FEDERAL TRADE COMMISSION

[File No. 951-0059]

RxCare of Tennessee, Inc; Consent Agreement With Analysis To Aid Public Comment

AGENCY: Federal Trade Commission. **ACTION:** Consent Agreement.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent agreement, accepted subject to final Commission approval, would bar the leading provider of pharmacy network services in Tennessee from having "most favored nation" clauses in its pharmacy participation agreements. The draft complaint accompanying the consent agreement alleges that RxCare's use of these clauses discourages the pharmacies from discounting and thereby limits price competition among the pharmacies in their dealings with pharmacy benefits managers and thirdparty payers.

DATES: Comments must be received on or before March 29, 1996.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary Room 159, 6th St. and Pa Ave., NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Michael D. McNeely, Federal Trade Commission, S–3231, 6th and Pennsylvania Avenue, NW, Washington, DC 20580. (202) 326–2904.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and § 2.34 of the Commission's rules of practice (16 CFR 2.34), notice is hereby given that the following consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with § 4.9(b)(6)(ii) of the Commission's rules of practice (16 CFR 4.9(b)(6)(ii)).

Agreement Containing Consent Order

The Federal Trade Commission ("Commission"), having initiated an investigation of RxCare of Tennessee, Inc. ("RXCare"), and its parent, the Tennessee Pharmacists Association ("TPA"), and it now appearing that RXCare and TPA, hereinafter sometimes referred to as "proposed respondents," are willing to enter into an agreement

containing an Order to remedy the alleged lessening of competition resulting from proposed respondents' practices and providing for other relief:

It is hereby agreed by and between proposed respondents, by their duly authorized officers and attorneys, and counsel for the Commission that:

- 1. Proposed respondent RxCare is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Tennessee with its office and principal place of business located at 1226 17th Avenue South, Nashville, Tennessee 37212.
- 2. Proposed respondent TPA is an unincorporated trade association organized, existing, and doing business under and by virtue of the laws of the State of Tennessee with its office and principal place of business located at 226 Capitol Blvd., Suite 810, Nashville, Tennessee 37219–1893.
- 3. Proposed respondents admit all the jurisdictional facts set forth in the draft of complaint.
 - 4. Proposed respondents waive: a. Any further procedural steps;
- b. The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law;
- c. All rights to seek judicial review or otherwise to challenge or contest the validity of the Order entered pursuant to this agreement; and
- d. Any claim under the Equal Access to Justice Act.
- 5. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission it, together with the draft of complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify the proposed respondents, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision, in disposition of the proceeding.
- 6. This agreement is for settlement purposes only and does not constitute an admission by proposed respondents that the law has been violated as alleged in the draft of complaint or that the facts as alleged in the draft complaint, other than jurisdictional facts, are true.

7. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant

to the provisions of § 2.34 of the Commission's rules, the Commission may, without further notice to the proposed respondents, (1) issue its complaint corresponding in form and substance with the draft of complaint and its decision containing the following Order in disposition of the proceeding, and (2) make information public with respect thereto. When so entered, the Order shall have the same force and effect and may be altered, modified or set aside in the same manner and within the same time provided by statute for other orders. The Order shall become final upon service. Delivery by the U.S. Postal Service of the complaint and decision containing the agreed-to Order to proposed respondents' addresses as stated in this agreement shall constitute service. Proposed respondents waive any right they may have to any other manner of service. The complaint may be used in construing the terms of the Order, and no agreement, understanding, representation, or interpretation not contained in the Order or the agreement may be used to vary or contradict the terms of the Order.

8. Proposed respondents have read the draft of complaint and Order contemplated hereby. Proposed respondents understand that once the Order has been issued, they will be required to file one or more compliance reports showing that they have fully complied with the Order. Proposed respondents further understand that they may be liable for civil penalties in the amount provided by law for each violation of the Order after it becomes final.

Order

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It is ordered That the following definitions shall apply herein:

A. "RxCare" means RxCare of Tennessee, Inc.; its predecessors, divisions, subsidiaries, affiliates, joint ventures, successors, and assigns; and all directors, officers, employees, agents, and representatives of the foregoing;

B. "TPA" means the Tennessee Pharmacists Association; its predecessors, divisions, subsidiaries, affiliates, joint ventures, successors, and assigns; and all directors, officers, employees, agents, and representatives of the foregoing;

C. "Third-party payer" means any person or entity that provides a program or plan pursuant to which such person or entity agrees to pay for prescriptions dispensed by pharmacies to individuals described in the plan or program as eligible for coverage ("coveraged persons") and includes, but is not limited to, health insurance companies: prepaid hospital, medical, or other health service plans, such as Blue Cross and Blue Shield plans; health maintenance organizations; preferred provider organizations; and health benefits programs for government employees, retirees and dependents;

D. "Participation agreement" means any existing or proposed agreement, oral or written, in which a third-party payer, prescription benefit manager (PBM), pharmacy service administrative organization (PSAO), or other firm agrees to reimburse a pharmacy firm for the dispensing of prescription drugs to covered persons, and the pharmacy firm agrees to accept such payment from the third-party payer, PMB, PSAO, or other firm for such prescriptions dispensed during the term of the agreement;

E. "Pharmacy firm" means any partnership, sole proprietorship, corporation, or other entity that owns, controls or operates one or more

pharmacies; and F. "Most Favored Nations Clause" or "MFN" means any agreement, understanding, or course of dealing between RxCare or TPA and any pharmacy firm under which, in the event the pharmacy firm accepts or agrees to accept from another third party payer, PBM, PSAO or other firm a lower reimbursement rate than the lowest RxCare reimbursement rate, the pharmacy firm must thereafter accept a reduction in its reimbursement rate for any or all RxCare contracts in which it participates. The term "Most Favored Nations Clause" includes, but is not limited to, any price protection clause, buyer protection clause, prudent buyer clause, consumer protection clause, meet or release clause, best price clause, or meeting competition clause.

It is further ordered That RxCare and TPA shall forthwith cease and desist, directly or indirectly, from:

A. Entering into, maintaining, or enforcing a Most Favored Nations Clause in any participation agreement with any pharmacy firm or by any other means or methods;

B. Auditing any pharmacy firm for the purpose of enforcing a Most Favored Nations Clause; or

C. Inducing, suggesting, urging, encouraging, or assisting any person or entity to take any action that if taken by RxCare or TPA would violate this order.

It is further ordered That RxCare shall, within thirty (30) days after the date this Order becomes final:

A. Remove all Most Favored Nations Clauses from its agreements with pharmacy firms;

B. Distribute a copy of this Order, the attached Appendix, and the complaint to each pharmacy firm with which RxCare has a participation agreement; and

C. Publish the Appendix to this Order in the RxCare Update and on the "RxCare Network News" page of the Tennessee Pharmacist, or any successor publication(s).

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It is further ordered That, for the purpose of determining or securing compliance with this Order, RxCare and TPA each shall:

A. Within sixty (60) days after the date this Order becomes final, submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order;

B. One year (1) from the date this Order becomes final, annually for the next four (4) years on the anniversary of the date this Order becomes final, and at other times as the Commission may require, file a verified written report with the Commission setting forth in detail the manner and form in which they have complied and are complying with this Order. Respondents shall include in their compliance reports all written communications, internal memoranda, and reports and recommendations concerning compliance with this Order;

C. For a period of ten (10) years after the date this Order becomes final, permit any duly authorized representative of the Commission:

1. 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 respondents relating to any matters contained in this Order; and

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

D. For a period of ten (10) years after the date this Order becomes final, notify the Commission at least thirty (30) days prior to any proposed change in TPA or RxCare 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.

It is further ordered That this Order shall terminate twenty (20) years from the date this Order becomes final.

Appendix

[Date]

Announcement

The Tennessee pharmacists Association (TPA) and RxCare of Tennessee, Inc. (RxCare), have entered into a consent agreement with the Federal Trade Commission. Pursuant to this consent agreement, the Commission issued a consent order on [Date] providing that RxCare and TPA may no longer enforce a most Favored Nations (MFN) clause in the RxCare network provider agreements. The MFN clause requires that if a participating pharmacy accepts a lower reimbursement rate than the lowest RxCare rate, the pharmacy shall accept its lower reimbursement rate for all RxCare contracts in which it participates. As a result of the consent order, RxCare will not require that pharmacies in its network that enter into any agreement at a lower reimbursement rate than the RxCare reimbursement rate shall accept such lower reimbursement rat for RxCare contracts.

For more specific information, TPA or RxCare pharmacy network members should refer to the FTC consent order itself. TPA and RxCare will provide a copy of the consent order to each pharmacy firm with which RxCare has a participation agreement. Baeteena Black,

Pharm. D., Executive Director, Tennessee Pharmacists Association.

Gary Cripps.

Pharm. D., Chairman and President, RxCare of Tennessee, Inc.

RxCare, 951 0059

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has agreed to accept, subject to final approval, a proposed consent order settling charges that RxCare of Tennessee, Inc., and the Tennessee Pharmacists Association (TPA) violated Section 5 of the Federal Trade Commission

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order, nor to modify in any way their terms.

The proposed consent order has been entered into for settlement purposes only and does not constitute an admission by RxCare or TPA that the law has been violated as alleged in the complaint.

Description of Complaint

The complaint prepared by the Commission for issuance along with the proposed order alleges the following:

TPA is the largest association of pharmacists in Tennessee. Among TPA's goals is to "define and promote appropriate compensation to pharmacists for patient care." TPA owns RxCare.

RxCare is a pharmacy network, *i.e.*, a group of pharmacies that offer their services to pharmacy benefit managers (PBMs) and to third-party payers (such as managed care plans, insurers, and employers who pay for prescription drugs provided as part of employee health benefit plans). Third-party payers pay for about half of all prescriptions in Tennessee.

The complaint further alleges that RxCare is the leading pharmacy network in Tennessee, providing PBM and/or network services to managed care plans and PMBs accounting for approximately 2.4 million residents of Tennessee, who represent more than half of Tennessee citizens with third-party pharmacy benefits. Because the RxCare network is the largest source of third-party business for Tennessee pharmacies, there is a strong incentive for those pharmacies to participate in the RxCare network. The RxCare network includes approximately 95% of Tennessee pharmacies.

According to the Commission's complaint, RxCare's agreements with the pharmacies in its provider network include a "most favored nation" or "MFN" clause. This clause requires that if a network pharmacy accepts a reimbursement rate lower than its RxCare reimbursement rate, the pharmacy shall accept the lower reimbursement rate for all RxCare business. Each pharmacy in the RxCare network agrees to this clause as a condition of remaining within the network and RxCare enforces this clause against pharmacies that have accepted lower reimbursement rates from other payers. In addition, RxCare has discouraged pharmacies from participating in rival networks seeking to offer prices below the RxCare reimbursement level. RxCare did so by urging pharmacies to refrain from such participation and by warning that acceptance of such rates could trigger the MFN clause.

The complaint further alleges that, because RxCare represents such a large portion of their business, most Tennessee pharmacies would incur an unacceptable revenue loss if violating the MFN clause caused them to accept reduced reimbursement rates on all of their RxCare business. Thus, the MFN clause has provided a mechanism to diminish significantly the incentives of RxCare network pharmacies to discount their rates to third-party payers seeking to offer network services with lower reimbursement rates. The MFN clause has also enabled the pharmacies to assure each other that they will not compete by selectively discounting their rates. Further, the complaint alleges that third-party payers in states other than Tennessee frequently offer reimbursement rates below the RxCare reimbursement rate and that the MFN clause has caused payers to pay higher rates in Tennessee than in other states.

The complaint alleges that RxCare's adoption and enforcement of the MFN clause

has injured consumers by restricting price competition among pharmacies in Tennessee, effectively establishing the RxCare network rate as a price floor for most Tennessee pharmacies and inhibiting the entry of lowerpriced pharmacy networks.

There are judicial decisions upholding the use of MFN clauses against antitrust challenges. See, e.g., Blue Cross and Blue Shield United of Wisconsin v. Marshfield Clinic, 65 F.3d 1406 (7th Cir. 1995); Ocean State Physicians Health Plan, Inc. v. Blue Cross and Blue Shield of Rhode Island, 883 F.2d 1101 (1st Cir. 1989), cert. denied, 494 U.S. 1027 (1990). The Commission notes that these cases rest on facts that differ significantly from those giving rise to this enforcement action. Cf. Marshfield, 65 F.3d at 1415 ("Perhaps * * * these clauses are misused to anticompetitive ends in some cases; but there is no evidence of that in this case"). In particular, the conduct challenged in the present enforcement action involved a combination of competing sellers using its market power to stabilize prices.

In Ocean State, the First Circuit Court of Appeals rejected a rival HMO's claim that Blue Cross and Blue Shield of Rhode Island violated Section 2 of the Sherman Act by requiring its participating physicians to adhere to a MFN clause. The court concluded that the MFN clause was not unreasonably exclusionary, despite the finding that Blue Cross possessed market power. Ocean State, 883 F.2d at 1110. The court in Ocean State reasoned that a health insurer's unilateral decisions about what it will pay providers do not violate the Sherman Act and stated that Blue Cross, "like any buyer of goods or services," may lawfully "bargain with its providers for the best price it can get." Id. at

In Marshfield, defendant Marshfield Clinic (a multi-specialty medical group practice) required independent physicians contracting with its subsidiary HMO to adhere to a MFN clause. The Seventh Circuit Court of Appeals, in holding that the Clinic's use of the MFN clause did not violate Section 1 of the Sherman Act, appears to have focused on the Clinic's role as a purchaser of physician services and found no evidence to warrant the conclusion that the MFN clause was used as a device to stabilize prices. 65 F.3d at 1415 (MFN clauses "are standard devices by which buyers try to bargain for low prices *. The Clinic did this to minimize the cost of physicians to it * * *."). In addition, the court concluded that the Clinic's HMO lacked market power, finding that less than 50 percent of physicians in the market were HMO providers and that the HMO did not represent enough of each physician's business to impede selective discounting. Id. at 1411 ("The 900 independent contractors derive only a small fraction of their income from these [Marshfield] contracts").

In the present case, however, the Commission found reason to believe that a group of competing sellers exercised market power through use of an MFN clause, and that the evidence, analyzed under a full rule-of-reason inquiry, demonstrated that the RxCare MFN clause, on balance, has harmed consumers. In particular, the Commission found reason to believe that:

The MFN clause, in conjunction with the high percentage of Tennessee pharmacies' participation in the RxCare network and the substantial amount of third-party business arising from participation in that network, has made it possible for RxCare to exercise market power. Under these conditions, the MFN clause effectively created a price floor by discouraging discounting. In addition, RxCare sought to use the MFN clause to stabilize prices. For example, RxCare sought to persuade payers to increase their reimbursement rates to the RxCare level. The evidence, as a whole, was sufficient to demonstrate that the anticompetitive effects of the MFN clause outweighed any potential efficiencies.

Description of the Proposed Consent Order

The proposed order would prohibit RxCare and TPA from entering into, maintaining, or enforcing any MFN clause, including auditing any pharmacy for the purpose of enforcing an MFN clause.

The proposed order would require RxCare to remove all MFN clauses from its contracts with pharmacies, to distribute the order and accompanying complaint to network pharmacies, and publish the order and related documents. The order would also require RxCare and TPA to file compliance reports, retain certain documents, and notify the Commission of certain changes in its corporate structure.

Donald S. Clark, *Secretary.*

Concurring Statement of Commissioner Mary L. Azcuenaga in RxCare of Tennessee, Inc., File No. 951–0059

I join in the Commission's decision to accept for public comment a consent order requiring the Tennessee Pharmacists Association ("TPA"), a trade association of pharmacists, and its affiliated provider of pharmacy network services, RxCare of Tennessee, Inc., to eliminate the most favored nation clause from its provider network contracts. I write separately to emphasize that this order does not call into question the general lawfulness of most favored nation clauses.1 Although most favored nation clauses usually raise no competitive concerns, in this case, the clause was used in furtherance of a horizontal agreement to stabilize the reimbursement rates for retail pharmacy services, as alleged in paragraph eight of the complaint.

Statement of Commissioner Christine A. Varney in the Matter of RxCare, File No. 951–0059

RxCare, a pharmacy network established and owned by the Tennessee Pharmacists Association, contracts with health plans to provide prescription drugs to the plans' subscribers. I have voted to issue the complaint and accept the consent order in this matter because I agree that the most favored nations clause, in this case, may have

¹ Although this point, among others, is made in the Analysis To Aid Public Comment, I express no opinion on that analysis, which by its own terms "is not intended to constitute an official interpretation" of the Commission's action.

lessened competition. But, in doing so, I want to emphasize that joint ventures by retail pharmacists can be precompetitive by injecting new competition into the market for pharmacy benefit management services.2 I believe many of RxCare's programs can be procompetitive. The matter before the FTC concerns only one aspect of RxCare's pharmacy benefit management programs—its imposition of a most favored nations clause. By working on an expedited basis, staff has been able to identify this concern quickly and, by working closely with RxCare, has resolved it in a mutually agreeable fashion. [FR Doc. 96-1497 Filed 1-28-96; 8:45 am] BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Product and Establishment License Applications, Refusal to File; Meeting of Oversight Committee; Cancellation

AGENCY: Food and Drug Administration,

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing cancellation of the meeting for January 1996 of its standing oversight committee (the committee) in the Center for Biologics Evaluation and Research (CBER) that conducts a periodic review of CBER's use of its refusal to file (RTF) practices on product license applications (PLA's) and establishment applications (ELA's). The meeting is being cancelled because there were no RTF actions taken by CBER in the previous quarter. CBER's RTF oversight committee examines all RTF decisions which occurred during the previous quarter to assess consistency across CBER offices and divisions in RTF decisions

DATES: The meeting scheduled for January 1996 is cancelled. The next meeting is scheduled for April 1996.

FOR FURTHER INFORMATION CONTACT: Joy A. Cavagnaro, Center for Biologics Evaluation and Research (HFM–2), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0372.

SUPPLEMENTARY INFORMATION: In the Federal Register of May 15, 1995 (60 FR 25920), FDA announced the establishment of a standing oversight committee in CBER to conduct periodic reviews of CBER's use of its RTF

practices on PLA's and ELA's. The May 15 notice stated that the committee meetings would be held quarterly to review all of the RTF decisions. The January 1996 committee meeting is being cancelled because there were no RTF actions taken by CBER in the previous quarter.

Dated: January 22, 1996.
William K. Hubbard,
Associate Commissioner for Policy
Coordination.
[FR Doc. 96–1513 Filed 1–26–96; 8:45 am]
BILLING CODE 4160–01–F

National Institutes of Health

"Infant Sleep Position and Sudden Infant Death Syndrome (SIDS) Risk" Study; Proposed Data Collection

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH) is publishing this notice to solicit public comment on the data collection proposed for the study on "Infant Sleep Position and SIDS Risk" for the Pregnancy and Perinatology Program. To request copies of the data collection plans and instruments, call Dr. Marian Willinger, (301) 496–5575 (not a toll-free number).

Comments are invited on: (a) whether the proposed collection is necessary, including whether the information has a practical use; (b) ways to enhance the clarity, quality, and use of the information to be collected; (c) the accuracy of the agency estimate of burden of the proposed collection; and (d) ways to minimize the collection burden of the respondents. Written comments are requested within 60 days of the publication of this notice. Send comments to Dr. Marian Willinger, Pregnancy and Perinatology Branch, Center for Research for Mothers and Children (CRMC), NICHD, NIH, Building 6100, Room 4B11H, 6100 Executive Boulevard, Bethesda, MD 20852.

Proposed Project

The Center for Research for Mothers and Children intends to conduct the study for "Infant Sleep Position and SIDS Risk." The CRMC is authorized by Section 452 of Part G of Title IV of the Public Health Service Act (42 U.S.C. 288) as amended by the NIH Revitalization Act of 1993 (Pub. L. 103–43)

The information proposed for collection will be used by the NICHD to study if there is any correlation between the events occurring prior to death for infants who died of SIDS or their parents to determine the causes of SIDS.

The annual burden estimates are as follows:

Case type	Est. total cases	Est. No. of re- sponses	Avg. hours re- quired for total re- sponses
SIDS	600 1200	480 960	1

Dated: January 19, 1996. Benjamin E. Fulton, Executive Officer, NICHD.

[FR Doc. 96–1448 Filed 1–26–96; 8:45 am]

BILLING CODE 4140-01-M

John E. Fogarty International Center for Advanced Study in the Health Sciences; Notice of Meeting of the Fogarty International Center Advisory Board

Pursuant to Public Law 92–463, as amended, notice is hereby given of the thirty-second meeting of the Fogarty International Center (FIC) Advisory Board, February 6, 1996, in the Lawton Chiles International House (Building 16) at the National Institutes of Health.

The meeting will be open to the public from 8:30 a.m. to 10:30 a.m. In addition to a report by the Director, FIC, the agenda will focus on the status of FIC programs and plans.

In accordance with the provisions of sections 552b(c)(4) and 552b(c)(6), Title 5, United States Code and section 10(d) of Public Law 92–463, as amended, the meeting will be closed to the public from 11:00 a.m. to adjournment for the review of applications for awards under the Senior International Fellowship Program and the International Research Fellowship Program; and the Fogarty International Research Collaboration Awards and HIV, AIDS and Related Illnesses Collaboration Awards.

Paula Cohen, Committee Management Officer, Fogarty International Center, National Institutes of Health, Building 31, Room B2C08, 31 CENTER DR MSC 2220, Bethesda, MD 20892–2220, telephone: 301–496–1491, will provide a summary of the meeting and a roster of the committee members upon request.

Írene Edwards, Executive Secretary, Fogarty International Center Advisory Board, Building 31, Room B2C08, telephone: 301–496–1491, will provide substantive program information.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other

² See Prepared Remarks of Christine A. Varney, "Responses to the Managed Care Revolution: A Competition Policy Perspective," Conference of the National Ass'n of Retail Druggists, March 27, 1995.