

evidence at this time to support claims that lutein can decrease the risk of developing cataract.

The proposed consent order contains provisions designed to prevent Hi-Health from engaging in similar acts and practices in the future. It also requires a monetary payment to the Commission.

Part I of the proposed order bans unsubstantiated claims that the Ocular Nutrition supplement, or any substantially similar product (1) restores vision lost from macular degeneration, or (2) eliminates floaters. "Substantially similar product" is defined as any product that is (1) substantially similar in ingredients to Ocular Nutrition and (2) promoted for the treatment of eye diseases and conditions, including age-related macular degeneration, cataract, or floaters.

Part II is a fencing-in provision that would prohibit unsubstantiated benefits, performance, efficacy, or safety claims for any covered product or service. The proposed order defines "covered product or service" as any health-related service or program, dietary supplement, food, drug, or device.

Part III prohibits misrepresentations of the existence, contents, validity, results, conclusions, or interpretations of any test or study in connection with the marketing of any covered product or service.

Part IV permits drug, food, or device claims approved by the Food and Drug Administration under any tentative final or final standard or any new drug application, pursuant to the Nutrition Labeling and Education Act of 1990, or under any new medical device application, respectively.

Part V requires Hi-Health to pay \$450,000 to the Commission as consumer redress no later than ten days after the order becomes final.

Parts VI and VII require Hi-Health to keep copies of relevant advertisements and materials substantiating claims made in the advertisements, and provide copies of the order to certain of its personnel.

Part VIII requires the corporate respondent to notify the Commission of changes in corporate structure.

Part IX of the proposed order requires the individual respondent to notify the Commission of his employment status.

Part X of the order requires Hi-Health to file compliance reports with the Commission, and Part XI provides that the order will terminate after twenty (20) years under certain circumstances.

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 or to modify in any way their terms.

By direction of the Commission.

Donald S. Clark,

Secretary.

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FEDERAL TRADE COMMISSION

[File No. 041 0099]

Preferred Health Services, Inc.; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of Federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before March 30, 2005.

ADDRESSES: Comments should refer to "Preferred Health Services, Inc., File No. 041 0099," to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission/Office of the Secretary, Room H-159, 600 Pennsylvania Avenue, NW., Washington, DC 20580. Comments containing confidential material must be filed in paper form, as explained in the **SUPPLEMENTARY INFORMATION** section. The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions. Comments filed in electronic form (except comments containing any confidential material) should be sent to the following e-mail box: consentagreement@ftc.gov.

FOR FURTHER INFORMATION CONTACT:

Steve Vieux, FTC, Bureau of Competition, 600 Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326-2306.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and § 2.34 of the Commission's

Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned 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 thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for March 2, 2005), on the World Wide Web, at <http://www.ftc.gov/os/2005/03/index.htm>. A paper copy can be obtained from the FTC Public Reference Room, Room 130-H, 600 Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326-2222.

Public comments are invited, and may be filed with the Commission in either paper or electronic form. Written comments must be submitted on or before March 30, 2005. Comments should refer to "Preferred Health Services, Inc., File No. 041 0099," to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission/Office of the Secretary, Room H-159, 600 Pennsylvania Avenue, NW., Washington, DC 20580. If the comment contains any material for which confidential treatment is requested, it must be filed in paper (rather than electronic) form, and the first page of the document must be clearly labeled "Confidential."¹ The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions. Comments filed in electronic form should be sent to the following e-mail box: consentagreement@ftc.gov.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. All timely and responsive public comments, whether filed in paper or electronic form, will be

¹ Commission Rule 4.2(d), 16 CFR 4.2(d). The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. See Commission Rule 4.9(c), 16 CFR 4.9(c).

considered by the Commission, and will be available to the public on the FTC Web site, to the extent practicable, at <http://www.ftc.gov>. As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC Web site. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at <http://www.ftc.gov/ftc/privacy.htm>.

Analysis of Agreement Containing Consent Order To Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a proposed consent order with Preferred Health Services, Inc. (Preferred Health). The agreement settles charges that Preferred Health violated section 5 of the Federal Trade Commission Act, 15 U.S.C. 45, by orchestrating and implementing agreements among members of Preferred Health to fix prices and other terms on which they would deal with health plans, and to refuse to deal with such purchasers except on collectively-determined terms. The proposed consent order has been placed on the public record for 30 days to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make the proposed order final.

The purpose of this analysis is to facilitate public comment on the proposed order. The analysis is not intended to constitute an official interpretation of the agreement and proposed order, or to modify their terms in any way. Further, the proposed consent order has been entered into for settlement purposes only and does not constitute an admission by Preferred Health that it violated the law or that the facts alleged in the complaint (other than jurisdictional facts) are true.

The Complaint

The allegations of the complaint are summarized below.

Preferred Health is a physician-hospital organization consisting of over 100 physicians and Oconee Memorial Hospital. Preferred Health does business in the Seneca, South Carolina, area, which is located in northwestern South Carolina. Preferred Health acts as a "contracting representative" for its physician members in negotiations with health plans, and a "collective

bargaining unit for the negotiation of managed care contracts."

Preferred Health's physician members account for approximately 70% of the physicians independently practicing (that is, those not employed by area hospitals) in and around the Seneca area. To be marketable in the Seneca area, a health plan must have access to a large number of physicians who are members of Preferred Health.

Although Preferred Health purports to operate as a "messenger model"²—that is, an arrangement that does not facilitate horizontal agreements on price—it orchestrated such price agreements. In contract negotiations with payors, Preferred Health uses a physician fee schedule created by its Executive Director and approved by its Board of Directors. Preferred Health's membership agreement automatically binds physician members to contracts using the Preferred Health fee schedule. Whenever a health plan rejects the Preferred Health fee schedule, Preferred Health's Executive Director negotiates, under the Board's direction, a contract with a "comparable" fee schedule. The Executive Director transmits these contracts to the Board, and then to the physician members if the Board approves it. If a contract contains a Board-approved "comparable" fee schedule, physician members have 30 days to reject the contract. The only recourse available to a physician member who rejects a contract with a "comparable" fee schedule is to terminate his or her membership in Preferred Health.

Preferred Health has orchestrated collective agreements on fees and other terms of dealing with health plans, carried out collective negotiations with health plans, fostered refusals to deal, and threatened to refuse to deal with health plans that resisted Respondent's desired terms. Respondent succeeded in forcing numerous health plans to raise the fees paid to Preferred Health physician members, and thereby raised the cost of medical care in the Seneca area. Preferred Health engaged in no efficiency-enhancing integration sufficient to justify joint negotiation of fees. By the acts set forth in the Complaint, Respondent violated section 5 of the FTC Act.

² Some arrangements can facilitate contracting between health care providers and payors without fostering an illegal agreement among competing physicians on fees or fee-related terms. One such approach, sometimes referred to as a "messenger model" arrangement, is described in the 1996 Statements of Antitrust Enforcement Policy in Health Care jointly issued by the Federal Trade Commission and U.S. Department of Justice, at 125. See <http://www.ftc.gov/reports/hlth3s.htm#9>.

The Proposed Consent Order

The proposed order is designed to remedy the illegal conduct charged in the complaint and prevent its recurrence. It is similar to recent consent orders that the Commission has issued to settle charges that physician groups engaged in unlawful agreements to raise fees they receive from health plans.

The proposed order's specific provisions are as follows:

Paragraph II.A prohibits Respondent from entering into or facilitating any agreement between or among any physicians: (1) To negotiate with payors on any physician's behalf; (2) to deal, not to deal, or threaten not to deal with payors; (3) on what terms to deal with any payor; or (4) not to deal individually with any payor, or to deal with any payor only through an arrangement involving the Respondent.

Other parts of Paragraph II reinforce these general prohibitions. Paragraph II.B prohibits the Respondent from facilitating exchanges of information between physicians concerning whether, or on what terms, to contract with a payor. Paragraph II.C bars attempts to engage in any action prohibited by Paragraph II.A or II.B, and Paragraph II.D proscribes Respondent from inducing anyone to engage in any action prohibited by Paragraphs II.A through II.C.

Paragraph II.E contains certain additional "fencing-in" relief, which is imposed for three years. Under this provision, Preferred Health may not, in connection with physician health plan contracting, either (1) act as an agent for any physicians; or (2) use an agent with respect to contracting. Such relief, designed to assure that Preferred Health does not seek to use other arrangements to continue the challenged conduct, is warranted in light of the complaint charges that Preferred Health engaged in overt price-fixing behavior, and its assertion that its conduct was legitimate "messaging" of health plan contract offers.

As in other Commission orders addressing providers' collective bargaining with health care purchasers, certain kinds of agreements are excluded from the general bar on joint negotiations. Respondent would not be precluded from engaging in conduct that is reasonably necessary to form or participate in legitimate joint contracting arrangements among competing physicians in a "qualified risk-sharing joint arrangement" or a "qualified clinically-integrated joint arrangement." The arrangement, however, must not facilitate the refusal

of, or restrict, physicians in contracting with payors outside of the arrangement.

As defined in the proposed order, a "qualified risk-sharing joint arrangement" possesses two key characteristics. First, all physician participants must share substantial financial risk through the arrangement, such that the arrangement creates incentives for the physician participants jointly to control costs and improve quality by managing the provision of services. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement.

A "qualified clinically-integrated joint arrangement," on the other hand, need not involve any sharing of financial risk. Instead, as defined in the proposed order, physician participants must participate in active and ongoing programs to evaluate and modify their clinical practice patterns in order to control costs and ensure the quality of services provided, and the arrangement must create a high degree of interdependence and cooperation among physicians. As with qualified risk-sharing arrangements, any agreement concerning price or other terms of dealing must be reasonably necessary to achieve the efficiency goals of the joint arrangement.

Paragraph III, for three years, requires Preferred Health to notify the Commission before participating in contracting with health plans on behalf of a qualified risk-sharing joint arrangement or qualified clinically-integrated joint arrangement. Paragraph III sets out the information necessary to make the notification complete.

Paragraph IV, for three years after the bar on messengering ends, requires Preferred Health to notify the Commission before entering into any arrangement to act as a messenger, or as an agent on behalf of any physicians, with payors regarding contracts. Paragraph IV also sets out the information necessary to make the notification complete.

Paragraph V requires Preferred Health to distribute the complaint and order to all physicians who have participated in Preferred Health, and to payors that negotiated contracts with Preferred Health or indicated an interest in contracting with Preferred Health. Paragraph V.C requires Preferred Health, at any payor's request and without penalty, or within one year after the Order is made final, to terminate its current contracts with respect to providing physician services. Paragraph V.D requires Preferred Health to

distribute payor requests for contract termination to all physicians who participate in Preferred Health.

Paragraph V.E.1.b requires Preferred Health to distribute the complaint and order to any payors that negotiate contracts with Preferred Health in the next three years.

Paragraphs VI and VII of the proposed order impose various obligations on Respondent to report or provide access to information to the Commission to facilitate monitoring Respondent's compliance with the order.

The proposed order will expire in 20 years.

By direction of the Commission, Chairman Majoras not participating.

Donald S. Clark,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Comparisons of Community with Facility Management of Malaria and Pneumonia in Rural Tanzania; Notice of Intent To Fund Single Eligibility Award

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the intent to fund fiscal year (FY) 2005 funds for a cooperative agreement program to establish the effectiveness of combination antimalarial therapy policies within the context of intense malaria transmission and to develop an evidence-based comparison between two approaches to managing febrile illness in rural sub-Saharan Africa. Specifically, the two approaches of interest are an enhanced facility-based management approach and a community- or household-based approach. The aim is to generate detailed data enabling international public health organizations to make recommendations to national governments based on quality scientific evidence. The Catalog of Federal Domestic Assistance number for this program is 93.283.

B. Eligible Applicant

Assistance will be provided only to the Ifakara Health Research and Development Centre, Ifakara, Tanzania. No other applications are solicited.

The Ifakara Health Research and Development Centre (IHRDC) is the only

institution located in Tanzania that possesses the requisite scientific and technical expertise, the infrastructure capacity and experience in conducting the described research topics and which has collaborative relationships with the Ministry of Health to ensure that all aspects of this agreement can be fulfilled. Because of its work in malaria for more than 15 years, the IHRDC is an internationally respected research institution.

Investigators at IHRDC have a detailed understanding of the epidemiologic patterns and geographic distribution of malaria infection and transmission in their area, are actively engaged in using state-of-the-art techniques for evaluating antimicrobial drug resistance, and have needed and proven expertise in socio-behavioral and economic research related to febrile illness. In addition, the IHRDC has the following required experience and capabilities:

- Maintains a DSS covering over 100,000 individuals, allowing for measurement of public health impact of malaria treatment policies.
- Proven experience in carrying out large-scale community-based public health interventions, to conduct malaria research, and to correctly diagnose drug resistant malaria infections in its laboratories and field activities.
- Located in an area of very intense malaria transmission in a country that is has adopted a national malaria treatment policy of ACT while remaining actively engaged in investigating future treatment options.
- Maintains a close relationship with the National Malaria Control Program of the Ministry of Health and as well as close relationship with other relevant research and public health entities in the country and region.
- Actively engaged in research activities that are directly related to the objectives of this RFA with proven experience and capacity.

C. Funding

Approximately \$1,000,000 is available in FY 2004 to fund this award. It is expected that the award will begin on or before September 1, 2005, and will be made for a 12-month budget period within a project period of up to three years. Funding estimates may change.

D. Where to Obtain Additional Information

For general comments or questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone: 770-488-2700.