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

Bureau of Competition

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Food and Drug Administration
Department of Health and Human Services

Companies (PBMs)" (*Draft Guidance*).(1) These comments discuss the relationship between the Bureau of Competition's law enforcement efforts related to PBMs and the concerns that the *Draft Guidance* addresses.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 FDG2n/o022i(heed)4(nsa3(l)-1(l) R(G213(s)gi3-s)-3(i)15(o)4(ns N(o)12(i)-1(c)-3(onr)17(el)qu 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 reg alo911(i(al3(ay)1o13(v)1(ner)4(c)-3(i)gh3(n)13

."(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.

(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*