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

Bureau of Competition

April 6, 1998

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

Re: Docket No. 97D-0525

Dear Sir or Madam:

The Bureau of Competition of the Federal Trade Commission is pleased to offer its comments on the Food and Drug Administration's Draft Guidance for Industry entitled "Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMs)" (*Draft Guidance*).(1) These comments discuss the relationship between the Bureau of Competition's law enforcement efforts related to PBMs and the concerns that the *Draft Guidance* addresses. Specifically, this comment provides a discussion of the Commission's consent order addressing Eli Lilly & Company's acquisition of PCS, a major PBM.(2) The FDA's Federal Register Notice requesting comments on the *Draft Guidance* makes particular note of this case.(3)

Interest and Expertise of the Federal Trade Commission

The Commission enforces the Federal Trade Commission Act, which prohibits unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce. 15 U.S.C. § 41 *et seq.* The Commission shares with the FDA responsibility for assessing the consumer impact of promotional activities in health care markets, including the markets for pharmaceuticals.(4) Pursuant to these responsibilities, the Commission has taken enforcement action against deceptive advertising of over-the-counter drugs and other misleading or unsubstantiated representations that affect consumer health or safety.(5) As part of its mission to prevent anticompetitive behavior from harming consumers, the Commission has taken enforcement action against anticompetitive mergers and agreements in various pharmaceutical and pharmacy services markets.(6)

In particular, the Commission has paid attention to possible consumer harm with respect to the PBM industry. After a Bureau of Competition investigation of Eli Lilly & Company's acquisition of PCS, the Commission issued a consent order aimed at preventing anticompetitive effects that were likely to have flowed from this vertical acquisition and has continued to monitor the industry.

The Bureaus of Economics and Consumer Protection also submitted comments to the FDA in 1996 recommending that it consider flexible criteria for regulating so-called pharmaco- economic claims and thereby encourage the free flow of truthful, nondeceptive information to consumers. Similarly, with respect to possible deception in the context of "switch programs" of vertically integrated PBMs, the Commission staff recommended that the FDA pursue a disclosure-based approach.(7) In those comments, staff suggested that when evaluating economic claims directed to sophisticated audiences, such as health care providers and insurers, 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.(8)

The *Draft Guidance*

The Federal Register Notice accompanying the *Draft Guidance* states that the FDA's concern is that medical product sponsors' ownership of or agreements with PBMs may allow the sponsors to avoid regulatory oversight and/or create a public health risk, *e.g.,* by allowing dissemination of deceptive promotional materials. The *Draft Guidance* states that, under appropriate circumstances, the FDA will hold a medical product sponsor responsible for the promotional activities that a PBM or healthcare organization performs on its behalf.(9) Specifically, it states that the FDA will generally hold a medical product sponsor responsible for the actions of its PBM subsidiary.(10) It also identifies two factors that the FDA will use to determine whether to hold a medical product sponsor responsible for the actions of a PBM that is *not* a subsidiary: the relationship between the sponsor and the PBM and the extent of control over the PBM's promotional activities.(11)

The Relationship Between the Commission's *Eli Lilly* Order and the *Draft Guidance*

As the Federal Register Notice states, on July 28, 1995, the Commission issued a Consent Order designed to remedy the anticompetitive effects of Eli Lilly's acquisition of PCS. The Complaint accompanying the Order states that PCS, through negotiations over prices, discounts, rebates, and other issues, influences the availability of manufacturers' drugs on PCS's formulary, and thereby affects the price and availability of drugs under the pharmacy benefit plans that PCS manages.(12) It alleges that the effects of the acquisition may be to foreclose non-Lilly products from the PCS formulary, encourage reciprocal dealing and tacit collusion between Lilly and other drug manufacturers, decrease innovation, and increase drug prices.(13) The *Lilly* Order focuses on protecting consumers by ensuring their access to drug products manufactured by Lilly's competitors. Such access benefits consumers by: (1) preserving the ability of PCS's customers to receive the drugs they and their doctors currently prefer; and (2) maintaining incentives for Lilly's rivals to continue to develop and market drugs in all therapeutic categories.

A central provision of the *Lilly* Order requires PCS to maintain an open formulary and offer it to all current and prospective customers.(14) The Order defines an open formulary as one that allows the inclusion of any prescription drug approved by the FDA for use in the United States that an independent Pharmacy and Therapeutics (P&T) Committee determines is appropriate for inclusion.(15) The Order ensures the independence of this Committee by requiring that a majority of its members (and all of its voting members) have no affiliation with, or financial interest in, Lilly, PCS, or any entity with an ownership interest in Lilly or PCS.(16) The Order further provides that the Committee will make all decisions concerning drug-related clinical and therapeutic advice and evaluation on the Open Formulary.(17) It allows the Committee to use only objective criteria (*e.g.,* safety, efficacy, FDA-approved indications, side effects, patient compliance, and cost) to determine placement of drugs on the Open Formulary, and states that the Committee may give no preference to Lilly products except on the basis of such objective criteria.(18) The Order also includes a "firewall" that prohibits Lilly and PCS from disclosing certain confidential information to each other.(19)

The Commission issued the *Lilly* Order to preserve consumer choice by ensuring the availability to PCS customers of an Open Formulary that does not favor Lilly products as a result of Lilly's ownership and control of PCS. The Order, however, explicitly allows PCS in addition to offer its customers restricted or closed formularies, and the Order is silent as to how PCS may select and promote drugs on such formularies.(20)

The Commission majority also noted that, notwithstanding its issuance of its Order, it "remain[ed] concerned that th[e] acquisition, together with other vertical integration in these markets, could lead to anticompetitive consequences. . .

."(21) In part, because the Order applies only to Lilly and PCS, the Commission directed the staff to continue monitoring the PBM industry for possible anticompetitive effects as a result of vertical integration between manufacturers and PBMs. The Commission majority was particularly concerned about (1) foreclosure of the products of non-vertically-integrated manufacturers; (2) reciprocal dealing, coordinated interaction, or interdependent conduct among vertically integrated manufacturers; and (3) an increase in the prices or a decrease in the availability of prescription drugs.(22)

The *Lilly* Order and the Bureau of Competition's continued monitoring of the PBM industry are meant to protect consumers by detecting and remedying anticompetitive conditions of the type described above. Because these law enforcement initiatives are focused on competition, they do not directly address the use of false and misleading information in the promotion of pharmaceuticals and other medical products and services. The Commission's Order and monitoring, therefore, are not directed at the specific concerns that underlie the *Draft Guidance*.

Concerns about deceptive claims more generally, however, are of interest to Commission staff. As noted above, in many areas the FDA and the Commission's Bureau of Consumer Protection share responsibility for preventing consumer harm that results from false or misleading promotional activities. To the extent that the FDA determines that the arrangements discussed in the *Draft Guidance* establish FDA jurisdiction over some representations by sponsor-controlled PBMs, staff is ready to consult with the FDA on how to protect consumers from deception and ensure the free flow of truthful, nondeceptive claims regarding the economic benefits of pharmaceutical treatment interventions.

As always, we are eager to cooperate with the FDA in whatever way we can be helpful. Please continue to contact Michael D. McNeely, Assistant Director, at (202) 326-2904, whenever we can be of service.

Very truly yours,

William J. Baer
Director

(1) These comments are the views of the staff of the Bureau of Competition. They do not necessarily represent the views of the Commission or any individual Commissioner.

(2) *Eli Lilly and Company*, Docket No. C-3594 (July 28, 1995) (Commissioner Azcuenaga dissenting).

(3) 63 Fed. Reg. 236, 237 (1998).

(4) An FTC-FDA memorandum of understanding provides that the FDA has primary regulatory responsibility for policing truth or falsity of prescription drug advertising and the FTC has that responsibility for over-the-counter drug advertising. "Updated FTC-FDA Liaison Agreement -- Advertising of Over-the-Counter Drugs," 4 Trade Reg. Rep. (CCH) ¶ 9,851 (1971).

(5) *E.g., Schering-Plough Healthcare Products, Inc.*, Docket No. C-3741 (May 16, 1997); *Johnson & Johnson Consumer Products*, Docket No. C-3636 (Jan. 18, 1996); *Olsen Laboratories, Inc.*, 119 F.T.C. 161 (1995); *Synchronal Corp*., 116 F.T.C. 989 (1993).

(6) *E.g., Ciba-Geigy Ltd., et al.*, Docket No. C-3725 (Mar. 24, 1997); *RxCare of Tennessee, Inc., et al*., Docket No. C-3664 (June 10, 1996); *Glaxo plc*, Docket No. C-3586 (June 14, 1995); *IVAX Corp.*, Docket No. C-3565 (Mar. 27, 1995; *order modified*, June 17, 1996); *Baltimore Metropolitan Pharmaceutical Association, et al*., 117 F.T.C. 95 (1994); *Chain Pharmacy Association of New York State, Inc.*, 114 F.T.C. 327 (1991).

(7) Comments of the staffs of the Bureaus of Economics and Consumer Protection of the FTC, *In the Matter of Pharmaceutical Marketing and Information Exchange in Managed Care Environments; Public Hearings* [Docket No. 95N-0228], at 16-19 (Jan. 16, 1996).

(8) *Id.* at 15.

(9) *Draft Guidance* at 2. For simplicity, the following discussion uses the term "PBM" to refer either to a pharmacy benefit management company or to a healthcare organization.

(10) *Id.* at 3.

(11) *Id.* at 4.

(12) *Eli Lilly*, *supra* note 2, Complaint ¶ 11.

(13) *Id.,* ¶ 13.

(14) *Eli Lilly*, *supra* note 2, Order ¶ II.A. The Order sunsets after ten years (in June 2005).

(15) *Id.,* ¶¶ I.E, I.J.

(16) *Id.,* ¶ II.B(2)-(4).

(17) *Id.*, ¶ II.B.

(18) *Id.,* ¶ II.B(7).

(19) *Id.,* ¶¶ I.H., I.I, III.

(20) *Id.,* ¶ II.D.

(21) *Eli Lilly, supra* note 2, Statement of the Commission at 1.

(22) *Id*.