

## FINAL ORDER

The parties having entered into a stipulation filed on May 27, 1966, providing, *inter alia*, that: the case would be submitted to the Commission on the record in Docket 8641, *American Home Products Corporation* (p. 1524 herein] and such other facts and records as provided for in said stipulation; that the facts applicable to the case support the stipulation that the advertisements in the case had no significantly different effect upon readers or hearers from the effect of the advertisements in *American Home Products* and that the effect of the use of respondent's preparation is not significantly different from the use of American Home Products' preparations; that to the extent that respondent's advertisements differ significantly from those in *American Home Products*, the Commission may, in its order disposing of this proceeding, include appropriate provisions to take into consideration such differences; that respondent waives any intervening steps before the hearing examiner; that the Commission may, on the basis of this stipulation, the advertisements attached thereto and the record in *American Home Products*, issue such order as it deems necessary in the public interest and that the record on which the Commission is to make its disposition of this proceeding is limited to the record at the time this stipulation is filed; and the Commission having rendered its decision and issued its Opinion herein;

Now therefore, on the basis of said stipulation and attachments, the pleadings herein and the record in Docket 8641, *American Home Products Corporation* [p. 1524 herein], it is hereby

*Ordered*, That the attached Findings of Fact, Conclusions and Order be and they hereby are entered and issued by the Commission in final disposition of this proceeding.

## IN THE MATTER OF

## AMERICAN HOME PRODUCTS CORPORATION

ORDER, OPINION, ETC., IN REGARD TO THE ALLEGED VIOLATION OF  
THE FEDERAL TRADE COMMISSION ACT

*Docket 8641. Complaint, Aug. 28, 1964—Decision, Dec. 16, 1966\**

Order requiring a New York City manufacturer of "Preparation H" ointment to cease falsely representing in its advertising that its product will

\*Modified on July 15, 1969 and June 9, 1970.

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## Complaint

shrink, avoid need for surgical treatment on, heal, cure, or remove hemorrhoids or effect any other cure beyond temporary relief.

## COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that American Home Products Corporation, hereinafter referred to as respondent, has violated the provisions of said Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint stating its charges in that respect as follows:

PARAGRAPH 1. Respondent American Home Products 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 and place of business located at 685 Third Avenue in the city of New York, State of New York.

PAR. 2. Respondent American Home Products Corporation is now and for more than one year last past has been, engaged in the sale and distribution of preparation offered for the treatment of piles or hemorrhoids and coming within the classification of drugs as the term "drug" is defined in the Federal Trade Commission Act.

The designation used by respondent for said preparations, the formulae thereof and directions for use are as follows:

*Designation:* "Preparation H" Ointment.

*Formula:* The active ingredients for Preparation H Ointment are as follows: Live Yeast Cell Derivative, Supplying 2,000 units, Skin Respiratory Factor (Bio-Dyne) Per Ounce of Ointment; Shark Liver Oil 3.0%; Phenylmercuric Nitrate 1:10,000 in a Specially Prepared Rectal Ointment Base.

*Directions:* Apply freely night and morning and after each bowel movement. Lubricate applicator before each application and thoroughly cleanse after use. Rectal conditions are more rapidly improved by continual application. In case of bleeding, a physician should be consulted. Keep all medicines out of the reach of children.

*Designation:* "Preparation H" Suppositories.

*Formula:* The active ingredients are Live Yeast Cell Derivative, supplying 2,000 units Skin Respiratory Factor (Bio-Dyne) Per Ounce of Suppository Base; Shark Liver Oil 3.0% Phenylmercuric Nitrate 1:10,000.

*Directions:* Remove wrapper and insert one suppository morning and night and after each bowel movement. Rectal Conditions are more rapidly improved by continual application. In case of bleeding, a physician should be consulted.

PAR. 3. Respondent American Home Products Corporation causes the said preparations, when sold, to be transported from

its places of business located at 1000 South Grand Street, Ham-monton, New Jersey and 1919 Superior Street, Elkhart, Indiana, to purchasers thereof located in various other States of the United States and in the District of Columbia. Respondent main-tains, and at all times mentioned herein has maintained, a course of trade in said preparations in commerce, as "commerce" is de-fined in the Federal Trade Commission Act. The volume of busi-ness in such commerce has been and is substantial.

PAR. 4. In the course and conduct of its said business, respond-ent has disseminated, and caused the dissemination of, certain advertisements concerning the said preparations by the United States mails and by various means in commerce, as "commerce" is defined in the Federal Trade Commission Act, including, but not limited to, advertisements inserted in newspapers, magazines and other advertising media, and by means of television and radio broadcasts transmitted by television and radio stations located in the District of Columbia and in the various States of the United States, having sufficient power to carry such broadcasts across State lines, for the purpose of inducing and which were likely to induce, directly or indirectly, the purchase of said preparations; and has disseminated, and caused the dissemination of, advertise-ments concerning said preparations by various means, including but not limited to the aforesaid media for the purpose of inducing and which were likely to induce, directly or indirectly, the pur-chase of said preparations in commerce, as "commerce" is defined in the Federal Trade Commission Act.

PAR. 5. Among and typical of the statements and representa-tions contained in said advertisements disseminated as herein-above set forth are the following:

*Radio Commercial*

Hemorrhoid sufferers . . . the proof is here! Proof of dramatic new relief of swollen injured tissue! Proof from doctors . . . from clinics . . . from hos-pitals.

Yes, doctors report a new healing medication . . . Preparation H . . . ac-tually shrinks hemorrhoids without surgery. Tests in famous hospitals and clinics reveal: Preparation H relieves pain promptly—heals injured tissue. The secret? Only Preparation H has the new wonder substance that we call Bio-Dyne to draw the body's own healing oxygen to the painful area. Here are the dramatic results: one—Preparation H relieves pain and itching promptly. Two—Preparation H heals injured tissue. And three—Preparation H shrinks hemorrhoids . . . *without* astringents, narcotics, or surgery . . . even in cases of twenty years' suffering. Yes, the proof is here—proof of the prompt relief of painful hemorrhoids. Get clinically tested, hospital tested

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Preparation H (optional: Ointment or Suppositories). Preparation H . . . shrinks hemorrhoids without surgery!

*TV Commercial**VIDEO*

OPEN MS MAN SEATED AT DESK. HE REACHES FOR BOOK FROM BOOK-SHELF BEHIND HIM.

OPENS BOOK TOWARD AUDIENCE, RESTS IT VERTICALLY ON DESK BEFORE HIM.

CUT TO OPEN BOOK. SEE CHAPTER TITLE: "SHRINKS HEMORRHOIDS WITHOUT SURGERY."

PKG. OF PREPARATION H MOVES FORWARD OUT OF TEXT TO MAXIMUM WIDTH SO PRODUCT NAME, CHAPTER HEADLINE BOTH ARE LEGIBLE.

CUT BACK TO MAN. HE REFERS TO BOOK.

PAN AS MAN TURNS TO HIS RIGHT. TAKES PIPETTE OUT OF RACK, HOLDS IT UP OVER EMPTY TEST-TUBE.

CUT TO ECU GLISTENING DROP HANGING FROM PIPETTE. SUPER TITLE: "BIO-DYNE" AT BOTTOM SCREEN.

*Car Cards*

CLINICAL TESTS SHOW PREPARATION H SHRINKS HEMORRHOIDS WITHOUT SURGERY. RELIEVES PAIN—STOPS ITCHING SHRINKS PILES.

*Periodical Advertising*

Science Shrinks Piles New Way Without Surgery Stops Itch—Relieves Pain.

*AUDIO*

ANNCR., DIRECT:

These are doctors' reports on hemorrhoids . . . revealing a new medication that relieves pain and itching promptly, heals injured tissue . . .

ANNCR., OVER.

. . . and actually shrinks hemorrhoids without surgery.

It's the new medical discovery, Preparation H. Clinically tested, hospital tested Preparation H.

ANNCR., DIRECT:

Yes, hospital tests and clinical tests now show prompt relief of pain . . . healing and shrinking of swollen, injured tissue.

The secret? Only Preparation H contains Bio-Dyne . . .

ANNCR., OVER:

. . . the remarkable substance that draws the body's own healing oxygen to the painful area.

Preparation H—The *Only* Hemorrhoidal Remedy In World That Contains New Healing Substance.

For the first time science has found a new healing substance with the astonishing ability to shrink hemorrhoids, stop burning rectal itch and relieve pain—without surgery or painful injections.

Pain and itching were promptly relieved. And while gently relieving this distress—actual reduction (shrinking) of hemorrhoids took place.

In fact, results were so thorough that sufferers were able to make such astounding statements as “Piles have ceased to be a problem!” And among these sufferers were a wide variety of hemorrhoid conditions some of 10 to 20 years’ standing.

All this was accomplished at home without surgery, injections, narcotics or astringents of any kind.

This new healing substance is offered in ointment or convenient suppository form called Preparation H. And Preparation H is the only hemorrhoidal remedy in the world containing this truly magical healing substance.

\* \* \* full of a new substance which has the astonishing power to heal injured skin. This substance was then scientifically combined with other effective medical ingredients into a product called Preparation H. And here’s why this remarkable hemorrhoid remedy is so successful—Preparation H promptly relieves pain and burning rectal itch. Shrinks hemorrhoids without surgery. Heals injured tissue back to normal \* \* \*.

PAR. 6. Through the use of said advertisements, and others similar thereto not specifically set out herein, respondent has represented and is now representing, directly and by implication that the use of Preparation H Ointment and Suppositories, and each of them, will:

1. Reduce or shrink piles;
2. Avoid the need for surgery as a treatment for piles;
3. Eliminate all itch due to or ascribed to piles;
4. Relieve all pain attributed to or caused by piles;
5. Heal, cure or remove piles, and cause piles to cease to be a problem.

PAR. 7. In truth and in fact the use of Preparation H Ointment or Suppositories, or both, will not:

1. Reduce or shrink piles;
2. Avoid the need for surgery as a treatment for piles;
3. Eliminate all itch due to or ascribed to piles;
4. Relieve all pain attributed to or caused by piles;
5. Heal, cure or remove piles or eliminate the problem of piles;
6. Afford any relief or have any therapeutic effect upon the conditions known as piles or upon any of the symptoms or manifestations thereof in excess of affording temporary relief of minor pain or minor itching associated with piles.

Therefore, the advertisements referred to in Paragraph Five

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## Initial Decision

were and are misleading in material respects and constituted and now constitute, "false advertisements" as that term is defined in the Federal Trade Commission Act.

PAR. 8. The dissemination by the respondent of the false advertisements, as aforesaid, constituted, and now constitutes, unfair and deceptive acts and practices in commerce, in violation of sections 5 and 12 of the Federal Trade Commission Act.

*Mr. Charles J. Connolly and Mr. William E. McMahon, II*, for the Commission.

*Donovan, Leisure, Newton & Irvine*, New York, N.Y., attorneys for respondent.

*Mr. Samuel W. Murphy, Jr., Mr. Kenneth N. Hart, and Mr. James M. Bergen*, of counsel.

INITIAL DECISION BY WALTER R. JOHNSON, HEARING EXAMINER

OCTOBER 22, 1965

By complaint dated August 28, 1964, the respondent has been charged with violation of Sections 5<sup>1</sup> and 12<sup>2</sup> of the Federal Trade Commission Act in its advertising of Preparation H ointment and suppositories used for the treatment of a condition known as piles or hemorrhoids. The respondent filed its answer to the complaint on October 16, 1964, denying the charges of deceptive advertising and stating that the Commission has previously approved the advertising alleged in the complaint to be unlawful, and that respondent has conducted its activities in reliance thereon. On November 9, 1964, counsel for the parties met with the hearing examiner in a reported pre-hearing conference, and an order was issued reciting the results of the conference, which was to control the subsequent course of the proceeding, unless modified to prevent manifest injustice. The order, among other things, required each party to file a pre-trial brief setting forth a statement of anticipated issues and divulging the names of the

<sup>1</sup> "Sec. 5(a) (1) Unfair methods of competition in commerce, and unfair or deceptive acts or practices in commerce, are hereby declared unlawful. \* \* \*."

<sup>2</sup> "Sec. 12(a) It shall be unlawful for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false advertisement—

"(1) By United States mails, or in commerce by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase of food, drugs, devices, or cosmetics ; or

"(2) By any means, for the purpose of inducing, or which is likely to induce, directly, or indirectly, the purchase in commerce of food, drugs, devices, or cosmetics.

"(b) The dissemination or the causing to be disseminated of any false advertisement within the provisions of subsection (a) of this section shall be an unfair or deceptive act or practice in commerce within the meaning of section 5."

witnesses and the documentary exhibits which the party plans to introduce. The order further provided that a party may not introduce any testimony or exhibits which have not been referred to in the trial brief. Trial briefs were filed by complaint counsel and respondent on December 11, 1964, and January 18, 1965, respectively. At a conference held on January 29, 1965, the subject of time and place of hearings was discussed, and, on the basis of information supplied by counsel for the parties, the hearing examiner scheduled hearings herein. In support of the complaint, hearings were held at New York, N.Y., on March 30, 31, and April 1, 1965; at Philadelphia, Pa., on April 7 and 8, 1965; at Pittsburgh, Pa., on April 12 and 13, 1965; and at Chicago, Illinois, on April 15 and 16, 1965. The respondent put in its defense from April 20 through May 6, 1965 (13 days) at Washington, D.C. Complaint counsel submitted rebuttal testimony at Washington, D.C., on May 17 and 18, 1965. Testimony was received from a total of 35 witnesses, 11 being called by complaint counsel, and 26 by respondent. The record includes 2139 pages of transcript and 54 exhibits, totaling more than 900 sheets. On July 19, 1965, the parties filed proposed findings, and on August 20, 1965 filed replies thereto. The hearing examiner heard oral arguments thereon on September 14, 1965. The following abbreviations have been used herein: "C." for Commission's Complaint; "A." for Respondent's Answer; "Par." for Paragraph; "Tr." for Transcript of Proceedings; "CX" for Commission Exhibit; "RX" for Respondent's Exhibit; "CPF" for Complaint Counsel's Proposed Findings; and "RPF" for Respondent's Proposed Findings. The proposed findings of fact and conclusions not hereinafter specifically found or concluded are herewith rejected. Upon consideration of the entire record herein, the hearing examiner makes the following findings of fact and conclusions:

Respondent American Home Products 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 and place of business located at 685 Third Avenue in the city of New York, State of New York (C., Par. 1; A., Par.1).

Respondent American Home Products Corporation is now, and for more than one year last past has been, engaged in the sale and distribution of preparations offered for the treatment of piles or hemorrhoids and coming within the classification of drugs as the term "drug" is defined in the Federal Trade Commission Act (C., Par. 2; A., Par. 2).

