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
Pharmaceutical Marketing and Information Exchange in Managed Care Environments; Public Hearings
[Docket No. 95N-0228]

Comments of the Staffs of the Bureaus of Economics and Consumer Protection of the Federal Trade Commission*

January 16, 1996

* 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. Inquiries regarding this comment should be directed to Matthew Daynard (202-326-

I. INTRODUCTION AND SUMMARY.

The Food and Drug Administration (FDA) recently held hearings on the evolving role of pharmaceutical marketing

Under a 1971 memorandum of understanding between the FDA and the FTC, the FDA has assumed the primary regulatory responsibility for prescription drug advertising, and the FTC has assumed primary responsibility for policing deception in over-the-

These types of claims all have the potential to provide useful information to health care markets. The substantiation rules governing such claims should be sufficient to prevent deceptive or unsubstantiated claims, but not too rigid or too costly to undermine firms' incentives to develop and provide a wide range of truthful, nonmisleading economic information.

2. Audience Considerations.

As noted in the FDA's Federal Register notice, many economic claims are likely to be directed to HMOs, physicians, insurers, and employer-insurers. Some claims will also be aimed directly at consumers, especially where the consumer pays part or all of the cost. We would encourage consideration of the view that the relevant audience for any claim should play a central role in identifying the claims made and assessing whether those claims are likely to be deceptive to that audience.

The economic and policy rationale for this position is straightforward. If a claim is likely to mislead a particular audience into inappropriate decisions, the claim is likely to do more harm than good and stopping it is likely to benefit consumers. Conversely, if a claim is not likely to mislead an audience, there is little potential for consumer injury and a greater potential that useful information is being provided to the target audience.

Health care providers, insurers, and other business customers may evaluate economic claims differently than individual consumers would, and these differences would be important in judging whether the claims are deceptive.(28) Specific investigation of how these types of claims are perceived by professional and business audiences would be useful in assessing the best way to regulate them. Moreover, it would be useful to have a clear understanding of how these economic claims may have misled these audiences and what type of regulation would be most effective in preventing deceptive claims without unnecessarily burdening other, truthful claims.

3. Substantiation Standards for Economic Claims for Drug Products.

As discussed above, a number of factors influence the type of evidence required for substantiation of advertising claims under the FTC's substantiation policy. One important factor is the relevant professional standards appropriate to judge the evidentiary support for the type of claim at issue. Under this approach, the required level of substantiation for economic claims for pharmaceutical products, such as cost-benefit or cost-(y)24(pe of)2(r)17(egu)13(l)-1()1(fo)- [(v)1

health care professionals and patients should base their decisions about drug products on sound scientific data and information. The FDA elsewhere has identified a concern that certain PBM pharmacists, when requesting that prescribers switch drug products or notifying patients of a physician-approved switch, may not be disclosing their affiliations and their financial incentives to promote the switch.(41)

As the FDA is aware, therapeutic switch programs have the potential to result in substantial cost savings to prescription benefit plans through the substitution of lower cost drugs. In the managed care setting, it is important to preserve this aspect of PBM efforts to control costs.

Switch programs that involve failures to disclose pharmacist-producer affiliations could raise deception issues that the FDA may want to consider in addressing these practices. Under the FTC's deception standard, deception can result from the omission of information depending on the setting in which a sale is made and the expectations of the buyer.(42) Traditionally, physicians, pharmacists and drug producers have been separate, independent decisionmaking entities. In light of that tradition, patients and their physicians, when faced with a PBM pharmacist's recommendation to switch drug products, may reasonably expect that the pharmacist is exercising independent professional judgment in the best interests of the patient. In those situations, the failure to disclose affiliations associated with the recommended switch may be a deceptive omission, because it may significantly affect physicians' and patients' expectations about the transaction, and, consequently, their decision about whether to approve the switch.(43)

The Commission addressed an analogous scenario in its Guides Concerning the Use of Endorsements and Testimonials in Advertising.(44) The Commission said in the Guides that connections between an endorser and seller of an advertised product "which might materially affect the weight or credibility of the endorsement" (i.e., the connection is not "reasonably expected by the audience") could be deceptive and must be disclosed. 16 C.F.R. §255.5. The FTC has applied this standard in cases in which the endorsers (physicians and other health care providers, among others) were distributors of the marketer's products(45) and in which the endorser was an officer and director or employee of the advertiser.(46) Under this analysis, if the pharmacist-producer connections associated with a recommended switch are not reasonably expected by the audience, disclosure of those connections might materially affect the "weight or credibility" of the switch recommendation.(47) The Commission in such circumstances might require disclosure of these material connections as a remedy to any alleged deception.(48)

Thus, if deception arises from affiliations of pharmacists with pharmaceutical producers associated with a recommended switch, then disclosure of such affiliations may correct it, while preserving the economic benefits of switch programs for the insured plans and their members. The FDA may wish to consider such an approach, if warranted by the facts.

(1) 60 Fed. Reg. 41,891 (Aug. 14, 1995).

(2) Therapeutic claims, or "efficacy" claims, regarding a drug's medical effects are not included in this class of claims, but some economic claims could include an efficacy component, as discussed below.

(3) These comments are the views of the staffs of the Bureaus of Consumer Protection and Economics of the Federal

i t 2 (- 1 8 1 e (i 2 (q ( )] T n / T T 0 1 T f 0 . 0 0 4 T c -

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. See Letter from the Federal Trade Commission to the Honorable John C. Dingell, August 15, 1983, for more discussion of the shared jurisdiction with the FDA regarding prescription drug advertising.

(6) Relevant FTC staff research includes: P. Ippolito and A. Mathios, Health Claims in Advertising and Labeling: A Study of the Cereal Market (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); and R. Bond et al., Effects of Restrictions on Advertising and Commercial Practices in the Professions: The Case of Optometry (1980); see also Advertising by Health Care Professionals in the 80's, Proceedings of a National Symposium Sponsored by the Federal Trade Commission (1985).

(7) See, e.g., A. Masson and R. Steiner, Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws (1985); Staff Report to the Federal Trade Commission, Drug Product Selection (1979); R. Bond and D. Lean, Sales, Promotion and Product Differentiation in Two Prescription Drug Markets (1977); and Staff Report to the Federal Trade Commission, Prescription Drug Price Disclosures (1976). More recently, the FTC has addressed potential competitive issues raised by vertical integration in the pharmaceutical industry. See, e.g., the Complaint and Agreement Containing Consent Order, In the Matter of Eli Lilly and Company, C-3594 (July 28, 1995).

(8) See, e.g., American Medical Ass n., 94 F.T.C. 701 (1979); Iowa Chapter of Am. Physical Therapy Ass n., 111 F.T.C. 199 (1988); Connecticut Chiropractors Ass n.

(15) See Cliffdale Assocs., Inc. 103 F.T.C. 110, 175 (1984), reprinted as appendix letter dated Oct. 14, 1983, from the Commission to The Honorable John D. Dingell, Chairman, Committee on Energy and Commerce, U. S. House of Representatives ("Deception Statement").

(16) FTC Policy Statement on Advertising Substantiation, 49 Fed. Reg. 30,999 (1984), reprinted in Thompson Medical Co., 104 F.T.C. 648, 839 (1984), aff d, 791 F. 2d 189 (D.C. Cir. 1986), cert. denied, 479 U.S. 1086 (1987) ("Substantiation Statement").

(17) Deception Statement, supra note 15, at 183.

(18) For a more detailed discussion of the full analysis, see Deception Statement, supra note 15, at 174.

(19) Deception Statement, supra note 15, at 175, fn. 4; see also International Harvester Co., supra note 14, at 1057; Campbell Soup Co., FTC Dkt. No. 9223 (Aug. 18, 1992) (consent order).

(20) International Harvester, supra note 14, at 1058.

(21) Deception Statement, supra note 15, at 177, citing Peacock Buick, in which the Commission held that "[a]bsent a clear and early disclosure...deception can result from the setting in which a sale is made and the clear expectations of the buyer…." 86 F.T.C. 1532, 1555 (1975), aff'd, 553 F.2d 97 (4th Cir. 1977).

(22)" Deception Statement, supra note 15, at 175, fn. 4; International Harvester, su15(l)-1(H)17 H).se(1412(45),13((t)2(10)13(58.)]TJ 4not, s

(42) The Commission also has addressed competition issues raised by vertical integration in the pharmaceutical industry. See In the Matter of Eli Lilly and Company, C-3594 (consent order issued July 28, 1995, Commissioner Azcuenaga dissenting).

(43) Staff observes that under the terms of a recent settlement involving allegedly deceptive switch programs between a drug producer, its allied PBM, and 17 states, the producer and PBM must, among other things, ensure that the
affiliation with the PBM; (2) the ownership interest of the drug producer in the PBM; and (3) the name of the manufacturer of the recommended drug if the switch involves one branded drug for another in the same therapeutic category. The PBM also must596.28 470.10(us)-T* BT -1(s)-3 ifhe1f313(d4(al)0 scn)-1117(ape)13(ut)0 s(1 Tf 72 600.24 T7.)13(k)-