufacturers whose success depends upon their good reputations may refrain from exaggerated claims for fear of tarnishing their reputations. Exaggerated claims can be challenged through counter-advertising by competitors, or brought to light by other information suppliers, especially the media. In addition, competitors can raise challenges through Lanham Act actions (15 U.S.C. § 1125(a)), or through complaints filed with the National Advertising Division of the Council of Better Business Bureaus, an industry self-regulatory body. See, e.g., A. Mathios and M. Plummer, Regulation of Advertising: Capital Market Effects, FTC Bureau of Economics Staff Report (1988).

(23) See, e.g., L. Benham, The Effect of Advertising on the Price of Eyeglasses, 15 J.L. & Econ. 337 (1972); J.F. Cady, An Estimate of the Price Effects of Restrictions on Drug Price Advertising, 14 Econ. Inquiry 493 (1976); K.B. Leffler, Persuasion or Information? The Economics of Prescription Drug Advertising, 24 J.L. & Econ. 45 (1981); J. Cady, An Estimate of the Price Effects of Restrictions on Drug Price Advertising, 14 Econ. Inquiry 493 (1976); W. Jacobs et al., Improving Consumer Access to Legal Services: The Case for Removing Restrictions on Truthful Advertising, Staff Report to the Federal Trade Commission (1984).

(24) The degree of competition between OTC and DTC drugs likely varies across therapeutic categories. The level of competition is likely to be particularly strong in categories where some prescription drugs are switched to OTC status. For a description of this process see P. Temin, Realized Benefits from Switching Drugs, 35 J.L. & Econ. 351 (1992).

(25) Some commentators believe that DTC advertising will increase prescription drug prices. See, e.g., Eric P. Cohen, Sounding Board: Direct-to-the-Public Advertisement of Prescription Drugs, 318 New Eng. J. Med. 373 (February 11, 1988). One argument is that advertising costs will be passed on to the consumer, resulting in higher prices. Although price effects cannot be predicted definitively a priori, we believe that DTC advertising may generally

(42) Some evidence suggests that consumers are receptive to “800” numbers in connection with the promotion of prescription drugs. Upjohn reportedly received calls from more than one million people through an “800” number appearing in its Depo- Provera ads, while three million have used an “800” number provided by the company in ads for Rogaine. See Singer, supra note 11, at 14, 35.

(43) See Murray et al., supra note 41, at 155, 164 (lack of viewer opportunity to process information disclosed in television advertising can contribute to reduction in comprehension).

(44) Id. at 165 (noting low comprehension rates for disclosures in television advertising and suggesting consideration of different roles for different media).

(45) E.g., Southwest Sunsites, Inc., 105 F.T.C. 7 (1985), aff’d, 785 F.2d 1431 (9th Cir.), cert. denied, 479 U.S. 828 (1986)(brief disclosure regarding risks Depo

(56) 21 C.F.R. § 200.200 (1994).

(57) Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976); Bond et al., Effects of Restrictions on Advertising and Commercial Practice in the Professions: The Case of Optometry 26 (1980); see also material cited supra, note 13.