

IN THE MATTER OF

ELI LILLY AND COMPANY, INC.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE
FEDERAL TRADE COMMISSION ACT

Docket C-3594, Complaint, July 28, 1995--Decision, July 28, 1995

This consent order requires, among other things, an Indiana producer of pharmaceutical products to: ensure that the acquired company, PCS Health Systems (PCS), maintains an open formulary; appoint an independent Pharmacy and Therapeutics (P&T) Committee of health care professionals to objectively evaluate drugs for inclusion in the PCS open formulary; and, ensure that PCS accepts all discounts, rebates or other concessions offered by Eli Lilly's competitors for drugs that are accepted for listing on the open formulary, and to accurately reflect such discounts in ranking the drugs on the formulary. Pursuant to the modification of the proposed consent agreement, Eli Lilly would only need to obtain prior approval for an exclusive distribution agreement with McKesson Corporation. In addition, the consent order prohibits PCS and Eli Lilly from sharing proprietary or other non-public information, such as price data, obtained from Eli Lilly competitors whose drugs may be placed on a PCS formulary.

Appearances

For the Commission: *Michael D. McNeely* and *Kenneth A. Libby*.

For the respondent: *Jack Kaufman*, *Dewey Ballantine*, New York, N.Y.

COMPLAINT

The Federal Trade Commission, having reason to believe that respondent Eli Lilly and Company ("Lilly"), a corporation subject to the jurisdiction of the Commission, has entered into agreements with McKesson Corporation ("McKesson") that violate Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, that pursuant to these agreements, Lilly has commenced a cash tender offer to acquire all outstanding common shares of McKesson and intends to merge McKesson into a subsidiary of Lilly following the cash tender offer, which cash tender offer, acquisition and merger would, if consummated, violate Section 7 of the Clayton Act, as

amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, and that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint pursuant to Section 11 of the Clayton Act, 15 U.S.C. 21, and Section 5(b) of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, stating its charges as follows:

PARAGRAPH 1. Respondent Eli Lilly and Company is a corporation organized, existing and doing business under and by virtue of the laws of the State of Indiana, with its principal office located at Lilly Corporate Center, Indianapolis, Indiana.

PAR. 2. Lilly is engaged in the development, production and sale of pharmaceutical products, including Prozac, an antidepressant (specifically, a selective serotonin reuptake inhibitor); Humulin, an injectable insulin; Ceclor, an oral antibiotic; and Axid, an anti-ulcer product (specifically, an H2 antagonist).

PAR. 3. McKesson Corporation is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its principal office located at One Post Street, San Francisco, California.

PAR. 4. Through its subsidiary PCS Health Systems, Inc. ("PCS"), McKesson is engaged in the business of providing pharmacy benefit management services to insurance companies, third party payors, and other members of the healthcare industry.

PAR. 5. At all times relevant herein, respondent Lilly has been, and is now, engaged in commerce as "commerce" is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. 12, and is a corporation whose business is in or affecting commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. 44.

PAR. 6. Lilly and McKesson entered into an Agreement and Plan of Merger on July 10, 1994, pursuant to which Lilly commenced a cash tender offer for all outstanding shares of McKesson's common stock for \$76 per share. Following the cash tender offer, Lilly intends to merge McKesson into a subsidiary of Lilly. The total value of the cash tender offer is approximately \$3.4 billion.

PAR. 7. A relevant line of commerce within which to analyze the effects of this acquisition is the provision of pharmacy benefit management ("PBM") services by national full-service PBM firms, and any narrower markets contained therein. Other relevant lines of

commerce within which to analyze the effects of this acquisition are the development, manufacture and sale of pharmaceutical products in specific therapeutic categories, and narrower markets contained therein (including, but not limited to, the markets for injectable insulin, selective serotonin reuptake inhibitors, antidepressants, H2 antagonists, and anti-ulcer drugs).

PAR. 8. A relevant section of the country within which to analyze the effects of this acquisition is the United States.

PAR. 9. The relevant market for PBM services by national full-service PBM firms, as well as the relevant markets for pharmaceutical products in specific therapeutic categories, are highly concentrated.

PAR. 10. There are substantial entry barriers into the relevant markets. Even if new entry were to occur, it would take a long time, during which time substantial harm to competition could occur.

PAR. 11. As part of its PBM services, PCS maintains a drug formulary, which is a listing, by therapeutic category, of ambulatory drug products that are approved for use by the U.S. Food & Drug Administration, and which is made available to pharmacies, physicians, third-party payors, and other persons, to guide in the prescribing and dispensing of pharmaceuticals. Lilly pharmaceutical products are included on the PCS formulary. PCS provides a variety of other PBM services, including claims processing, drug utilization review, pharmacy network administration, and related services. PCS negotiates with pharmaceutical manufacturers, including Lilly, concerning placement on the PCS formulary, rebates, discounts, prices to be paid for pharmaceutical products purchased pursuant to pharmacy benefit plans managed by PCS, and other issues. PCS thereby influences the prices of pharmaceutical products and the availability of such products under the PCS pharmacy benefit plans.

PAR. 12. The Agreement and Plan of Merger contain a Memorandum of Understanding ("MOU") in which Lilly and McKesson agreed to investigate closing Lilly's distribution centers and having McKesson handle physical distribution of Lilly products to wholesalers and possibly be the sole distributor of Lilly products. Implementation of this MOU would force wholesalers to deal with McKesson to obtain Lilly products or deny them access to Lilly products.

PAR. 13. The effects of the proposed acquisition of McKesson by Lilly may be substantially to lessen competition in the relevant

markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, in the following ways, among others:

(a) Products of manufacturers other than Lilly are likely to be foreclosed from the PCS formulary;

(b) Reciprocal dealing, coordinated interaction, interdependent conduct, and tacit collusion among Lilly and other vertically integrated pharmaceutical companies will be enhanced;

(c) PCS will be eliminated as an independent negotiator of pharmaceutical prices with manufacturers;

(d) Incentives of other manufacturers to develop innovative pharmaceuticals will be diminished;

(e) Entry into the relevant markets may be more difficult because it will require entry at more than one level;

(f) Competition among drug wholesalers may be reduced because of the competitive advantage that control over Lilly drugs will provide McKesson; and,

(g) The price of pharmaceuticals is likely to increase and the quality of the pharmaceuticals available to consumers is likely to diminish.

PAR. 14. The proposed acquisition of McKesson by Lilly would, if consummated, violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45.

PAR. 15. The Agreement and Plan of Merger between Lilly and McKesson violates Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45.

Commissioner Azcuenaga dissenting and Commissioner Starek recused.

DECISION AND ORDER

The Federal Trade Commission ("Commission") having initiated an investigation of the proposed acquisition by respondent Eli Lilly and Company of the stock of McKesson Corporation, and the respondent having been furnished thereafter with a copy of a draft of complaint which the Bureau of Competition proposed to present to

the Commission for its consideration and which, if issued by the Commission, would charge respondent with a violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, and a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. 18; and

The respondent, its attorneys, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the said Acts, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of sixty (60) days, and having duly considered the comments received, now in further conformity with the procedure prescribed in Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Eli Lilly and Company ("Lilly") is a corporation organized, existing and doing business under and by virtue of the laws of the State of Indiana, with its office and principal place of business located at Lilly Corporate Center, in the City of Indianapolis, State of Indiana.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER

I.

It is ordered, That the following definitions shall apply herein:

A. "*Respondent*" or "*Lilly*" means Eli Lilly and Company, its predecessors, divisions, subsidiaries, affiliates, partnerships, joint ventures, successors and assigns, and all directors, officers, employees, agents and representatives of the foregoing.

B. "*McKesson*" means McKesson Corporation, its predecessors, divisions, subsidiaries, affiliates, partnerships, joint ventures, successors and assigns, and all directors, officers, employees, agents and representatives of the foregoing.

C. "*PCS*" means PCS Health Systems, Inc., its predecessors, divisions, subsidiaries, affiliates, partnerships, joint ventures, successors and assigns, and all directors, officers, employees, agents and representatives of the foregoing.

D. "*Commission*" means the Federal Trade Commission.

E. "*Formulary*" means a listing, by therapeutic category, of branded and generic ambulatory drug products that are approved for use by the U.S. Food & Drug Administration ("FDA"), and which is made available to pharmacies, physicians, third-party payors, or other persons involved in the healthcare industry, to guide in the prescribing or dispensing of pharmaceuticals. An "Open Formulary" is a formulary that allows the inclusion of any ambulatory prescription drug product approved by the FDA for use in the United States, which the P&T Committee (defined below) determines is appropriate for inclusion in such formulary. For purposes of this order, an Open Formulary may provide truthful information stating or indicating the relative costs or benefits of drugs on the formulary.

F. "*Pharmacy Benefit Management Services*" or "*PBM Services*" means services provided by a pharmacy benefits manager, such as formulary services, negotiation of rebates or discounts from pharmaceutical manufacturers, prescription claims processing, and drug utilization review.

G. "*Formulary Services*" means the provision, development, establishment, management or maintenance of a formulary by a pharmacy benefits manager. For purposes of this order, "management" of a formulary includes the negotiation and administration of rebate or discount agreements with pharmaceutical manufacturers for drugs included on a formulary.

H. "*Lilly Non-Public Information*" means information not in the public domain that is provided to Lilly in its capacity as a pharmaceutical manufacturer by a supplier of PBM Services and that

concerns bids, proposals, contracts, prices, rebates, discounts, or other terms or conditions of sale of any person other than PCS.

I. "*PCS Non-Public Information*" means information not in the public domain that is provided to PCS in its capacity as a supplier of PBM Services by a manufacturer or seller of prescription drug products and that concerns bids, proposals, contracts, prices, rebates, discounts, or other terms or conditions of sale of any person other than Lilly.

J. "*Pharmacy and Therapeutics Committee*" or "*P&T Committee*" means a group of healthcare professionals, such as doctors, pharmacists, and pharmacologists, appointed for the purpose of evaluating prescription drug products for inclusion on a formulary.

II.

It is ordered, That respondent:

A. Within thirty (30) days from the date this order becomes final, Lilly shall cause PCS to maintain an Open Formulary. As of the date this order becomes final, the PCS "Clinical Formulary and Prescribing Guidelines 1994-1995," shall be deemed an Open Formulary that complies with this paragraph II.A.

B. Within thirty (30) days from the date this order becomes final, Lilly shall cause PCS to appoint an independent P&T Committee with the authority and responsibility to maintain the Open Formulary required by paragraph II.A above. Such P&T Committee shall make all decisions concerning the inclusion of drugs on such Open Formulary, the exclusion of drugs from such Open Formulary, and the clinical and therapeutic advice and evaluation concerning drugs on such Open Formulary, and shall operate according to the following provisions:

1. Such P&T Committee shall consist of at least nine (9) members, all of whom shall be physicians, pharmacists, pharmacologists, or other healthcare professionals.

2. A majority of the P&T Committee shall consist of persons who are not employees, officers, directors, or agents of, and who have no financial interest in: (a) Lilly, (b) PCS, or (c) any other person who has an ownership interest in Lilly or PCS. Such persons shall be referred to herein as "independent" members of the P&T Committee.

3. Each independent member of the P&T Committee shall have one vote on all decisions of the P&T Committee.

4. All members of the P&T Committee who are employees, officers, directors, or agents of, or who have a financial interest in, Lilly, PCS, or any other person who has an ownership interest in Lilly or PCS, shall not be entitled to vote on decisions of the P&T Committee.

5. All independent members of the P&T Committee shall be appointed for three-year terms, except that for the initial board, one-third of the independent members shall be appointed for one-year terms, one-third shall be appointed for two-year terms, and the remaining independent members shall be appointed for three-year terms. At the expiration of their terms, or upon the occurrence of a vacancy, members may be reappointed, or new members may be appointed, by a majority of the then-appointed independent members of the P&T Committee.

6. No independent member of the P&T Committee may be removed except for cause by vote of a majority of the independent members of the P&T Committee.

7. In performing its responsibilities in maintaining the Open Formulary, the P&T Committee shall utilize only criteria relating to safety, efficacy, FDA approved indications, side effects, contraindications, pharmacokinetics, patient compliance, physician follow-up requirements, effect on emergency room visits and hospitalizations, laboratory tests, cost, and similar objective factors. Such P&T Committee shall give no preference to the products of Lilly, or of any other person with an ownership interest in PCS, except on the basis of such objective criteria.

8. Lilly shall cause PCS to cover the costs and expenses of the P&T Committee, and Lilly shall cause PCS to indemnify the P&T Committee against any losses or claims of any kind that might arise out of its performance of functions under this order, except to the extent that such losses or claims result from misfeasance, gross negligence, willful or wanton acts, or bad faith.

9. Such P&T Committee shall maintain written records, for five (5) years from the date thereof, explaining the basis and rationale for all P&T Committee decisions relating to the exclusion of any products from, or the ranking of products on, the Open Formulary required by paragraph II.A.

C. Lilly shall cause PCS to accept all discounts, rebates or other concessions offered by any manufacturer, seller or distributor of pharmaceutical products included by the P&T Committee on the Open Formulary, and Lilly shall cause PCS to ensure that all such discounts, rebates, or concessions are truthfully and accurately reflected in determining relative rankings of products on the Open Formulary.

D. Nothing in this order shall preclude PCS from offering any formulary other than the Open Formulary to any customer.

E. Lilly shall cause PCS to provide a copy of this order to each member of the P&T Committee on or before the date of each such person's appointment to such P&T Committee.

III.

It is further ordered, That:

A. Lilly shall not provide, disclose, or otherwise make available to PCS any Lilly Non-Public Information; and

B. PCS shall not provide, disclose, or otherwise make available to Lilly any PCS Non-Public Information.

IV.

It is further ordered, That Lilly shall retain all documents, and shall cause PCS to separately retain all documents, that relate to (A) the exclusion of any prescription drug products from the Open Formulary required by paragraph II.A above, (B) any preference or ranking accorded to any prescription drug product on the Open Formulary required by paragraph II.A above, or (C) statements or indications of discounts, rebates, or other concessions, as described in paragraph II.C above, for a period of five (5) years from the date such document is created or received.

V.

It is further ordered, That Lilly shall disclose the availability of the Open Formulary as follows:

A. Lilly shall cause PCS to disclose the availability of the Open Formulary to all persons who currently have an agreement with PCS concerning PBM services or concerning the inclusion of pharmaceuticals on a formulary, by providing to each such person a letter containing the following statement within ten (10) days after initiation of contact between PCS and such person regarding renewal or extension of such person's existing agreement with PCS:

PCS maintains an Open Formulary that allows, subject to the determination of an independent Pharmacy and Therapeutics Committee, the inclusion of any ambulatory prescription drug product approved by the FDA for use in the United States. This Open Formulary will be provided to you upon request.

B. For a period of five (5) years from the date this order becomes final, Lilly shall cause PCS to provide in writing the statement set forth in paragraph V.A above to each prospective customer of PCS at the time of PCS's response to such prospective customer's request for proposal, or at the time of PCS's initial written proposal to such prospective customer, whichever occurs first.

VI.

It is further ordered, That, for a period of five (5) years from the date this order becomes final, respondent shall not, without the prior approval of the Commission, directly or indirectly, through subsidiaries, partnerships, or otherwise, enter into any agreement, understanding, or condition with McKesson that Lilly will sell or distribute pharmaceutical products bearing any brand or trade name used by Lilly, in the United States or any part of the United States, exclusively through McKesson.

VII.

It is further ordered, That respondent shall notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent such as dissolution, assignment, sale resulting in the emergence of a successor corporation, or the creation or dissolution of subsidiaries or any other change in the corporation that may affect compliance obligations arising out of the order.

VIII.

It is further ordered, That:

A. Within sixty (60) days after the date this order becomes final, respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this order.

B. One year (1) from the date this order becomes final, annually for the next nine (9) years on the anniversary of the date this order becomes final, and at other times as the Commission may require, respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with this order.

C. Respondent shall include in its compliance reports a copy of the Open Formulary required by paragraph II.A above, and all written communications, internal memoranda, and reports and recommendations concerning compliance with the order.

IX.

It is further ordered, That, for the purpose of determining or securing compliance with this order, respondent shall permit any duly authorized representative of the Commission:

A. Access, during office hours and in the presence of counsel, to inspect and copy all books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of respondent relating to any matters contained in this order; and

B. Upon five days' notice to respondent and without restraint or interference from it, to interview officers, directors, or employees of respondent.

X.

It is further ordered, That this order shall terminate ten (10) years from the date this order becomes final.

Commissioner Azcuenaga dissenting and Commissioner Starek recused.

STATEMENT OF THE COMMISSION

The Commission has determined to approve and issue as final, with two modifications, the consent order ("order") agreed to with Eli Lilly and Company ("Lilly") in connection with its acquisition of PCS Health Systems, Inc. from McKesson Corporation. We reached this decision after careful and thorough consideration of the public comments received and discussions with consumer and industry representatives.

The Commission believes that, based on the evidence currently before it, this order provides the most appropriate relief available. Nevertheless, in light of the rapidly evolving nature of the markets for pharmaceutical products and pharmacy benefits management ("PBM"), the Commission remains concerned that this acquisition, together with other vertical integration in these markets, could lead to anticompetitive consequences that require additional relief. Thus, the Commission will continue to monitor this industry carefully, both through ongoing investigations and Lilly's compliance obligations under the order. More specifically, the Commission will assess, among other things:

- (1) The extent and effects of foreclosure of the products of other pharmaceutical manufacturers, especially those not vertically integrated with a PBM;
- (2) Whether, and to what extent, vertical integration in this industry fosters anticompetitive reciprocal dealing, coordinated interaction, or interdependent conduct among the vertically integrated firms; and
- (3) Whether vertical integration among pharmaceutical manufacturers and PBMs increases the prices or diminishes the availability of pharmaceuticals to consumers.

If the Commission concludes that competition is being reduced as a result of these vertical arrangements, it will seek appropriate relief against any firms engaged in anticompetitive conduct, including if necessary post-acquisition divestitures. The Commission may, of course, subsequently reopen a judgment in this or any matter

"whenever in the opinion of the Commission conditions of fact or law have so changed as to require such action or if the public interest shall so require." 15 U.S.C. 45(b); *see* 15 U.S.C. 21(b). The Commission believes that this course of action is both prudent and appropriate, given the significant and ongoing changes occurring in this segment of the health care industry.

Because the Commission has recently adopted a policy limiting the imposition of prior approvals, paragraphs VI(a) and VI(b) of the proposed order, which required Lilly to obtain prior approval before acquiring another PBM, have been eliminated. The acquisition of another PBM in the relevant market by Lilly would likely require premerger notification under the Hart-Scott-Rodino Act. 15 U.S.C. 18a. The Commission has modified paragraph VI of the order to require Lilly to obtain prior approval before distributing pharmaceuticals through an exclusive arrangement with McKesson, rather than through any exclusive arrangement with a wholesaler.

DISSENTING STATEMENT OF COMMISSIONER MARY L. AZCUENAGA

Today, the Commission accepts a consent order that is simultaneously inadequate to remedy the potential competitive harm from Eli Lilly and Company, Inc.'s acquisition of PCS Health Systems, Inc. ("PCS") from McKesson Corporation and overreaching in that it imposes restrictions on Lilly without a coherent theory of competitive harm. I dissent because the order does not resolve the competitive concern raised by the acquisition and because it encumbers the company with pointless and unnecessary restrictions. The Statement of the Commission, which holds out the possibility of further investigations and monitoring, implicitly reflects a lack of confidence in the remedial value of the order.¹

Paragraph thirteen of the complaint identifies several ways in which the proposed acquisition may substantially lessen competition. The most specific and plausible theory of violation is described in paragraph thirteen C of the complaint, which alleges that the acquisition eliminates PCS as "an independent negotiator of pharmaceutical prices with manufacturers." PCS is a pharmacy benefits manager (PBM) and provides administrative services for

¹ See Dissenting Statement of Commissioner Mary L. Azcuenaga (on the occasion of accepting the consent order for public comment), Eli Lilly and Company, Inc., File No. 941-0102 (Nov. 4, 1994) (attached and incorporated by reference).

pharmacy benefits plans to insurers, third party payers, and others. As alleged in paragraph eleven of the complaint, one service provided by a PBM is to negotiate, on behalf of the benefit plans, with pharmaceutical manufacturers regarding the price paid for drugs purchased through the plans.

The price negotiation function of a PBM, such as PCS, has competitive significance because PBMs, acting on behalf of many pharmacy benefits plans covering millions of covered patients, apparently have been successful in negotiating low prices for pharmaceuticals. Since the consent order is being entered without an administrative trial, we do not have a record sufficient to assess the role of PCS (and that of other PBMs) in bargaining for low drug prices. Based on the limited information presently available, it seems possible that PBMs may have been able to act as power buyers by aggregating the purchasing power of millions of covered patients and using this leverage to negotiate competitive prices. After the merger, PCS will continue to negotiate on behalf of its millions of covered patients. The merger, however, may alter the incentives of a Lilly-owned PCS. Lilly's role as a major drug producer may temper PCS's enthusiasm for bargaining down pharmaceutical prices. Lilly may be unwilling to lower prices and forgo profits on its own drugs sold through PCS, and a Lilly-owned PCS may hesitate to give any preference to a Lilly competitor in reward for low prices.

Assuming that the Commission has reason to believe that the merger violates Section 7 on the basis of this theory, the consent order provides no remedy. The order does nothing to preserve the role of PCS as an independent bargaining agent on behalf of pharmaceutical consumers. Section II of the order requires Lilly to offer an open formulary and to accept whatever discounts sellers may choose to offer, but passive acceptance of proffered discounts is hardly the same thing as aggressively pursuing price reductions. To the extent that the theory of competitive harm alleged in paragraph thirteen C of the complaint has merit, the order does not remedy the harm to competition.

A second theory of violation is contained in paragraph thirteen A of the complaint, which alleges that "[p]roducts of manufacturers other than Lilly are likely to be foreclosed from the PCS formulary." Although cases such as *United States Steel v. FTC*, 426 F.2d (6th Cir. 1970) (vertical market foreclosure resulting from a vertical merger deemed to be anticompetitive), support the theory of violation in

paragraph thirteen A, reliance on such cases ignores subsequent scholarly and judicial repudiation of the vertical foreclosure theory.

The Commission's apparent resuscitation of this theory calls for an explanation. Although the Commission used the foreclosure theory to challenge vertical mergers in the 1970's,² the Court of Appeals for the Second Circuit decisively rejected it in 1979. *Freuhauf Corp. v. FTC*, 603 F.2d 345 (2d Cir. 1979). The court was unwilling to rely on vertical foreclosure alone as a basis for liability. 603 F.2d at 352 and 352 n.9. It observed that "[a] showing of some probable anticompetitive impact is still essential" 603 F.2d at 353. Antitrust commentators also have criticized the foreclosure approach.³ The Court of Appeals for the Third Circuit agreed with the scholarly criticism and rejected the vertical foreclosure theory. *Alberta Gas Chemicals v. E.I. du Pont de Nemours and Co.*, 826 F.2d 1235 (3d Cir. 1987), *cert. denied*, 486 U.S. 1059 (1988).⁴

A truly effective prohibition on foreclosure of Lilly's competitors may preclude a closed formulary from achieving efficiencies. Closing a formulary may be essential to achieve certain efficiencies. By steering all patients to one of several equivalent drugs, the PBM may be able to negotiate a highly favorable, low price with a manufacturer by offering a large number of purchasers of that drug. Absent the ability to steer patients to one of several equivalent products, the PBM would lack negotiating leverage. In an analogous situation, the Commission's staff has opposed state legislation to require medical plans to deal with "any willing provider."⁵ The staff's argument has been that requiring a plan to deal with any pharmacy (or other provider) willing to provide the services diminishes the incentives of pharmacies to compete to secure places in the provider network and thereby drives up consumer prices. At this point, we lack empirical evidence establishing that closed formularies are able to realize similar efficiencies, but the

² See, e.g., *Ash Grove Cement v. FTC*, 577 F.2d 1368 (9th Cir. 1975), *cert. denied*, 439 U.S. 982 (1978).

³ See, e.g., 4 P. Areeda & D. Turner, *Antitrust law* ¶ 1004 at 211 (1980); R. Bork, *The Antitrust Paradox* 226, 237 (1978); Page, *Antitrust Damages and Economic Efficiency*, 47 U. Chi. L. Rev. 467, 495 (1980).

⁴ But see generally *United States v. American Cyanamid Co.*, 719 F.2d 558 (2d Cir. 1983), *cert. denied*, 465 U.S. 1101 (1984).

⁵ Letter to The Honorable Roger Madigan, The Senate of Pennsylvania, from the staff of the Federal Trade Commission, April 19, 1993; Letter to The Honorable E. Scott Garrett, Chairman, Assembly Insurance Committee of the New Jersey State Assembly from the staff of the Federal Trade Commission, March 29, 1993.

Commission staff's analysis of any willing provider provisions suggests that closed formularies may realize efficiencies.

Reliance on the theory of vertical foreclosure, given its history, seems to cry out for an explanation why the Commission is reviving it. Recent economic literature has suggested that under certain narrow conditions vertical arrangements may have harmful horizontal competitive effects.⁶ The complaint alleges the foreclosure "from the PCS formulary" as an anticompetitive effect, standing alone, which allegation does not appear to reflect the potential issue addressed in the economics literature. The complaint does not allege that the "PCS formulary" is a relevant antitrust market, and it does not (and insofar as I can tell, could not) allege that any relevant antitrust market, such as the markets for antidepressants, injectable insulin, H2 antagonists, or antiulcer drugs, will be totally (or even significantly) foreclosed to any competitor. Sales of these drugs through PCS account for only a portion of sales through PBM companies, and sales of these drugs through all PBMs are only a fraction of all drugs sold through the various channels of distribution. In short, PCS accounts for only a fraction of total United States drug sales, and it is not self evident what impact, if any, the merger has on the relevant markets for drugs alleged in paragraph seven of the complaint, including the markets for antidepressants, injectable insulin, H2 antagonists, or antiulcer drugs (or any other relevant markets).

Even assuming that the vertical foreclosure theory is sound, the remedy, which is to require Lilly to offer an open formulary, is singularly ineffective. A PBM's formulary is a list of drugs approved or recommended for particular therapeutic purposes. The formulary is made available to physicians, pharmacists, and others who treat patients covered by health plans using the PBM's services. A formulary is open if it includes all drugs recommended for treatment of a condition covered by the benefit plan. A closed or restricted formulary may limit reimbursement under the benefit plan to certain approved drugs, or may employ other incentives to encourage the use of a particular product in the treatment of a medical condition.

Although the Commission's order requires Lilly/PCS to offer an open formulary, it does nothing to ensure that PCS's open formulary remains an economically attractive or even viable option for benefit

⁶ See e.g., Riordan and Salop, "Evaluating Vertical Mergers: A Post-Chicago Approach," 63 Antitrust Law J. 513 (1995); Janusz Ordover, Garth Saloner & Steven Salop, "Equilibrium Vertical Foreclosure," 80 Am. Econ. Rev. 127 (1990); Steven Salop & David Scheffman, "Cost-Raising Strategies," 36 J. Indus. Econ. 19 (1987).

plans to select. Under the order, PCS is free to offer a high priced open formulary and a closed formulary with lower prices. Simply by adjusting the relative prices of the open and closed formularies, Lilly/PCS should be able to shift sales from one formulary to another. Even if Lilly concludes that it is commercially advantageous for PCS to offer an open formulary at an attractive price, PCS is free to shift patients away from other drugs to Lilly products. For example, PCS might waive copayments by end users for Lilly drugs, while requiring copayments on competing drugs, or it might promote Lilly products directly to physicians and pharmacists. To the extent that the Commission finds reason to believe that foreclosure from "the PCS formulary" is anticompetitive, the Commission's order does not solve the problem.

Third, paragraph thirteen E of the complaint alleges that "[e]ntry into the relevant markets may be more difficult because it will require entry at more than one level." This is a theoretically plausible competitive effect from a vertical merger that I would support in an appropriate case. Here, however, the alleged foreclosure resulting from this acquisition is not remotely related to the established standards for proving this competitive effect. Section 4.2 of the Department of Justice 1984 Merger Guidelines, which the Commission adopted by reference in joining the Statement Accompanying the Release of Revised Merger Guidelines in April 1992, sets forth the standard for evaluating this competitive effect. Section 4.2 states, as one "necessary" condition for this anticompetitive effect, that "the degree of vertical integration between the two markets must be so extensive that" entrants to one market must also enter the second market simultaneously. A second prerequisite is that the need for entry at the secondary level must make primary level entry "significantly more difficult and less likely to occur." In addition, competitive conditions in the primary market must be sufficiently conducive to noncompetitive performance that the increased difficulty of entry is a matter of concern. Even if these conditions are satisfied, the Merger Guidelines indicate that an antitrust challenge is unlikely if sales by unintegrated firms in the secondary market are sufficient to service two minimum-efficient-scale plants in the primary market.

The conclusory allegations of the complaint do not set forth a plausible claim under the standards in the 1984 Merger Guidelines. For example, the Guidelines adopt the standard of two minimum-

efficient-scale plants as a threshold level for an antitrust challenge. Although the complaint does not allege the size of efficient scale operations to produce the products identified in paragraph seven (injectable insulin, selective serotonin reuptake inhibitors, antidepressants, H2 antagonists and antiulcer drugs), the fact that a substantial proportion of total drug sales is made through non-PBM channels tends to mitigate any concern regarding the need for two level entry under the Guidelines. Furthermore, even assuming that a competing manufacturer of one primary product, say injectable insulin, would be foreclosed from sales through PCS, it does not follow that it would be foreclosed from sales through other PBMs, whether or not they are owned by a drug producer. Other vertically integrated PBMs would not necessarily be foreclosed to an unintegrated insulin supplier unless the PBM/drug manufacturer also produced insulin. In short, the complaint does not allege a *prima facie* case under the Guidelines.

Fourth, paragraph thirteen B of the complaint alleges that "[r]eciprocal dealing, coordinated interaction, interdependent conduct, and tacit collusion among Lilly and other vertically integrated pharmaceutical companies will be enhanced." These allegations evoke a sinister image without providing any explanation of what anticompetitive harms are likely and why this merger is likely substantially to lessen competition. Although under notice pleading little specificity is required in articulating a theory of harm to competition, and this is especially so in a complaint accompanying a consent order, I seriously question whether this allegation has any substance at all. In horizontal merger cases, when the Commission alleges that a merger lessens competition by enabling the firms in the relevant market to engage in coordinated interaction, that allegation reflects a carefully considered judgment based on established standards. Several substantial hurdles must be crossed before a judgment of anticompetitive effects will be reached. After markets are identified, the structure of the industry is examined, as are the likelihood of entry and efficiencies. Under Section 2.1 of the 1992 Horizontal Merger Guidelines, the Commission considers various conditions conducive to coordination. Careful allegations, well supported in fact, law and economic analysis, have served the Commission well in challenging horizontal mergers. Given that this vertical merger does not fit within a familiar template, it is particularly inappropriate to abandon careful consideration of

competitive conditions in the relevant markets in favor of casual conclusions about competitive effects.

The allegations in paragraph thirteen B are so conclusory that it is difficult to pinpoint any coherent antitrust theory of liability. One antitrust concern relating to the pharmaceutical industry in general appears to be that Lilly/PCS may reach agreements with other vertically integrated drug manufacturer/PBM companies regarding inclusion on each other's formularies. That is, Lilly might agree, for example, to include Merck drugs on the PCS formularies in exchange for Merck's inclusion of Lilly drugs on the Medco formularies. If enough vertically integrated firms engaged in such reciprocal agreements and if they excluded drugs made by other firms from their formularies, then drug manufacturers that did not own a PBM (and thus were not part of a series of reciprocal deals) might be foreclosed from sales through many PBM firms. I agree that horizontal reciprocal deals that created a noncompetitive market might well raise serious antitrust concerns. If reciprocal agreements among integrated drug producers do produce anticompetitive results, an antitrust action under Section 5 of the Federal Trade Commission Act would lie. I seriously question, however, whether on the present record, there is reason to believe that the anticompetitive practices are occurring or are likely to occur or that Lilly's acquisition of PCS would make them more likely. Even assuming that such a cartel of drug manufacturers is likely to be formed, the remedy in this order, which merely prohibits some limited information sharing between Lilly and PCS, is totally inadequate. If at some time in the future the Commission has reason to believe that this anticompetitive practice is occurring, I would suggest consideration of a much stronger remedy that is more related to the competitive harm. The other theories of violation alleged in paragraph thirteen of the complaint are even less compelling than those I have discussed.

Fifth, paragraph twelve of the complaint alleges that Lilly and McKesson have signed a memorandum of understanding "to investigate closing Lilly's distribution centers and having McKesson handle physical distribution of Lilly products to wholesalers and possibly be the sole distributor of Lilly products." Paragraph thirteen F of the complaint alleges that competition among drug wholesalers may be reduced "because of the competitive advantage that control over Lilly drugs will provide McKesson."

The memorandum of understanding is not an exclusive distribution agreement. It is not even an agreement to agree on an exclusive distribution arrangement. It is an agreement "to investigate" possible distribution arrangements in the future. In my view, there is no colorable factual basis to allege that competition in drug wholesale distribution is threatened because McKesson will control Lilly drugs. Indeed, the allegation that a major pharmaceutical manufacturer such as Lilly would hand over "control" of its products to McKesson seems so implausible that it begs for an explanation.

The Commission's hasty allegation of a Section 7 violation from the mere consideration of innovative, new distribution arrangements could chill consideration of efficient, procompetitive channels of delivering products to consumers. At this point, all we know is that McKesson and Lilly proposed to investigate a novel concept in distribution. Perhaps nothing would have come of the investigation, but perhaps the two firms could have found ways to save costs and improve efficiency. Because the Commission acted peremptorily and without the benefit of a specific proposal, the order could well chill consideration of innovative approaches to distribution.

The consent order imposes a five-year prior approval requirement on any exclusive distribution agreement between Lilly and McKesson. It is at least somewhat amusing that having recently abandoned its prior approval requirement in cases enjoining unlawful mergers (citing as one reason the cost of compliance),⁷ the Commission chooses here to impose a prior approval requirement in the context of an acquisition that is being allowed to proceed and on the basis of a separate alleged violation that is only a gleam in the Commission's eye.

Lilly's acquisition of PCS followed several other acquisitions of PBMs by drug manufacturers that the Commission did not challenge. Although the elimination of PBMs as an independent force in the pharmaceutical marketplace would be a source of legitimate antitrust concern, the evidence does not come close to showing that this transaction would likely lead to such a result, and even assuming that it did, requiring PCS to maintain an open formulary would be no

⁷ Statement of Federal Trade Commission Policy Concerning Prior Approval and Prior Notice Provisions (June 21, 1995), Commissioner Azcuenaga dissenting in a separate statement. According to the Commission's Statement, "as a general matter, Commission orders will not include . . . prior approval . . . requirements . . . [except possibly] where there is a credible risk that a company . . . would, but for the provision, attempt the same or approximately the same merger." *Id.* at 2-3.

solution. This order is no more than a fig leaf to conceal apparent indecision about the extent and nature of the competitive problem. Implementation of the bureaucratic provisions of the order will waste private resources and may provide a false sense of security that will lull us into complacency. Although I support the Commission's promise to continue monitoring the industry, the murky allegations in the complaint and the ineffective order are not an auspicious beginning. The allegation that the Lilly/McKesson agreement to investigate new distribution concepts is unlawful already has done its harm. That peremptory action, which is entirely unnecessary at this time, may cost consumers by blocking the exploration of innovative ideas for distribution.

I dissent.

DISSENTING STATEMENT OF COMMISSIONER MARY L. AZCUENAGA

Today, the Commission accepts a consent order for public comment that exudes a lack of conviction in the underlying theory of competitive harm on which the order is based. The order does not cure the competitive problems alleged in the complaint. Three of the four primary provisions in the order are inadequate, and the fourth, which addresses a memorandum of understanding between Lilly and McKesson, is based on no colorable factual showing of a violation of law. In addition, there is no justification for making the duration of the order half that of other Commission orders. Finally, imposing this order without addressing similar acquisitions raises a question of evenhandedness and leaves unanswered the broader question of the competitive effect of vertical integration in this industry.

I dissent.

Complaint

120 F.T.C.

IN THE MATTER OF

IHI CLINICS, INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-3595, Complaint, Aug. 1, 1995--Decision, Aug. 1, 1995*

This consent order prohibits, among other things, a Georgia corporation and its officers from misrepresenting the performance, success or efficacy of their smoking cessation, weight loss and maintenance seminars, or any such program, and from representing that the U.S. Government has rated their group hypnosis method as the best way to stop smoking. The consent order requires the respondents to possess and rely upon competent and reliable scientific evidence to substantiate any representation about the performance or efficacy of any smoking cessation or weight loss program, before they make such a claim.

*Appearances*For the Commission: *Matthew Daynard.*For the respondents: *Pro se.*

COMPLAINT

The Federal Trade Commission, having reason to believe that IHI Clinics, Inc. ("IHIC"), a corporation, Gordon Brick, individually and as an officer of said corporation, and Larry Brick, individually and as a former officer of said corporation ("respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, alleges:

PARAGRAPH 1. Respondent IHIC is a Georgia corporation, with its principal office and place of business at 1962 Carthage Road, Tucker, Georgia.

Respondent Gordon Brick is the sole officer, director and shareholder of the corporate respondent. Larry Brick is the former President of the corporate respondent. Together, they formulated, directed, and controlled the acts and practices of the corporate respondent, including the acts and practices alleged in this complaint.