



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 (202-326-3291), Bureau of Consumer Protection, or Pauline Ippolito (202-326-3477), Bureau of Economics.

**I. INTRODUCTION AND SUMMARY.**

The Food and Drug Administration (FDA) recently held hearings on the evolving role of pharmaceutical marketing and information exchange in managed care environments. The agency has also solicited information and views concerning the potential impact of changing organizational structures and information dissemination channels on the agency's responsibilities to regulate prescription drug marketing, especially as it regards new types of claims, such as claims about the economic attributes of drug products.(1) In this comment, we will use the term "economic claims" to refer to marketing claims dealing with the cost or value elements of pharmaceutical products, as in cost, cost-effectiveness, or cost-benefit claims.(2) Based on our experience in analyzing the effects of information in markets, in implementing regulations and enforcement activities that address information issues, and in assessing competition and other economic questions, the Bureau of Consumer Protection and the Bureau of Economics of the Federal Trade Commission (FTC)(3) offer the following comments to assist the FDA in its deliberations on appropriate substantiation standards for economic claims for pharmaceutical products and on the deception issues raised by so-called "switch programs.(4)

The FTC enforces the Federal Trade Commission Act, which among other things prohibits deceptive acts or practices in or affecting commerce.(5) One of the FTC's major responsibilities is enforcement against deception in national advertising and other forms of marketing. The staff of the FTC has developed considerable expertise in assessing the role of advertising and marketing in providing consumers and others with information, as well as the broader effects of advertising on market performance.(6) The FTC staff also has considerable experience in assessing the economic performance of prescription drug and other health care markets.(7) The FTC has investigated the competitive effects of restrictions on advertising and other business practices of health care providers, including dentists, physicians, and pharmacists,(8) and the staff of the FTC has submitted comments on these issues to state legislatures, administrative agencies, and others.(9)

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-counter drug advertising.(10) While we recognize that the FDA's regulation of advertising and other marketing practices is governed by a somewhat different legislative mandate, we believe that our experience with these issues, and with economic issues more generally, has a bearing on many of the FDA's questions regarding economic claims in this market.

Deceptive economic claims about prescription drug products are likely to have deleterious effects on consumers. However, as described below, in this area it is important to distinguish between efficacy claims for drug products, which may require controlled trials as substantiation, and other effectiveness components of economic claims,(11) where other types of evidence may be appropriate substantiation (as for example, when behavioral, market, and clinical conditions play a role in affecting outcomes). Both a drug's efficacy and its effectiveness may have implications for the quality of health care, a topic on which we defer to the FDA's expertise. These comments focus on the economic and behavioral elements in effectiveness components of economic claims for drug products. We suggest that the FDA may find it useful to consider a more flexible substantiation standard for these economic claims.

The FDA may also wish to consider disclosures of the corporate affiliations associated with particular drugs recommended in "switch programs" as a direct, narrowly focused way to eliminate any deception that may arise due to vertical relationships in this industry, rather than focusing on ensuring independence *per se* in the drug decisions of pharmaceutical benefit management firms (PBMs) allied with drug producers.(12)

Legal requirements imposed on advertising have the potential to discourage truthful claims about the economic aspects of pharmaceutical products, especially if the rules impose substantially disproportionate burdens on different types of providers, as the FDA proposals apparently would. Forces are pushing the market to find institutional arrangements for providing health care that will maintain high quality standards while controlling costs more effectively. Truthful economic claims for drug products have the potential to play an important role in this process.

## **II. BACKGROUND**

### **1. Basic Issues.**

The FTC's advertising enforcement reflects its dual consumer protection and competition roles. The FTC's enforcement endeavors to deter deceptive claims that harm consumers but not to interfere unnecessarily with the dissemination of truthful, nondeceptive information. These twin goals reflect a body of scholarly literature that has accumulated to provide a better understanding of advertising's role in markets.(13)

From an economic perspective, information provided through advertising strengthens firms' incentives to compete on price and quality. Through advertising, sellers inform potential customers of product features, spurring competition on advertised dimensions. Competition among sellers, each of whom has incentives to point out the advantages of its own products and the disadvantages of its competitors' products, helps to provide more balanced information than that created by an individual seller's claims. Nondeceptive advertising promotes competition by easing the entry of new products, facilitating the market growth of better or less costly products, and helping consumers make choices. These economic forces are as relevant for health-related markets or business-to-business advertising as they are for basic consumer good markets, since information plays a critical role in all these cases.

Of course, advertising is not invariably beneficial. For example, advertising claims may be deceptive, leading to consumer loss through faulty decisions based on the claims.(14) The challenge in this arena is to establish standards that deter deceptive claims but do not interfere unnecessarily with the flow of truthful advertising claims.

### **2. The FTC's Approach to Deception and Substantiation.**

In enforcing its law against deception, the FTC has developed a legal framework for assessing advertising claims. We briefly describe some of the key principles in the FTC's approach that underlie our discussion of the questions raised in the FDA's *Federal Register* notice regarding economic claims in prescription drug markets.

The FTC's advertising enforcement policy is described in its Deception Policy Statement<sup>(15)</sup> and its Statement on Advertising Substantiation.<sup>(16)</sup> As set out in the Deception Statement, the Commission considers an advertisement deceptive if it contains a material representation or omission of fact that is likely to mislead consumers acting reasonably under the circumstances.<sup>(17)</sup> Among the key components of this analysis are the need to identify the express or implied claims made in the ad and to determine whether these claims are truthful.<sup>(18)</sup> In determining the meaning of an advertisement, the Commission focuses on the ad's overall net impression, rather than on individual elements of the advertisement in isolation.

In certain circumstances the omission of material information may be deceptive. Deception may occur through omission of information necessary to prevent an affirmative representation from being misleading<sup>(19)</sup> or simply by remaining silent, if doing so constitutes an implied but false representation.<sup>(20)</sup> Material information may be deceptively omitted from the commercial transaction, as well as from written or oral representations.<sup>(21)</sup> However, under the Commission's standards, "[n]ot all omissions are deceptive, even if providing the information would benefit consumers.<sup>(22)</sup> An omission is deceptive only if the absence of the information causes the advertisement to give the audience an inaccurate impression of the product.<sup>(23)</sup>

The likelihood of deception is generally considered from the perspective of the audience.<sup>(24)</sup> What constitutes deception may differ, for example, for advertising aimed at the terminally ill, a group that might be particularly susceptible to exaggerated cure claims, and advertising aimed at a well-educated group, such as prescription drug advertising to doctors.<sup>(25)</sup>

Under FTC law, an express or implied claim is deceptive unless the advertiser has a reasonable basis for the claim when it is made.<sup>(26)</sup> A reasonable basis consists of competent and reliable evidence substantiating the claim. If the ad contains an express or implied representation regarding the amount of support the advertiser has for the claim, the Commission expects the firm to have at least the advertised level of support. Absent an express or implied claim about the level of support, the Commission assumes that consumers expect a reasonable basis for claims, which the Commission determines from a number of factors relevant to the benefits and costs of substantiating a particular claim. These factors include the type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation experts in the field believe is reasonable.<sup>(27)</sup>

### **III. ISSUES RAISED BY ECONOMIC CLAIMS FOR PHARMACEUTICAL PRODUCTS.**

#### **1. Nature and Importance of Economic Claims.**

As recognized in the FDA's *Federal Register* notice, pharmaceutical marketing is changing to reflect the growing interest in reducing the costs of health care. In understanding the issues raised by economic claims, it is important to recognize the wide range of claims potentially included in this class. For example, these claims include cost-effectiveness information for a particular drug, that is, information describing some type of cost advantage relative to a competing drug or other therapy. Claims aimed at a health maintenance organization (HMO) might estimate the cost advantages of a staged therapy approach, in which a less effective, but lower cost drug is used first, followed by a higher cost, more effective therapy for those who do not respond to the first drug. Claims might highlight the need for fewer doctor visits for a drug with a lower potential for adverse effects. Another type of economic claim could discuss the cost advantages of a relatively high cost drug as compared to the even higher costs of surgical treatment for the condition. Claims aimed at employer-insurers could highlight the faster recovery achieved by a higher priced drug and the employers' payroll cost savings. Cost-benefit claims to an insurer could attempt to place a value on the superior therapeutic results of a higher priced drug to demonstrate that the insurer's customers would be willing to pay the higher prices for the better drug.

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.<sup>(28)</sup> 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-effectiveness claims, would depend on the content of the claim made. If an economic claim included a substantial efficacy component, that component would be assessed using the standards of the relevant medical field, as with any efficacy claim. Applying this analysis in the over-the-counter drug market, the FTC has often required well controlled clinical studies to substantiate claims about a drug product's therapeutic efficacy.<sup>(29)</sup> Other cost or effectiveness components of an economic claim (that is, those that are not substantial efficacy components), would be assessed using the standards normally applied by experts in the field in assessing economic cost-benefit questions.<sup>(30)</sup> Because economic and effectiveness components of claims are relatively new features of pharmaceutical marketing, this comment will focus on substantiation issues for them.

A variety of field and other types of data are used in assessing economic questions, including cost-benefit and cost-effectiveness questions. While controlled trial data are often desirable for assessing certain types of questions, economic practice would not necessarily require such data for assessments of cost-benefit issues in general or of health issues in particular.<sup>(31)</sup> In part, this reflects the high cost and long time lag necessary for collecting this type of data in many circumstances.<sup>(32)</sup> It also reflects the fact that actual use experience can deviate from the experience observed in controlled trials due to potential biases in controlled trial data and to the different conditions in actual doctor-patient interactions, as described below.

For economic questions, the literature suggests that differences in the outcomes from controlled trials and actual experience can be important in predicting behavior and in estimating the costs and benefits of various health care options. For instance, in the pharmaceutical context, side effect or convenience differences between drugs can significantly affect the likelihood that physicians and consumers will stay with a particular drug treatment. Controlled

trials, in which compliance is tightly restricted for the duration of the trial in order to get a better measure of efficacy, can give substantially different results than would be found in a clinical setting, where continuation of treatment is more likely to vary with characteristics of the drug.(33) Similarly, the literature suggests that behavioral results can be substantially affected by randomization bias, a type of selection bias that occurs when random assignment causes the type of person participating in the trial to differ from the type of person who would receive the drug in the normal clinical setting.(34) As a result, controlled trial data can sometimes predict actual clinical implementation poorly. In this type of situation, experience with the drug in a field setting may substantially add to the available knowledge based on trial data, or may actually give superior information about economic and effectiveness issues in actual practice to that provided by a controlled trial. Such data may also raise questions about the results from controlled trials.

Certainly, a strong recognition exists in the economics literature, as well as in the medical literature, that selection bias, unmeasured characteristics, and other methodological issues can be substantial concerns in efforts to measure cost-benefit questions using both trial and nontrial data. A great deal of econometric research and attention continues to be devoted to designing and evaluating methods that address these issues.(35) Poor quality data, inadequate statistical design decisions, and inappropriate methodological decisions in formulating the basic economic model can all bias or otherwise corrupt measurement efforts for both trial and nontrial data.(36) Any substantial problems of these types could undermine the competence or reliability of studies, thus making them unsuitable for substantiation of a particular economic claim.

Depending on how it is interpreted and applied, the FDA statement in the *Federal Register* notice that all “effectiveness” elements of cost-effectiveness claims must be based on adequate and well-controlled studies(37) could result in the prohibition of many truthful, nondeceptive claims describing the cost-effectiveness or cost-benefit characteristics of pharmaceutical products in actual treatment settings. Claims substantiated by competent and reliable epidemiologic, administrative, or other clinical data would appear to be prohibited under this standard. Claims based on shared data from HMOs or other insurers nationwide would also appear to be excluded.

If an economic claim clearly discloses the nature of the result and the data on which it is based, and the data are competent and reliable, it could provide truthful, nonmisleading information to professional and insurance customers. Accurate economic claims based on actual experiences in the field, particularly when directed to these types of audiences, do not appear to us to be inherently deceptive or otherwise misleading.

Thus, the FDA may wish to consider a more flexible substantiation standard for economic claims for pharmaceutical products, for instance, one requiring “competent and reliable evidence” to support the claim that is made, without an *a priori* specification as to the type of evidence required. Such a reasonable basis standard could be effective in limiting deceptive claims without having the undesirable effect of preventing truthful economic claims. In some instances, controlled trial testing may be the appropriate type of substantiation for a particular type of economic claim, as when an efficacy claim is included, but in other circumstances other types of evidence might constitute appropriate substantiation.(38)

#### **IV. DECEPTION ISSUES RAISED BY “SWITCH PROGRAMS”**

The FDA in its *Federal Register* notice has solicited information on how to address so-called “switch programs” by pharmaceutical manufacturers. In a switch program, pharmacist employees of PBMs allied with a pharmaceutical manufacturer(39) telephone physician prescribers to request that they switch their patients from the drug initially prescribed to a preferred drug, which often is a drug product of their employer’s allied manufacturer. The PBM pharmacists follow up those requests with communications to the affected patients, informing them that their physician has approved the switch.(40)

The FDA appears to question whether these alliances and switch programs may alter adversely the traditional independence of physicians and pharmacists in choosing and recommending medications based solely on their own professional judgment, in the best interests of the patient. The FDA states its underlying public health concern that

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 Bureau of Consumer Protection and Economics of the Federal Trade Commission. They do not necessarily represent the views of the Commission or any individual Commissioner.

(4)" In a "switch program," pharmacist employees of a managed care organization typically telephone physician prescribers to request that a patient be switched from one prescription drug to another preferred drug.

(5) 15 U.S.C. §§ 45 *et seq.* In 1962 Congress limited a portion of the FTC's authority over prescription drug advertising under sections 12-17. Specifically, under section 502(n) of the Food, Drug & Cosmetic Act, the FTC may not bring a law enforcement action against an advertisement under sections 12-17 of the FTC Act if the advertisement complies with FDA requirements about drug name, formula, and summary of effectiveness and consequences of use. It 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. 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.*, 114 F.T.C. 708 (1991) (consent); and *Westchester County Pharmaceutical Society, Inc.*, 113 F.T.C. 653 (1990) (consent).

(9) For recent examples, see Comments to the Massachusetts Committee on Health Care, June 15, 1993 (on H. 1109 addressing "any willing provider" requirements for pharmacy and other health care services); Comments to Sunset Advisory Commission of the State of Texas, August 14, 1992 (on review of licensing restrictions on business practices required by the boards for optometry, dentistry, and medicine); and Comments to the New Hampshire Senate Legal Counsel, March 17, 1992 (on House Bill 470 addressing requirements on HMOs soliciting bids on "preferred provider" pharmacy services).

(10) Working Agreement Between FTC and Food and Drug Administration, 4 Trade Reg. Rep. (CCH) ¶ 9,851 (1971).

(11) In our comment generally, we differentiate between a drug's *efficacy*, that is, whether a chemical entity administered consistently at a given dosage has a therapeutic effect, and its *effectiveness*, that is, its expected outcome as it is actually applied in practice, reflecting behavioral, clinical, market, and other considerations (in addition to its efficacy) that can affect outcomes. See, e.g., *Valuing Health Care*, 8 (Frank A. Sloan ed., 1995).

(12) Cf. Notice and Request for Comments, 60 Fed. Reg. 41,891 at 41,892-93 (Aug. 14, 1995).

(13) See, e.g., Howard Beales *et al.*, *The Efficient Regulation of Consumer Information*, 24 J. L. & Econ. 491 (1981); Lee Benham and Alexandra Benham, *Regulating through the Professions: A Perspective on Information Control*, 18 J. L. & Econ. 421 (1975); Philip Nelson, *Advertising as Information*, 81 J. Pol. Econ. 311 (1974); and George J. Stigler, *The Economics of Information*, 69 J. Pol. Econ. 213 (1961).

(14) See, e.g., *International Harvester, Co.* 104 F.T.C. 949, 1056 (1984), in which the Commission stated:

Deception is a particularly troublesome form of conduct. It is harmful to consumers, undermines the rational functioning of the marketplace, and, unlike some other practices we are called upon to review, never offers increased efficiency or other countervailing benefits that must be considered.

(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*, *supra* note 14, at 1059.

(23) Deception Statement, *supra* note 15, at 175, fn. 4.

(24) *Id.* at 177.

(25) *Id.* at 179.

(26) Substantiation Statement, *supra* note 16, at 839.

(27) Substantiation Statement, *supra* note 16, at 840; *Thompson Medical*, 104 F.T.C. at 821.

(28) From an economic perspective, firms that establish reputations for providing unreliable information to their business customers risk adversely affecting their future relationships with these customers. On the economic effects of reputations generally, see B. Klein and K. B. Leffler, *The Role of Market Forces in Assuring Contractual Performance*, 89 J. Pol. Econ. 615 (1981), and C. Shapiro, *Consumer Information, Product Quality and Seller Reputation*, 13 Bell J. Econ. 20 (1982).

(29) See, e.g., *American Home Products* 98 F.T.C. 136 (1981), *aff'd as modified*, 695 F.2d 681 (3d Cir. 1982), *modified*, 101 F.T.C. 698 (1983), *modified*, 103 F.T.C. 57 (1984), *modified*, 103 F.T.C. 528 (1984); *Bristol-Myers Co.* 102 F.T.C. 21 (1983), *aff'd*, 738 F.2d 554 (2d Cir. 1983), *cert. denied*, 469 U.S. 1189 (1985); *Sterling Drug, Inc.* 102 F.T.C. 395 (1983), *aff'd* 741 F.2d 1146 (9th Cir. 1984), *cert. denied*, 470 U.S. 1084 (1985); and *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).

(30) See *Pfizer, Inc.*, 81 F.T.C. 23 (1972).

(31) For a recent example of the economic debate about the usefulness and problems with controlled trial data in evaluating economic questions, see Gary Burtless, *The Case for Randomized Field Trials in Economic and Policy Research*, 9 J. Econ. Perspectives 63 (1995), and James J. Heckman and Jeffrey A. Smith, *Assessing the Case for Social Experiments*, 9 J. Econ. Perspectives 85 (1995), and the many references cited there.



(32) One measure of the costliness of controlled trials in the case of drug testing can be seen from the cost of Phase III clinical trials for new drug approvals. In 1987 these trials were estimated to cost approximately \$12.8 million on average (in 1987 dollars) for each tested drug. See Joseph A. DiMasi *et al.*, *Cost of Innovation in the Pharmaceutical Industry*, 10 J. Health Econ. 107 (1991), or Office of Technology Assessment, *Pharmaceutical R and D: Costs, Risks and Rewards*, Chapter 3 (1993).

(33) See, *e.g.*, Allan S. Detsky, "Evidence of Effectiveness: Evaluating its Quality," in *Valuing Health Care*, *supra* note 11, at 15-29, and Heckman and Smith, *supra* note 31, at 85- 100.

(34) See, *e.g.*, Heckman and Smith, *supra* note 31, at 100, and Michael Kramer and Stanley Shapiro, *Scientific Challenges in the Application of Randomized Trials*, 252 JAMA 2739 (November 16, 1984). The issue arises because the decision to join a randomized trial may not generate a representative sample of the relevant population. Simple issues such as location of the trial or methods used to recruit participants may affect sample characteristics. More fundamentally, the decision to join a trial requires the sick person to take a substantial chance of being assigned to the placebo group and thereby forgoing an effective treatment. Thus, those who volunteer for such experiments may be systematically different from the general population with the relevant disease or condition. For instance, individuals who are risk averse may be less likely to participate. Risk aversion affects many other health-related behaviors that could interact with disease states or other relevant issues and, thus, could result in a biased measurement of a drug's therapeutic effects. Also, once a drug has been found to be more effective or to have fewer side effects in treating a particular condition in the field, the ability to recruit a representative sample for a controlled test becomes a particular problem (and raises ethical issues as well).

(35) For a recent summary in the health care context, see, *e.g.*, John Mullahy and Willard Manning, "Statistical Issues in Cost-effectiveness Analyses," in *Valuing Health Care*, *supra* note 11, at 149.

(36) For a general review of cost-benefit methodological issues, see, *e.g.*, E. J. Mishan, *Cost-Benefit Analysis: An Informal Introduction*, (4th ed., 1988).

(37)" 60 Fed. Reg. 41,892.

(38) Government standards for cost-benefit assessments of regulations also reflect this position. For instance, the Office of Management and Budget's "Regulatory Impact Analysis Guidance" for federal cost-benefit assessments for regulations, including health and safety regulations, reflects the broad economic view that good information can be derived from a variety of data sources. Documentation of those sources and compliance with professional economic standards are the focus of these guidelines. See *Regulatory Program of the United States Government*, Executive Office of the President, Appendix V, 625-638 (1993).

(39) Much of the interest in "switch programs" has arisen since the acquisition of three of the largest PBMs by three large pharmaceutical firms: Smith Kline Beecham/Diversified Pharmaceuticals; Merck/Medco Containment Services; and Eli Lilly/PCS Health Systems. Contractual alliances between other PBMs and drug producers have developed that grant the manufacturers' drug products exclusive or "preferred" positions on the PBM's drug formulary in exchange for rebate payments and other financial incentives.

(40) The PBM may further inform patients that they can contact their doctor if they do not want their prescription changed. These communications to prescribers and patients often are accompanied by representations that the prescription benefit plan, or the plan members themselves, will realize cost savings as a result of the switch.

(41) See, *e.g.*, the discussion with Commissioner Kessler in J.G. Dickenson, *As I See It*, Med. Marketing & Media, at 86-88, November 1994.

(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 PBM's pharmacists disclose to a prescriber, when making a switch recommendation: (1) the pharmacists' 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 must make these disclosures to prescribing physicians and their affected patients in letters confirming a switch. The settlement further requires the PBM to distribute informational booklets for the purpose of advising prescription benefit plan members about the nature of the switch program, the affiliations between the PBM and the drug producer, and the fact that patients may contact their physician if they do not want their prescription changed. See, e.g., *In re Merck & Co., Inc. et al.*, File No. C695 10614 (2d Jud. Dist., Minn., October 25, 1995) (Order Approving Assurance of Discontinuance); see also *Drug Benefit Plan and Drug Maker Resolve State Charges of Deception*, Antitrust & Trade Reg. Rep. (BNA), No. 1735, at 483 (October 26, 1995).

(44) 16 C.F.R. §255 (1995).

(45) *Body Wise Int'l*, C- 3617 (consent order issued September 25, 1995).

(46) *Numex Corp.*, C-3463 (consent order issued October 7, 1993); *Buckingham Products, Inc.*, 110 F.T.C. 37 (1987).

(47) Additional disclosures by PBM pharmacists recommending a switch might be necessary to prevent deception even in the absence of affiliations with producers. For example, if there were significant differences between the medication initially prescribed and the drug product recommended for substitution (i.e., dosing, side effects, or drug interaction profile), failure to disclose those differences might be viewed as deceptive, because the reasonable expectations of patients and physicians in the switch transaction could be that the two products do not differ significantly in those respects.

(48) In determining whether to require disclosure, the Commission, among other issues, considers whether the benefits of a particular disclosure outweigh the costs it may impose. Also, once it determines that disclosure is an appropriate remedy, the FTC generally requires that the disclosures be made "clearly and prominently" (i.e., the disclosures must be made in a manner calculated to be noticeable, readable (or intelligible, if made orally), comprehensible, and timely). See, e.g., Trade Regulation Rule Pursuant to the Telephone Disclosure and Dispute Resolution Act of 1992, 16 C.F.R. §308 (1995); *European Body Concepts*, C-3590 (June 23, 1995) (consent).