



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 our experience in analyzing the effects of information in consumer product markets and in considering legal requirements that address information issues.

The FTC enforces the Federal Trade Commission Act, which among other things prohibits deceptive or unfair practices in or affecting commerce. One of the FTC's primary responsibilities is to enforce the law prohibiting deceptive practices in national advertising.(3) The FTC considers the prevention of deceptive health-related advertising claims to be of utmost importance, and has taken action in numerous cases involving deceptive health-related claims about OTC drugs,(4) food products,(5) dietary supplements,(6) and medical devices.(7) In implementing its mandate, the FTC has developed considerable expertise in the role of advertising in the consumer information environment.

The staff of the Commission also has experience examining the effects of laws affecting advertising on market performance,(8) including in the prescription drug market.(9) While important differences between advertising for prescription drugs and advertising for other products might lead to different approaches, we believe that the staff's experience, particularly regarding marketing and economic issues, has a bearing on many of the DTC advertising issues on which the FDA is seeking comment.

Truthful and non-misleading advertising can help consumers manage their own health care. Advertisements can, for example, provide timely information regarding medical advances, remind consumers about good health care practices, and supply information needed by consumers to understand and evaluate their physician's recommendations. On the other hand, deceptive or misleading advertisements in the prescription drug area can impose particularly high costs on consumers. Whether or not a particular advertisement might mislead consumers will turn on the specific facts associated with that ad (and a determination of the claims being made). Any analysis of the

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⁾

Despite the existence of these sources, economic reasoning suggests that advertising can be an important supplemental source of information.⁽¹⁷⁾ Information, like most goods, is costly to provide. However, in contrast to most products, information is not used up when it is consumed, and it is often possible to use information without paying for it, that is, to "free ride." As a result, markets may tend to provide consumers with less than the optimal amount of information.

Advertising can reduce this problem. Firms will provide health information to consumers when it is profitable to do so. Profitability depends on several factors that affect the marginal benefits and costs of advertising. For example, extensive disclosure requirements can substantially increase the cost of advertising, thereby decreasing a firm's incentive to advertise.⁽¹⁸⁾ (Of course, such disclosures may nonetheless be needed sometimes to prevent deception).

Firms have strong incentives to provide information about disease conditions and possible treatments if they can associate the information with products they sell. Although firms with relatively large market shares may find it profitable to provide advertising messages that do not make such an association, smaller competitors are less likely to find such advertising profitable, due to the "free-riding" phenomenon.

Incentives to advertise are also enhanced when firms can initiate new campaigns quickly. For example, the sooner information on product improvements reaches consumers, the sooner firms can begin through sales to recoup research and development investments and advertising expenditures. Similarly, the incentive to advertise is likely to be greater when firms can respond rapidly to advertising by competitors.

B. Prescription Drug Advertising as a Unique Source of Some Information that Can Enhance Consumer Welfare.

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 others. For example, broadcast advertisements are relatively good for disseminating short bits of information to large audiences but not for providing complex information. Complex information is often disseminated more effectively at another point in the product consideration and purchasing process, such as through labeling at the point of sale.(19) Although reference books that describe drug characteristics are useful, they may lack information about recent innovations and may not reach a wide audience. In contrast, advertising can inform about product innovations as soon as they are brought to market. Advertising can also remind people of information that they might already know but that has faded from memory.

Different forms of advertising may have different advantages and disadvantages as means of communicating information. Complex information is often communicated more effectively through print media than through broadcast media. Internet advertising may be particularly efficient at reaching small sub-populations with a strong interest in certain types of drugs.(20)

Obviously, one concern with advertised information is that manufacturers will be inclined to favor their products.(21) Although some forces weigh against this outcome,(22) they may be insufficient to prevent firms from making unfounded claims, whether intentionally or inadvertently. Deceptive claims in the prescription drug area can have serious consequences.

Although prescription drug advertising shares many characteristics of advertising in other markets, prescription drugs have several characteristics that make the analysis of prescription drug advertising to consumers distinctive. For example, product safety and efficacy is a particularly important issue in this advertising market. At the product level, this concern is addressed by the requirement that all prescription drugs be pre-approved by the FDA for safety and efficacy.

Concerns about product safety and efficacy are reflected in control of access to prescription drugs. Doctors must prescribe them, and they must be dispensed by pharmacists. These controls should help ensure that inappropriate drugs are not used.

Advertising may make consumers aware of more convenient or otherwise more desirable versions of drugs than those they currently use. 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.

C. Potential Effects of Prescription Drug Advertising on Price and Quality Competition

Advertising is an important catalyst for price and quality competition. Advertising can put downward pressure on prices by spurring competition among alternative therapies.(23) To the extent that prescription drugs compete with OTC drugs,(24) prescription drug advertising potentially can lead to lower average prices for both product categories. We recognize, however, that the ultimate effect is likely to depend on the evolution of the health care market and on the individual characteristics of drug classes and disease conditions.(25)

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 with their doctors, then their demand for the advertised products is reflected in sales and the market reflects consumer preferences.

D. Considerations Regarding Regulation.

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.

The Commission's policy with respect to deceptive advertising is set out in its Deception Policy Statement(28) and its Statement on Advertising Substantiation.(29) An advertisement is considered deceptive if it contains a representation or omission that is likely to mislead consumers acting reasonably under the circumstances, and the representation or omission is material, that is, it is likely to affect consumers' decisions regarding purchase or use of a product.(30) Thus, the FTC's approach involves identifying the claims that are conveyed by an advertisement, both expressly and by implication, and determining whether those claims are truthful and substantiated.(31)

In analyzing an advertisement, the FTC focuses on the net impression it conveys rather than on the individual elements of the ad in isolation. Because advertisements can mislead consumers by what they do not say as well as by what they do say, the omission of material information may also render an advertisement deceptive in some circumstances. Deception can occur through omission of information when that information is necessary to prevent an affirmative representation from being misleading(32), or simply by remaining silent, if doing so constitutes an implied but false representation.(33) The Commission has made clear, however, that "[n]ot all omissions are deceptive, even if providing the information would benefit consumers.(34) An omission is considered deceptive only if the absence of the information causes the advertisement to convey an inaccurate impression about a material fact.(35)

The FTC's focus when analyzing the adequacy of disclosures is on their effectiveness in communicating the necessary information in the context of the advertising at issue. When disclosure of information is necessary to prevent an advertisement from conveying an inaccurate impression, the mere physical presence of the information may not be sufficient to prevent the ad from being considered deceptive.(36) Thus, the information must be included in a manner that is calculated to be noticed, read (or heard, if orally presented), and comprehended by consumers.(37)

IV. Considering DTC Prescription Drug Advertising Issues in Light of the FTC's Approach

A. The "Brief Summary."

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.

Under an FTC deception analysis, the primary questions would be whether the brief summary requirements are necessary to prevent deception, and, if so, whether they effectively communicate the necessary information to consumers.(38) Pursuant to the FTC’s deception authority, this would be a case-by-case analysis, as the focus would be on the net impression conveyed by a specific advertisement, and whether any or all of the brief summary requirements would be necessary to prevent that advertisement from conveying a deceptive impression.(39)

The FTC’s experience in enforcing the law pertaining to deception indicates that it is often difficult to effectively communicate information to consumers. More complicated messages are more difficult to convey to consumers in an understandable manner. Fine print disclosures, whether in print or broadcast advertising, are often insufficient to effectively communicate important information.(40)

The “brief summary” that currently appears in consumer directed prescription drug advertising is obviously highly technical, complicated, and lengthy. It is often presented in fine print, in language that is designed for health care professionals rather than lay persons. We believe that the information contained therein is therefore unlikely to be readily focused on and understood by consumers.

Moreover, if the “brief summary” included information that was necessary to prevent deception or other consumer injury, we would be concerned that it would not be effectively communicated by the current format. The sheer volume of information required to be disclosed may itself contribute to a reduced comprehension of any such specific important information.(41)

Alternative means could be considered for ensuring consumer access to information that is important for consumers to have but that is not necessary to prevent deception or injury. For instance, certain kinds of DTC advertisements could provide an “800” number for consumers to call for further information(42), or an alternative source for consumers to obtain the information. They could also encourage consumers to ask their doctors about product risks and benefits and to ask their pharmacists for package insert information.

B. Tailoring Regulation to the Advertising Medium.

The FDA also asked whether broadcast advertisements should be subject to the same “brief summary” requirements as advertisements in other media.

Differences among media may affect the likelihood of deception from advertising claims and, therefore, the appropriateness of particular approaches to preventing deception. Television advertising typically is presented in thirty to sixty second lengths, although fifteen and even ten second advertisements are not uncommon. The brevity of television advertising makes it very difficult to include lengthy or complex disclosures, or to do so in a comprehensible manner.(43) Print advertising, on the other hand, is more conducive to communicating relatively complex information than TV advertising because people can read print advertisements at their own speed, and even re-read the information if so inclined. Similarly, advertising on the Internet can be read at one’s own pace and can be saved or printed for future reference. Thus, a claim read quickly in a broadcast advertisement might present a different likelihood of deception than does the same claim appearing in a print or on-line format. Given the variety of media in which advertising appears, it may be appropriate in designing measures to prevent deception, such as disclosure requirements, to take into account practical differences among various advertising venues.(44) For instance, the FTC has recognized these differences and in some cases in which disclosures have been imposed has designed abbreviated versions for use in broadcast media.(45) If necessary, abbreviated disclosures could be supplemented through requirements that more detailed information be made available on request and that consumers be made aware of this option.

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 Endorsements and Testimonials in Advertising⁽⁵⁰⁾ and in law enforcement actions. The Guides suggest that the 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 disclosed.⁽⁵¹⁾ The FTC has applied the standards described in the Guides in particular cases, involving endorsers that were business associates of the marketer,⁽⁵²⁾ an endorser that was an officer or director,⁽⁵³⁾ an endorser that was an employee of the advertiser,⁽⁵⁴⁾ and an endorser that was a product distributor.⁽⁵⁵⁾ The concern in these cases is that the endorsers had an undisclosed financial interest in promoting the products. Again, the likelihood of deception depends on the specifics of an individual ad, and the analysis is therefore conducted on a case-by-case basis.

D. Regulation of Price Advertising.

As the FDA reviews its advertising regulations, one issue not mentioned in the Notice may also deserve attention. The FDA's existing brief summary requirements may have the inadvertent effect of unnecessarily restricting the dissemination of price information. While the FDA regulations exempt certain types of price claims from the brief summary requirement, the exemption is narrow⁽⁵⁶⁾ and apparently would apply only to advertisements of the price of a specific quantity of a drug, and not, for instance, to comparative price claims, coupons or other forms of price reduction information.

The brief summary requirement adds to the cost of advertising and may be expected therefore to reduce the amount of advertising. With respect to price advertising, therefore, the brief summary requirements may result in less price competition. Price advertising can result in lower prices for consumers.⁽⁵⁷⁾ We therefore suggest that FDA evaluate whether its limitations on the exemption for price claims are necessary and desirable.

(1) These comments are the views of the staff of the Bureaus of Consumer Protection and Economics of the Federal Trade Commission. They do not necessarily represent the views of the Commission or any individual Commissioner. Inquiries regarding this comment should be directed to Susan Cohn (202) 326-3053, Bureau of Consumer Protection or Jan Pappalardo (202) 326-3380, Bureau of Economics.

(1)" 60 Fed. Reg. 42,583 (Aug. 16, 1995).

(2) These comments are the views of the staffs of the Bureaus of Consumer Protection and Economics of the Federal Trade Commission. They do not necessarily represent the views of the Commission or any individual Commissioner.

(3) 15 U.S.C. §§ 45, 52-57. The FTC and FDA have overlapping jurisdiction with respect to the advertising, labeling, and promotion of foods, over-the-counter drugs, cosmetics and medical devices. Under a long-standing liaison agreement between the agencies, the FDA exercises primary responsibility for regulating the labeling of these products, while the FTC has primary responsibility for enforcing laws against false or misleading advertising of these products. Working Agreement Between FTC and Food and Drug Administration, 4 Trade Reg. Rep. (CCH) ¶ 9,851 (1971).

In 1962 Congress limited a portion of the FTC's authority over prescription drug advertising under sections 12-17. Specifically, section 502(n) of the Food, Drug and Cosmetic Act precludes FTC jurisdiction under sections 12-17 of the FTC Act with respect to three items: drug name, formula, and summary of effectiveness and consequences of use. The Food, Drug and Cosmetic Act does not address FTC jurisdiction under these sections over statements other than those that fall into these three categories, nor does it affect the FTC's basic jurisdiction over advertising, including prescription drug advertising, under section 5 of the FTC Act. The 1971 liaison agreement between the two agencies reflects the understanding that the FDA would exercise primary responsibility for the truth or falsity of prescription drug advertising. See Letter from the Federal Trade Commission to the Honorable John C. Dingell, August 15, 1983, for further discussion of the FTC's shared jurisdiction with FDA regarding prescription drug advertising.

(4) See, e.g., Johnson & Johnson Consumer Products, Inc., File No. 9433277 (Oct. 11, 1995) (proposed consent); Olsen Laboratories, Inc., C-3556 (Feb. 6, 1995); FTC v. Pantron 1 Corp., No. 88-6696 RG(JRx) (C.D. Cal. July 27, 1992) (judgment), rev'd in part and aff'd in part, (9th Cir. Aug. 25, 1994); St. Ives Laboratories, Inc., C-3366 (Jan. 24, 1992); U.S. v. Sterling Drug, Inc., No. CA 90-1352 (D.D.C. June 12, 1990) (consent decree); Walgreen Co., 109 F.T.C. 156 (1987) (consent); Thompson Medical Co., 104 F.T.C. 648 (1984), aff'd, 791 F.2d 189 (D.C. Cir. 1986), cert. denied, 479 U.S. 1086 (1987).

(5) See, e.g., Egglund's Best, Inc., C-3520 (Aug. 15, 1994) (consent); Gracewood Fruit Co., C-3470 (Oct. 26, 1993) (consent); Pompeian, Inc., C-3402 (Oct. 27, 1992) (consent); Campbell Soup Co., D. 9223 (Aug. 18, 1992) (consent); Pacific Rice Products, Inc., C-3395 (Aug. 17 1992) (consent); Bertolli U.S.A., Inc., C- 3396 (Aug. 17, 1992) (consent).

(6) See, e.g., Home Shopping Network, Inc., D. 9272 (Mar. 3, 1995) (complaint issued; matter in administrative litigation); Bee-Sweet, Inc., C-3550 (Jan. 17, 1995) (consent); Schering Corp., D. 9232 (Sept. 16, 1991) (Initial Decision), (Oct. 31, 1994) (consent); FTC v. Redhead, No. 93-1232-JO (D. Ore. June 20, 1994) (stipulated permanent injunction); U.S. v. General Nutrition, Inc., No. 94-686 (W.D. Pa. Apr. 28, 1994) (consent); Miles, Inc., 114 F.T.C. 31 (1991) (consent); General Nutrition, Inc., 111 F.T.C. 387 (1989) (consent); FTC v. PharmTech Research, Inc., 576 F. Supp. 294 (D.D.C. 1983) (preliminary injunction), 103 F.T.C. 448 (1984) (consent).

(7) See, e.g., Lifestyle Fascination, Inc., C-3513 (Aug. 5, 1994) (consent); FTC v. LaserVision, Inc., No. 94-1691 WJR (C.D. Cal. Mar. 15, 1994) (stipulated permanent injunction); In re Dahlberg and the FTC, No. 4-94-CV-165 (D. Minn. Nov. 21, 1995) (consent decree); Numex Corp., C-3463 (Oct. 7, 1993) (consent); Conair Corp., C-3431 (June 14, 1993) (consent); Viral Response Systems, Inc., D. 9245 (July 31, 1992) (consent); Haverhills, C- 3322 (Jan. 25, 1991) (consent); Removatron International Corp., 111 F.T.C. 206 (1988), aff'd, 884 F.2d 1489 (1st Cir. 1989); Sun Industries, Inc., 110 F.T.C. 511 (1988) (consent).

(8) Relevant FTC staff research includes: P. Ippolito & A. Mathios, Health Claims in Advertising and Labeling: A Study of the Cereal Market (1989); J. Calfee and J. Pappalardo, How Should Health Claims for Foods Be Regulated? An Economic Perspective (1989); M. Lynch et al., Experimental Studies of Markets with Buyers Ignorant of Quality Before Purchase: When Do ?Lemons' Drive Out High Quality Products (1986).

(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.

(12) Singer, *supra* note 11, at 30. According to the trade press, drug companies spent a total of \$11.6 million on DTC campaigns in 1989. In 1994, they spent \$242.4 million. During the first five months of 1995, they spent \$141.2 million.

(13) See, e.g., J. Schwartz, *FDA Approved Drug for Treatment of AIDS: 3TC Compound Used in Combination with AZT*, *Washington Post*, Nov. 21, 1995, at A3.

(14) Three prescription drug reference books were listed among the thirty-nine top selling reference books in 1994: *The Physician's Desk Reference Family Guide to Prescription Drugs* (205,000 copies), *The 1994 Physicians' Desk Reference* (110,000 copies), and *The Essential Guide to Prescription Drugs 1994* (52,948 copies). See *Publishers Weekly*, March 7, 1994, at S26.

(15) See, e.g., *Your Health: New Treatment for Ulcers — and Other Stomach Pains*, *Consumer Reports*, Aug. 1995, at 552-553, (comparing ulcer treatments using antibiotic therapies to ulcer treatments using H2 blockers).

(16) See, e.g., *Washington Post Magazine*, Nov. 12, 1995 (insert between pages 26 and 27 sponsored by the American Cancer Society and the Ad Council urging women to get mammograms and providing an "800" number for people to call for further information).

(17) Many scholars have discussed prescription drug advertising from an economic and marketing perspective. See, e.g., M. J. Sheffet and S. W. Kopp, *Advertising Prescription Drugs to the Public: Headache or Relief?* 9 *J. Pub. Pol'y & Marketing* 42 (1991); A. Masson, "Direct-to-Consumer Advertising: A Continuing Controversy," in *Enhancing Consumer Choice: Proceedings of the Second International Conference on Research in the Consumer Interest* p. 159-168 (R. N. Meyer ed., 1991); J. H. Beales, III, *Economic Analysis and the Regulation of Pharmaceutical Advertising*, 24 *Seton L. Rev.* 1370 (1994).

(18) For an extensive discussion of the costs and benefits of disclosure requirements see *Consumer Information Remedies: Policy Review Session*, Staff Briefing Book to the Federal Trade Commission (1979).

(19) The FDA has recently issued a proposed rule intended to increase the availability to consumers of information accompanying dispensed prescription drugs. 60 *Fed. Reg.* 44,182 (Aug. 24, 1995). Changes in the availability of extensive product information at the point of sale are likely to affect the role of advertising in the consumer's information environment.

(20) For example, according to the trade press, cyberspace provides an efficient means of communicating to people with Lou Gehrig's disease. See P. Weisz, *Out of the Lab and into the Screening Room: Direct-to-Consumer Ads are Now at \$200 Million and Growing*, *Brandweek*, at 31, April 18, 1994.

(21) Survey evidence suggests that most consumers recognize this potential and therefore tend to evaluate advertising with skepticism. Nevertheless, surveys also suggest that most consumers also find advertising to be a valuable source of information. See J. Calfee & D. Ringold, *The 70% Majority: Enduring Consumer Beliefs About Advertising*, 13 *J. Pub. Pol'y & Marketing* 228 (1994).

(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 reduce drug prices. First, as discussed above, advertising can trigger competition among alternative therapies, which, in the long run, should result in lower average prices for the therapeutic category, assuming all else (including quality) remains constant. Second, increases in DTC advertising expenditures might not indicate that total promotional expenditures have increased. For example, resources devoted to consumer advertising may partially displace resources devoted to professional advertising. (The trade press suggests that such substitutions might occur. See Singer, *supra* note 11, at 32.) Finally, even if overall advertising expenditures for a product increase, advertising costs per unit sold may decline.

(26) See S. Everett, Lay Audience Response to Prescription Drug Advertising, J. Advertising Res. 43-49 (April/May 1991); M. Perri and W. M. Dickson, Consumer Reaction to a Direct-to-Consumer Prescription Drug Advertising Campaign, 8 J. Health Care Marketing 66 (June 1988).

(27) See, e.g., testimony of Nancy Buc, Mary Jane Sheffet, and John F. Kamp at FDA Public Hearing on Direct-to-Consumer Promotion (October 18, 1995).

(28) FTC Policy Statement on Deception, Cliffdale Assocs., 103 F.T.C. 110, 174 (1983), Letter from the Commission to Chairman John D. Dingell, Committee on Energy and Commerce, U.S. House of Representatives, Oct. 14, 1983 ("Deception Statement").

(29) FTC Policy Statement on Advertising Substantiation, 49 Fed. Reg. 30,999 (Aug. 2, 1984), Thompson Medical Co., 104 F.T.C. 648, 839 (1984) ("Substantiation Statement").

(30) Deception Statement, *supra* note 28, at 183. For prescription drugs, unlike most other consumer products, consumers cannot make and act on purchase decisions individually. The requirements to obtain a prescription from a practitioner and have it filled by a pharmacist introduce checks in the system that may reduce the likelihood of consumer harm from deceptive DTC advertising.

(31) Under the Commission's substantiation policy, advertisers must have substantiation for all objective claims before the claims are disseminated. The type and amount of substantiation required depends on the specifics of each case. If an advertisement represents, directly or by implication, that a claim is based on a particular type or amount of

substantiation, the claim must in fact be supported by at least that type and amount of evidence. If the advertisement contains no such specific representation, the appropriate level of substantiation is determined by consideration of a number of factors: 1) the type of product advertised; 2) the type of claim; 3) the benefits of a truthful claim; 4) the ease of developing substantiation for the claim; 5) the consequences of a false claim; and 6) the amount of substantiation that experts in the relevant field believe is necessary. See Pfizer, Inc., 81 F.T.C. 23, 64 (1972); Thompson Medical Co., 104 F.T.C. 648, 813, 821 (1984), aff'd, 791 F.2d 189 (D.C. Cir. 1986), cert. denied, 479 U.S. 1086 (1987); Bristol-Myers, 102 F.T.C. 21, 321 (1983), aff'd, 738 F.2d 554 (2d Cir. 1984), cert. denied, 469 U.S. 1189 (1985). See also Substantiation Statement, supra note 29, at 840.

(32) Deception Statement, supra note 28, at 175, fn.4; see also International Harvester Co., 104 F.T.C. 949, 1057 (1984); see, e.g., Campbell Soup Co., D. 9223 (Aug. 18, 1992) (consent); North American Philips Corporation, 111 F.T.C. 139 (1988).

(33) International Harvester, 104 F.T.C. at 1058.

(34) Deception Statement, supra note 28, at 175, fn.4; see also International Harvester, 104 F.T.C. at 1059.

(35) Deception Statement, supra note 28, at 175, fn.4.

(36) See, e.g., Haagen-Dazs, Inc., C-3582 (June 2, 1995) (consent) (advertising that contained an asterisk and some qualifying information in fine print challenged as deceptive).

(37) In orders the FTC generally has required that disclosures be made "clearly and prominently," or "clearly and conspicuously." See, e.g., Nutri/System, Inc., C-3474 (Dec. 22, 1993) (consent); Diet Center, Inc., C-3476 (Dec. 22, 1993) (consent). In some instances the FTC provides specific instructions for the required disclosure presentation. See, e.g., Trade Regulation Rule Pursuant to the Telephone Disclosure and Dispute Resolution Act of 1992, 16 C.F.R. § 308; European Body Concepts, C-3590 (June 23, 1995) (consent); Egglund's Best, Inc., C-3520 (Aug. 15, 1994)(consent).

(38) In the context of prescription drug advertising to health care professionals, the information included in the brief summary may serve a different purpose from that in DTC advertising.

(39) Under the FDA's "fair balance" requirements advertisers must include, in the text of an advertisement, balanced information regarding a drug's benefits and risks. To the extent that this requirement assures that information that is important for consumers to know in order to avoid deception or other harm is presented in the body of an ad, it may reduce the need for the extensive brief summary.

(40) See, e.g., Foxman et al., Disclaimer Footnotes in Ads: Discrepancies between Purpose and Performance, 7 J. Pub. Pol'y & Marketing 127, 134 (1988) (miscomprehension level after exposure to smaller-print footnotes is higher).

(41) See Murray et al., Public Policy Relating to Consumer Comprehension of Television on Commercials: A Review and Some Empirical Results, 16 J. Consumer Pol'y 145, 155, 160-161 (1993) (demonstrating that the number of words in a disclosure is negatively correlated with comprehension); Murphy & Richards, Investigation of the Effects of Disclosure Statements in Rental Car Advertisements, 26 J. Consumer Aff. 351, 355-356 (1992). Murphy & Richards find that if the amount of information presented exceeds consumers' ability to process it, the quality of consumer decision-making may be negatively affected. Murphy and Richards further state that "[a]lthough any efforts by regulators to facilitate informed decision-making may be laudable, failure to ensure that the chosen method of presentation is appropriate for consumer use can make those regulations worthless or even detrimental to consumer interests. If consumers are unable to understand or recall the information in the legally mandated form another disclosure technique...may be more efficacious." Id. at 373 (emphasis in original).

(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 risk in land purchases required for radio, television, and short print advertisements; lengthier disclosures required in larger print advertisements, promotional materials, and oral sales presentations). See Murphy & Richards *supra* note 41, at 371 (finding that a shortened disclosure regarding rental car restrictions provided adequate communication).

(46) In this regard, the FTC recently hosted a workshop on “Consumer Protection and the Global Information Infrastructure” (see FTC press release, March 16, 1995) and consumer protection issues were part of the recent hearings on global commerce and innovation (see FTC press release, September 26, 1995).

(47) One challenging issue posed by these new media is the difficulty of distinguishing between the non-commercial information or entertainment content and an advertising component. Unlike, for instance, the television venue where advertising and programming are typically separable, these components are frequently more interrelated when presented via the new information delivery vehicles.

(48) E.g., *Olsen Laboratories, Inc.*, C-3556 (Feb 6, 1995) (consent); *Wayne Phillips*, D-9237 (Oct. 11, 1991) (consent); *Twin Star Productions, Inc.*, C-3307 (Oct. 2, 1990) (consent); *TV, Inc.*, C-3296 (July 25, 1990) (consent); *Synchronal Corp.*, D. 9251 (Oct. 1, 1993) (consent); *JS&A Group, Inc.*, C-3248 (Feb. 24, 1989) (consent). See also FTC Advisory Opinion No. 191, *Advertisements which Appear in News Format*, 73 F.T.C. 1307 (1968) (ad simulating format of news or feature article should “clearly and conspicuously disclose it is an advertisement”); *National Dietary Research, Inc.*, D. 9263 (Nov. 7, 1995) (consent); *FTC v. LaserVision, Inc.*, No. 94-1691 WJR (C.D. Cal. Mar. 15, 1994) (challenging format of advertising appearing to be newspaper articles as deceptive).

(49) We believe disclosure requirements can be effective when the advertised product is sold through ordering information provided in the infomercial. However, when the product is not sold in that manner other measures may be necessary to ensure that the format of the infomercial does not mislead consumers as to the source of the information presented. We would be happy to work with the FDA in considering what measures might be effective and practical.

(50) 16 C.F.R. § 255 (1995). The Guides describe FTC enforcement policy.

(51) *Id.* at § 255.5.

(52) *Cliffdale Assocs.*, *supra* note 28, at 172.

(53) *Numex Corp.*, C-3463 (October 7, 1993) (consent).

(54) *Buckingham Products, Inc.*, 110 F.T.C. 37 (1987).

(55) *Body Wise Int'l*, C-3617 (Sept. 25, 1995) (consent).

(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.