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.

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, Hammonton, 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 maintains, and at all times mentioned herein has maintained, a course of trade in said preparations in commerce, as "commerce" is defined in the Federal Trade Commission Act. The volume of business in such commerce has been and is substantial.

PAR. 4. In the course and conduct of its said business, respondent has disseminated, and caused the dissemination of, cretain 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, advertisements 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 purchase of said preparations in commerce, as "commerce" is defined in the Federal Trade Commission Act.

PAR. 5. Among and typical of the statements and representations contained in said advertisements disseminated as hereinabove 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 hospitals.

Yes, doctors report a new healing medication . . . Preparation H . . . actually 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

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

TV Commercial

VIDEO	*AUDIO*
OPEN MS MAN SEATED AT DESK. HE REACHES FOR BOOK FROM BOOK-SHELF BEHIND HIM.	ANNCR., DIRECT: These are doctors' reports on hemorrhoids . . . revealing a new medication that relieves pain and itching promptly, heals injured tissue . . .
OPENS BOOK TOWARD AUDIENCE, RESTS IT VERTICALLY ON DESK BEFORE HIM.	
CUT TO OPEN BOOK. SEE CHAPTER TITLE: "SHRINKS HEMORRHOIDS WITHOUT SURGERY."	ANNCR., OVER. . . . and actually shrinks hemorrhoids without surgery.
PKG. OF PREPARATION H MOVES FORWARD OUT OF TEXT TO MAXIMUM WIDTH SO PRODUCT NAME, CHAPTER HEADLINE BOTH ARE LEGIBLE.	It's the new medical discovery, Preparation H. Clinically tested, hospital tested Preparation H.
CUT BACK TO MAN. HE REFERS TO BOOK.	ANNCR., DIRECT: Yes, hospital tests and clinical tests now show prompt relief of pain . . . healing and shrinking of swollen, injured tissue.
PAN AS MAN TURNS TO HIS RIGHT. TAKES PIPETTE OUT OF RACK, HOLDS IT UP OVER EMPTY TEST-TUBE.	The secret? Only Preparation H contains Bio-Dyne . . .
CUT TO ECU GLISTENING DROP HANGING FROM PIPETTE. SUPER TITLE: "BIO-DYNE" AT BOTTOM SCREEN.	ANNCR., OVER: . . . the remarkable substance that draws the body's own healing oxygen to the painful area.

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.

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

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 [1] and 12 [2] 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

[1] "Sec. 5(a)(1) Unfair methods of competition in commerce, and unfair or deceptive acts or practices in commerce, are hereby declared unlawful. * * * ."

[2] "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).

The designations used by respondent for said preparations, the formulae [3] thereof and directions for use are as follows:

(1) 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 base composed of petrolatum, lanolin, falba, mineral oil and oil of thyme.

Directions: Remove new protective cover. 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.

CAUTION: In case of bleeding, a physician should be consulted. Keep all medicines out of the reach of children.

(2) 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 in a base made up of cocoa butter, beeswax, polyethylene glycol 600 dilaurate, and glycerin.

Directions: Remove wrapper and insert one suppository morning and night and after each bowel movement. Rectal conditions are more rapidly improved by continual application.

CAUTION: In case of bleeding, a physician should be consulted.

(C., Par. 2; A., Par. 2; CX 5-8; RX 9-10; Stipulation, Tr. 68; Tr. 1017-19.)

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, Hammonton, 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 maintains, and at all times mentioned herein has maintained, a course of trade in said preparations in commerce, as "commerce" is defined in the Federal Trade Commission Act. The volume of business in such commerce has been and is substantial (C., Par. 3; A., Par. 3).

In the course and conduct of its said business, respondent 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

[3] The quantitative formulae for Preparation H are trade secrets and were received in evidence as *in camera* exhibits (CX 7, 8; Tr. 92–93, 97).

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 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, advertisements 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 purchase of said preparations in commerce, as "commerce" is defined in the Federal Trade Commission Act (C., Par. 4; A., Par. 4).

Among and typical of the statements and representations contained in the advertisements disseminated as set forth in the foregoing paragraph are the following:

Radio Commericial

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

Yes, doctors report a new healing medication . . . Preparation H . . . actually 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 Preparation H (optional: Ointment or Suppositories). Preparation H . . . shrinks hemorrhoids without surgery!

TV Commercial

VIDEO	*AUDIO*
OPEN MS MAN SEATED AT DESK. HE REACHES FOR BOOK FROM BOOK-SHELF BEHIND HIM.	ANNCR., DIRECT: These are doctors' reports on hemorrhoids . . . revealing a new medication that relieves pain and itching promptly, heals injured tissue . . .
OPENS BOOK TOWARD AUDIENCE, RESTS IT VERTICALLY ON DESK BEFORE HIM.	

CUT TO OPEN BOOK. SEE CHAPTER TITLE: "SHRINKS HEMORRHOIDS WITHOUT SURGERY."	ANNCR., OVER . . . and actually shrinks hemorrhoids without surgery.
PKG. OF PREPARATION H MOVES FORWARD OUT OF TEXT TO MAXIMUM WIDTH SO PRODUCT NAME, CHAPTER HEADLINE BOTH ARE LEGIBLE.	It's the new medical discovery, Preparation H. Clinically tested, hospital tested Preparation H.
CUT BACK TO MAN. HE REFERS TO BOOK.	ANNCR., DIRECT: Yes, hospital tests and clinical tests now show prompt relief of pain . . . healing and shrinking of swollen, injured tissue.
PAN AS MAN TURNS TO HIS RIGHT. TAKES PIPETTE OUT OF RACK, HOLDS IT UP OVER EMPTY TEST-TUBE.	The secret? Only Preparation H contains Bio-Dyne . . .
CUT TO ECU GLISTENING DROP HANGING FROM PIPETTE. SUPER TITLE: "BIO-DYNE" AT BOTTOM SCREEN.	ANNCR., OVER: . . . the remarkable substance that draws the body's own healing oxygen to the painful area.

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

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

Every Claim Verified by Doctors and Proved By 4 Leading Clinics.

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.

In one hemorrhoid case after another prompt relief was reported—also a "striking improvement" in from 2 to 4 days. These reports were verified by a doctor's observations and proved by four leading clinics.

Pain and itching were promptly relieved. And while gently relieving this distress—actual reduction (shrinking) of hemorrhoids took place. Most amaing of all—this improvement was maintained in cases where a doctor's observations were continued over a period of many months!

In fact, results were so thorough that sufferers were able to make such as-

tounding 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. The secret is a new healing substance (Bio-Dyne)—the discovery of a world famous research institute. 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.

Magic Healing Power
Discovered by Accident

Like many great discoveries—the effectiveness of Preparation H was also discovered quite by accident. In the laboratories of a famous research institution in Cincinnati, Ohio—renowned scientists were conducting advanced medical tests.

During an ether-extracting procedure, there was a sudden explosion. An assistant was severely burned. As an emergency measure, large quantities of an ointment (still in an experimental stage) were smeared on. To everyone's amazement—pain ceased immediately and the skin healed remarkably fast without scarring.

Later tests revealed this ointment was 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 and helps prevent infection of hemorrhoids.

Every claim made for Preparation H has been verified by doctors. This is the *only* hemorrhoidal remedy containing Bio-Dyne. Just ask for Preparation H at any drug counter in ointment or suppository form.

(CX 9–14; RX 21, 22; Tr. 1917.)

Paragraph Six of the complaint alleges that, through the use of said advertisements, respondent has represented, directly and by implication, that the use of Preparation H Ointment and Suppositories 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.

Paragraph Seven of the complaint alleges that in truth and in fact the use of said preparations 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.

The respondent denies the allegations in Paragraph Six of the complaint, except that it admits it has represented the use of its preparations will:

a. reduce or shrink hemorrhoids without surgery;

b. stop itching due to hemorrhoids; and

c. relieve pain due to hemorrhoids (A., Par. 6).

Respondent denies the allegations of Paragraph Seven of the complaint (A., Par. 7), and takes the position that the advertising, properly interpreted, is truthful in every respect.

Complaint counsel did not call any public or consumer witnesses to support their interpretation of the advertising and rely solely on the advertisements themselves.[4] As to alleged lack of efficacy of the preparations involved, complaint counsel rely on the testimony of nine proctologists called as witnesses in support of the complaint. The respondent presented six medical witnesses, who had conducted clinical studies of Preparation H, and five other doctors who testified as to conservative therapy and the effectiveness of ointments and suppositories in general in the treatment of hemorrhoids; testimony relating to the pharmacology of the product; and seven consumer witnesses, who testified on the impression respondent's advertisements made on them and on the relief they had obtained from the use of Preparation H.

The governing law, which is applicable in this proceeding, can be well stated by employing the words of the Court in *F.T.C.* v. *Sterling Drug, Inc., et al.*, 317 F. 2d 669, 674 (C.A. 2, 1963), reading:

> The legal principles to be applied here are quite clear. The central purpose of the provisions of the Federal Trade Commission Act under discussion is in effect to abolish the rule of *caveat emptor* which traditionally defined rights

[4] In the opinion of the Commission in Docket No. 8586 (July 31, 1964), *In the Matter of United States Rubber Company*, it is stated [66 F.T.C 387, 397]:
"It is well settled that the Commission is not required to sample public opinion in order to determine the meaning conveyed by an advertisement. *Royal Oil Corporation* v. *F.T.C.*, 262 F. 2d 741 (1959); *New American Library of World Literature* v. *F.T.C.*, 213 F. 2d 143 (1954). In holding that the Commission was not required to call consumer witnesses the court in *Zenith Radio Corporation* v. *F.T.C.* [143 F. 2d 29 (1944)] stated 'The Commission has a right to look at the advertisements in question, consider the relevant evidence in the record that would aid it in interpreting the advertisements, and then decide for itself whether the practices engaged in by the petitioner were unfair or deceptive, as charged in the complaint.'"

and responsibilities in the world of commerce. That rule can no longer be relied upon as a means of rewarding fraud and deception, *Federal Trade Commission* v. *Standard Education Society*, 302 U.S. 112, 116, 58 S.Ct. 113, 82 L.Ed. 141 (1937), and has been replaced by a rule which gives to the consumer the right to rely upon representations of facts as the truth, *Goodman* v. *Federal Trade Commission*, 244 F. 2d 584, 603 (9th Cir., 1957). In order best to implement the prophylactic purpose of the statute, it has been consistently held that advertising falls within its proscription not only when there is proof of actual deception but also when the representations made have a capacity or tendency to deceive, *i.e.*, when there is a likelihood or fair probability that the reader will be misled. See *American Life & Accid. Ins. Co.* v. *Federal Trade Commission*, 255 F. 2d 289, 293 (8th Cir.), *cert. denied* 358 U.S. 875, 79 S.Ct. 115, 3 L.Ed. 2d 105 (1958); *Charles of the Ritz Distributors Corp.* v. *Federal Trade Commission*, 143 F. 2d 676, 680 (2d Cir., 1944); *Herzfeld* v. *Federal Trade Commission*, 140 F. 2d 207 (2d Cir., 1944). For the same reason, proof of intention to deceive is not requisite to a finding of violation of the statute, *Gimbel Bros., Inc.* v. *Federal Trade Commission*, 116 F. 2d 578 (2d Cir., 1941); since the purpose of the statute is not to punish the wrongdoer but to protect the public, the cardinal factor is the probable effect which the advertiser's handiwork will have upon the eye and mind of the reader. It is therefore necessary in these cases to consider the advertisement in its entirety and not to engage in disputatious dissection. The entire mosaic should be viewed rather than each tile separately. [T]he buying public does not ordinarily carefully study or weigh each word in an advertisement. The ultimate impression upon the mind of the reader arises from the sum total of not only what is said but also of all that is reasonably implied. *Aronberg* v. *Federal Trade Commission*, 132 F. 2d 165, 167 (7th Cir. 1942).

Respondent's Advertising Claims for Preparation H. The radio commercial (CX 9) asserts that:

Yes, doctors report a new healing medication . . . Preparation H . . . actually shrinks hemorrhoids without surgery. * * * 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. . . . * * * Preparation H . . . shrinks hemorrhoids without surgery!

In the television commercial (CX 10), it is said:

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

* * * * * * *

. . . and actually shrinks hemorrhoids without surgery.

It's the new medical discovery, Preparation H.

The car cards (CX 11) displayed on subways and buses state:

Clinical Tests Show *PREPARATION H* SHRINKS HEMORRHOIDS WITHOUT SURGERY Relieves Pain—Stops Itching Shrinks Piles

A typical and representative periodical advertisement (CX 12) claims:

SCIENCE SHRINKS PILES NEW WAY WITHOUT SURGERY STOPS ITCH—RELIEVES PAIN

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.

* * * * * * *

In fact, results were so thorough that sufferers were able to make such astounding statements as "Piles have ceased to be a problem!"

* * * * * * *

Preparation H promptly relieves pain and burning rectal itch. Shrinks hemorrhoids without surgery. Heals injured tissue back to normal. . . .

A newspaper advertisement (CX 13) reads:

A world-famous institute has discovered a new substance which has the astonishing ability to shrink hemorrhoids without surgery.

* * * * * * *

Only Preparation H contains this magic new substance which quickly helps heal injured cells back to normal and stimulates regrowth of health tissue again.

A typical advertisement (CX 14; RX 21) reads:

For the first time science has found a new healing substance. . . .

Most amazing of all—results were so thorough that sufferers made astonishing statements like "Piles have ceased to be a problem!"

The secret is a new healing substance (Bio-Dyne)—discovery of a world-famous research institute.

Seven consumer witnesses testified about the messages which were conveyed to them by the advertising now under attack. These witnesses testified that, on seeing or hearing the advertising, they had received the impression that Preparation H will relieve hemorrhoidal symptoms:

(1) *Vincent*: "To me, it just struck me that it would relieve it, not as a cure-all (Tr. 1815).

(2) *Garth:* "I got the message that they would . . . give me immediate relief and stop the itching and pain. . . ." (Tr. 1837).

(3) *Poltrek:* ". . . relief from pain and itching, and reducing swelling" (Tr. 1851).

(4) *Clancey:* "That it would bring relief to me" (Tr. 1863).

(5) *Valentine:* "I thought it would get me over a bad time" (Tr. 1875).

(6) *Rollins:* ". . . that the only claim made by Preparation H was it gives relief" (Tr. 1887).

(7) *Jones:* "Well, that it would give me some relief" (Tr. 1902).

All seven of these witnesses testified to the effect that the advertisements did not give the impression that Preparation H would cure hemorrhoids (Vincent, Tr. 1817; Garth, Tr. 1838; Poltrek, Tr. 1851–52; Clancey, Tr. 1863; Valentine, Tr. 1875; Rollins, Tr. 1887; Jones, Tr. 1902). When the attention of the witnesses was specifically focused on respondent's car ad (CX 11) reading "Clinical Tests Show PREPARATION H SHRINKS HEMORRHOIDS WITHOUT SURGERY . . . ," the answers of three of the witnesses are significant:

Vincent: To me, it means it's going to give me relief and prevent my having to be operated on or help me. . . . (Tr. 1816.)

Garth: As I look now, it does shrink the hemorrhoids without surgery. . . . (Tr. 1840.)

Poltrek: Well, I think anyone would try something without surgery, and this certainly would hit the public eye. . . . Do I understand you correctly, sir, you mean without surgery? This is the one thing I would say. No one is going to have surgical procedure if they don't need to have it. If they do, it would be something else. But in this case you don't. . . . (Tr. 1852.)

All of respondent's advertisements received in evidence claim, in substance, that Preparation H will shrink hemorrhoids without surgery (CX 9–14; RX 21, 22). It is the opinion of the hearing examiner that respondent has represented in its advertising, as has been alleged in the complaint (Par. Six (2)), that Preparation H will enable the user to avoid the need for surgery where surgery is required as a treatment for hemorrhoids. It is also the hearing examiner's opinion that respondent's advertisements do not claim that Preparation H will eliminate *all* itch or relieve *all* pain as has been alleged in paragraphs Six (3) and Six (4) of the complaint. The word "all" is never used in any of the advertisements to describe the relief to be afforded by the product from itch or pain. The word "all" is that of complaint counsel and not respondent.[5] It is further the opinion of the hearing examiner

[5] In *International Parts Corp.* v. *Federal Trade Commission*, 133 F. 2d 883 (7th Cir. 1943), the Court dealt with a similar problem:

"In Paragraph 2 of the Commission's order, the petitioner is ordered to cease and desist from representing that the finish on its mufflers *permanently* prevents rust or corrosion. The petitioner never represented that the finish on its mufflers would prevent rust *permanently*. The word '*permanently*' was interpolated by the Commission. The Commission's finding is that 'While the finish may serve to prevent rust and corrosion for a *limited period of time*, it does not afford permanent protection against such conditions.' (Our [7th Circuit's] emphasis.) The petitioner never said that it did afford permanent protection against such conditions. The petitioner said only that the finish prevents rust and corrosion. . . . The Commission cannot interpolate into the petitioner's representations words not there, and then find the petitioner guilty of misrepresentation because the petitioner's product does not meet the Commission's revised representations. . . . Without the word 'permanently' interpolated, there is no misrepresentation. The word 'permanently' is the Commission's word, not the petitioner's." (133 F. 2d 885–86.)

that with use of such expressions as "Most amazing of all—results were so thorough that sufferers made astonishing statements like 'Piles have ceased to be a problem!' "; "The secret is a new healing substance (Bio-Dyne)" CX 14; RX 21); and "Heals injured tissue back to normal . . ." (CX 12), respondent has represented, as charged in paragraph SIX (5) of the complaint, that Preparation H will "Heal, cure or remove piles, and cause piles to cease to be a problem." It is found that through the use of said advertisements, and other 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. Stop itch due to piles;
4. Relieve pain due to piles;
5. Heal, cure or remove piles, and cause piles to cease to be a problem.

The nine physicians called by complaint counsel in connection with their case-in-chief were Dr. Richard A. Hopping, East Orange, New Jersey (Tr. 102–182); Dr. A. W. Martin Marino, Jr., Brooklyn, New York (Tr. 185–245); Dr. Sylvan D. Manheim, New York (Tr. 247–329); Dr. Samuel W. Eisenberg, Philadelphia, Pa. (Tr. 335–406); Dr. Joseph B. Sarner, Philadelphia, Pa. (Tr. 409–470); Dr. Andrew Jack McAdams, Pittsburgh, Pa. (Tr. 474–528); Dr. Karl Zimmerman, Pittsburgh, Pa. (Tr. 536–597); Dr. Charles Evans Pope, Evanston, Ill. (Tr. 601–692); and Dr. Durand Smith, Chicago, Ill. (Tr. 695–794). Each specializes in proctology, which deals with diseases affecting the anus, rectum, and lower colon, including hemorrhoids. They are members of, and certified by, the American Board of Colon & Rectal Surgery, an exclusive group of less than 500 surgeons.

The medical witnesses called by respondent were Dr. Frederick Steigmann, Chicago, Ill., a specialist in internal medicine and gastroenterology (Tr. 808–834)[6]; Dr. Fred J. Phillips, Quakertown, Pa., a general practitioner (Tr. 835–860); Dr. Russel John Sacco, Kinnelon, New Jersey, a general practitioner (Tr. 864–885); Dr. Harold S. Feldman, Livingstone, New Jersey, a general practitioner (Tr. 887–926); Dr. Donald Berkowitz, Phila-

[6] Dr. Steigmann explained that gastroenterology "is more of a medical specialty while proctology deals more with surgical principles." Both specialties deal generally with the same parts of the anatomy (Tr. 810).

delphia, Pa., a gastroenterologist (Tr. 1075–1218); Dr. William Lieberman, Brooklyn, New York, a proctologist (Tr. 1219–1419); Dr. Robert Young, Columbus, Ohio, a general surgeon (Tr. 1441–1512); Dr. Orum Philip Burt, Columbus, Ohio, an obstetrician and gynecologist (Tr. 1514–1546); Dr. Jerome Epstein, Washington, D.C., a specialist in internal medicine and gastroenterology (Tr. 1549–1650); Dr. Norman Isaacson, Washington, D.C., a general surgeon (Tr. 1651–1682); and Dr. Arthur Grollman, Dallas, Texas, a consulting physician and an authority on pharmacology (Tr. 1750–1797).

Hemorrhoids, also called piles, are varicose (dilated) veins in and around the rectal opening. They are classified as internal, external, and mixed, based upon the location of the hemorrhoidal veins in relation to the sphincter, the ringlike muscle that surrounds the opening to the rectum. Internal hemorrhoids originate from veins above the sphincter, and are covered with a mucous membrane, while external hemorrhoids arise from veins outside the sphincter, and are covered by skin. Mixed hemorrhoids are a combination of internal and external hemorrhoids. Hemorrhoids are common among the adult population, and estimates of its incidence range upwards from fifty percent. There is a tendency for varicose veins to run in families. Hemorrhoids are quite common during pregnancy as a result of increased pressure of the enlarging abdomen and uterus, which tends to overdistend these veins. In and of themselves, such hemorrhoidal varicosities are not troublesome, and many people have asymptomatic hemorrhoids (causing no symptoms) without being aware of the fact. Asymptomatic hemorrhoids are harmless and do not require treatment. Such a condition, however, may become symptomatic from time to time as a result of one or more exciting or complicating factors, such as constipation, diarrhea, straining, trauma, infection, or conditions or activities which increase pressure on the hemorrhoidal veins. In medical terminology, "symptoms" are subjective complaints given by the patient, while "signs" are objective signals which can be seen and felt by the examining physician. To the patient, the symptoms are the essence of the disease. He feels pain. To make a diagnosis, the doctor pieces together the history and symptoms reported to him with the signs of the disease he sees. The most usual hemorrhoidal symptoms include one or more of bleeding, pain, protrusion, swelling, discharge, itching, and a sense of discomfort or fullness at the anus. The signs of hemorrhoids include protrusion, swelling, bleeding, and discoloration of

the area involved. These symptoms vary in degree from mild to severe, and symptomatic hemorrhoids are frequently very painful, irritating, and troublesome. The mucosal and skin-like tissue surrounding the varicose veins is integrally involved in a symptomatic hemorrhoidal conditions. Symptoms are usually caused by complications, such as inflammation, edema, ulceration, or infection, in the adjacent tissue, rather than by the mere existence of varicose veins. (This finding is based on CPF Nos. 9, 10, 11, 12, 13, 14 and 18; RPF Nos. 8, 9, 10 and 11; and the citations of record set forth therein.)

The opinion testimony of each of the nine proctologists called as witnesses by complaint counsel was that the only treatment which would effect a cure of hemorrhoids was surgery. The basis for such an opinion is that a hemorrhoid is a vascular dilation and, until that vascular dilation is eliminated, the hemorrhoid will remain (Hopping, Tr. 118; Marino, Tr. 195, 200, 201, 208; Manheim, Tr. 262; Eisenberg, Tr. 352–53; Sarner, Tr. 422–23; McAdams, Tr. 487; Zimmerman, Tr. 550; Pope, Tr. 616; and Smith, Tr. 719–720). For instance, Dr. Marino said (Tr. 213):

Unless the venous dilatation is eliminated the piles or hemorrhoids will not be cured.

In a hemorrhoidal problem, the supporting and covering tissues are involved, as well as the varicose veins:

Dr. Hopping:

Q. Leaving out of consideration the secondary manifestations, what problem does the hemorrhoid itself cause the patient?

A. That is why we call them asymptomatic. Absolutely none (Tr. 181).

Dr. Marino:

Q. Isn't it true that many of the symptoms that a patient with hemorrhoids has, in terms of a direct effect, come from a pathology in the tissue rather than from the vein itself?

A. I think that is true, yes (Tr. 235).

Dr. McAdams:

Q. Are the supporting tissues and the covering tissues separate anatomic entities from the dilated vein?

A. No. They are separate and distinct microscopically and the hemorrhoids or dilated veins can be dissected away from the overlying skin or mucous membrane, but for practical purposes they are related to the supporting tissue, the veins and the covering of them are a unit (Tr. 480).

* * * * * * *

Q. Now, if this enlargement can be protected against trauma, and if some of the secondary complications to which we have referred can be cleared up, may the hemorrhoid be returned to an asymptomatic state?

A. Yes (Tr. 509).

* * * * * * *

A. Yes, but in talking about hemorrhoids, I don't believe you can separate the mucosal covering from the underlying varicosity (Tr. 517).

Dr. Zimmerman:

Q. Now, Doctor, where a patient has a hemorrhoidal problem which is causing him symptoms, there is more involved in that problem than simply the varicose veins, isn't there?

A. Yes.

Q. The tissue is involved to some extent and the overlying mucosa, isn't that so?

A. Yes.

Q. And his problem, his immediate problem is made up of all those things; the veins, the tissue and the mucosa, is that so?

A. Yes (Tr. 571).

* * * * * * *

Q. Now, Doctor, if you can prevent or clear up infection and prevent or clear up irritation to relieve edema, protect against trauma, may that not have a beneficial effect on the symptoms which a patient is suffering from his hemorrhoidal problems?

A. Yes (Tr. 577).

Dr. Pope:

A. The problem of the hemorrhoids to the physician, naturally, involves all of the tissue, both under the mucous membrane and the overlying portion externally.

Q. And you are concerned when you are treating a patient for hemorrhoids with the whole complex of tissue and vein and mucosa involved in that particular problem, are you not?

A. Yes, very definitely (Tr. 636).

Dr. Smith:

Q. Doctor, in terms of the entire problem of a hemorrhoid, is it correct that there is involved in addition to the varicose vein or group of varicose veins the overlying and surrounding tissue?

A. Yes, I stated that before, that the components consisted of the covering plus the varicosity, sir (Tr. 745–A).

Surgery does not insure that a troublesome hemorrhoid will not recur:

Dr. Hopping:

A. It all depends on who does it and how thorough he is. The recurrence rate is obviously present in every surgical procedure. But the recurrence rate in good hands of a good hemorrhoidectomy is rather small (Tr. 146).

Dr. Zimmerman:

Q. Were any of those patients, those on which you performed hemorrhoidectomies, people who had had previous hemorrhoidectomies?

A. Yes (Tr. 578).

* * * * * * *

Q. Are you familiar with the fact, Doctor, that Dr. Fansler has estimated that there may be unsatisfactory results from hemorrhoidectomies, perhaps in as many as 20 per cent of all cases?

A. I didn't know the 20 per cent figure (Tr. 581).

* * * * * * *

Q. . . . could you make an estimate of the percentage of all hemorrhoidectomies in which there is apt to be an unsatisfactory result?

A. I wouldn't like to make a percentage estimate, but I believe that Walter Fansler is probably a little high. But there is certainly an area there where it is true about the recurrence and trouble afterwards (Tr. 582).

The nine witnesses testified that palliative treatments were available which would not effect a cure, but would relieve the symptoms. One of the procedures employed by the proctologists in connection with internal hemorrhoids is the injection treatment, which consists of injecting an irritating solution, such as phenol or quinine urea, into the area where the network of veins is situated, causing scar tissue to form which will compress the veins involved and shrink the hemorrhoidal mass. (Hopping, Tr. 118, 144–145; Marino, Tr. 200–201; Manheim, Tr. 262–63; Eisenberg, Tr. 352–53; Sarner, Tr. 422–23; McAdams, Tr. 487–88; Zimmerman, Tr. 550–52; Pope, Tr. 616–17; and Smith, Tr. 720–21.) Dr. Marino explained:

As regards injection treatment, you can achieve long palliation, but, of course, the vascular tissue is still there and frequently people who have been treated with injectional therapy for hemorrhoids will require subsequent injections as time goes by, so that I don't think you can really speak of cure. You can speak of palliation with injections (Tr. 201).

In some instances relief can be achieved by altering the diet to eliminate irritative foodstuffs; using medications to soften the stool; improving the bowel habits; avoiding straining at stool; taking hot Sitz baths (sitting in hot water); and using ointments and suppositories. (Hopping, Tr. 120–21, 136; Marino, Tr. 202; Manheim, Tr. 306–307; Eisenberg, Tr. 354–360; Sarner, Tr. 423–24; McAdams, Tr. 487–88; Zimmerman, Tr. 553–54; Pope, Tr. 617; and Smith, Tr. 721–23.)

The discomforts and symptoms of hemorrhoids frequently subside spontaneously (CPF No. 37):

Dr. Hopping:

Nature and the resources of the body frequently take care of the immediate acute situation and heal it in the course of time. They don't heal the hemorrhoids (Tr. 119).

Dr. Marino:

The swelling subsides. Any infection or inflammation that may be present subsides. Irritative bowel movements may be relieved, and this would effect some degree of relief of an acute process, an acute hemorrhoidal situation (Tr. 202).

Dr. Eisenberg:

Just mother nature and time, both of which are excellent helpers, and we see patients many times who are made appointments for an acute ephisode of what they call hemorrhoids and if we are not able to see them for several days, by the time they come in, much of their symptomatology has been relieved, spontaneously, though they have done nothing. So we know from experience that many of these complications will subside spontaneously (Tr. 355).

Dr. McAdams:

The inflamatory reaction around the hemorrhoids was induced perhaps by constipation or diarrhea or excessive lifting or straining. It subsides in the course of that which makes life possible for all of us, Mother Nature's tendency to correct abnormalities.

* * * * * * *

Time is a great healer (Tr. 488–89).

Dr. Zimmerman:

Well, if a person has irritation in the hemorrhoidal area and the irritation subsides, just like irritation on the hand, the leg, or anywhere else, if it subsides spontaneously, the body healing will take care of it and the patient will gradually become free from symptoms even though nothing is done (Tr. 554).

Dr. Pope:

Time itself plays its biggest factor as far as treatment other than surgery and other than injection treatment. Topical application of heat may help and benefit.

After a period of time, nature herself causes the subsidance of whatever symptoms are present.

* * * * * * *

Yes, which is the usual story in most cases (Tr. 617).

Based upon their education, training, and experience, the nine proctologists gave opinion testimony,[7] the substance of which

[7] The testimony was permitted over the objections of respondent's counsel who stated (Tr. 127–28):

"The question that is being asked of the Doctor as a hypothetical question is one that appears to require expert qualifications either as a pharmacologist or a biochemist, or, at the very least, the establishment of some foundation that, through observation and clinical tests or use or prescription on his patients, he has in fact observed what results, if any, have been achieved with these products."

In *John J. Fulton* v. *F.T.C.*, 130 F. 2d 85, 86 (9th Cir. 1942), the Court said:

"The witnesses were shown to possess wide knowledge in the field under inquiry. There is no good reason to suppose them incompetent to express an opinion as to the lack of therapeutic value of petitioner's preparation merely because they had had no personal experience with it in the treatment of the disease. Their general medical and pharmacological knowledge qualified them to testify."

In later decisions, the same Circuit employed the same language in *Feil* v. *F.T.C.*, 285 F. 2d 878, 893 (1960); and in *Stauffer Laboratories, Inc.* v. *F.T.C.*, 343 F. 2d 75, 78, 80 (1965).

was that Preparation H ointment and suppositories containing the ingredients listed in the formula (CX 7 and 8), when used as directed, will not: (1) Reduce or shrink piles; (2) avoid the need for surgery as a treatment for piles; (3) stop all itch due to piles; (4) relieve all pain due to piles; (5) heal, cure or remove piles or eliminate the problem of piles; and (6) have any therapeutic effect upon piles or the symptoms thereof in excess of affording temporary relief of minor pain or minor itching associated with piles. (Hopping, Tr. 128–131, 173–74; Marino, Tr. 212–215; Manheim, Tr. 276–79; Eisenberg, Tr. 369–373; Sarner, Tr. 436–440; McAdams, Tr. 500–504, Zimmerman, Tr. 563–66; Pope, Tr. 629–633; and Smith, Tr. 740–44, 784–86, 792–93.)

The lack of familiarity on the part of witnesses with some of the ingredients in Preparation H is indicated by their testimony:

Dr. Hopping:

Q. I would like to explore for a few minute the basis of some of your answers to a couple of the hypothetical questions put to you on direct examination. Referring to Commission Exhibit 7, . . . are you familiar with each of the ingredients listed on there?

A. In a very superficial way, yes (Tr. 162).

* * * * * * *

Q. What source did you go to Doctor for your knowledge of SRF?

A. A resume of its properties were given to me.

Q. By whom?

A. Mr. McMahon [complaint counsel].

* * * * * * *

Q. Is that the sole source of your knowledge of SRF?

A. Yes (Tr. 165–66).

* * * * * * *

Q. In these answers that you gave to some of the hypothetical questions posed to you this morning about oxygen uptake, vitamin deficiency and so forth, were you answering on the basis of expert knowledge in the field of pharmacology or biochemistry, or were you answering based on the experience you described in talking [with] patients who have treated themselves prior to coming to you?

A. Well, since neither my patients who give me the story nor I are experts on pharmacology, I wouldn't expect to formulate an opinion on these particular subjects (Tr. 168).

Dr. Marino:

A. I have seen Bio-Dyne mentioned in three articles, one medical article and two articles in the lay press, but this is the only knowledge that I have of that particular substance. I am aware of shark liver oil as being one of the oils high in vitamin content. Phenyl mercuric nitrate I am not familiar with (Tr. 210).

* * * * * * *

Q. . . . I have specifically not prescribed Preparation H because I do not know what it contains (Tr. 244).

Dr. Manheim:

Q. You will note that on the cartons, 5 and 6, the active ingredients for these products are listed as live yeast cell derivative, supplying 2,000 units skin respiratory factor, bio-dyne, per ounce of ointment or suppository base; shark liver oil, 3.0 percent; phenylmercuric nitrate, 1 to 10,000. Are you generally familiar with these substances?

A. Some of them; not all of them (Tr. 273).

* * * * * * *

Q. Do you have any knowledge of the effect that is achieved by combining that SRF business with phenylmercuric nitrate?

* * * * * * *

A. No. I don't even know what is SRF (Tr. 300).

Dr. Eisenberg:

Q. Do I understand, correctly Doctor, that your only familiarity with respiratory factor reported in the two formulae that you looked at is only from what is said on the cartons containing the products?

A. Yes, sir.

Q. I believe you stated that you were familiar with phenylmercuric nitrate?

A. Only by name. I have heard the name and the fact that it is used as a local antiseptic.

Q. And is that also generally the degree of your familiarity, Doctor, with shark liver oil?

A. Only that it is probably similar to cod liver oil in its basis.

Q. Are you qualified in pharmacology, Doctor?

A. No, sir (Tr. 388–89).

Dr. McAdams:

Q. Do you know, Doctor, whether a substance which can stimulate cellular respiration and proliferation may have a beneficial result on the healing of injured tissues?

A. I don't know (Tr. 509).

* * * * * * *

Q. Well, what is your knowledge about the effect of combining Biodyne or skin respiratory factor with phenylmercuric nitrate in the amounts disclosed in the right-hand column on Commission Exhibit 7?

A. I have no opinion on that (Tr. 513).

Dr. Zimmerman:

Q. Doctor, I show you the following Commission exhibits . . . CX 7 and 8, which are the quantitative formulae of these two products. Would you examine these four exhibits carefully, please?

* * * * * * *

A. What is SRF?
Q. I am sorry, Doctor, I can't answer that question for you at this point.
A. The first thing is SRF Crude Concentrate, and I don't know what it is.
Q. For the sake of the question, suppose it means skin respiratory factor.
A. I don't know what Falba is, either (Tr. 560–61).

Dr. Smith:

[Q.] Are you generally familiar with these, Doctor, these ingredients?
A. There is one I don't know anything about. It is called falba. I haven't the least idea what falba is (Tr. 735).

None of the Commission's witnesses, with the exception of Dr. Zimmerman, had treated patients with Preparation H, nor observed the results which might be achieved with such treatment (Hopping, Tr. 151; Marino, Tr. 217, 221–22; Manheim, Tr. 303; Eisenberg, Tr. 378–80; Sarner, Tr. 447, 460; McAdams, Tr. 511–12; Pope, Tr. 670, 690–91; and Smith, Tr. 775–76, 791–92). On cross-examination, Dr. Zimmerman revealed that in 1959 or 1960, at the request of the Commission's Dr. Hall (who sat with complaint counsel in an advisory capacity during the trial of this proceeding), he had undertaken a clinical study of Preparation H and its use on hemorrhoids. Dr. Zimmerman explained that the study took place over a period of about a year or a year and a half, and involved two different things. One—each patient, who would come into his private office, was asked whether or not he had used Preparation H, and, if he had, whether it was suppositories or ointment and over what period of time he had used one or the other product or both. Two—at the Falk Clinic, which is connected with the Presbyterian University Hospital and a charity clinic for the University of Pittsburgh Medical School, under the direction of Dr. Zimmerman pictures in the form of color slides were taken of patients' internal hemorrhoids. The patients were then given Preparation H, which was used by them for various lengths of time from one to three months. Pictures were then again taken of the hemorrhoids. When respondent's counsel requested the production of these records, Complaint Counsel McMahon responded (Tr. 584–85).

Mr. Examiner, if you please, sir, we anticipated that this information might come forward. The Commission does not rely upon it in any sense, has not offered it in evidence, and we do not intend to offer it in evidence. We will furnish a copy of the Dr. Zimmerman's report to counsel, but we do not feel that it is legally competent evidence and, therefore, we are not relying on it and have not presented it as part of our case in chief.

A report in the form of a letter, dated March 6, 1962, addressed

to the Commission by Dr. Zimmerman, and 129 pages of clinical studies, together with color slides, were forthwith delivered in the hearing room to respondent's counsel by complaint counsel. Following a short recess, during which period respondent's counsel perused the material supplied him, such counsel stated that the studies were not such that they could be analyzed in a short period of time, and asked that, at the conclusion of Dr. Zimmerman's testimony that morning, the Doctor be excused subject to recall for further cross-examination (Tr. 582–590). After some further testimony on the part of Dr. Zimmerman, he was excused with the understanding that the hearing examiner would give consideration to respondent counsel's request for the return of the witness (Tr. 597). A number of days subsequent thereto, respondent's counsel stated on the record that it would not be necessary for him to ask for the return of Dr. Zimmerman for further cross-examination (Tr. 1804). It should be noted that the testimony given by Dr. Zimmerman was not based on the results of the clinical studies made by him of Preparation H.

As to the efficacy of suppositories and ointments in the treatment of hemorrhoids, the nine proctologists testified in part:

Dr. Hopping:

Q. In prescribing such ointment or suppositories, what effects would you expect to be achieved by their use?

A. Decrease in the immediate complaint or symptom of the patient.

Q. Do you propose to cure the hemorrhoids by these measures?

A. No, sir (Tr. 121).

* * * * * * *

A. Topical applications can relieve the symptoms of hemorrhoids, yes.

Q. Is this a permanent relief of symptoms?

A. This is temporary.

Q. Will this relieve the severe symptoms or the minor symptoms?

A. To a certain extent, it will relieve some of the severe symptoms and some of the minor symptoms (Tr. 122).

* * * * * * *

Q. Again, Doctor, do you have an opinion as to whether any medication, ointment, suppository or combination of them will cause hemorrhoids to cease to be a problem?

A. Temporarily, yes, they might very well.

Q. And on what basis?

A. That it relieves the symptoms of the disease.

Q. Will it relieve all of the symptoms?

A. No, sir (Tr. 125).

* * * * * * *

A. Yes, sir. They may very well relieve the symptoms of the acute attack at

the moment, but they [Preparation H ointment and suppositories] do not effect a cure (Tr. 128).

* * * * * * *

Q. On the rare occasions that this does occur, would you say that Preparation H ointment or suppositories will eliminate all of the itch?

A. They may temporarily do so, yes (Tr. 129–130).

* * * * * * *

By Mr. McMahon:

Q. Doctor, I am concerned about that salesman in Chicago that called you long-distance and you stated, I believe, that you prescribed Preparation H for him. What was your purpose in prescribing Preparation H for this patient?

A. Well, on the basis of what I knew about him already, as I prefaced my statement then. I said I had examined him previously, two years before, in the office. I knew that he had a skin problem as well as hemorrhoids, and from his immediate story I tried to in my mind go through the simplest procedure to give him relief of this intense discomfort that he was having in his anal rectal area. I can't send him a prescription over the phone. The simplest thing I could ask him to do was to go to a drug store and ask for some Preparation H. I did that on the spur of the moment.

Q. You did not expect this to cure the hemorrhoids?

A. No, sir.

Q. Would the prescription of any other lubricant material have been just as effective as the prescription of Preparation H in his case?

A. Any other lubricant? No, I don't think so. He couldn't have used Vaseline, for instance, or a simple petrolatum with anything more than aggravation of the symptoms (Tr. 176–78).

Dr. Marino:

Q. I gather from what you said that on occasion you do prescribe ointments or suppositories for your patients for the relief of symptoms of hemorrhoids. What circumstances would prevail for you to make such a prescription?

A. If a patient were having a hard, dry stool, a suppository would be very beneficial to lubricate the anal canal. If a patient with protruding hemorrhoids were experiencing chaffing due to undergarments scraping against the hemorrhoid, I think a lubricating ointment is very beneficial (Tr. 203–204).

* * * * * * *

A. If hemorrhoids are present, there is, in my opinion, no suppository or ointment that is going to cure the underlying pathology. While the symptoms may be relieved temporarily, another attack of inflammation in the hemorrhoid will produce a recurrence of the same symptoms (Tr. 206–207).

* * * * * * *

Q. . . . do you have an opinion as to whether Preparation H ointment or suppositories, . . . will reduce or shrink piles?

* * * * * * *

A. I do not think they will shrink piles.

Q. Will they reduce piles?

A. If so far as any lubricant would reduce or aid in reducing the skin edema overlying a pile, they might give temporary and minor relief.

* * * * * * *

A. Yes, it will not avoid the need for surgery in the treatment of piles.

* * * * * * *

A. . . . Unless the venous dilatation is eliminated, the piles or hemorrhoids will not be cured (Tr. 212–13).

* * * * * * *

Q. Isn't it true that many of the symptoms that a patient with hemorrhoids has, in terms of a direct effect, come from a pathology in the tissue rather than from the vein itself?

A. I think that is true, yes (Tr. 235).

* * * * * * *

Q. If you clear up those pathological tissue conditions entirely, just assuming you can do that, do you then have an asymptomatic hemorrhoid?

A. You would, temporarily.

Q. How temporarily, until the next exciting attack of something?

A. Until they became symptomatic again.

Q. How long might that take?

A. It might take quite a while. I really would have no basis for answering that question (Tr. 235–36).

Dr. Manheim:

A. They are all worthless.

Q. Would you please state your reason?

A. I have never seen a patient who has had any relief from any ointment or suppository, except the lubricating effect.

Q. Could they achieve this same lubricating effect with any lubricating substance?

A. Plain vaseline (Tr. 269).

* * * * * * *

A. My opinion, based on patients' histories to me and my examination of them, is that Preparation H, in the form of suppositories or ointment, has absolutely no beneficial effect on Hemorrhoids (Tr. 276).

* * * * * * *

A. I don't think that anything in the Preparation H suppository or ointment will even give minor relief, except the lubricant value.

HEARING EXAMINER JOHNSON: And what is the value of the lubricant?

THE WITNESS: It relieves dryness of the skin. It relieves dryness of the anal canal. Anything that you put in the anal canal or rectum would ease the bowel movement through. The lubrication effect of the ointment can cause an easier bowel movement and with an easier bowel movement, there would be less minor irritation, but this could be accomplished with vaseline with much less danger (Tr. 279–280).

* * * * * * *

Q. Isn't the substance of your testimony today that there is no such thing as drug of choice in the treatment of hemorrhoids?

A. I would say there is none (Tr. 308).

* * * * * * *

A. . . . Frequently, people will say to me, "It feels a little better if I put Vaseline on it."

I say, "If it feels a little better, use it" (Tr. 312).

* * * * * * *

Q. . . . However, is it your testimony now that lubrication in the form of a topical application will have no beneficial effect on a hemorrhoid?

A. Oh, no, it must have some.

Q. What is it?

A. A feeling of ease, a feeling of smoothness, less dryness (Tr. 313).

Dr. Eisenberg:

A. . . . Many of these patients of self-medicated themselves on more than one occasion and when asked specifically, which we often do ask, do you think the medication helped you any, some will say definitely yes, and how long did it take, well, I was all better in ten days or two weeks. We know that some of these proctologic symptoms will relieve themselves in that length of time, or even a shorter period of time. So that generally, I would, in my own opinion, this self-medication does not relieve the vast majority of these patients (Tr. 361).

* * * * * * *

A. My opinion is that this does not do good in most instances.

Q. Would you state your reasons? I am sure you have said this before.

A. Well, my reasons are these:That these patients come to me as they do to others in my specialty, for relief when these praparations have failed to give them relief. I don't know how else to state it, sir (Tr. 363).

* * * * * * *

Q. Doctor, on the basis of your professional education and training and experience do you have an opinion as to whether any preparation is applied topically or as a suppository will afford any relief from pain and itching associated with or attributed to hemorrhoids?

A. Yes, there are some. There are some which will afford relief. But these are affording relief to the complications which have occurred in those hemorrhoids.

Q. Are they affording any relief to the hemorrhoid itself?

A. I don't believe they do, sir.

Q. In other words, you are saying that in your definition of the hemorrhoid as a collection of varicose veins, that the application of these preparations does not get to them, is that the substance of your statement?

A. That is correct (Tr. 365).

* * * * * * *

THE WITNESS: I have an opinion and my opinion is that it will not heal, cure, or eliminate piles. May I add, the simple application of any harmless preparation may alleviate some of the symptoms but will not cure (Tr. 372).

* * * * * * *

Q. My question is specifically addressed to the patients whom you have seen on successive occasions, so that you feel able to state that their hemorrhoids were in substantially the same condition after they had used Preparation H as they were prior to the time that they had used Preparation H.

A. I feel, sir, that I cannot answer that question. The only way that I have of making a positive statement would be if I had prescribed Preparation H and then had these patients come back at intervals so that I could see the effects that the preparation might have had. But the patients whom I see or whom I have seen who have used this are those who have used it either on their own or on the advice of friends or pharmacy and who then come to me and say that I have used it and here I am, please do something else (Tr. 376–77).

* * * * * * *

Q. In your opinion, Doctor, is the natural healing process or natural subsidence of hemorrhoids in cases where that is going to occur apt to be assisted by some treatment which may relieve the complications which are present in the hemorrhoids?

A. Yes.

Q. In your opinion, does a relief of the edema if it is present assist the natural healing process?

A. The relief of the edema is part of the healing process.

Q. If infection were present, would the relief of such an infection assist the healing process?

A. If it were possible to relieve the infection, yes.

Q. And is protection of the protrusion or buldge of the mucosa in an internal hemorrhoid of assistance to the natural healing process?

A. Yes.

Q. Would you agree, Doctor, that there may be patients with hemorrhoids which, if not treated in conservative fashion, may develop such complications that they may have to undergo surgery whereas surgery might not have been required in those cases had the problem been caught at an early enough stage?

A. Probably in some instances (Tr. 380–81).

* * * * * * *

A. Yes, I think that one of the most frequently prescribed suppositories in my practice is a preparation known as desitin suppository which is basically a cocoa butter base and cod liver oil.

Q. Are there any other active ingredients in the desitin suppository that you know of?

A. Not that I know of (Tr. 382).

* * * * * * *

Q. . . . If you can, in an internal hemorrhoid protect the enlargement in the mucosa against trauma, reduce inflamation, relieve the edema, perhaps if it is present, aameliorate the infection. Would not that kind of treatment assist both in reducing the possibility of further complications and perhaps in returning the hemorrhoid to its asymptomatic state?

A. Possibly (Tr. 387).

* * * * * * *

Q. Isn't it a fact, Doctor, that some cases of hemorrhoids respond well enough to conservative treatment that surgery is not necessary?

A. Oh, yes (Tr. 388).

* * * * * * *

By Mr. McMahon:

Q. To go on with the question, would the topical application of Preparation H or any other ointment stop rectal bleeding whose source was an internal hemorrhoid?

A. Possibly.

Q. In what way would this be effected?

A. In the fact that it would act as a protective coating and may, by this fact promote healing—allow it to heal.

Q. Allow what to heal?

A. The mucosal surface that is bleeding.

Q. Would this have any effect on the underlying hemorrhoid?

A. No, sir, I feel it would not (Tr. 403).

Dr. Sarner:

A. I prescribe ointments. Never a suppository.

Q. Under what circumstances would you prescribe an ointment?

A. Chiefly to facilitate reduction of prolapse. We recommend patients who have prolapse that they have hemorrhoidectomy but for some people who are poor risk because of severe heart involvement, or I can recall a leukemia, pregnancy in the wrong trimester, we prescribe palliative things, principally topical steroids which are not curative but are palliative. They reduce itching in many people. . . (Tr. 426–27).

* * * * * * *

Q. What are your observations as to the results that have been achieved by such medication with Preparation H or any other ointment?

A. The patients who seek my care obviously have not benefited (Tr. 428).

* * * * * * *

THE WITNESS: At best they have a palliative effect, but—and no definitive effect on hemorrhoids.

By Mr. McMahon:

Q. Would you state your reasons for this?

A. Well, if we define hemorrhoids as we have defined them, no ointment is capable of restoring a deficient, muscular coate in a vein to normal. The only effect could be some alleviation of the results of the varicosity but could have no effect on the varicosity itself (Tr. 429).

* * * * * * *

Q. If you can arrest or clear up those problems in the overlying or surrounding tissue, would it not assist the natural processes of the body by which that hemorrhoid may be subsided?

A. If you could do that, yes.

Q. If you could do that?

A. Yes.

Q. Do you doubt, Doctor, that you can do that in some cases.
A. Overcome Inflamation?
Q. Edema or infection?
A. It can be done in some cases (Tr. 460).

* * * * * * *

Q. . . . I would like your opinion as to the efficacy of Preparation H with regard to the treatment of edema, inflamation and infection in tissue overlying a hemorrhoid?

A. I don't think it would affect it beyond this phenylmercuric nitrate if it is antiseptic. It is not antiseptic. It has bacteriostatis properties according to the information that I have. It might influence an infection favorably. The other ingredients—I don't know—I can't really state because I don't know how effective phenylmercuric nitrate in this dilution would be. The dilution becomes outrageous as soon as it mixes with the other fluids present (Tr. 463-64).

Dr. McAdams:

A. No, it could not cure hemorrhoids, because it cannot alter a structural defect (Tr. 481).

* * * * * * *

A. That opinion is that the effect would depend upon the vehicle largely with which it was applied.
Q. Would you explain a little more fully?
A. Well, there are any number of things that would make anything sore feel better and the ordinary ointment bases, such as lanolin and vaseline, would have the effect you describe (Tr. 482).

* * * * * * *

A. By cure, you refer to an absolute cure, not amelioration of symptoms or a restoration of an asymptomatic state, but—
Q. A cure.
A. There is only one way to really cure hemorrhoids and that is to remove them surgically.
Q. In terms of effecting a cure, is there any other treatment available?
A. Not if we use the word "cure" in the sense I just talked about (Tr. 487).

* * * * * * *

A. . . . We sometimes prescribe Anusol, a suppository which contains—as most all suppositories do—a cocoa butter base which actually is a major part—wherein lies a major part of the advantage, but which also contains, I believe, balsam of Peru and bismuth.
Q. Now under what circumstances would you prescribe such medication, Doctor?
A. I would prescribe such medication when a patient with hemorrhoids came in with an acute inflamatory reaction due to strain as a result of constipation or diarrhea, that would be common.
Q. Now, in prescribing such ointments or suppositories, what effect do you expect to be achieved by their use?

A. We expect them to make the patient more comfortable until the inflammatory process and the swelling recedes.

Q. Do you expect the hemorrhoids to be cured?

A. No. The hemorrhoids are still there after the patient is rendered comfortable and after the swelling has subsided (Tr. 490–91).

* * * * * * *

A. Well, we have a number of patient who have a basic hemorrhoidal problem which is quite tolerable until something comes along to produce some swelling or inflammation. Either they, or their own, or I prescribe something soothing and lubricating to the area and that gives them some relief.

Q. Again, is this temporary relief that you are referring to, Doctor?

A. Well, this is relief for that particular acute episode of pain and discomfort (Tr. 493).

* * * * * * *

A. Yes, I have an opinion, and I believe that an acute episode of hemorrhoids and inflammation or swelling can be relieved, along with the healing power of time, to the point where they will, at least for the time being, cease to be a problem (Tr. 494).

* * * * * * *

A. There are many factors that enter into the reduction of hemorrhoids or piles. What portion of that reduction would be attributable to the application you put upon it, upon the hemorrhoid, and what portion of that reduction would be due to the natural tendency for these hemorrhoids to return to the original state, I have no way of knowing (Tr. 500).

* * * * * * *

A. Many of the patients whom I see and subsequently are subjected to surgery for the removal of hemorrhoids have already used this preparation over an appreciable period of time and found that it does not solve their problem (Tr. 501).

* * * * * * *

Q. Doctor, when you used the word "temporary" on a number of occasions in your direct testimony, in context such as temporary relief, were you using the term to mean until the next episode occurs?

A. I was using the term to mean until the acute episode subsided; the present episode subsided.

Q. And temporary in the sense that it is relieved until another acute episode occurs?

A. No, I don't believe that is quite what I meant. One never knows when hemorrhoids are going to become symptomatic sufficiently to require medication, so I don't assume that what I apply today will protect that patient for any specific length of time.

Q. Well, you were using the word, weren't you, Doctor, to differentiate, basically, between—or to differentiate from the kind of absolute relief you get from a cure? Isn't that correct?

A. Yes, that is correct (Tr. 506–507).

* * * * * * *

Q. Now, if this enlargement can be protected against trauma, and if some of the secondary complications to which we have referred can be cleared up, may the hemorrhoid be returned to an asymptomatic state?

A. Yes (Tr. 509).

* * * * * * *

Q. Now, Doctor, in the hemorrhoid we were talking about a few moments ago, if it returns to an asymptomatic state, that patient hasn't been cured in the absolute sense, has he?

A. No.

Q. He still has the underlying vascular anatomical weakness?

A. That is correct.

Q. But his hemorrhoids have ceased to be a problem to him, is that not so, Doctor?

A. That is correct (Tr. 509–510).

* * * * * * *

A. When a patient comes to me and it is decided that he should be admitted to the hospital for surgery and there is a lapse of time between my examination and the admission to the hospital, I usually inquire as to what he has done to manage to get along up until that point; and whatever it is, whether it is Preparation H or anything else, I say, "Now, if you have learned to get along with these by using this, you continue to use it until you are admitted to the hospital for definitive treatment" (Tr. 511–12).

* * * * * * *

Q. What is the drug of choice for the treatment of hemorrhoids?

A. I don't know (Tr. 513).

* * * * * * *

Q. And you have also expressed the opinion, I believe, that as long as that underlying vascular abnormality remains, that particular person is either going to continue to have hemorrhoids or is going to be subject of recurrent attacks of hemorrhoids. Is that not so, Doctor?

A. He is going to have hemorrhoids, and he may or may not be subject to recurring aggravations of them, but the hemorrhoids are there and will always be there.

Q. Now, when you say recurring aggravation, you are speaking in terms of symptoms?

A. Yes (Tr. 516).

Dr. Zimmerman:

A. What causes the pain is the distention of the tissue, especially skin, and after the skin and tissue has once been distended, the pain usually stops. Then, as this clot dissolves spontaneously—and unless they are very large, many of them dissolve spontaneously—after the skin has been stretched, the pain stops and the clot dissolves spontaneously and nature cures the condition (Tr. 554–55).

* * * * * * *

A. The patients seem to get some relief from applying these various things, but I have never seen them cure it. It is hard to evaluate just how

much good, if any, these things do, because one patient will come in with a thrombosed hemorrhoid and say "I put nupercainal on this," a topical anesthetic, "and it helped," and the next patient comes in and says, "I put nupercainal on it, and it didn't help." But I think anyone feels better if he puts a little something on a place that hurts or is irritated, but I have never seen these things cure any condition (Tr. 556–57).

* * * * * * *

A. They do practically no good.

Q. Would you state why?

A. Because hemorrhoids are under the mucous membrane, under the skin, and unless the skin is involved, the mucous membrane is involved, anything they put on there is not going to do any good (Tr. 557).

* * * * * * *

Q. Afford any relief from pain and itching associated with hemorrhoids.

* * * * * * *

A. That there are some topical things that might give some relief (Tr. 558)

* * * * * * *

Q. Doctor, do you have an opinion as to whether any medication, ointment, suppository or combination of them will cause hemorrhoids to cease to be a problem?

* * * * * * *

A. I don't think it would cease to be a problem (Tr. 560).

* * * * * * *

A. It will not reduce or shrink piles.

Q. Will you state why again, sir?

A. Again, piles or hemorrhoids are varicose veins and what is put on the skin or mucous membrane above that, I can see no way it would shrink them (Tr. 563–64).

* * * * * * *

A. I do not believe it will do anything except afford a temporary minor relief.

Q. Would you state why?

A. Again, for the same reason that the hemorrhoids are varicose veins, they are under the skin or under the membrane, and whatever is put on top of the skin or membrance can have little effect on what is under it (Tr. 566).

* * * * * * *

Q. Now, Doctor, where a patient has a hemorrhoidal problem which is causing him symptoms, there is more involved in that problem than simply the varicose veins, isn't there?

A. Yes.

Q. The tissue is involved to some extent and the overlying mucosa, isn't that so?

A. Yes.

Q. And his problem, his immediate problem is made up of all those things; the veins, the tissue and the mucosa, is that so?

A. Yes.

Q. Now, you expressed the opinion, Doctor, that a topical application applied either to the mucosa, when you have an internal hemorrhoid, or to the skin, when you have an external hemorrhoid, couldn't penetrate deeply enough to effect the varicose veins. But you would agree, wouldn't you, Doctor, that where you have a symptomatic hemorrhoid involving the tissues and the mucosa as well as the vein, that such an application could have a beneficial effect on the mucosa?

A. Yes (Tr. 571).

* * * * * * *

Q. Now, Doctor, if you can prevent or clear up infection and prevent or clear up irritation to relieve edema, protect against trauma, may that not have a beneficial effect on the symptoms which a patient is suffering from his hemorrhoidal problems?

A. Yes.

Q. And if you can do those things, may it assis[t] the body's natural processes in causing those hemorrhoidal problems to subside?

A. Yes (Tr. 577).

* * * * * * *

Q. . . . If, as a result of clearing up the types of complications we have just been talking about, and as an added result of the body's own natural healing processes, a hemorrhoid subsides so as to render a patient symptom-free, that symptom-free condition or that disappearance of the hemorrhoidal symptoms is only temporary, is it not, in the sense that the underlying vascular abnormality remains?

A. Yes.

Q. And is that the situation that you intended when you have used the word "temporary" in terms of relief that might be achieved in some cases from conservative management?

A. Yes (Tr. 578).

* * * * * * *

Q. But if something is done at some stage to protect that enlargement against further trauma and perhaps to clear up things like infection, inflammation and edema, that patient may avoid the need for surgery, may he not?

A. That is one factor.

Q. Well, I don't want to be putting unfair questions to you, but if you can answer my question yes or no, I would appreciate it. If you can't, you may explain.

A. I would have to say yes, anything that decreases the irritational cause of hemorrhoids would be a benefit; for one of the causes of hemorrhoids, it would be a benefit (Tr. 580–81).

* * * * * * *

Q. In your opinion, Doctor, is there anything in Preparation H that would clear up infection, clear up edema, protect against trauma?

A. Yes. The Preparation H is an ointment, it is a grease, and it would lubricate the canal and prevent a certain amount of trauma.

Q. And is this lubricating effect one that could be achieved with a number of other lubricants?

A. Yes (Tr. 592).

Dr. Pope:

A. For hemorrhoids, I give no medication that way at all, unless we have an ulcerated condition with a very severe strangulation and usually necrotic type of prolapsed hemorrhoidal tissue. And that is for the relief of hemorrhoids but for the ulceration of the skin over the hemorrhoids and distinguishing between the treatment of hemorrhoids and the condition of pain and discomfort (Tr. 620).

* * * * * * *

A. The opinion is that the use of suppositories is of value only in lubrication and that again, as far as having any effect on the patient is concerned, used only with the complicated hemorrhoids.

Q. What is the use of ointments?

A. Ointments are for their lubrication value only, excepting where you have open ulcerations immediately treated, but is not the treatment of hemorrhoids, but the skin and tissue overlying them, or in some condition which is thought to be hemorrhoids which, after proper examination and diagnosis would show not to be due to hemorrhoids itself (Tr. 621–22).

* * * * * * *

Q. Again, Doctor, do you have an opinion as to whether any medication, ointment, suppository, or combination of them will cause hemorrhoids to cease to be a problem?

* * * * * * *

A. The opinion is that there is none (Tr. 624).

* * * * * * *

A. The opinion is that it has no effect whatsoever as far as the treatment of the hemorrhoidal condition in itself, as far as that condition in itself is concerned (Tr. 628).

* * * * * * *

A. The reason is that there is a vein underneath the integument, the covering, under the muc[o]us membrane of the skin that can't be reached by the drug, . . . (Tr. 628–29).

* * * * * * *

A. I would not agree that even with minor pain and minor irritation that it gives any particular relief, and it certainly doesn't in those symptoms that are more severe—it certainly would not in those conditions that are already more marked than just even moderate which refers to itching, pain, as well as all other symptoms (Tr. 633).

* * * * * * *

Q. What is the drug of choice for the treatment of hemorrhoids?

A. There is no drug of choice in the treatment of hemorrhoids, excepting where partial improvement can be used by injection treatment which could be as far as the drug of choice of the various drugs that are used for that, that which is used the most in which I use is a five percent solution of quinine-uria hydrochloride.

Q. That is for injections?

A. That is for injections (Tr. 634).

* * * * * * *

A. If other conditions are ruled out and you are definitely treating that alone, yes. It is not necessarily a vein of importance to treat it. I would have to say that, necessarily; but, if you showed your attacks became more frequent and you are sometimes involved in something that is more marked for severe pain, then those are the indications for treatment (Tr. 650).

Dr. Smith:

A. . . . External hemorrhoids, or external—let me put it this way—any condition causing an irritation of the rectum can be given symptomatic relief by the use of certain medications or certain ointments, any lubricating medicine, oil or petroleum, vaseline or any other lubricant will then prevent the irritation of the stool on the outside, and would be helpful in treating symptoms due to this particular condition (Tr. 723).

* * * * * * *

A. . . . I have never seen any ointment which can be applied which is going to cause a resolution of this thing more quickly than if nothing had been applied (Tr. 726).

* * * * * * *

A. That other than the relief of mild irritation, they are of no value as far as the hemorrhoids themselves are concerned (Tr. 730).

* * * * * * *

A. I mentioned before the use of emollient types of ointments, the use of an antiseptic agent applied locally may give some temporary and some mild relief (Tr. 732).

* * * * * * *

A. And that while such things may be of temporary benefit as far as soothing is concerned, they have no effect whatsoever on the hemorrhoid, and hence they cannot cure hemorrhoids (Tr. 733).

* * * * * * *

A. That they do not cause the hemorrhoids not to be a problem (Tr. 734).

* * * * * * *

Q. The overlying tissue, however, may be treated perhaps even to a degree of rendering the symptom—of rendering it symptom free by measures short of surgical excision, is that not so?

A. I testified to that before when I stated that irritations of the skin would be helped by the use of ointments, et cetera, any type of emollient preparation, yes.

Q. Including irritations of the skin or mucosa overlying the hemorrhoidital varicosity?

A. That is correct (Tr. 745–A).

* * * * * * *

Q. Now, are you using temporary in the same sense both with respect to relief and with respect to cessation of symptoms?

A. That is rather difficult to answer because I may see people who may not bleed for ten or fifteen years.

Now, if you want to call fifteen years a temporary thing, then it would have to apply. My use of the word temporary was in reference, in the frame of reference to the specific episode that brought them into my office.

Q. And if you relieve that specific episode as for example if you suc-[c]eed in stopping the bleeding, that is temporary relief, is it not?

A. I would say temporary because it doesn't necessarily follow that in every instance the man is going to bleed again.

Q. Yes, but it is temporary in the sense that short of surgical excision he is still going to have that varicose dilation of the veins?

A. That is correct, but it doesn't necessarily follow that that hemorrhoid is going to give him trouble again because we don't operate on a hundred percent of the people (Tr. 769–770).

* * * * * * *

Q. And if you can relieve that edema may you be able to relieve the pain?

A. That would follow (Tr. 771).

* * * * * * *

Q. And the ointment may have some beneficial effect in treating that, might it not?

A. It may, because if you cut the skin, it is going to be sore, so you put a local anesthetic agent or some soothing agent until the skin regenerates and their problem is over.

Q. And does this sort of treatment have a beneficial effect on the patient's symptoms from hemorrhoids?

A. It helps their symptoms, but it doesn't help their hemorrhoids (Tr. 778–780).

* * * * * * *

Q. Well, now, does it, on occasions, occur that a patient of yours for whom you prescribed one or more of these ointments plus the other conservative methods used—you have referred to, will become symptom-free?

A. Yes, I think so.

Q. And he has gotten temporary relief?

A. If you want to call cessation of symptoms as temporary relief, I agree with you. I think it is a question of semantics (Tr. 780–81).

* * * * * * *

Q. Beyond lubrication, would Preparation H be of any benefit in the treatment of external hemorrhoids which are ulcerated or infected?

A. It does contain an antiscep-—an agent, Phenylmercuric nitrate is in there, which is one of the antibacterial things under certain circumstances, which might be a plus in lubricating value (Tr. 792).

* * * * * * *

Q. In your opinion, Doctor, would Preparation H ointment relieve the edema, inflammation, irritation such as occurs with the ulceration or inflammation of external hemorrhoids?

A. Again in answering that question, I am sure that any type of emollient ointment, and this would include Preparation H, would be of some minor help, or let me say would be of some help for minor complaints, such as irri-

tation, et cetera. I think that would be a true statement, yes, sir (Tr. 792–93).

The Commission witnesses, who testified on the subject, stated that a large number of their patients came to them as referrals from other physicians:

Dr. Hopping:

A. Most of them.
Q. Ninety percent?
A. Or better (Tr. 139).

Dr. Marino:

A. Yes, sir, the majority of our patients (Tr. 225).

Dr. Manheim:

A. . . . In the early practice, when I kept a graph, it was a very high percentage of doctors. Now, it is about even, 50–50, from doctors and from other patients (Tr. 286).

Dr. Eisenberg:

A. Yes, sir, most of them (Tr. 383).

Dr. Sarner:

A. . . . 50 per cent by patients and 50 per cent by professional colleagues (Tr. 458).

In the treatment of hemorrhoids, the proctologists utilize surgery (the operation is known as a "hemorrhoidectomy") in a substantial number of their cases. Dr. Hopping operates on about 200 to 250 of his hemorrhoid patients annually. He estimated that three out of four of the patients he sees are operated on either by himself or by other surgeons (Tr. 133–34); Dr. Marino sees between 12 and 15 new patients a week, and in a year operates on about 120 to 125. Some are not operated on because of the patient's general medical condition, and others choose not to have surgery. Frequently, when surgery is recommended, the patient will go back to his referring doctor (Tr. 223–26); Dr. Eisenberg sees between 300 and 400 hemorrhoid patients a year, and estimates that 60 to 70% go to surgery (Tr. 382–83); Dr. Sarner, who operates on "Somewhere between 200 and 250" of his patients in a year (Tr. 459), said, "Even a conservative man would have to operate on half the hemorrhoids he sees" (Tr. 467); Dr. McAdams operates on about 250 a year, stating that the total of hemorrhoid cases which he sees in such a period would be more than double that number (Tr. 510); Dr. Zimmerman estimated that he performed about 300 to 350 hemorrhoidectomies last year

(Tr. 578). Patients who have problems such as severe diabetes, high blood pressure, and heart conditions are not suitable subjects for surgical care (Hopping, Tr. 134; Marino, Tr. 226, 244; Sarner, Tr. 426). Some patients choose not to have surgery, although surgery is recommended. Dr. Hopping explained, "A good many people that I see want to be reassured, and when you tell them they have hemorrhoids, they say, 'This is fine. I know what it is. Can I live to be ninety or hundred with hemorrhoids?' I say, 'Yes, indeed, it doesn't kill you.' They are perfectly content to go along with their disability" (Tr. 135; Marino, Tr. 226).

As to respondent's defense, at the outset consideration will be given to the testimony of the six doctors who participated in clinical studies of the products involved.

Dr. Young, a Fellow of the American College of Surgeons and a diplomate of the American Board of Surgery, has performed between 20,000 and 25,000 operations during his career since 1934. At the time he appeared as a witness, in addition to carrying on his private practice in his specialty as a general surgeon and being an instructor in surgery at Ohio State University, he was the director of the Institute of Medical Research, Inc. of Columbus, Ohio. This organization was formed in 1950 for the purpose of industrial medical research and the testing of drugs, "bringing a number of men together who have various talents in the medical field to work together to this end" (Tr. 1445). The Institute was recently requested by the Federal Trade Commission to review some books relating to the medical practice, and Dr. Young issued an opinion giving his views with reference to the validity of some of the statements contained therein. Dr. Young testified that at the present time he sees between 50 and 100 hemorrhoid patients in the course of a year, and that most of these cases are medical failures and require surgery. He estimated that about half of the patients are referred to him by other physicians—usually for surgery. For the patients who are not operated on, "We inquire about the character of their stool. If their stool is hard, we give them a stool softener, rcommend sitz baths and treatment with suppositories or ointment, or both" (Tr. 1450). Dr. Young was the medical director of Curtis Wright Corporation from 1942 to 1949, and North American Aviation, Columbus Division, from 1949 to 1956 when there were about 20,000 people in their plant. ". . . we saw or had around 250,000 visits a year to our hospital and first aid rooms. And hemorrhoids are a rather common complaint. . . . When I was at North American and Curtis

Wright I saw more of a cross section problem" (Tr. 1446–47). At the request of Dr. John M. Shaul, Medical Director of Whitehall Laboratories, a division of the respondent corporation, during 1958 and 1959 Dr. Young undertook a study of Preparation H suppositories and ointment for the purpose of giving an opinion as to whether or not the products were effective in the treatment of hemorrhoids and what the side reactions were. As to the source of the subjects used in the study, Dr. Young said (Tr. 1457):

> Some of them were my own private patients. In order to get additional patients I asked nurses and medical directors in industry who were friends of mine [i]f they would send patients who were willing to be placed on the trial at no charge to them. And the patients that were on the trial brought other patients who they knew were suffering from hemorrhoids, also. Then we found patients in some ten or twelve rest homes and also patients in the city prison in Columbus, Ohio.

Some of the subjects were to be pregnant women, and, as Dr. Young did not see those in his practice, he made an arrangement with Dr. Burt, an obstetrician, who occupied an office next to him. When Dr. Burt selected a patient for the study, he would call Dr. Young and the two doctors would examine the subject. This procedure was followed on subsequent visits during the period of the study. There were times when Dr. Young was not available and in such instances Dr. Burt did the follow-up by himself and gave Dr. Young the results of his examination. Each patient used in the study was told by Dr. Young that it was a clinical investigation, and that he did not know whether the product would be of value or not. The patients were not told what the product was. The suppositories used in the test were contained in a plain, white package, and the ointment in plain tubes with no marking thereon to identify the product. The patients were instructed to use the medication after each bowel movement and at night when they went to bed. The patients were also instructed not to use any other type of medication or treatment. After the initial visit, the patient was seen again in three or four days and at intervals thereafter until there was no further need for observation. On each subsequent visit, the patients were again instructed not to employ any other measures than the ointment or suppositories, and anybody who used any other type of medication or treatment was then out of the study. Dr. Young recorded the results achieved by 127 patients (including 19 patients observed with Dr. Burt) who were treated with Preparation H in the course of the

study (RX 5A–5Z103). Dr. Young stated that, as a result of the study, he has prescribed the preparation in the course of his regular practice (Tr. 1468). Based on the clinical investigation and on his experience with Preparation H since that time, Dr. Young testified that Preparation H is effective and worthwhile in the conservative treatment of hemorrhoids, will reduce the swelling, edema, and size of enlarged hemorrhoids, will relieve pain, and stop and relieve itching (Tr. 1470–72). Dr. Young also testified that the study influenced him to the point that he subsequently used Preparation H to treat his own hemorrhoids (Tr. 1473, 1512). The basis for some of Dr. Young's opinions is illustrated by his testimony on cross-examination:

Q. You gave the opinion, Doctor, that Preparation H would reduce hemorrhoids in size. You also stated, Doctor, that this would have no effect on the varicose veins that was underlying the integument over it.

A. That's true.

Q. So that even though you applied the Preparation H, the varicose vein would remain as before, is that right?

A. Well, basically that's right, with inflammation and edema present, there may be some local obstruction to the vein which at the time is in the acute phase and makes it larger than it will a month later but you never can, in my opinon, eliminate the basic varicose vein by the use of this ointment or suppository preparation (Tr. 1497).

* * * * * * *

Q. What about in the relief of pain, Doctor? What is your opinion with regard to Preparation H in this circumstance?

A. I think it's of value.

Q. Will it relieve all pain, Doctor, associated with or ascribed to hemorrhoids?

A. Within a matter of a short time and I mean by that within 12 to 24 hours, patients say that they receive some benefit and within a week, most of the patients say that pain has disappeared (Tr. 1497–98).

* * * * * * *

Q. Doctor, do you have an opinion based on your education, on your training and experience and your clinical study that you have reported to as to whether Preparation H ointment or suppositories contains the active ingredients that are presently in them and used as directed will avoid the need for surgery as a treatment for piles or hemorrhoids? Do you have an opinion?

A. It would have to be a qualified opinion.

Q. Would you give your opinion, please, sir?

A. I would say that in the majority of cases as seen in a cross section of the population, as I saw it at Curtis Wright, and North American, that it was effective and would be successful enough that surgery was not necessary but it certainly would not prevent all cases from developing to the point where they need surgery.

Q. Doctor, I'm sorry but you confused me. Would you re-state your answer, please, sir?

A. In a cross section of the population, where you see hemorrhoids of all kinds, that the conservative treatment is sufficient to render the patient asymptomatic and that surgery is not necessary in most of these patients. However, it will not prevent the necessity of surgery in all hemorrhoid patients (Tr. 1500–1501).

* * * * * * *

Q. Now, Doctor, if you have a patient who, in your opinion, should have a hemorrhoidectomy performed and there are no other physical conditions present that would contraindicate surgery, do you feel the application of Preparaton H ointment or suppositories for the patient would eliminate that procedure?

A. I think you are in a situation where you have to make a decision as to whether to keep this patient under constant conservative treatment with periods in which your treatment is a failure to some extent, or whether you are going to subject him to surgery in the hope that all this may be eliminated.

I personally think that it's better to do surgery in this particular type patient and get away from the constant treatment.

Q. I see.

Doctor, do you have an opinion as to whether Preparation H ointment or suppositories will eliminate all itch due to or ascribed to piles? I want you to take particular note of the word "all."

A. In this series, we had 28 patients that reported itching and 27 relief from itching.

Q. Doctor, I don't think that's responsive to my question.

A. Well, all of the patients were not relieved from itching. One was not.

Q. Were they relieved of all itching when they were using this medication?

A. Yes.

Q. And I am using the term "all" in particular.

A. Yes.

Q. Is that borne out by the clinical study, Doctor?

A. Yes (Tr. 1501–1502).

* * * * * * *

Q. Do you have an opinion as to whether Preparation H ointment or suppositories will heal hemorrhoids or piles?

A. Well, I would assume from you[r] usage of the word "heal" that you mean have an effect upon acute inflammation or edema or some complication of the varicosity and I would say yes (Tr. 1504).

Q. The symptoms that you have described are secondary, are they not, to the hemorrhoid itself?

A. Right.

Q. Will the application of Preparation H ointment or suppositories heal the hemorrhoid itself?

A. Do you mean heal the varicose vein?

Q. Yes.

A. I don't think so (Tr. 1505).

* * * * * * *

Q. . . . Doctor, in your opinion, will Preparation H ointment or suppositories eliminate the problem of piles or hemorrhoids?

A. In the majority of the patients, for all practical purposes, yes, I think it will.

Q. It will eliminate the problem?

A. Most patients do not complain of the varicose vein itself unless it is tremendously enlarged and results in prolapse or strangulation or some complication of its being large. Most patients complain of the complications of the hemorrhoids, that is secondary infection, edema, swelling, thrombosis (Tr. 1505–1506).

Dr. Burt, a Fellow of the American College of Obstetricians and Gynecologists, who delivered his 9000th baby during the month of April, 1965, testified that hemorrhoids are quite common in women during pregnancy (Tr. 1514–17). In his regular practice, in the treatment of these patients, he prescribes stool softeners and the use of suppositories. In addition thereto, he advises the assumption of a prone position by the patient frequently (Tr. 1522, 1535). With reference to surgery, he stated (Tr. 1521):

A. I see very few cases, in my judgment, that it is necessary to go to the surgical approach, except if one of the hemorrhoidal veins that's prolapsed becomes, a thrombus or blood clot forms in them, then it becomes strangulated in the edematous and perhaps infection into those. That is a modified form of hemorrhoid. I refer those to the appropriate individual to, for the most part just to have them enucleated, to remove that clot per se. That's as far as I usually recommend.

Dr. Burt was shown a series of nineteen documents (RX 5D–5K; 5W–5Z7), which identified the records of his patients, and which were utilized in the experiment in association with Dr. Young (Tr. 1524). Dr. Burt stated that, subsequent to the study, he has used or prescribed Preparation H in the course of his regular practice (Tr. 1532). Based upon his clinical observations and as a result of the further experience he has had with the product since the study, Dr. Burt expressed an opinion that Preparation H will, in patients during pregnancy or during the period immediately after childbirth, reduce the hemorrhoids in size (but there is no assurance that they will not enlarge again), relieve the pain and stop the itching due to hemorrhoids, and render the patients symptom free until or unless the symptoms reoccur (Tr. 1530–32). On cross-examination, we find this exchange:

Q. Now, Doctor, you stated that the presence of hemorrhoids in pregnant women was due to mechanical factors based upon pressure caused by the growth of the fetus and the engorgement of the tissue surrounding the

uterus, and so on, plus the systemic flow of hormones to increase the blood supply to provide sufficient nutrition for the fetus.

Now, if all of these things caused the hemorrhoids in the pregnant woman, how can the application of a suppository to the patient's rectum change this?

A. Sir, it doesn't change the situation that exists. It only relieves them of, temporarily relieves them of their symptoms, but it is associated with the condition.

Q. Would you say, then, it does not cure the hemorrhoids?

A. It does not cure the hemorrhoids (Tr. 1533–34).

* * * * * * *

Q. Do you consider lubrication to be the greatest benefit derived from the use of suppositories by one of your patients?

A. No, sir.

Q. What do you consider to be the greatest benefit?

A. I think the combination of all of the factors of it.

* * * * * * *

Q. Please continue.

A. Based on the fact that patients frequently will resort—when other things are not available, at their disposal, at their home or place of abode, that they will resort to the use of vaseline or various creams or lotions, and they have very little results.

But that is in comparison of what I have observed in my experience with the use of the more medicated suppositories, which of course have a lubricating type base with it (Tr. 1535–36).

* * * * * * *

Q. Doctor, you asked Mr. Murphy's—you answered Mr. Murphy's question concerning your experience as to the effect of Preparation H, and stated that you felt that Preparation H would provide temporary relief in the reduction of hemorrhoids, that they would relieve the pain of hemorrhoids, that would stop the itch of hemorrhoids.

Now are you basing that conclusion on the 19 cases which you shared with Doctor Young?

A. Not entirely.

Q. Well, what else are you basing it on, Doctor.

A. On my experience with those cases, and those cases that, numerous cases that I have had since that have used this particular preparation (Tr. 1536–37).

* * * * * * *

Q. In response to a question from Mr. Murphy, Doctor, you stated that you felt that Preparation H would render your patient symptom free while Preparation H was being used.

Now, did you mean free from all symptoms?

A. As I recall, I think he categorically asked me about it broken down in various specific symptoms. I don't think there is any drug that at all times will relieve all symptoms, to my knowledge (Tr. 1538).

* * * * * * *

Q. Do you feel that Preparation H suppositories will cure varicosities of veins of the hemorrhodial plexis?

A. It will not cure the varicosities. It will cure the secondary symptoms that go along with it.

* * * * * * *

Q. Is it your testimony, Doctor, that Preparation H suppositories will in your opinion relieve all pain in your patients?

Now, I want you to take particular note of the word "all," and I am speaking, of course, of pain attributable to or caused by the hemorrhoids?

A. All is a pretty inclusive word, and I don't think you can say all pains, but the usual pain associated with hemorrhoids it will give symptomatic relief.

Q. I don't think you have answered my question, Doctor.

A. Will you rephrase it for me, please?

MR. MAC MAHON: Would you read the question back, Mr. Reporter.

(Whereupon the reporter read the question back.)

THE WITNESS: No, it won't relieve all of the pain (Tr. 1540–41).

* * * * * * *

Q. Excuse me, Doctor, I am limiting my question to itch that is attributed to or caused by piles or hemorrhoids?

A. It will relieve itching?

Q. All of it?

A. In my observations it has (Tr. 1542).

* * * * * * *

Q. . . . Do you have an opinion as to whether Preparation H suppositories will heal, cure, or remove piles or eliminate the problem of piles in your patients?

A. It will alleviate or relieve most of these situations if there is nothing more basically undermining or producing them, pure symptomatic ones.

Q. Would you say that this was temporary relief of minor symptoms?

A. It will give temporary relief from minor symptoms (Tr. 1542).

* * * * * * *

REDIRECT EXAMINATION

* * * * * * *

Q. As a doctor, sir, when you use the phrase "relief symptoms," or similar phrases, what do you mean to convey—do you mean that the patient's symptoms are cleared up?

A. Yes, sir.

* * * * * * *

THE WITNESS: Their complaints (Tr. 1546).

Dr. Epstein specializes in internal medicine and gastroenterology, and is Assistant Clinical Professor of Medicine at the George Washington University School of Medicine. He was formerly "a new Drug Officer" with the Federal Food and Drug Administration. In the course of a usual year in his practice, he sees and treats between 40 and 50 hemorrhoidal cases. In the eight years that he has been in practice, he has referred possibly 10 pa-

tients for hemorrhoidectomies. With respect to cases not referred to surgery, he describes his method of treatment as follows (Tr. 1555):

A. I use the standardly recommended, conservative medical measures. I use a hemorrhoidal suppository, and sometimes a hemorrhoidal ointment. I instruct my patients to take care with their diet, with respect to the avoidance of constipation, the avoidance of highly spiced foods, and alcohol. And I also impress upon them the necessity for careful anal hygeine.

As to the results he has been able to achieve with this kind of therapy, he said (Tr. 1555–56):

A. I think my results probably fall in generally with those of my colleagues. We get uniformly successful results with conservative medical management in mild to moderate hemorrhoidal disease.

Q. And in speaking there of mild to moderate hemorrhoidal cases are you speaking generally in terms of that type of hemorrhoidal disease which in your opinion does not require surgery or surgical treatment?

A. I think that is a fair statement.

Sometime during the latter part of 1961, he was contacted by Dr. James Kelly of Whitehall Laboratories, and agreed to undertake a clinical investigation of Preparation H. Dr. Kelly wanted approximately a hundred cases, and, as Dr. Epstein felt that he could not supply such volume within a reasonable time, he made an arrangement with Dr. Norman Isaacson to carry on a parallel experiment, with each doing his work independently. Dr. Epstein's study involved 33 subjects who were patients in his private practice. A patient selected for the study, with his consent, was told that the doctor was evaluating some hemorrhoidal preparations which were completely safe, but the patient was not informed as to the name of the drug. The product used in the study was packaged in plain, white containers on which there was a label which stated that they were hemorrhoidal suppositories or hemorrhoidal ointment, with directions for use, but there was no identification as to its marketing name. On the first visit, the patient was put on the doctor's usual, conservative program heretofore described, using Preparation H as the medication involved. The patient was instructed by the doctor to use the preparation morning, evening, and following each bowel movement. Arrangements were made with respect to return visits by the patient. On the first and each subsequent visit, the doctor examined the patient and noted on the patient's chart his observations, together with the patient's complaint, which information was set forth on a case report form (RX 6A–6Z7). Such records show that each

patient made either two or three visits after the initial examination, usually about a week apart. Only one subject involved in the study was referred to surgery. Since the conclusion of the investigation, Dr. Epstein has prescribed Preparation H for some of his hemorrhoidal patients in the regular course of the conservative therapy which he employs. Based upon the investigation and his subsequent experience with Preparation H, Dr. Epstein expressed an opinion that "it is an efficacious agent in the conservative management of patients with mild to moderate hemorrhoidal diseases" (Tr. 1569), can reduce hemorrhoids in size, will relieve pain where pain is present as a symptom, can reduce edema, or swelling, or inflammation where they are present, and can render a patient's asymptomatic hemorrhoids symptomatic free with this qualification (Tr. 1571):

A. When you say symptom free, it is merely the amelioration of the symptoms that the patient came in complaining of. This does not of cour[s]e, mean that I have cured the disease.

On direct examination, he testified (Tr. 1572):

Q. Now, I will ask you, Doctor, whether, on the basis of your clinical investigation, plus your general education, training and experience, you can express a view as to whether Preparation H alone and without the conservative adjuncts involved in your program, would have the same beneficial effect on symptomatic hmorrhoids as you have testified it would have as part of your conservative program?

A. I think that this is a fair assumption to make.

The witness was subjected to substantial cross-examination, reading in part:

Q. Did you indicate to the patient [involved in the study] in any way that you thought that he might obtain some benefit from it?

A. Only what he might have been able to gain from his own thinking from the standpoint that I told him that this was a popularly used hemorrhoidal preparation.

Q. Do you think that this would have a psychological effect on the patient if he knew that this was a popular, broadly used preparation, that he would figure, well, if it is widely used and well-known, it must be good, do you think this effect would take place?

A. I don't think that that is really a significant attribute in a situation like this. I realize that outside of these hearings you don't have a lot of personal experience with patients who have hemorrhoids. But these are people who are quite uncomfortable, and if they are uncomfortable they are going to let you know about it, and if what you give them does not help, they are going to let you know about it, and then want something else. Because this is something that can make your life miserable (Tr. 1577–78).

* * * * * * *

Q. But at the same time you admit, do you, Doctor, that knowing what the drug is and knowing that every patient is getting the same drug would have a tendency to bias you in favor of the drug that was being used?

A. I don't know whether that is a fair statement on your part, sir, because I think we try to approach any of these studies with an unbiased attitude. There is no point in me or anyone doing clinical investigations, if you are going to merely turn out testimonial. I think it is more important to know whether an agent does not work or whether it has problems with side effects and the like than it is to know whether the drug is basically efficacious (Tr. 1580).

* * * * * * *

Q. So that you would say that this study that you did on Preparation H was not the best type of scientific approach, is that right?

A. This is again a difficult question to answer. I think it is difficult for you to answer it as well. As far as the study itself is concerned, the technique that we used with this study was a matter of evaluation of whether the drug was efficacious in this particular type of patient. This is what we were asked to determine, and we did this in an unbiased fashion.

You also must take into account that any study and the one that you will hear about later were done with private patients. And I have a responsibility to my patients to make him comfortable. And if I felt that the agent that I was using would not help render him comfortable I don't think we would have gone into this (Tr. 1581).

* * * * * * *

Q. Doctor, do you feel that the patients would have had any bias with regard to the results that they reported to you? Would you think that the patients would be anxious to come up with positive findings, since they were trying something new?

A. I think that the patients would only be anxious to come up with an improvement in their problem. They don't have to satisfy me from this standpoint (Tr. 1583).

* * * * * * *

Q. You have done clinical investigations of work before, have you not?

A. Yes.

Q. And you have undoubtedly prepared yourself for that by reading in the field, is that right?

A. I have read in the field, yes.

Q. And in your readings have you come across any data or studies or reports of the psychological effect that I am speaking of?

A. Yes, these things appear in the literature, I think, with regularity with people who write review articles with respect to clinical investigations. But this is a very difficult thing to measure. And this is such a difficult entity to assay.

Q. Without measuring it do you feel that it exists?

A. In all likelihood it does (Tr. 1584–85).

* * * * * * *

Q. And, Doctor, you stated that in your opinion hemorrhoids includes the

whole picture. Now, by that do you mean the perivascular tissue that surround the dilation or varicosities that constitute the hemorrhoids.

A. I think that it is very difficult from a clinical standpoint sir, to merely say that hemorrhoids are the dilated venul or the varix, when most people discuss hemorrhoids they are talking about a clinical entity. That is what the patients tell you what is bothering them, plus what the physician has the opportunity to observe.

Q. But as a physician do you not consider that the varix and the edema, the swelling, and so forth, are secondary, they are two separate disease entities or three separate disease entities?

A. No,—unless we are having differences in semantics here. I think that the hemorrhoid—the peri-hemorrhoidal inflammation, the swelling, the edema, the evidences of infection, are all basic[al]ly part of the same clinical entity . . . (Tr. 1593).

* * * * * * *

A. My training and medical, personal medical philosophy, leads me to steer away from injection therapy. I try to avoid it if I can.

Q. Do you refer patients for injection therapy?

A. I personally, have never done so (Tr. 1595).

* * * * * * *

Q. You stated on direct testimony, Doctor, that your method of treatment that you described as being a conservative method was the standard, recommended treatment. Now, whose standard and who recommended it?

A. Well, I think that is not a project of my own thinking, this was what you get from reading medical literature with respect to the conservative management of hemorrhoidal disease. For example, if you pick up Eddie Palmer's text of clinical gastro-enterology you will find that he states that a very high percentile of hemorrhoids are ameanable to conservative therapy (Tr. 1595–96).

* * * * * * *

Q. In your opinion has this program of therapy produced any cures of hemorrhoids?

A. Mr. McMahon, there is only one way to cure hemorrhoids.

Q. And what is that, Doctor?

A. And that, sir, is to remove them surgically.

I would like to elaborate a little further along those lines, because I think it is germane to the present discussion. When you say "cure" you are merely referring to the situation as it exists today. This does not mean that the surgical removal of hemorrhoids today will prevent the patient from developing the disease in the future, because according to the experts in this field—and I don't pass myself off as an international expert by any manner of means—but according to the experts, there is a high incidence of recurrence of t[h]is disease (Tr. 1597).

* * * * * * *

Q. In relating your subsequent experience with Preparation H,—and by "subsequent" I mean since the study—you indicated that you used Preparation H with some patients. Can you estimate how many patients you have used this with?

A. I would venture to say this might be in the neighborhood of possibly ten to 30 more.

Q. And what other medications of this type do you prescribe, that is, ointment or suppositories?

A. I occasionally use Wyanoid, Anusol, and rectal Medicone—I use, for example, in getting the patients samples in the office, that product which might be currently present that the detail man left, which aids the patient as well financially (Tr. 1608).

* * * * * * *

Q. In response to a series of questions from Mr. Murphy eliciting your opinion as to the efficacy of Preparation H in several categories, you stated that it had been your experience that Preparation H did reduce hemorrhoids in size, is that correct, Doctor?

A. I think that is substantially correct, yes, sir.

Q. Now, how would you account for this reduction in size?

A. I think the reduction in size is due to the elimination of secondary problems, the protective effect that the liver oil adds, possibly to the ability of the Biodyne to affect the metabolic activity of the local tissue, as well as the fact that there is time as an interval.

Q. Now, first of all, Doctor, you are assuming, are you, that the effect of the Biodyne or shark liver oil would cause this reduction in size?

A. I think the reduction in size is primarily the nature of the body's healing process, sir, which has been aided and abetted by the therapy.

Q. Wouldn't the same thing happen if you let the hemorrhoid alone?

A. That is conceivable. I don't know whether it would happen as rapidly or as simply. That is a very difficult question to answer.

Q. You mentioned the factor of time, Doctor. Would you say that this is of equal importance with the ointment or the suppository?

A. Again, this is difficult to quantitate, because some patients in time don't improve. Some patients will improve in time on a program of this type, or any other similar type of conservative program (Tr. 1612–13).

* * * * * * *

Q. If it is the nature of the hemorrhoids to come and go, you mean that this will occur spontaneously?

A. This can occur spontaneously, and it may not occur spontaneously. And I think all therapy in medicine is merely aimed at aiding the body with its own healing processe[s]. I don't think anybody who practices medicine says that "My treatment is solely responsible for your improvement," it is a matter of aiding and abetting a whole picture. You treat the patient, sir, as a whole, and not as a single disease entity (Tr. 1613–14).

* * * * * * *

Q. What does Preparation H do that cause the pain to be relieved?

A. I think it reduces some of the inflammation and infection.

Q. And how does it accomplish that, Doctor?

A. By its protective action on the area, and possibly by cutting out the infectious element, and by protecting it with its oily base, the entire gamut of what is purported to be the therapeutic effect of the ingredients.

Q. What is purported to be the effect of the therapeutic ingredients, is that what you said, Doctor?

A. Yes, sir.

Q. But not what you know of your own personal knowledge?

A. I think I have said so to that effect.

Q. Again your opinion is based on assumption, is it not?

A. And my own observations, sir.

Q. But your observations simply show the results?

A. Yes (Tr. 1616–18).

* * * * * * *

Q. You stated, Doctor, that it was your opinion that with the use of Preparation H alone, and without the conservative adjunctive therapy that you usually prescribe, that you would obtain the same benefits in your patients as had been obtained with the conservative therapy, is that right?

* * * * * * *

A. I think that this is a fair statement to make (Tr. 1620).

* * * * * * *

Q. My question is this, Doctor. Then why do you prescribe this conservative adjunctive therapy?

A. Because anything that you can do to aid and abet a patient's rapidity of improvement to remove annoying other problems is just an extra added attraction in getting a patient to feel better more rapidly, sir.

Q. But if you are going to achieve the same result with Preparation H alone, why bother the patient with the other procedure?

A. We are going into the matter of medical philosophy now. And I think the philosophy is that if you feel that there is some etiological factor involved you try to remove the cause as well. For example, if perchance I treated a patient—and this is strictly hypothetical now—if perchance I treated a patent with hemorrhoidal disease whom I felt had hemorrhoids strictly as the result of poor bowel habit and chronic constipation, I would treat the hemorrhoids. And at the same time I would make every effort to get the bottom of the bowel habit problem so that he could ameliorate this, specially with respect to the future, because as we both have discussed before, and we both agree, this is a disease that can recur with rapidity and regularity (Tr. 1620–21).

Dr. Isaacson, a general surgeon with a "special interest in Proctology," is certified by the American Board of Surgery. In addition to carrying on his private practice, he is a Clinical Instructor in Surgery at George Washington University Medical School. He sees between 150 and 200 hemorrhoid cases in a year, and he estimates that between two-thirds and three-quarters of those patients come to him on referral from other physicians (Tr. 1651–54). As to those that come from other physicians, he testified (Tr. 1654):

A. Under two circumstances—those that come from general practitioners or internists who would come after they have been tried on a conservative

regimen, and then referred to me for either continued care or surgery. The others would come from specialists who are in a limited field, such as ear, nose and throat man, cardiologist, who would not undertake the care of hemorrhoids even from its initial onset, and those would be referred to me directly.

About one-third of his cases are subject to hemorrhoidectomies. In terms of severity and complications, he assumes that the cases he sees and treats are probably a little more severe compared with the cases a general practitioner or internist is apt to see (Tr. 1654). As to the type of hemorrhoid cases in which surgery is the indicated method of treatment, he said (Tr. 1656):

A. The patient who, because of severe bleeding, comes in with a significant anemia, that patient should have surgery. A patient who has a condition called srangulated hemorrhoid, in which the hemorrhoid, particularly internal hemorrhoids, has prolapsed through the sphincter muscle, grasped by the muscle, and its return flow impeded, and who is in imminent danger of getting gangrene of the hemorrhoids. A patient who has a significant amount of prolapse of his hemorrhoids, in which they push out, either requiring manual implacement at the time of a bowel movement or which are irreducible at the time of prolapse, should be subjected to surgery.

The patient who comes in with a large thrombosed hemorrhoid usually has office surgery. A thrombosed hemorrhoid is a clot within an external varix just beneath the skin, and this can usually be evacuated and give the patient symptomatic relief.

Beyond this, the indications for surgery become nebulous. If you cannot relieve symptoms by other methods, or relieving symptoms, have the patient come back repeatedly with recurrences, then these patients should probably have surgery.

With reference to treatment of the two-thirds of his patients who do not have surgery, Dr. Isaacson said (Tr. 1656–57):

A. Well, they are given dietary instructions, they are taught to avoid spices and alcohol, which will irritate the rectum on evacuation. They are usually given a bowel softener, such as mineral oil or colase, which keeps the bowel relatively soft. They are given Sitz baths, which consists of soaking in a hot tub of water two or three times a day and they are usually given a local ointment or suppository.

As to the effects of such therapy, he says that "Approximately two-thirds will get symptomatic relief, at least for a time," and that such treatment can succeed in avoiding the need for surgical treatment, "at least temporarily" (Tr. 1657). In 1961, through Dr. Jerome Epstein, he agreed to participate in a clinical investigation of Preparation H. He identified RX 6Z8 through RX 6Z93 (eighty-six cases) as the forms filled out by him of the subjects involved in the study. When a patient was seen, the doctor's ob-

servations or remarks were entered on the patient's chart, which were later noted on the form (Tr. 1663). On the initial contact with the patient in the course of the investigation, the patient was put on a bland diet and given a bowel softener. The patient was supplied with the ointment or suppositories in containers which did not reveal the name of the product. There were printed instructions on the tubes or boxes as to the use of the product, and, in addition, the patient was told verbally to apply it morning, evening, and after each bowel movement (Tr. 1662). The patient was also told that this ointment or suppository was reported to be pretty good (Tr. 1661). The records show that each subject was treated two to four times following the initial visit, such visits usually being spaced three to seven days apart (RX 6Z8–RX 6Z98). Twenty-six of the eighty-six patients employed in the study required hemorrhoidectomies. Since the conclusion of the investigation, Dr. Isaacson has used Preparation H in his practice. Based on the study and subsequent experience, Dr. Isaacson expressed the opinion that Preparation H "is a safe and effective remedy in the treatment of mild and moderate hemorrhoids and can render the patient symptomatic free after local application," and that it can relieve pain where pain is present as a symptom of hemorrhoids (Tr. 1667). As to whether Preparation H will reduce hemorrhoids in size, he stated (Tr. 1668):

A. A hemorrhoid is a varicose vein, and because of secondary edema and swelling and inflammation they increase in size due to that. The application of Preparation H can reduce the secondary swelling, the secondary edema and inflammation. It cannot reduce the size of the hemorrhoid and no preparation, I believe, can except surgery.

To the question, "When you are treating a patient for hemorrhoids, Doctor, do you find that you are required to treat only that dilated or varicose vein, or are you called upon to treat a hemorrhoids as a complex of things?", he replied (Tr. 1668):

In most cases, you are treating the complex, or the secondary inflammation of the hemorrhoid. Probably the majority of people over the age of 20 have hemorrhoids, and yet by the same token, the majority of people are not symptomatic from these hemorrhoids.

Dr. Isaacson testified that prior to the study he had the opinion or impression that Preparation H "was no good" (Tr. 1659), and he explained the basis of such an opinion: "I think that I was seeing the patients who were failures with Preparation H, just as we had failures in this study" (Tr. 1667). Dr. Isaacson also said

that he had hemorrhoids, and for their treatment, "Lately I have been using Preparation H" (Tr. 1670). On cross-examination, the witness testified:

Q. Considering the procedure and protocol that was employed in this present test, and on the basis of your experience in these two previous studies, plu[s] what you have just said regarding double blind studies, do you consider this test of Preparation H in which you participated to be a valid scientific study?

A. I believe you can form an impression from the study, as I have. Had this been a double blind study, the impression of course would have been on firmer ground.

Q. Well, do I take it, then, Doctor, that your testimony is that despite the conclusions which you have expressed, that you do not consider them to be based on real firm ground?

A. I believe that on the basis of this study I can form an impression, as I have, and I have actually recommended to the company that a double blind study should be performed to eliminate the variables.

Q. So you feel that this study had deficiencies, is that correct?

A. Yes, sir.

Q. And making it a double blind study, would this be the only change that you would suggest if you were to devise a procedure?

A. Yes. There might be a few minor changes in the protocol, but this would be the major change that I would make in an investigation of this drug.

Q. Now, in telling your patients about the use of the ointment or suppositories that had been furnished to you for this test, you did not tell them that it was Preparation H, if my notes are correct.

A. I did not.

Q. You did say, however—if I am not mistaken—that it was reported to be pretty good.

A. Yes, sir.

Q. Do you feel that this had any influence in terms of a psychological effect on the patients?

A. I think it's possible.

Q. Did you see any evidence of that?

A. I would not know what evidence would indicate to me that this was a major factor (Tr. 1673–74).

* * * * * * *

Q. Do you feel, Doctor, that with a bowel softener and a Sitz bath taken frequently, and diet, that if this treatment were supplemented by any emollient or lubricant type of ointment or suppository that you could achieve the same results that were achieved here with Preparation H?

A. Are you talking about similar preparations or are you talking about just a bland vaseline?

Q. Well, let's start with the vaseline.

A. My impression would be that it would not. I think that hemorrhoids, given diet, a bowel softener, Sitz baths, will in time become asymptomatic without the use of any preparation. I would not expect the subsidence of

symptoms to be quite as rapid as it was with the use of Preparation H in this study (Tr. 1675–76).

* * * * * * *

Q. Doctor, you have used the term "impression" several times. Now, would you differentiate for me, please, between your use of the word "impression" and your use of the word "opinion"?

A. An impression is an intelligent opinion. For instance, if you come into me with a variety of symptoms, I can make an impression of your diagnosis. I can prove that diagnosis with a series of tests. For instance, if you come to me with upper adominal pain, particularly after eating, my impression is that you have an ulcer. That's an opinion. When I confirm this with an X-ray of your stomach, that you have an ulcer, I now have a diagnosis.

By the same token, in this study I can only give you an impression, since there was not a control study, as you pointed out. These patients were given the ointment. On the basis of my previous experience with a similar type of case, I achieved results that I thought were superior than no treatment or with just diet and mineral oil alone.

Had I alternately given patients, say, simply a suppository of no therapeutic result, and achieved significant differences, then I would have a much firmer conclusion, rather than just an impression.

Q. Well, now, in response to Mr. Murphy's series of questions, soliciting your opinion, were these firm opinions, Doctor, or were these impressions?

A. These are firm opinions (Tr. 1676–77).

* * * * * * *

Q. . . . You stated that it was your opinion, then, that Preparation H would relieve pain associated with symptomatic hemorrhoids.

A. That's correct.

Q. How do you explain this affect, Doctor?

* * * * * * *

THE WITNESS: I cannot explain it. I can only tell you the results we obtained. In a certain series of cases, as I can see by read[ing] over these 86 cases, there was relief of pain (Tr. 1678).

* * * * * * *

Q. Well, then, Doctor, is it your opinion that the active ingredients in Preparation H are responsible for the rapidity of the relief?

A. I would have to say yes (Tr. 1678).

Dr. Berkowitz, a physician specializing in gastroenterology, is an Associate Professor of Medicine at Hahnemann Medical College, attending Chief in Gastroenterology at the Albert Einstein and Sidney Hillman Medical Centers in Philadelphia, and a member of the Board of Internal Medicine and Gastroenterology. In addition to his medical degree, he has a Master of Arts in biochemistry and a Master of Science in biochemistry (RX 76A–G; Tr. 1075–1080). In the course of his practice, he has maintained his interest and experience in biochemistry, and several of his cur-

rent projects are concerned with biochemical studies. Recently he was elected as a member and a Fellow of the American College of Clinical Pharmacology and Experimental Therapeutics. Dr. Berkowitz said the requirements for such an election were (Tr. 1078):

A. . . . You have to have first completed certain professional requirement, and secondly, you have to have been actively engaged in and published meritorious works in the general field of clinical evaluation. (RX 76A–G; Tr. 1075–1080.)

He estimates that he sees annually between 200 and 250 patients who have active symptoms of hemorrhoids, and during the past year he has referred four or five patients to a proctologist or to a general surgeon for the reason that the patients needed some type of treatment other than what he could do conservatively (Tr. 1080–82). As the principal symptoms and signs of hemorrhoids, he said (Tr. 1082–83):

A. Well, I think the principal symptoms and signs are pain, bleeding, itching, spasm, problems with defecation, and various types of feelings, such as pressure in the rectum, or a bearing down sensation in the rectum, and possibly a discharge may be a symptom.

The signs of hemorrhoids that I would see would be evidences of the hemorrhoid itself, evidences of spasm, evidences of discharge, of spasm, and evidences of the results of itching.

As to the treatment employed by him of patients with hemorrhoid problems, he said (Tr. 1085):

Well, first I try to correct any precipitating cause that I can find. For example, if they have diarrhea, I try to treat their diarrhea. If they are constipated, I try to improve their bowel habits.

Secondly, I prescribe good anal hygiene.

Thirdly, I would prescribe the use of Sitz baths, and fourthly, I would prescribe the use of some local rectal medication, either ointment or suppositories.

He explained the results of such treatment (Tr. 1086):

Well, I have achieved excellent results as evidenced by the fact that I have only found it necessary to refer a few people to—for surgical treatment.

Through discussions had with Mr. Basil Candon, Assistant to the Medical Director of Whitehall Laboratories, Dr. Berkowitz undertook and performed a clinical study of Preparation H (Tr. 1087). Mr. Candon, who has a Master of Science degree in the field of Histology and Physiology, testified that Dr. Berkowitz was requested to undertake the study of approximately 100 cases

in August of 1963, which was designed as a double blind evaluation of Preparation H, "a technique in which neither the investigator nor the patient knows the specific drug that he is receiving," which "has been employed to eliminate bias on the part of the patient or on the part of the physician in charge of the study" (Tr. 1040–41). The products employed in the study were Preparation H ointment and Anusol Unguent, and Preparation H suppositories and Anusol suppositories (Tr. 1041). As to why Anusol was used in the study, as well as Preparation H, he explained (Tr. 1041–42):

> On the basis of experience in setting up clinical studies, we frequently use a reference drug for comparative purposes and we selected anusol on the basis of an independent marketing report which is provided us at regular intervals, which indicated that anusol was the most—was the drug most widely used by physicians—used or recommended by physicians for the treatment of anorectal diseases.

On cross-examination Mr. Candon further explained the basis for the use of Anusol as a comparative product (Tr. 1053):

> Well, standard procedure in recent years in the evaluation of drugs—a reference drug is usually used. Now, that reference drug may be a placebo or it may be an active drug. There is a school of thought that believes that the use of an established active drug as a reference drug is much more meaningful than using a placebo.

The products sent to Dr. Berkowitz and used in the study were in plain containers so as not to reveal to the doctor or the patients the name of the drug contained therein. However, there was noted on each package a code number which would serve to identify after the study the product given to the patient. The key to the code number was contained in a document (RX 7–Z267) which was sent to Dr. Berkowitz "not to be opened [until the study was completed] except in an emergency" (Tr. 1044). Dr. Berkowitz knew that the products to be used in the study were Preparation H and Anusol, but he was not given any information as to the identity of each individual package (Tr. 1042–1045). Mr. Candon identified RX 7A through RX 7Z267 as the reports of Dr. Berkowitz on 96 patients involved in his study. The following eight tables are a compilation of the results appearing on the middle of the first pages of the report forms of Dr. Berkowitz for the patients treated with Preparation H. The responses indicated on the final examination of these patients during the study were used. Identification of the cases in which Preparation H was used is made by reference to the key for the study, RX 7Z267. The re-

port forms for the patients treated with Preparation H used for these compilations and tables are: RX 7D, 7P, 7S, 7V, 7Y, 7Z2, 7Z11, 7Z22, 7Z25, 7Z28, 7Z40, 7Z58, 7Z61, 7Z67, 7Z82, 7Z88, 7Z91, 7Z94, 7Z99, 7Z101, 7Z106, 7Z108, 7Z111, 7Z117, 7Z123, 7Z126, 7Z132, 7Z140, 7Z145, 7Z147, 7Z154, 7Z156, 7Z161, 7Z169, 7Z178, 7Z181, 7Z183, 7Z185, 7Z191, 7Z199, 7Z201, 7Z208, 7Z211, 7Z213, 7Z215, 7Z220, 7Z223, 7Z236, 7Z239, 7Z241, 7Z249, 7Z252, 7Z261. The report forms of two patients given Preparation H, but who did not return for subsequent examination and observation, (7Z158 and 7Z196) were not included.

TABLE 1. NUMBER OF CASES IN WHICH RELIEF WAS AFFORDED

Symptom	*No. of cases where presented*	*No. of cases where improvement*	*No. of cases where no improvement*	*Percentage of cases where improvement*	*Percentage of cases where no improvement*
Pain	54	50	4	92.6%	7.4%
Spasm	52	48	4	92.3%	7.7%
Bleeding	48	45	3	93.8%	6.2%
Discharge	14	12	2	85.7%	14.3%
Protrusion	51	47	4	92.2%	7.8%
Edema	54	50	4	92.6%	7.4%
Pruritus (Itching)	49	46	3	93.9%	6.1%

TABLE 2. RELIEF OF PAIN: Grades of Response to Treatment

Grade of Response	*Number of Cases*	*Per Cent of Total*
"A"—Excellent—complete remission	39	72.2%
"B"—Good	5	9.3%
"C"—Fair	6	11.1%
"D"—No Change	4	7.4%
"F"—Failure	0	----
Total	54	

TABLE 3. RELIEF OF SPASM: Grades of Response to Treatment

Grade of Response	*Number of Cases*	*Per Cent of Total*
"A"—Excellent—complete remission	38	73.1%
"B"—Good	4	7.7%
"C"—Fair	6	11.5%
"D"—No Change	4	7.7%
"F"—Failure	0	----
Total	52	

TABLE 4. RELIEF OF BLEEDING: Grades of Response to Treatment

Grade of Response	*Number of Cases*	*Per Cent of Total*
"A"—Excellent—complete remission	37	77.1%
"B"—Good	2	4.2%
"C"—Fair	6	12.5%
"D"—No Change	3	6.3%
"F"—Failure	0	----
Total	48	

TABLE 5. RELIEF OF DISCHARGE: Grades of Response to Treatment

Grade of Response	*Number of Cases*	*Per Cent of Total*
"A"—Excellent—complete remission	10	71.4%
"B"—Good	1	7.1%
"C"—Fair	1	7.1%
"D"—No Change	2	14.3%
"F"—Failure	0	----
Total	14	

TABLE 6. RELIEF OF PROTRUSION: Grades of Response to Treatment

Grade of Response	*Number of Cases*	*Per Cent of Total*
"A"—Excellent—complete remission	33	64.7%
"B"—Good	8	15.7%
"C"—Fair	6	11.8%
"D"—No Change	4	7.8%
"F"—Failure	0	----
Total	51	

TABLE 7. RELIEF OF EDEMA: Grades of Response to Treatment

Grade of Response	*Number of Cases*	*Per Cent of Total*
"A"—Excellent—complete remission	40	74.1%
"B"—Good	4	7.4%
"C"—Fair	6	11.1%
"D"—No Change	4	7.4%
"F"—Failure	0	----
Total	54	

TABLE 8. RELIEF OF ITCHING (PRURITUS): Grades of Response to Treatment

Grade of Response	*Number of Cases*	*Per Cent of Total*
"A"—Excellent—complete remission	36	73.5%
"B"—Good	4	8.2%
"C"—Fair	6	12.2%
"D"—No Change	3	6.1%
"F"—Failure	0	----
Total	49	

The reports of Dr. Berkowitz in the instances where Anusol was used as the medication show that results obtained were similar to the results indicated by the foregoing tables. Dr. Berkowitz testified (Tr. 1091):

> The protocol was set up in such a way that 50 patients would be treated with a suppository, and 50 patients would be treated with an ointment, and the medication was to be dispensed in random fashion, the patients were to be instructed as how to take the ointment or the suppository. Their other medications, if they were taking them, were not to be changed. And there would be no gross departure from anything that they were doing.

In all, he studied 105 patients, but, because 9 patients did not return after the initial visit, the results were given on 96 patients (RX 7A–RX 7Z266). Of this number, 54 were treated with Preparation H suppositories or ointment. The study took approximately fifteen months, and was completed in December 1964 or January 1965 (Tr. 1091, 1102). The patients came from three sources: His private practice, the Sidney Hillman Medical Center, and the Albert Einstein Medical Center (Tr. 1092). As to the standards he employed in selecting a patient for the study, he said (Tr. 1092):

> First of all the patient must have had hemorrhoidal disease that was symptomatic enough to require treatment. And secondly, the other qualification was that he had to be a patient that I thought was intelligent enough to follow instructions. And thirdly, that I thought would come back.

The patients were not told that they were a part of the study. The record shows that in practically all instances the patients were examined by the doctor two to four times after the initial visit, the last visit usually coming the fourteenth day after the initial visit. Dr. Berkowitz stated that the suppositories and ointments sent to him and used in the study were in plain cartons, each bearing an identification number, but that there was nothing to indicate which was Preparation H and which was Anusol (Tr. 1089–1090). He also testified that the key for the study (RX 7Z267) was sent to him in a sealed envelope, and it was not opened prior to the completion of the study. On the basis of the observations that he made in the course of the study, Dr. Berkowitz testified as follows:

> . . . a significant improvement in both subjective signs and objective findings were produced in anywhere from 84 to 91 per cent of the patients [treated with Preparation H] (Tr. 1112).
>
> . . . Preparation H can certainly reduce the size of hemorrhoids (Tr. 1112–13).

. . . treatment with Preparation H was effective in reducing pain in the vast majority of patients who had pain (Tr. 1113).

. . . it was my conclusion that treatment with Preparation H could definitely render the primarily initially symptomatic hemorrhoid to a status where it was no longer a problem (Tr. 1113).

There is no doubt in my opinion that a good percentage of the patients that I saw initially, prior to treatment, would have been treated surgically had they been seen initially by surgeons (Tr. 1114).

. . . it was my impression that the vast majority of patients with itching as a symptom of symptomatic hemorrhoids had their itching relieved (Tr. 1114).

. . . it was my conclusion that Preparation H treatment was effective in reducing edema in the vast majority of patients treated (Tr. 1115).

When asked whether Preparation H would effect any relief other than the relief of minor pain or minor itch, Dr. Berkowitz replied (Tr. 1115):

Yes, sir. The patients used in my study all had major pain or major itch as a prerequisite, and if their symptoms were only of a minor nature, they were not included in the study.

On cross-examination, Dr. Berkowitz testified in part:

Q. Doctor, you stated that you had concluded, following this study, that Preparation H reduces hemorrhoids in size. Would you explain how you came to this conclusion?

A. Yes sir, I could see it. You can see the size of a hemorrhoid, and you can see whether it is bigger or smaller.

Q. Well, now, you would see a patient, we will say, today, and not see him again for a week. How did you record the size of the hemorrhoid the first time as opposed to the size the second time? Did you measure them?

A. This was a visual impression, based on my experience as to the degree of improvement in size (Tr. 1128–29).

* * * * * * *

Q. Isn't pain a subjective symptom?

A. Yes.

Q. And what is painful for me may not be painful for you?

A. That is exactly right.

Q. So that you are entirely dependent on what the patient tells you as to whether the pain has been relieved or not, is that not so?

A. Yes (Tr. 1129–1130).

* * * * * * *

Q. And if he left the hemorrhoids alone completely in a period of time wouldn't the pain go into remission spontaneously?

A. Well, I cannot answer that, because it has not been my custom to just casually observe people with symptomatic hemorrhoids and do nothing about it. So I know of no study like this. But I do think that even with no treatment, if they were to get better, it would sure take them a much longer time to get better (Tr. 1130).

* * * * * * *

Q. Now, you also stated that you had concluded that Preparation H would cause hemorrhoids to cease to be a problem. Now, did you mean that literally, Doctor?

A. Yes, sir.

Q. That once they have used a course of treatment of Preparation H, that they are free of their hemorrhoids, and they will have no more problems? Is that what you mean?

A. I did not say that exactly, sir. I said that I have seen people with symptomatic hemorrhoids that I have treated, that I have seen again three months, six months, a year later, who have no further problems.

Now, whether they will have problems a year from now or two years or five years from now, I cannot say.

Q. Are the hemorrhoids still there?

A. If you look for them, you will find a small hemorrhoid, yes.

Q. So that you have not actually cured the hemorrhoid, have you?

A. No, sir, I have not cured the hemorrhoid. I doubt if you can ever cure a hemorrhoid, except by removing it (Tr. 1132).

* * * * * * *

Q. Do I take it, Doctor, you are opposed to hemorrhoid surgery?

A. No, I think that hemorrhoid surgery is definitely indicated in certain conditions. But I am opposed to hemorrhoidal surgery in patients who can be treated medically.

Q. Well, now, if you are treating a patient medically, are you not simply forestalling the day when he is going to end up being operated on if he has a severe hemorrhoidal condition?

A. Well, sir, the facts do not bear out what you stated. Many people with active hemorrhoidal symptoms merely are having symptoms at that time because of a specific reason, and once you can get them over this, they may not be bothered again. You cannot predict that they will (Tr. 1135–36).

* * * * * * *

Q. Doctor, did you prescribe Preparation H before this test?

A. I have used it for some patients, yes.

Q. To what extent?

A. To no greater extent than I have prescribed other medications of a similar nature.

Q. Now, if Preparation H is as good as your conclusions would indicate, why would you not prescribe it for all of your patients?

A. You asked me if I had done it in the past.

Q. Yes?

A. Well, I was not aware of the results of this study in the past. You mean subsequent to this?

Q. Subsequent to this study.

A. Well, the types of medications that a doctor uses, sir, are based on many things. If it were necessary for me to prescribe an anal suppository or an anal ointment, I would probably use Preparation H, but I could not say with certainty that this would be the only one I would ever use. For example, I might find a patient who has taken Anusol before, and who has done well

on Anusol. So I would not see any particular reason they need to change it in this case (Tr 1213–14).

Dr. Lieberman, a proctologist who received his medical degree in 1928, is the director of the Department of Proctology at the Unity Hospital, Brooklyn, New York, and a fellow and president elect of the International Academy of Proctology (RX 77A–D; Tr. 1219–1224). He sees about 300 patients in a year who have active symptoms of hemorrhoids (Tr. 1224). The therapy he employs, he said, "will depend upon the type of hemorrhoid and upon the degree of severity. The usual treatments would be either conservative treatment or injection therapy, or surgical removal of the hemorrhoids" (Tr. 1225). He estimated that probably about one in ten or one in eight would fall into the latter category, and added, "This may be less than perhaps the estimates that might be given by other proctologists, because I have a tendency to shy away from surgery unless it is unavoidable" (Tr. 1226). He further testified, "The injection treatment is especially useful in internal hemorrhoids of an uncomplicated variety . . ." (Tr. 1229). In October of 1963, Dr. Lieberman undertook a double blind study to evaluate the action or lack of action of Preparation H suppositories and ointment. The medications used in the study and the procedures employed in making the study were the same as those in the Dr. Berkowitz study which has been heretofore related (Tr. 1045–1057; 1230–35). The patients selected for the study, 100 in number, were from Dr. Lieberman's practice, and a few were taken from the clinic at Unity Hospital. He chose those who had moderate to severe hemorrhoids as against the milder types (Tr. 1235). When asked how he determined what type of medication he would give to any particular patient, he stated (Tr. 1240):

I would first decide after examination whether I wanted to use a suppository or ointment. And as I said, I have a leaning toward suppositories rather than ointments in the treatment of hemorrhoids, although I am far from denying that there is a place for each of these modalities. However, I would decide which one to use according to the findings. And usually my feeling in the matter is that if the pathology was external or easily in reach of the patient, very near the external opening, I would tend to use the ointment. If it was internal, I would be more likely to use the suppositories. I also felt that suppositories had some additional benefits in every case which also made me lean more toward them.

He told the patients (Tr. 1243):

. . . to use the ointment or suppositories in the morning, in the evening, and

following each bowel movement, or more often if he desired it in case of pain or if the symptoms were particularly severe on each particular date, but a minimum of twice to three times a day per patient.

* * * * * * *

I told him [the patient] to continue with whatever treatment he was giving himself at the time, questioning him of course on what treatment this was. And this would usually be limited to perhaps taking mineral oil, if he was constipated, sitz baths in some cases, the patient might give it to himself, and watching his diet to avoid spicy foods, which sometimes patients do [of] their own accord. In other words, I told them to continue with any of these simple measures if he was already doing so, but didn't instruct him to do if he was not doing it.

The study was conducted over a period of 12 to 16 months (Tr. 1251). The keys for the study (RX 8Z175 and RX 8Z176) were received by Dr. Lieberman in a sealed envelope which he did not open prior to the time the study was completed (Tr. 1234). Respondent's Exhibits 8A through 8Z176 were identified in the reports made by Dr. Lieberman (Tr. 1045, 1230). The following eight tables are a compilation of the results appearing on the middle of the first pages of the report forms of Dr. Lieberman for the patients treated with Preparation H. The responses indicated on the final examination of these patients during the study were used. Identification of the cases in which Preparation H was used is made by reference to the keys for the study (RX 8Z175 and RX 8Z176). The report forms for the patients treated with Preparation H used for these compilations and tables are: 8C, 8K, 8M, 8O, 8Q, 8S, 8Y, 8Z9, 8Z11, 8Z19, 8Z31, 8Z33, 8Z35, 8Z41, 8Z45, 8Z47, 8Z49, 8Z55, 8Z61, 8Z63, 8Z65, 8Z67, 8Z73, 8Z75, 8Z81, 8Z85, 8Z87, 8Z93, 8Z95, 8Z97, 8Z99, 8Z101, 8Z103, 8Z107, 8Z109, 8Z121, 8Z123, 8Z129, 8Z131, 8Z133, 8Z139, 8Z143, 8Z145, 8Z149, 8Z157, 8Z163, 8Z169, 8Z171. The report forms of two patients given Preparation H, but who did not return for subsequent examination and observation, (8Z7 and 8Z51) were not included.

TABLE 1. NUMBER OF CASES IN WHICH RELIEF WAS AFFORDED

Symptom	*No. of cases where presented*	*No. of cases where improvement*	*No. of cases where no improvement*	*Percentage of cases where improvement*	*Percentage of cases where no improvement*
Pain	29	25	4	86.2%	13.8%
Spasm	6	6	0	100%	----
Bleeding	32	30	2	93.8%	6.3%
Discharge	8	8	0	100%	----
Protrusion	24	19	5	79.2%	20.8%
Edema	26	25	1	96.2%	3.8%
Pruritus (Itching)	7	7	0	100%	----

TABLE 2. RELIEF OF PAIN: Grades of Response to Treatment

Grade of Response	*Number of Cases*	*Per Cent of Total*
"A"—Excellent—complete remission	13	44.8%
"B"—Good	10	34.5%
"C"—Fair	2	6.9%
"D"—No Change	3	10.3%
"F"—Failure	1	3.4%
Total	29	

TABLE 3. RELIEF OF SPASM: Grades of Response to Treatment

Grade of Response	*Number of Cases*	*Per Cent of Total*
"A"—Excellent—complete remission	0	----
"B"—Good	4	66.7%
"C"—Fair	2	33.3%
"D"—No Change	0	----
"F"—Failure	0	----
Total	6	

TABLE 4. RELIEF OF BLEEDING: Grades of Response to Treatment

Grade of Response	*Number of Cases*	*Per Cent of Total*
"A"—Excellent—complete remission	14	43.8%
"B"—Good	13	40.6%
"C"—Fair	3	9.4%
"D"—No Change	2	6.3%
"F"—Failure	0	----
Total	32	

TABLE 5. RELIEF OF DISCHARGE: Grades of Response to Treatment

Grade of Response	*Number of Cases*	*Per Cent of Total*
"A"—Excellent—complete remission	2	25.0%
"B"—Good	3	37.5%
"C"—Fair	3	37.5%
"D"—No Change	0	----
"F"—Failure	0	----
Total	8	

TABLE 6. RELIEF OF PROTRUSION: Grades of Response to Treatment

Grade of Response	*Number of Cases*	*Per Cent of Total*
"A"—Excellent—complete remission	2	8.3%
"B"—Good	9	37.5%
"C"—Fair	8	33.3%
"D"—No Change	5	20.8%
"F"—Failure	0	----
Total	24	

TABLE 7. RELIEF OF EDEMA: Grades of Response to Treatment

Grade of Response	*Number of Cases*	*Per Cent of Total*
"A"—Excellent—complete remission	5	19.2%
"B"—Good	14	53.8%
"C"—Fair	6	23.1%
"D"—No Change	1	3.8%
"F"—Failure	0	----
Total	26	

TABLE 8. RELIEF OF ITCHING (PRURITUS): Grades of Response to Treatment

Grade of Response	*Number of Cases*	*Per Cent of Total*
"A"—Excellent—complete remission	4	57.1%
"B"—Good	2	28.6%
"C"—Fair	1	14.3%
"D"—No Change	0	----
"F"—Failure	0	----
Total	7	

Based on the study and his general experience, Dr. Lieberman gave the opinion that Preparation H "is effective in the treatment of hemorrhoids, to varying degrees in various cases" (Tr. 1251); "It would have an ameliorative effect upon pain in many cases to varying degrees" (1252); and that "the hemorrhoids were reduced in size . . . in varying degrees in different cases" (Tr. 1252). He stated that it would improve the itching in a number of cases to varying degrees, and "could render a patient asymptomatic of hemorrhoidal symptoms" (Tr. 1254). On cross-examination, Dr. Lieberman testified in part:

Q. . . . When you dispensed the ointment or suppository to the patient, you gave it to him with some instructions. How did you know the patient followed out your instructions?

A. Several ways. First, the patient would tell me, the fact that I would inquire of him what he had done, whether he had followed the instructions and the patient would inform me that he had.

Secondly, it is so rare for a patient to come—its practically unheard of for a patient to come and receive medication from a doctor and then not use it.

Q. This is a matter of your opinion, is it not?

A. Yes (Tr. 1271–72).

* * * * * * *

THE WITNESS: It is unheard of—I won't say it has never happened with psychotics or bad neurotics that they wouldn't take the medication, but there would be some reason for investigating his mental state if he continue to come to the doctor and doesn't take his medicine because I am sure any of us can assume that when a patient comes to a doctor, he is sincere in his desire

to get well and looking for aid and he is definitely going to try the medication.

It's true he might stop after a while if he doesn't have good effect but it's simply taken for granted, especially by a doctor, that the patient is taking the medicine. We don't go home with him and feed him the medicine. This is just taken for granted (Tr. 1273).

* * * * * * *

Q. Well, now, did you feel you were doing the most that you could for the patients who came to you in pain and discomfort by offering them a suppository or an ointment?

A. Definitely, yes.

Q. Would you treat your regular office patients in the same fashion?

A. In most cases, I would.

Q. Simply give them a suppository or ointment and say that this will relieve the problem?

A. Of course, because the ointment or suppository would very likely relieve the pain that the patient had.

Q. You don't ever prescribe any adjunctive treatment to your patients?

A. Yes, I do, in general, but in order to do a test, we have to have some sort of basic ground rules and since the period of the test is a very short time, two weeks, I could afford, and the patient could afford, to use the simple treatment first, because in many cases, the simple treatment was enough to give him relief (Tr. 1276).

* * * * * * *

A. By what method I can cure hemorrhoids?

Q. That's right.

A. First of all, the word "cure," as we ordinarily use it, as used in your question, is a very hazy matter. In fact, in hospital records, even when we operate upon a patient, we shy away from using the word "cure" because we feel that would be more like a God-like prerogative to claim you have cured a patient and use the word absolutely in terms of a hundred per cent. We always mark that a patient has been improved, even if we may personally feel that he is cured. We say "improved." That's for modesty and self-protection, more or less.

Q. When you do a hemorrhoidectomy and remove hemorrhoidal tissue from a patient, do you consider that he has been improved?

A. We mark it down on the chart that way. As I said, in many cases, I may personally feel that he has been cured but the word cured, but would you use that word if, a few years later, he gets a recurrence? So we don't know in advance, not being able to look into the future, whether he was really cured in the absolute sense of the word. We always say "improved" even though we like to feel personally that we have cured him.

Q. What would your comment be if I told you the record in this case shows testimony from nine Board-certified proctologists who say that hemorrhoids are cured by surgical excision?

A. They are looking at the matter in a rather narrow form. I would disagree with them (Tr. 1286–87).

* * * * * * *

THE WITNESS: . . . On my examination, I could still see that hemorrhoids were present. We removed his symptoms in the case of a disease like hemorrhoids that is tantamount to a cure because almost every one will have hemorrhoids at some time in his life. Frequently, this is without knowing it. You and I, if we were examined, I think that a proctologist would probably find some hemorrhoids.

But you don't feel that we have hemorrhoids in the sense of hemorrhoids with symptoms. When a man says he has hemorrhoids or piles, he usually means symptoms of hemorrhoids because actually, most of us do have hemorrhoids in a quiet state which may give us no trouble, so this man was cured from his point of view. From my point of view, I could still see hemorrhoids. But that was of no importance. It's not a serious disease. It's a minor condition if it doesn't give you trouble and most of us live out our lives without knowing we had it.

The statistics are, I believe, that most of us will have hemorrhoids at some time in life and probably 50 per cent of the population will have hemorrhoids with symptoms at some time in his life, so this man would be cured, to all intents and purpose, that is cured with quotation marks around it, because of the possible double meaning of the word.

A Proctologist would examine him and see piles. The patient could consider himself as cured and to all intents and purposes, he is tantamount to cured (Tr. 1287–88).

The respondent called four medical witnesses who, in the course of their practice, treat a substantial number of hemorrhoidal cases. None of them perform surgery or give injection treatments.

Dr. Frederick Steigmann, a physician who has been in the practice of medicine since 1933 and specializes in internal medicine and gastroenterology, is a Diplomate of the Board of Internal Medicine and Gastroenterology. He is the director of the Department of Therapeutics and Chief of the Gastrointestinal Section of Cook County Hospital—a hospital with approximately 3,000 beds located in Chicago, Illinois. He also serves as Associate Clinical Professor of Medicine at the University of Illinois, College of Medicine, and Professor of Gastroenterology of Cook County Graduate School of Medicine (RX 71A; Tr. 808–813). Dr. Steigmann sees about 200 patients a year with active symptoms of hemorrhoids (Tr. 814), of which number approximately 25% end up being operated on (Tr. 825). He testified that the kinds of emollient substances he prescribes and uses for hemorrhoid cases are mostly Nupercarnal, Medicoe and Anusol ointment or suppositories. He does not prescribe Preparation H, "Because as a rule we do not prescribe so-called proprietary preparations which we are not familiar with"; and he added, "I was not familiar [with Preparation H] except from what patients have been telling me

that they used the preparation, but I didn't know what it was" (Tr. 831). He also stated, "They told me they have used the preparation, and they got good results at the time of their use" (Tr. 823).

Dr. Fred J. Phillips, a physician who obtained his medical degree in 1943, is engaged in the general practice of medicine, and has an association of two other general practitioners, a surgeon and himself at Quakertown, Pa. During the past two years, he has seen and treated approximately 100 patients with symptomatic hemorrhoids, and only one of such cases required surgery. In the treatment, he almost invariably uses a steroid ointment or a suppository that he made up from his own formula (Tr. 835–843). He never prescribes Preparation H, explaining (Tr. 852):

> There is a very simple reason. I never prescribe anything that can be sold over the counter. As a physician, I think this is not good for me in my practice.
>
> * * * * * * *
>
> I feel that if a patient can buy something over the counter without a prescription, they are probably wasting money coming to me in the first place.

He also added (Tr. 845):

> A number of the patients that have used Preparation H without it being prescribed by me, they have bought it themselves in the drug store, have told me they have been quite satisfied with the results that they have had with it. I wouldn't propose to change their way of taking care of themselves. These people have been found to have hemorrhoid perhaps on an examination for insurance, an internal hemorrhoid which is entirely symptom-free to them, and they will use an ointment or a suppository that they purchase over the counter, with no ill effects whatsoever.

Dr. Russell John Sacco, who received his medical degree in 1947, has been engaged in the general practice of medicine since 1962 at Kinnelon, New Jersey. In the course of a year, he sees and treats about 250 people suffering from hemorrhoids, and in the three year period he has not sent any one of his patients on for a hemorrhoidectomy or for injection treatment (Tr. 864–69). Dr. Sacco said that he does not give nor prescribe Preparation H ointment or suppositories, but that he gives his patients samples that he has in his office and "this seems to be adequate enough to tide them over the [ir] acute phase" (Tr. 881).

Dr. Harold S. Feldman, prior to a medical degree which he obtained in 1949, received a degree of Bachelor of Science in Pharmacy in 1939, a Master of Science in Pharmacy in 1942, and Doc-

tor of Philosophy in Medical Sciences with a Major in Pharmacology in 1945. In addition to carrying on his general practice of medicine in Livingston, New Jersey, where he has been for approximately thirteen years, he is a Clinical Instructor in the New York Medical College and an instructor in Psychopharmacology at Seton Hall Medical School (RX 72A–D; Tr. 887–891). He treats about 100 to 150 patients with symptomatic hemorrhoids in a year, and in the past thirteen years he has sent only one hemorrhoid patient to surgery (Tr. 894). The testimony of Dr. Feldman does not reveal the names of the ointments or suppositories that he employs in the treatment of his patients.

All of the four doctors just mentioned testified in substance that, in the course of the treatment of patients suffering from hemorrhoids, they prescribe stool softeners, hot Sitz baths, and ointments or suppositories; that the results they have achieved with such treatment have been very good; and that, based on their experience, the use of ointments or suppositories in the treatment of hemorrhoids in a vast majority of cases succeeds in reducing the swelling, relieves the pain, and stops the itching, where such symptoms are present due to hemorrhoids.

Dr. Arthur Grollman of Dallas, Texas, called as a witness by the respondent, based upon his curriculum vitae, has had an impressive career in the field of medicine and pharmacology. Complaint counsel, in his reply to respondent's proposed findings, refers to Dr. Grollman as "an internationally recognized authority on pharmacology" and "the author of a textbook on pharmacology ["Pharmacology and Therapeutics"] which is used as a standard reference throughout the United States" (CRB, p. 13). Prior to the time he obtained his medical degree in 1930, he received a degree of Doctor of Philosophy in Chemistry in 1923. In the course of his career, he has on many occasions appeared as an expert witness on behalf of the Food and Drug Administration in proceedings of various types, and once for the Federal Trade Commission. At the present time, in addition to practicing medicine, principally as a consultant, Dr. Grollman is a Professor and Chairman of the Department of Experimental Medicine of the Southwestern Medical School of the University of Texas (RX 83A–L; Tr. 1750–54). Dr. Grollman in his testimony explained how a topical medication, which does not contain a local anesthetic, might relieve the symptoms of pain, swelling, itching, and other symptoms which may be involved in a symptomatic hemorrhoid (Tr. 1763) :

Well, in the first place, it protects the surface. Any emmolient substance will protect the surface and that in itself has a soothing effect, such as you apply petroleum, for example, on a superficial abrasion. It protects from the air and that has a symptomatically, at least, has an emmolient and soothing action. The use of oils from time immemorial on the surface of the skin is based on this action. In addition, of course, if they do penetrate and do exert a specific effect by overcoming the inflammation and the infection, this would obviously get at the root of the cause of the symptoms.

Dr. Grollman expressed the view that only a very small portion of the people—one per cent or less—who were affected with symptomatic hemorrhoids were subjected to surgery (Tr. 1791). On cross-examination, he said in part:

Q. Do you know of any drug or combination of drugs, Doctor, that will cure varicos[e]veins when applied to them?

A. I know of no method, drug or otherwise, that might be said to be really a cure for a varicose vein.

HEARING EXAMINER JOHNSON: How about surgery?

A. I wouldn't even call it that. That is a cure in the sense of removing the object, such as a bad infection of the hand where you would cut off the hand. The same is true here. You are removing a tissue. You may remove the object of the cause but I'd like to use the word cure in a pure sense, not used in that sense, sir.

By Mr. McMahon:

Q. Well, would you elaborate on that a little bit, Doctor, as to just what you mean by a cure?

A. A cure, I use that word in the sense, for example, if you have an infection, pneumonia, and you take a certain drug and that pneumonia disappears and there are no serious effects, that is a true cure of the pneumonia. On the other hand, if you have protuberant, let's say, as occurs in a prolapsed hemorrhoid and you cut it off, you are not curing it, you are just removing it and removing the tissue which happens to be obnoxious and undesirable in the pure sense, you are removing the symptom. You no longer have a mass but you are not curing the condition. Your fundamental condition is still there (Tr. 1777).

Seven consumer witnesses testified that self-treatment with Preparation H had achieved immediate and substantial improvement of their hemorrhoids (Vincent, Tr. 1809–1830; Garth, Tr. 1832–1844; Poltrek, Tr. 1847–1855; Clancey, Tr. 1856–1868; Valentine, Tr. 1871–77; Rollins, Tr. 1884–1893; and Jones, Tr. 1897–1910). They had found the drug of greater therapeutic benefit than other conservative measures—including prescription drugs—to which they had resorted, and with its use had obtained relief from pain and itching and a reduction in the size of their hemorrhoids (Tr. 1810–1814, 1817–18, 1834–38, 1840, 1842, 1849–1850, 1853, 1859, 1861–63, 1873–74, 1876, 1879–1881, 1886,

1899–1901, 1908–1909). Medical diagnosis had confirmed that six of the seven consumer witnesses in fact had hemorrhoids. All of the consumer witnesses, with one exception (Rollins), testified that they had been diagnosed by physicians and had been told that they did have hemorrhoids (Vincent, Tr. 1818–19; Garth, Tr. 1833–34; Poltrek, Tr. 1849; Clancey, Tr. 1857–58; Valentine, Tr. 1877–78; and Jones, Tr. 1898–99).

John Garth, a taxicab driver, testified:

A. . . . Since I used that and it shrunk them up, mostly, I don't have no trouble with piles much now as long as I use it but if I don't use it, from driving a cab or bouncing around, it comes back on me again. As long as I use the ointment about two or three times a week, I don't have too much trouble (Tr. 1834).

* * * * * * *

Q. Has it been your experience and have you found Preparation H would relieve any pain or discomfort you might have had from your hemorrhoids?

A. It does.

Q. Have you found it affords relief from the itching?

A. Very much so.

Q. Have you found it would shrink or reduce in size any hemorrhoids protruding from your anus?

A. It do. If I use Preparation H like I'm supposed to, it softens that up and it shrinks up and it goes back (Tr. 1835).

Mrs. Shirley Poltrek, a registered nurse, testified:

Q. Could you tell us what results, if any, you experienced from the use of Preparation H?

A. Yes, certainly. I feel that it was of tremendous relief, and being that this was the one thing it was wonderful.

Q. Did you find that it afforded you relief from any pain or discomfort you were experiencing?

A. Yes, the pain and the thrombosing subsided.

* * * * * * *

Q. Did you find that the use of Preparation H shrunk up or reduced your hemorrhoids in size?

A. Yes, it did (Tr. 1849–1850).

Frank Clancey stated (Tr. 1861):

Well, I used the suppositories on the advice of a druggist, where they sell it, and the next day after—I had used them the night before—the itching stopped altogether, and then the next day the soreness left. And within a week it had shrunk right up. It was like a deflated innertube.

And Mrs. Denise Jones, a registered nurse, testified:

A. Well, I would say within 24 hours, the itching would have stopped, and

I would say within approximately two or three days, the hemorrhoids would have shrunk. I mean, they were no longer swollen.

Q. You have testified you had some soreness or discomfort. What effect, if any, did Preparation H [have] on that?

A. The soreness and discomfort was taken away when the hemorrhoids shrunk (Tr. 1899–1900).

The respondent offered evidence pertaining to the pharmacology of the ingredients of Preparation H:

(a) *"Biodyne"*

Dr. George Sperti, the president and director of the Institutum Divi Thomae at Cincinnati, Ohio, since it was founded in 1935, is one of only seven American members of the Pontifical Academy of Sciences, and has been responsible for a number of scientific discoveries in the fields of medicine and electricity. The Institutum is a graduate school of science, and its primary function is teaching and researching in the fundamental sciences, such as physics, chemistry, biochemistry, and experimental medicine (RX 73A–G; Tr. 930–34). In April 1941, he obtained a United States patent "that covered a group or family of substances that we had discovered that stimulate the metabolism of cells—normal human cells, bacteria, yeast cells, many types of cells" which "we called . . . biodynes" (RX 73E–29; Tr. 936–37). The work was done at the Institutum under his direction and control. Dr. Sperti testified in great detail as to the circumstances which led to the discovery of "Biodyne" and the manner in which experiments were conducted. He testified that the laboratory experiments with microorganisms and animal tissues demonstrated that "Biodyne" had the peculiar ability to stimulate both the respiration and proliferation of injured cells and thus to stimulate the healing processes of nature (Tr. 930–949; Cook,[8] (Tr. 1005–1012). Subsequently, this "Biodyne" was incorporated in a topical ointment on which a patent was obtained in August of 1943, and was made available for the treatment of burns and wounds. The formulation of that ointment was the same in substance as that of the present Preparation H Ointment (RX 73F–35, Tr. 948–958; Shaul, Tr. 1016–17, 1023).

The Evans Research and Development Corporation of New York, New York, at the instance of respondent, in November

[8] Dr. Elton S. Cook, Vice President and Dean of the Institution and Professor of Chemistry and Biochemistry, holds a Ph.D. in organic chemistry from Yale University and has engaged in extensive research on many phases of cellular metabolism and wound healing (RX 74A–H; Tr. 998–1001).

1963 undertook an investigation to determine the chemical factors in "Biodyne," and in May 1964 to evaluate the biological activity of "Biodyne." The results of such investigations were submitted to the respondent in a report dated January 22, 1965 (RX 70A–I; Holland, Tr. 1689). Dr. William E. Holland, vice president, and Mr. Ernest L. Klemm, a biochemist, with the Evans organization, testified that the studies demonstrated that "Biodyne":

(i) Is composed of such nutrients as amino acids, mineral salts and the water soluble vitamins of the "B" complex, including relatively high concentrations of pantothenic acid (RX 70A, pp. 3, 4–8, Tables I–IV; Klemm, Tr. 1714–15).

(ii) Stimulates the growth and proliferation of mouse fibroblast cells in vitamin-deficient media, whereas without "Biodyne" such cells sicken and die (RX 70A, pp. 3, 9–12; Holland, Tr. 1691; Klemm, Tr. 1714, 1715–20, 1725; RX 70B–I; Klemm, Tr. 1721–25).

(iii) Increases the metabolic rate of tissue cells and explants from rat abdominal tissue. (RX 70A, pp. 3, 12–17, Tables VI, VII; Holland, Tr. 1691–92; Klemm, Tr. 1714, 1726–29).

The importance and justification of incorporating a substance with these properties in a drug product for the treatment of hemorrhoids was explained by the testimony of three physicians, whose medical testimony has heretofore been related, and who are also qualified as pharmacologists. Dr. Grollman pointed out that fibroblast cells are always involved in the healing process and "act as a sort of mortar to heal the injured area" (Tr. 1760). As a consequence, he was of the opinion that the laboratory reports on "Biodyne" offered an explanation of the mechanism by which Preparation H achieved the clinical results shown for it (Tr. 1765–66). Dr. Feldman testified (Tr. 901):

> Well, if this substance affords the necessary materials from which—which will aid in the tissue repair, or will act like a catalyst in the requirements of the metabolic needs of the given injured cells, then these cells certainly will be stimulated to repair themselves—in other words, this catalyst, this substance, would encourage fibroblastic activity, which would then in turn repair the cells that have been injured.

Dr. Berkowitz, in relating the laboratory studies of "Biodyne" to the therapeutic effects of Preparation H, noted that "a hemorrhoid exerts its effects . . . by creating an associated condition of inflammation" (Tr. 1117); and that "Biodyne's" nutrients can provide "for the local inflamed tissue a source of nutrient materials which are most important in the recovery and repairative

stages of the inflammatory processes present" (Tr. 1120). Having reviewed the most recent laboratory studies of "Biodyne" (RX 70A–I), Dr. Berkowitz testified that in his opinion they are of considerable significance in explaining the therapeutic properties of Preparation H (Tr. 1117):

> Now, I have been particularly impressed with the effects of the biodyne in the tissue culture studies where they showed, to my satisfaction, that when a tissue culture containing fibroblast—and fibroblast are the major constituents of fibrous tissue, which is important in healing—and when biodyne was incorporated in cultures where various things had been removed from these cultures, and where these fibroblast were not able to live, and when the biodyne was added, now the fibroblast became normal again, and regenerated, this to me certainly gives rationale for the incorporation of such a thing in a preparation where healing is important.

(b) *Phenylmercuric Nitrate*

Phenylmercuric nitrate is a well-recognized antiseptic and germicidal agent of long standing (Grollman, Tr. 1761–62), and was included in the formulation of Preparation H in order to inhibit infection from bacteria (Sperti, Tr. 954–56). Such an agent plays an important role in the treatment of symptomatic hemorrhoids in view of the complications stemming from infection and the importance of its elimination (Grollman, Tr. 1756–1760; Epstein, Tr. 1614–15; Hopping, Tr. 167; Marino, Tr. 237; Sarner, Tr. 459–460; and Zimmerman, Tr. 576).

(c) *Shark Liver Oil*

This ingredient of Preparation H is a source of vitamins A and D, has local emollient and healing properties and tends "to have a certain antiseptic action" (Grollman, Tr. 1762; Hopping, Tr. 163; Marino, Tr. 210; cx 7, 8; Sperti, Tr. 974–75).

(d) *The Ingredients Combined with the Respective Bases of Preparation H Ointment and Suppositories*

Heretofore this initial decision sets forth the formulas of Preparation H ointment and suppositories, which describe the substances included in the bases of such product in which "Biodyne," phenylmercuric nitrate, and shark liver oil have been incorporated. The advantages of any lubrication or emollient substances in the treatment of hemorrhoids were recognized by most of the medical witnesses (see, for example, Grollman, Tr. 1763, 1771–72; Berkowitz, Tr. 1119, 1140; Marino, Tr. 207, 212; Eisenberg, Tr. 355, 358), and Dr. Berkowitz outlined the effects of the entire product as follows (Tr. 1119–1120):

The first thing that happens, I presume, is that by its local contact of the inflamed tissue with the ingredients themselves, it produces first amelioration of pain. The pain thereby lessens the degree of spasm that is present, and I think it is important to bring out that spasm, by causing actually a constriction of the muscle on the veins, actually increases the engorgement of the veins, because veins being different than arteries, fill from below up, and when you clamp down on something, you prevent blood in that vein from getting back, so that actually it becomes more engorged. So you set up a vicious circle. When you relieve the pain, you relieve the spasm, thereby some of the congestion in the vein is decreased.

Secondly, I think the local application of the suppository or the ointment, by the nature of the specific constituents, provides for the local inflamed tissue a source of nutrient materials which are most important in the recovery and the repairative stages of the inflammatory processes present.

Thirdly, I think it is not at all inconceivable that some of the medication, some of the constituents in these local medications, are actually absorbed into the general systemic circulation. It is an accepted fact that the expense and the accuracy of healing locally is also dependent on the generalized and systemic ability of the body to respond and the presence or absence of necessary ingredients systemically, not only locally. And certainly enough work has been done in the last three or four years to show that many many substances can be absorbed systemically from the rectum.

I would say these are the three ways that I would presume the medication may physiologically work.

The respondent acquired the rights to "Biodyne" and "Preparation H" and has marketed the ointment since 1952 for treatment of hemorrhoids without changing in any material respect the formulation of the product as it was first marketed. The respondent has marketed "Preparation H Suppositories" since 1954 without any material change in their formulation (Sperti, Tr. 950, 958, 962–63; Shaul, Tr. 1016–17, 1023; Stipulation, Tr. 67–68; RX 12).

On rebuttal, complaint counsel presented two witnesses. Mr. William Weiss, a statistician for the National Institutes of Health at Bethesda, Maryland, testified as to the validity of conclusions drawn by Dr. Nathan Jaspen, one of respondent's witnesses (Tr. 1948–2055). Dr. Jaspen, a professor of educational statistics at New York University, presented testimony relating to a statistical analysis he made of the clinical reports of Dr. Lieberman and Dr. Berkowitz (Tr. 1420–1438). The hearing examiner has not recited the testimony of Dr. Jaspen in his initial decision for the reason that he does not consider it of any consequence in resolving any of the issues in this proceeding. Therefore, he will not discuss the testimony of Mr. Weiss. Dr. Albert I. Mendeloff, a physician of Baltimore, Maryland, testified with respect to his

evaluation of the protocols and procedures employed in the clinical studies by the six doctors who were used as witnesses by the respondent (Tr. 2060–2088). It is the opinion of the hearing examiner that the testimony of this witness was of no value, for which reason it will not be related herein. Furthermore, complaint counsel have not cited or relied upon any of the testimony of the two rebuttal witnesses in the proposed findings submitted by them.

The hearing examiner has given consideration to the entire record in this proceeding and in his opinion the facts can be summarized as follows:

Hemorrhoids are common among the adult population—particularly in pregnant women and persons over the age of fifty—and estimates of its incidence range upwards from 50%. The physical abnormality which underlies the condition and technically defines its presence is the existence of one or more groups of dilated or varicose veins in the hemorrhoidal venous plexus which may be distended, together with the tissue overlying them, at the distal portion of the rectum, the anal canal, or just exterior to the anus. In and of themselves, such hemorrhoidal varicosities are not troublesome and many—perhaps most—people have asymptomatic hemorrhoids for years without being aware of the fact. Asymptomatic hemorrhoids are harmless and do not require treatment. Such a condition, however, may become symptomatic from time to time as a result of one or more exciting or complicating factors such as constipation, diarrhea, straining, trauma, infection, or conditions or activities which increase pressure on the hemorrhoidal veins. The most usual hemorrhoidal symptoms include one or more of bleeding, pain, protrusion, swelling, discharge, itching, and a sense of discomfort or fullness at the anus. These symptoms vary in degree from mild to severe, and symptomatic hemorrhoids are frequently very painful, irritating and troublesome. The term "hemorrhoids" is used to describe both the symptomatic and the asymptomatic conditions. The mucosal, perivascular and skin-like tissue surrounding the varicose veins is integrally involved in a symptomatic hemorrhoid condition. Symptoms are usually caused by complications—such as inflammation, edema, ulceration, or infection—in the adjacent tissue rather than by the mere existence of varicose veins. Such complications lead to spasm, swelling, increased protrusion, pain, bleeding, discharge, itching, and sometimes thrombosis. If they are not treated, symptomatic hemorrhoids may either become more serious and complicated or may

undergo spontaneous remissions over a period of time. In any event, hemorrhoids will persist longer and be more troublesome without, than with, treatment. Surgery to excise varicose veins in the hemorrhoidal plexus (the operation is known as "hemorrhoidectomy") is only indicated in cases of unusual persistence or severity, and is contra-indicated in the presence of heart, liver and kidney disease and certain other concomitant conditions. In practice, physicians specializing in ano-rectal surgery ("Proctologists") perform such operations on a high percentage of their hemorroid patients. A substantial proportion of such patients are referred to them by other physicians who have obtained negative results through conservative therapy. Physicians who do not specialize in surgery, however, very rarely find it necessary or desirable to recommend surgery for the treatment of hemorrhoids. Varicose veins in the hemorrhoidal plexus can only be removed or eliminated by surgery, and even then the recurrence rate is estimated at between ten and twenty percent. The vast majority of hemorrhoid cases are successfully treated by conservative measures. In most cases, conservative measures are sufficiently effective that surgery can be avoided. Topical ointments and suppositories are widely used and recommended for the conservative treatment of hemorrhoids, and they are effective to varying degrees in the treatment of hemorrhoidal swelling, protrusion, pain, bleeding, discomfort and itching.

It is the opinion and finding of the hearing examiner that the preponderance of substantial, reliable, and probative evidence in the record establishes that Preparation H ointment and suppositories have a significant therapeutic effect in the treatment of hemorrhoids, and that, when used as directed, they will, in most cases, but not in all instances:

(1) Reduce or shrink hemorrhoids;

(2) Relieve pain due to hemorrhoids; and

(3) Stop or relieve itching due to hemorrhoids; but that they will not:

(1) Avoid the need for surgery as a treatment for hemorrhoids where surgery is indicated; or

(2) Heal, cure, or remove hemorrhoids, or cause hemorrhoids to cease to be a problem.

The Federal Trade Commission investigated respondent's advertising of Preparation H in 1954 and "on the basis of a scientific opinion" which it had obtained challenged a claim that the

product "stops bleeding." (RX 13–16; Rettig, Tr. 1923.) Following communications and negotiations between representatives of respondent and the Commission (RX 16–18; Rettig, Tr. 1923), respondent agreed to delete the challenged claim from its advertisements and submitted for the Commission's review proofs making that deletion and replacing it with the claim, "relieves pain" (RX 17–18). In a letter dated October 19, 1954, the Secretary of the Commission wrote to the respondent as follows (RX 19):

> Consideration has been given to the above matter involving alleged violation of Sections 5 and 12 of the Federal Trade Commission Act, in connection with the dissemination of advertising for Preparation H by Whitehall Pharmacal Company.
>
> *In view of the information presently in this file no further action is contemplated at this time.* In arriving at this decision consideration has been given to the modification of your advertising agreed to in your letter dated September 15, 1954, and illustrated by the revised copy submitted with your letter of September 21, 1954. (Emphasis added.)

The advertising claims now at issue in this case are the same as those on which the Commission passed in 1954 (Rettig, Tr. 1917, 1922; RX 21; CX 9–14). The formulation of the product is the same now as it was in 1954 (Shaul, Tr. 1016–17, 1023). It is the position of the respondent that "After the Commission closed its file in 1954, respondent proceeded in the belief that its advertising had received Commission approval" and under the related circumstances "every consideration of equity militates against the issuance of an order to cease and desist" (RPF, p. 59). There is no merit to the contention. Respondent's witness acknowledged that with the words, "no further action is contemplated at this time," the Commission had left the door open to further consideration of the matter (Rettig, Tr. 1933). In *P. Lorillard Co.* v. *Federal Trade Commission*, 186 F. 2d 52, 55 (4th Cir. 1950), the Court said:

> It must not be forgotten that the Commission is not a private party, but a body charged with the protection of the public interest; and it is unthinkable that the public interest should be allowed to suffer as a result of inadvertence or mistake on the part of the Commission or its counsel where this can be avoided.

In *Wallace Corporation* v. *National Labor Relations Board, et al.*, 141 F. 2d 87, 91 (4th Cir. 1944), it is said:

> Settlements approved by the Board should ordinarily be observed and administrative orders should not be lightly disregarded . . . but these are guides for the exercise of discretion by the Board, not limitations upon its power.

CONCLUSIONS OF LAW

1. "Preparation H Ointment" and "Preparation H Suppositories" are "drugs" within the meaning of Section 15(c) of the Federal Trade Commission Act (15 U.S.C.§55(c)).

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent.

3. The advertisements referred to in Paragraph Five of the complaint herein 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.

4. 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.

ORDER

It is ordered, That respondent American Home Products Corporation, a corporation, and its officers and respondent's representatives, agents, and employees, directly or through any corporate or other device, in connection with the offering for sale, sale or distribution of Preparation H Ointment or Suppositories, or any other preparation or preparations of substantially similar composition or possessing substantially similar properties, do forthwith cease and desist from directly or indirectly:

1. Disseminating or causing the dissemination of any advertisement by means of the United States mails or by any means in commerce, as "commerce" is defined in the Federal Trade Commission Act, which represents directly or by implication that the use of Preparation H Ointment or Suppositories, or both, will:

(1) Reduce or shrink hemorrhoids in all cases;

(2) Avoid the need for surgery as a treatment for hemorrhoids where surgery is indicated;

(3) Stop or relieve itching due to or ascribed to hemorrhoids in all cases;

(4) Relieve pain attributed to or caused by hemorroids in all cases; or

(5) Heal, cure or remove hemorrhoids or cause hemorrhoids to cease to be a problem.

2. Disseminating or causing to be disseminated by any means for the purpose of inducing or which is likely to in-

duce, directly or indirectly, the purchase in commerce, as "commerce" is defined in the Federal Trade Commission Act, of said preparation or preparations, any advertisement which contains any of the representations prohibited in Paragraph 1 hereof: *Provided, however,* That nothing contained in this Order shall prevent nor be construed to prevent respondent, its officers, representatives, agents or employees from representing, or from disseminating or causing to be disseminated by any of the means or for any of the purposes referred to in Paragraphs 1 and 2 hereof any advertisements which represent, that the use of Preparation H Ointment and Suppositories, or either of them, or any other preparation or preparations of substantially similar composition and intended use, will in most cases:

(a) Be of significant therapeutic effect in the treatment of hemorrhoids;

(b) Enable persons with hemorrhoids to avoid surgery except in unusually severe or persistent cases;

(c) Reduce or shrink hemorrhoids;

(d) Relieve pain due to hemorrhoids; or

(e) Stop or relieve itching due to hemorrhoids.

OPINION OF THE COMMISSION
DECEMBER 16, 1966

BY JONES, *Commissioner*:

This matter is before the Commission on an appeal by complaint counsel from the initial decision of the hearing examiner in which he sustained some of the allegations in the complaint, rejected others, and issued an order substantially different from the proposed order attached to the complaint. Respondent, urging that the hearing examiner's decision and order should be upheld, has not appealed.

I

The complaint, issued on August 28, 1964, charged that respondent made false representations in advertising its suppositories and ointment, sold under the trade name of "Preparation H" for the treatment of hemorrhoids or piles [1] in violation of Sections 5 and 12 of the Federal Trade Commission Act.

Among the statements made by respondent in its advertising of

[1] The words "hemorrhoids" and "piles" are synonymous and will be used interchangeably herein.

Preparation H suppositories and ointments on which the complaint was based were the following: [2]

Preparation H * * * actually shrinks hemorrhoids without surgery. * * * 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.

Clinical tests show Preparation H shrinks hemorrhoids without surgery. Relieves pain—stops itching. Shrinks piles.

For the first time science has found a new healing substance with the astounding ability to shrink hemorrhoids, stop burning rectal itch and relieve pain—without surgery or painful injections. * * * In fact results were so thorough that sufferers were able to make such astounding statements as "Piles have ceased to be a problem!" * * * Heals injured tissue back to normal.

The complaint alleged in Paragraph Six that through the use of these advertisements, and others, respondent has represented that the use of its products [3] 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.

In Paragraph Seven of the complaint it was alleged that the preparations will not in fact:

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.

The hearing examiner found that respondent's advertising did make the claims alleged in the complaint with respect to the use of Preparation H to avoid surgery and to heal, cure or remove hemorrhoids, which he found to be false, and to reduce or shrink hemorrhoids, which he found to be true in most cases. He agreed with respondent however, that respondent's advertisements did not make the representations alleged in the complaint that Prepa-

[2] Respondent's advertisements are set forth in greater detail in Finding 6 of our Findings of Fact.

[3] The terms "products," "preparations" and "Preparation H,' as used herein, each refer to Preparation H ointments and suppositories.

ration H would relieve "all" itch and pain and found that respondent's representations that Preparation H would relieve itch and pain meant only that it would relieve some itch and pain and that these representations were true in most instances. Finally, he concluded that Preparation H would have a "significant therapeutic effect in the treatment of hemorrhoids" (I.D., p. 1602).

Neither counsel has appealed the examiner's findings and conclusions that respondent falsely claimed that Preparation H will avoid the need for surgery as a treatment for hemorrhoids and will heal, cure or remove hemorrhoids. The hearing examiner's findings and conclusions with respect to this aspect of the case are accepted and adopted.

Complaint counsel's appeal challenges the examiner's findings as to the meaning of the claims which respondent's advertising makes with respect to relief of itch and pain and also his conclusions that "in most cases" Preparation H will shrink piles, stop itch and relieve pain and that it has a significant therapeutic effect in the treatment of hemorrhoids. These are the only substantive issues, therefore, which are before us on this appeal. Complaint counsel has also raised questions about the scope of the order proposed by the examiner which must be determined on this appeal.

II

THE EVIDENCE RESPECTING THE CAUSE AND TREATMENT OF HEMORRHOIDS

Hemorrhoids [4] are masses of dilated weak-walled veins located underneath the mucous membrane of the lower portions of the rectum and under the skin of the anal canal and the perianal area (F. 1).[5] Hemorrhoidal veins do not have valves, and hence tend to dilate if the column of blood flowing into these veins causes excess pressure. Other factors leading to the development of hemorrhoids include an hereditary tendency to develop hemorrhoids, abnormally long periods of standing, straining, difficulty with

[4] There are two types of hemorrhoids: internal hemorrhoids, which occur above the pectinate line and are covered by mucosa; and external hemorrhoids, which occur below the pectinate line and are covered by skin (F. 16). Respondent argues that hemorrhoids must be defined to include the surrounding mucosa and skin as well as the veins themselves. While we have concluded that the definition set forth above is in accord with the weight of evidence of record, including the testimony of four of respondent's own medical experts (Tr. 817, 838, 867, 892), as well as the examiner, who defined hemorrhoids as "varicose (dilated) veins in and around the rectal opening" (I.D., p. 1540), our conclusions with respect to the issues in this case would not be affected by the use of the definition proposed by respondent. See *e.g.*, pp. 1609–1611, *infra*.

[5] Citations refer to the Findings of Fact entered by the Commission herein.

bowel movement, impacted stool, pregnancy and cirrhosis of the liver (F. 19).

The most common symptom of internal hemorrhoids is bleeding. The other principal symptom of internal hemorrhoids is prolapse.[6] Secondary symptoms include discharge and itching which may be caused by such discharge. Itching, however, is not a usual symptom of internal hemorrhoids. Pain rarely occurs in internal hemorrhoids since the sympathetic nervous system which services the region above the pectinate line where internal hemorrhoids are located do not contain sensory nerve fibers (F. 20, 23).[7]

The most common symptoms of external hemorrhoids, on the other hand, are pain and swelling. Pain in external hemorrhoids is frequently caused by thrombosis or blood clot known as an external thrombotic hemorrhoid. Other causes of pain in external hemorrhoids are inflammation, swelling, ulceration and infection. Swelling may result from thrombosis or from edema. Itching may occur in external hemorrhoids but normally only as the result of the healing of the hemorrhoid (F. 20, 22, 23).

Surgical removal is the only means by which either internal or external hemorrhoids can be permanently cured. Any measures short of surgery merely provide palliation and do not effect a cure. However, even surgery does not effect a complete cure in every case (F. 26).

While hemorrhoids themselves cannot be eliminated without surgery, hemorrhoidal symptoms may frequently disappear, at least temporarily, on their own account within several days to two weeks (F. 25). Moreover, hemorrhoidal symptoms can in some instances be alleviated by various types of therapy (F. 27, 28). A common treatment for the symptoms of simple, uncomplicated internal hemorrhoids of small size is injectional therapy, which causes scar tissue to form and cut off the blood vessel feeding the hemorrhoid. A more recent treatment used for the symptoms of internal hemorrhoids is the baron ligation method whereby a ligature of rubber is placed around the internal hemorrhoid as another means of cutting off the blood circulation to the hemorrhoid (F. 27).

Finally, a so-called "conservative" course of treatment may be

---

[6] "Prolapse" refers to an internal hemorrhoid which has fallen outside the anal canal and protrudes to the surface (F. 18).

[7] Pain, however, may occur in infrequent cases of severe complicated internal hemorrhoids as a result of spasm or strangulation caused by prolapse or as the result of an involvement of tissues beyond the pectinate line (F. 20).

utilized to relieve temporary minor symptoms associated with both internal and external hemorrhoids. These methods include cleanliness, altering the diet to eliminate irritative foodstuffs, control of the bowels to ensure a smooth, soft stool, warm baths, witch-hazel, boric acid, local anesthetic, ointments, suppositories, avoidance of standing, and manual re-insertion of prolapse. Ointments and suppositories contain lubricants which may protect the anal and rectal canal against the passage of hard, dry stool. Such lubricants may also serve to relieve dryness and soften the skin as well as provide a psychological advantage; many people derive mental relief from the fact that some sort of treatment is applied (F. 28).

III

DISCUSSION OF ISSUES RAISED ON APPEAL

A. *Meaning of Respondent's Advertisements Respecting Relief of Itch and Pain*

The hearing examiner found that respondent's representations that its products would "relieve pain" and "stop itch" meant only that some itch and some pain would be relieved or stopped. He held that the complaint allegations that respondent claimed that "all itch" and "all pain" would be relieved were not proved (I.D., pp. 1538–1539).

Respondent during the hearing called seven consumer witnesses to support its position that its advertisements did not claim that Preparation H would relieve all itch and pain.[8] These witnesses testified that to them respondent's advertising meant that its products would "relieve" hemorrhoids (Tr. 1815), "give me immediate relief and stop the itching and pain" (Tr. 1837), bring "relief from pain and itching" (Tr. 1851), "bring relief to me" (Tr. 1863), "get me over a bad time" (Tr. 1875), "give [ ] relief" (Tr. 1887) and "give me some relief" (Tr. 1902).

The examiner noted this consumer testimony in his discussion of the meaning which should be attributed to respondent's advertising. However, he did not expressly rest on it in reaching his conclusion that respondent's advertising did not represent that *all* pain and itching would be stopped or relieved by its products. Rather, he was apparently chiefly influenced in his conclusion by the fact that "[t]he word 'all' is never used in any of the adver-

[8] The seven consumers consisted of an astronautical technician, a taxicab operator, a porter, a city councilman and three registered nurses.

tisement to describe the relief to be afforded by the product from itch and pain" (I.D., p. 1538).

We do not agree with the examiner that the omission of the word "all" conclusively establishes that the advertisement in question did not represent that Preparation H would relieve all pain and itch. It is clear that in determining the meaning of representations made by respondent the Commission must concern itself not only with the express language of the assertion in question but also with the overall impression which it conveys. The Commission may "draw upon its experience in order to determine * * * the natural and probable result of the use of advertising expressions" (*E. F. Drew & Co. Inc.* v. *F.T.C.*, 235 F. 2d 735, 741 (2nd Cir. 1956)). See also to the same effect *Stauffer Laboratories, Inc.* v. *Federal Trade Commission*, 343 F. 2d 75, 78 (9th Cir. 1965). Moreover, the Commission is not bound in making such determination by the statements of witnesses that they were not deceived. As the Tenth Circuit recently reiterated:

> If the Commission can find deception without evidence that the public was deceived * * * it can make the same finding on the basis of its visual examination of exhibits, even though numerous members of the public have testified that they were not deceived.

(*Double Eagle Lubricants, Inc.* v. *F.T.C.*, 360 F. 2d 268, 270 (10th Cir. 1965), *cert. denied*, 384 U.S. 434 (1966)).

Respondent's repeated references to the "healing" powers of its medication punctuate its claims with respect to pain and itching and in our view are equivalent to a declaration that the relief afforded by Preparation H will be total. If a consumer is led to believe that his hemorrhoids will be cured by using Preparation H, he will necessarily also understand that all symptoms associated with these hemorrhoids will also disappear. Moreover, even standing alone we are of the view that the implication of respondent's representations that its products will "stop" itching and "relieve" pain is that they will stop *all* itch and pain even though they do not use the word "all." Indeed, the testimony of the consumers called by respondent on this point would seem to bear this out and certainly does not support respondent's interpretation of these claims. Not one of these witnesses stated explicitly that he interpreted the advertisement in question as representing that only "some" itch and pain would be relieved by using respondent's products. These witnesses testified fairly flatly that respondent's advertisements meant that Preparation H would stop pain and itch.

We therefore conclude that the examiner was in error in his interpretation of these representations and we specifically find that respondent's advertisements represented that its products will eliminate *all* itch due to or ascribed to piles or hemorrhoids and will relieve *all* pain attributed to or caused by piles or hemorrhoids.

B. *Truth or Falsity of Respondent's Representations Respecting Efficacy of Preparation H*

The four issues to be considered herein in determining whether respondent's representations are misleading in a material respect are: (1) the ability of respondent's products to "reduce or shrink hemorrhoids"; (2) the effect of respondent's products on pain; (3) their effect on itching; and (4) the existence of other therapeutic effects of Preparation H products.

(1) The Ability of Preparation H to Reduce or Shrink Piles

The examiner found that Preparation H would reduce or shrink hemorrhoids "in most cases, but not in all instances," but cannot remove or eliminate the varicose veins themselves. Each of complaint counsel's medical experts testified that Preparation H cannot shrink or reduce the size of hemorrhoids, which they defined to mean the hemorrhoidal veins themselves (Tr. 128–129, 212–213, 276, 369–370, 436–437, 500, 563–564, 629–630, 740). Two of respondent's witnesses specifically concurred (Tr. 1497, 1668).[9] Respondent did not dispute the accuracy of this testimony but contended that under its definition of hemorrhoids as encompassing both the hemorrhoidal veins and the surrounding tissue, its products will reduce the swelling in the tissues surrounding the hemorrhoid and hence that its claims that hemorrhoids will be shrunk or reduced in size by its products are correct.[10]

Respondent's advertisements state flatly that "Preparation H

[9] Other experts testifying for respondent stated generally that Preparation H would reduce the size of hemorrhoids (Tr. 1112–1113, 1252, 1530). However, it does not appear from their testimony whether they were referring to the shrinkage of the veins themselves or to the reduction of swelling in the hemorrhoidal tissues. Two of respondent's other witnesses explicitly testified that the reduction which would occur would be in the edema or swelling (Tr. 832, 1570). Four of respondent's consumer witnesses testified that in their experience Preparation H had "shrunk up" their hemorrhoids (Tr. 1849–50, 1834, 1861, 1899–1900). We do not believe that their testimony, assuming the patient can determine for himself whether or not the hemorrhoid has shrunk, outweighs the clear implication which we find respondent's advertisements had in this regard that use of Preparation H would shrink all hemorrhoids and would heal them.

[10] This is apparently also the rationale of the examiner's conclusion that "in most cases" Preparation H will reduce or shrink hemorrhoids, although he did not articulate the basis for his conclusions (I.D., p. 1602).

shrinks hemorrhoids" (*e.g.*, CX 13). In no case do they make any distinction between shrinking hemorrhoidal veins and hemorrhoidal tissue. Therefore, the clear implication is that the shrinkage which will take place will not be limited to the covering tissue, but will include the underlying hemorrhoidal vein. Indeed, in the context of respondent's total advertising message, respondent's claim with respect to shrinking hemorrhoids is tantamount to an assertion that the hemorrhoidal condition, including all of its symptoms, will be eliminated and even that the hemorrhoids will be cured or healed. Yet respondent has conceded on this appeal that its products will neither cure nor heal hemorrhoids.

Since, as respondent concedes and the examiner found, Preparation H will not reduce the varicosity of hemorrhoidal veins or cure hemorrhoids, the reduction, if any, which will occur will not be of the type implicitly promised by respondent's advertising. Thus, even if we were to assume that some reduction of swelling in the surrounding tissue does take place, which claim is not wholly supported by the evidence,[11] respondent's absolute claims with regard to shrinkage can only be regarded as highly misleading.

For all of these reasons we conclude that the hearing examiner was in error in his finding that respondent's Preparation H is correctly represented as shrinking hemorrhoids and we hold that respondent's representations that its product would reduce or shrink piles are in all respects false and misleading.

(2) Effect of Preparation H on Pain

The hearing examiner concluded that respondent's Preparation H will relieve pain in most cases. Respondent accepts this finding, as well as the provision of the order proposed by the examiner to cover representations respecting pain. Complaint counsel argues that the finding is in error and that the order is unduly limited.

Complaint counsel's medical witnesses[12] testified either that Preparation H will have no effect on pain or that it will afford only temporary relief of minor pain associated with hemorrhoids (Tr. 131, 207, 279, 372–373, 439–440, 503, 562, 632–633, 744). The

[11] Some of the respondent's witnesses took the position that the product may have an effect on swelling. Dr. Young stated that it was "of value" as a lubricant in reducing swelling (Tr. 1471); Dr. Epstein said that it "can reduce edema or swelling" (Tr. 1570). Dr. Isaacson testified that it "can reduce the secondary swelling, secondary edema and inflammation" (Tr. 1668). On the other hand, complaint counsel's witness Dr. Pope testified that it would have "no effect, none whatsoever" on this symptom (Tr. 684). To the same effect see also the testimony of Dr. Sarner at Tr. 463 and Dr. Hopping at Tr. 129.

[12] A brief description of the qualifications of each of these experts is set forth in Finding 8 of our Findings of Fact entered herein.

consensus of these experts was that pain is a symptom associated almost entirely with external hemorrhoids and that even with this type of hemorrhoid if the pain is caused by thrombosis, a principal cause of pain in such hemorrhoids, it cannot be affected by the application of any external treatment such as ointment and suppositories. Where pain in external hemorrhoids results from ulceration, inflammation or swelling, some of these witnesses testified that pain might be relieved to a minor degree by the lubricants contained in Preparation H, although other of complaint counsel's witnesses were of the opinion that Preparation H would not even alleviate pain when attributable to these causes (Tr. 129, 648, 742–743). Finally, it appears from the testimony of complaint counsel's witnesses that in the unusual case of internal hemorrhoids where pain results from spasm or strangulation, Preparation H will rarely be of benefit. (See Tr. 631–632.)

Respondent did not attempt to refute the testimony of complaint counsel's witnesses concerning the causes of pain in hemorrhoids or to offer any scientific explanation as to how their product in fact affected these causes of pain. Instead, respondent based its argument that pain would be relieved by use of its products on the testimony and clinical studies of its medical experts,[13] that persons using Preparation H or other ointments and suppositories gained relief from pain and on the testimony of consumer witnesses to the same effect.

In general, respondent's medical witnesses did not seriously controvert much of the testimony of complaint counsel's medical witnesses respecting the effect of Preparation H or of suppositories and ointments in general to relieve pain.

Four of respondent's eleven medical experts testified not with respect to Preparation H, which they did not use in their practice, but with respect to general conservative courses of treatment, including various ointments and suppositories which they prescribed for their patients. The first of these witnesses, Dr. Steigman,[14] testified that ointments and suppositories will relieve pain due to hemorrhoids "in some cases" (Tr. 822). Dr. Phillips [15] was of the opinion that certain ingredients in the ointments and sup-

[13] A brief description of respondent's medical experts is contained in Finding 9 of our Findings of Fact entered herein.

[14] Dr. Steigman, a specialist in internal medicine, testified on the basis of his use in his practice of ointments and suppositories as part of a conservative course of treatment (Tr. 809, *et seq.*).

[15] Dr. Phillips, a general practitioner, testified on the basis of his use in his practice of an ointment and suppository which he prescribed as part of a general conservative course of treatment (Tr. 835–843).

positories which he prescribed relieved pain (Tr. 854–855); but none of these ingredients are found in Preparation H. Dr. Sacco [16] placed primary emphasis in his testimony on sitz baths rather than ointments and suppositories in relieving the symptoms of pain (Tr. 873). Dr. Sacco also stated that nature will clear up the symptoms of external hemorrhoids in about two weeks and the acute symptoms of internal hemorrhoids within a period of one to ten days (Tr. 875). Dr. Feldman [17] testified generally that his "conservative course of treatment can render the patient free of the symptoms of hemorrhoids" (Tr. 896), but did not express an opinion concerning the value of Preparation H or any other ointment or suppository when not used as part of a general course of treatment.

Of the six medical experts called by respondent who testified with respect to clinical studies which they had conducted, four had prescribed Preparation H as part of a general conservative course of treatment, including sitz baths, stool softeners, and other like measures (Tr. 1107, 1275, 1571–1572, 1675), and accordingly could not testify on the basis of their actual experience as to what effect use of Preparation H by itself had on the relief of pain. Nevertheless, even when prescribed as part of an overall conservative course of treatment, neither the testimony nor the clinical studies conducted by these doctors supports respondent's claim that use of Preparation H by itself would permanently eliminate all pain.

Dr. Epstein [18] testified that in "mild to moderate" hemorrhoids Preparation H, when used as part of a conservative course of treatment, "will relieve pain where pain is a symptom of hemorrhoids" (Tr. 1569–1570), but he did not specify whether the relief was partial or complete. He also acknowledged that symptoms of hemorrhoids subside spontaneously and hence it can never be determined in a given instance whether the remission of a hemorrhoidal symptom was spontaneous or due to treatment (Tr. 1613). When asked whether Preparation H would have the same beneficial effects without the conservative adjunctives in his

[16] Dr. Sacco, a specialist in internal medicine, testified on the basis of his experience in his general practice with conservative measures prescribed for the treatment of hemorrhoids (Tr. 864, *et seq.*).

[17] Dr. Feldman, a general practitioner and psychopharmacologist, testified on the basis of his use in his practice of ointments and suppositories as part of a conservative course of treatment (Tr. 887, *et seq.*).

[18] Dr. Epstein, a gastroenterologist, testified on the basis of a study which he and Dr. Isaacson, a surgeon, working independently of each other, conducted at the request of respondent covering 119 patients. This study in 1961–1962 is described in F. 12 of our Findings of Fact entered herein.

program he could only speculate that this was a "fair assumption" to make (Tr. 1572). Dr. Isaacson,[19] who reported that 30% of the patients in his study of Preparation H required surgery, stated, in response to the question as to whether Preparation H will relieve pain due to hemorrhoids: "It can" (Tr. 1667). On further inquiry as to whether he had "any idea" how Preparation H acted to relieve the secondary symptoms of hemorrhoids, he frankly admitted, "No sir, I do not" (Tr. 1680). Dr. Berkowitz [20] concluded that "* * * treatment with Preparation H was effective in reducing pain in the vast majority of patients who had pain" (Tr. 1173), and was "sure" that the other conservative measures which he prescribed had an effect on the results which he obtained (Tr. 1107). Dr. Berkowitz's study showed that 28% of the patients still had some symptoms of pain at the end of the study. This should be compared with Dr. Lieberman's study in which 25% of his patients were referred for surgery and 55% with pain still had this symptom at the end of the study. Thus, the most that Dr. Lieberman [21] could claim for the product in relief of pain was that it "would have an ameliorative effect upon pain in many cases to varying degrees" (Tr. 1252).

Dr. Young,[22] who conducted the only clinical study in which adjunctive conservative measures were not prescribed along with Preparation H, testified that on the basis of this study he felt that Preparation H was "of value" in the relief of pain and that "[w]ithin a matter of a short time, and I mean by that within 12 to 24 hours, patients say that they received some benefits and within a week, most of the patients say that pain has disappeared" (Tr. 1497–1498). This conclusion contrasts strikingly with respondent's claim in its advertising that pain will be relieved "promptly * * * in minutes" (CX 13). Furthermore, Dr. Young conceded that nature "definitely takes a large hand" in correcting some of the minor disorders associated with hemorrhoids (Tr. 1487) and thus that his studies were "subject to some error because some hemorrhoids not treated at all will clear up" (Tr. 1471). It should be noted that the results of Dr. Young's study bear little relationship to his experience in his practice in

[19] Note 18, *supra*.

[20] Dr. Berkowitz, a specialist in internal medicine and Dr. Lieberman, a proctologist, working independently of each other, each made a study at respondent's request in 1963–1964 of 196 patients. This study is described in Finding 13 of our Findings of Fact entered herein.

[21] Note 20, *supra*.

[22] Dr. Young, a surgeon, testified on the basis of a study which he and Dr. Burt had conducted at the request of respondent in 1958–1959 covering 127 patients. This study is described in Finding 11 of our Findings of Fact entered herein.

which, according to his testimony, most of his patients "go to surgery" (Tr. 1481) and those who do not, undergo a general conservative course of treatment which keeps them only "fairly comfortable" and which "must be continuous. They can never get away from it * * *" (Tr. 1501). Dr. Burt,[23] who assisted Dr. Young in his study, after testifying on direct examination that his patients reported that they were relieved of pain with Preparation H (Tr. 1531), clarified this response on cross-examination by stating that "it won't relieve all of the pain" (Tr. 1541) and then concluded virtually in the language of the complaint, that Preparation H will "give temporary relief from minor symptoms" (Tr. 1542), thus indicating that if any pain is relieved, it is minor. Finally, Dr. Grollman[24] testified that an emollient "might" relieve pain due to hemorrhoids (Tr. 1763).

At best the testimony of respondent's medical experts[25] would support the conclusion that Preparation H may afford some relief for pain in some instances when used as part of a general conservative course of treatment. Yet nowhere does respondent in its advertising indicate that its product should be used in connection with other conservative measures, such as diet, sitz baths or the like.

Moreover, the evidence is clear that pain is normally associated only with external hemorrhoids and is not a symptom common to all hemorrhoids. Yet the overall purport of respondent's advertisements is to imply that pain is a usual symptom of all types of hemorrhoids. Thus, many hemorrhoid sufferers may be misled by respondent's advertisements and take its Preparation H as a precautionary measure even though they do not have any pain and in most circumstances may never experience pain.

---

[23] Note 22 *supra*.

[24] Dr. Grollman, a pharmacologist, testified on the basis of his general knowledge of the condition of hemorrhoids.

[25] The consumer witnesses appearing for respondent testified that the use of Preparation H had relieved pain, discomfort or soreness resulting from hemorrhoids. However, it is impossible to determine whether the reduction in pain which they claim had been achieved came as the result of the product used or merely by the passage of time. Therefore, we believe that the medical testimony on this issue is entitled to greater weight in our determination. Dr. Berkowitz's testimony indicating that the only pain-relieving quality of Preparation H was as an emollient or lubricant (Tr. 1130) would mean that it would have no effect on pain symptoms caused by thrombosis, spasm or strangulation which are major causes of pain in hemorrhoids (F. 19, 20). Respondent's own pharmacological evidence respecting the ingredients of Preparation H would seem to support this testimony. Preparation H does not have any special pain-relieving ingredients. Respondent itself advertises that its products do not contain any anesthetics (CX 5C) and its active ingredient, Bio-Dyne, which is so much stressed as having "healing" qualities, does not contain any special pain killer or pain reliever. The only pain-relieving ingredients in Preparation H would seem to be the lubricants which it contains. (See F. 28.)

We therefore conclude that respondent's representation that Preparation H will relieve all pain is false and misleading.

The hearing examiner in his findings and conclusions not only came to the opposite conclusion but also found affirmatively that respondent's product will "in most cases" relieve pain. We do not believe that this finding is supported by the evidence which we have discussed above. Accordingly, we reject this finding and hold that at best respondent's products may afford some temporary relief against some types of pain associated with certain types of hemorrhoids.

(3) Effect of Preparation H on Itching

The hearing examiner found that respondent only advertised its products as stopping some itch and that since he also found that Preparation H will stop or relieve some itching due to hemorrhoids in most cases, he concluded that its advertising claims were true. As we pointed out above, we have concluded that respondent's claims were unqualified and represented that respondent's products "would stop itch," meaning all itch under all conditions. The evidence on the effect of respondent's products on itch must be evaluated in terms of this unqualified claim which we find is contained in respondent's advertisements.

According to complaint counsel's witnesses, itching is only in rare cases a symptom of hemorrhoids and is almost always caused by some other condition such as fungus infection or by unknown factors (F. 23).[26] The testimony of some of these witnesses indicated that whether or not itching in the anal and rectal area is connected with a hemorrhoidal condition, it would not be palliated by Preparation H. Dr. Manheim pointed out that "[t]here is nothing in this formula that could possibly be considered as * * * [a]n anti-itch agent" (Tr. 278). Dr. Smith was of the opinion that Preparation H "doesn't relieve the itch * * * [since] there is nothing in this prescription itself which would reduce itching or relieve itching" (Tr.741). Dr. Pope stated that he "would not agree that even with * * * minor irritation that it gives any particular relief, and it certainly doesn't in the symptoms that are more severe * * *" (Tr. 633).

[26] This testimony would seem to be borne out by the clinical studies offered into evidence by respondent. Thus, Dr. Epstein's study indicates that only 7 of the 33 patients who participated had itching due to hemorrhoids (RX 5G, 6N, 6–O, 6Q, 6U, 6V, 6X).

In Dr. Isaacson's study only 25 of the 86 patients participating in the study reported having symptoms of itching due to hemorrhoids.

Dr. Lieberman, in his study, reported only 7 cases of itching due to hemorrhoids among the 48 patients who participated in the study and used Preparation H (I.D., p. 1590).

Respondent's own pharmacological evidence respecting the ingredients of Preparation H would seem to support this testimony. None of the ingredients contained in respondent's products was claimed to have any anti-itch properties (Answer, par. 3). Indeed, respondent specifically advertises its products as not containing any anesthetics (CX 5C).

Other of complaint counsel's medical experts felt, however, that Preparation H may provide some temporary relief for minor itching due or attributed to hemorrhoids (Tr. 131, 215, 372–373, 439–440, 503–505, 566). The only explanation given by any of these doctors for its effect on minor itching was that it acts as a lubricant and may thereby possibly relieve dryness and soothe surface irritation. (See, *e.g.*, Dr. Sarner's testimony at Tr. 440).

As in the case of the proof relating to pain, respondent did not attempt to refute any of complaint counsel's witnesses concerning the causes of itching or offer any scientific explanation as to how its product would affect the causes of itching. Again, its case in support of the truth of its claims that Preparation H will relieve itching was based primarily on evidence of clinical studies and on the testimony of its medical and consumer witnesses. However, once again the testimony of respondent's medical witnesses generally failed to support the totality of respondent's flat assertion that its preparation would stop itching and at best only warrants the finding that Preparation H may in certain cases temporarily relieve some of the itching due or ascribed to hemorrhoids. Thus, the only conclusion that Dr. Young, for example, whose clinical studies revealed that itching stopped for 27 out of 28 of his patients involved in his clinical study (Tr. 1501–1502), could draw from the results of his study with respect to itching was that it indicated that Preparation H had "some bearing" on this symptom (Tr. 1472). Dr. Steigman concluded that the use of ointments and suppositories will stop itch "in some cases" (Tr. 822). Dr. Isaacson's clinical study revealed that 10 out of his 25 patients having itching symptoms derived no improvement as a result of Preparation H (F. 12). Dr. Phillips testified that a local application would only alleviate itching if it contained a steroid, antihistamine or anesthetic (Tr. 855–856), none of which may be found in Preparation H. Dr. Lieberman's study indicated that out of the 7 cases of itching which he had found among his 48 patients studied, 4 were totally relieved of this symptom at the conclusion of his study (I.D., p. 1590). He was able to conclude from these results only that Preparation H "will improve itching in a number

of cases to varying degrees" (Tr. 1252). Only Dr. Burt, among all of respondent's medical experts, stated flatly that Preparation H, based on his observations, relieved all itch (Tr. 1542). In the light of the weight of all of the other medical testimony offered by both complaint counsel and respondent, in our judgment the conclusion is compelled that in fact Preparation H will not, when used by itself, relieve all itch in all cases of hemorrhoid suffering, and we so find. Finally, as we noted with respect to pain, respondent's witnesses, with the exception of Drs. Young and Burt, prescribed other conservative measures which could easily have influenced the results obtained in their medical practices and clinical studies (Tr. 819, 842–843, 870–871, 895, 1107, 1275, 1571–1572, 1675); and as three of respondents witnesses testified, the symptoms often subside spontaneously within a short period, so that results apparently attributable to Preparation H may actually be due to the passage of time (Tr. 875, 1471, 1487, 1613).

Four of respondent's seven consumer witnesses stated that they had had itching associated with their hemorrhoids and that this itching had been relieved by Preparation H (Tr. 1835, 1859, 1873–1874, 1899–1900). However, this testimony is of dubious probative value in view of the fact that the cause of these witnesses' itching was not disclosed. For example, some itch is caused by the process of healing of the tissues (F. 23). If this was the case with these witnesses, there would be no way of determining whether their itch had been stopped by Preparation H or by the healing of their hemorrhoidal tissues.

Respondent's representation that Preparation H will stop itch due to hemorrhoids is unqualified. It neither disclosed that much of the itch in the anal and rectal areas is not due to hemorrhoids nor did it state that itching is not a symptom of the great bulk of the hemorrhoids which people usually suffer from. When viewed in the context of the totality of respondent's advertising, the implication is clear that itching is a common symptom of all hemorrhoids and that such itching will stop by using respondent's products. The record does not support this claim.

Accordingly, we hold that the hearing examiner erred in his findings and conclusions on this claim and conclude that the evidence fully supports the allegation in the complaint that Preparation H will not eliminate all itch attributed to or caused by hemorrhoids and will at best only afford temporary relief of minor itching associated with hemorrhoids.

The hearing examiner not only sustained the truth of respond-

ent's claims with respect to itch but affirmatively found that when used as directed respondent's products will "in most cases, but not in all instances" stop itching. We do not find any record support for this finding and accordingly we reject it.

Complaint counsel's witnesses testified that in their opinion Preparation H may provide some temporary relief for minor itching due to hemorrhoids (*supra*). We do not read the testimony of respondent's witnesses as making substantially any different claim. We certainly do not read this testimony as supporting the examiner's finding that itching will be stopped in most cases. A statement such as Dr. Young's that Preparation H "has some bearing" on itch certainly does not support this finding; nor does Dr. Lieberman's testimony that itching will be improved "in a number of cases to varying degrees." Dr. Steigman specifically confined his observations that Preparation H would relieve itching to "some cases." Finally, Dr. Phillips testified that without certain ingredients (which Preparation H lacked) an ointment or suppository will not benefit itching. Accordingly, we hold that the examiner's finding on this point was in error and that the most that the evidence indicates on this point is that respondent's products may afford temporary relief against itching in some cases.

(4) Therapeutic Effects of Preparation H

The hearing examiner concluded that Preparation H ointments and suppositories "have a significant therapeutic effect in the treatment of hemorrhoids, and that, when used as directed, they will in most cases, but not in all instances" shrink hemorrhoids, relieve pain and stop itching.

Counsel for the parties herein have assumed that the examiner's finding on this point was based on his prior findings and conclusions with respect to the effect of respondent's products on pain, itching and swelling or protrusion. These were the only specific symptoms enumerated by the examiner as affected by Preparation H and respondent in its brief confined its discussion of the evidence to these three symptoms.[27]

[27] In stating the issues raised on appeal in its brief, respondent pointed out that the examiner "concluded that respondent's product has 'a significant therapeutic effect in the treatment of' this condition * * *. More specifically, he found * * * that Preparation H will: (1) reduce or shrink hemorrhoids; (2) relieve pain due to hemorrhoids; and (3) stop or relieve itching due to hemorrhoids" (Resp. Brief, p. 5).

In the argument portion of its brief respondent summarized the evidence supporting this finding of the examiner as follows: "All six doctors were of the opinion that Preparation H has a significant therapeutic effect in the treatment of hemorrhoids. They testified, on the strength of observation made in the course of clinical studies and in the light of their extensive training, education and experience, that Preparation H would reduce the size of hemorrhoids,

We do not agree with the examiner's conclusion that Preparation H when used as directed would have a significant therapeutic effect in the treatment of hemorrhoids.

The dictionary definition of therapeutic when used as an adjective is "of or pertaining to the healing art, concerned with remedies for diseases, curative." When used as a noun, it is defined simply as "a healing or curative medicine." [28] Thus, the examiner's finding of significant therapeutic effect if used by respondent in its advertising would convey an impresion which is entirely at variance with the conclusion of the examiner that Preparation H will not heal or cure hemorrhoids—a conclusion which respondent does not even challenge on this appeal. For this reason alone, the examiner's conclusion would seem to be erroneous.

Even if we should view the examiner's finding as relating solely to the efficacy of respondent's products to relieve hemorrhoidal symptoms as distinct from the hemorrhoids themselves, we do not believe that the claim has probative record support.[29]

It is significant that the only hemorrhoidal symptoms which respondent itself claimed would be affected by Preparation H were itching, pain and swelling.[30]

As we have already pointed out, the evidence does not support the examiner's conclusion respecting the efficacy of Preparation H on respondent's specific claims respecting itch, pain and shrinking. We, therefore, do not agree that the examiner's further conclusion of significant therapeutic effect has any greater support in the record.[31]

---

relieve pain and itching and avoid the need for surgery except in unusually severe or persistent cases" ((Resp. Brief, p. 30; see complaint counsel's brief generally, pp. 2–6; 52–54).

[28] *Webster's New International Dictionary*, 2d Ed., unabridged.

[29] We note that most of the medical witnesses called by both counsel agreed that hemorrhoids could be both symptomatic and asymptomatic and that if any symptoms were relieved, however temporarily, to the hemorrhoid sufferer, this was equivalent to relief of his hemorrhoids (Tr. 141–143, 181–182, 233, 235, 341–342, 352, 457, 814, 818, 884–885, 1080–1081, 1136, 1375, 1377, 1552, 1668, 1754, 1757–1758). However, we do not read any of this testimony as implying on the part of the witness any opinion that the use of Preparation H had any significant therapeutic effect beyond the particular symptoms referred to in respondent's advertisements and separately discussed above.

[30] There is little doubt that the absence of any other claims was deliberate. For example, respondent made no claim in its advertising that its product is effective for bleeding and has not done so in its advertising since 1954 when it agreed with the Commission to delete the claim that Preparation H "stops bleeding" (Tr. 1923, RX 17–18). In fact, in its labeling it specifically cautions the consumer to consult a physician in case of bleeding. Yet the examiner's finding on therapeutic effect could possibly be construed, if respondent made the claim in its advertising, which it might well do so, as representing that Preparation H would affect bleeding, among one of its significant thereapeutic effects, whereas the evidence established that no such effect will occur (Tr. 682–683, 315–316, 424).

[31] The clinical studies conducted by Drs. Epstein, Isaacson, Berkowitz and Lieberman, offered into evidence by respondent dealt with the effect of the use of Preparation H or similar ointments on prolapse, bleeding and spasm and discharge (RX 6, RX 7, RX 8), indicating that

We conclude that the examiner's finding with respect to the therapeutic effect of Preparation H is merely a summarization of the purport of his findings on itching, pain and swelling and must be rejected to the same extent that these findings were rejected.

IV

THE ORDER

In view of our rejection of some of the examiner's findings and conclusions as discussed above, we are entering our own order in this matter consistent with our findings and conclusions respecting the properties of respondent's products and the false and misleading nature of respondent's representations concerning the efficacy of its products.

In determining what order is necessary to ensure that respondent's misrepresentations respecting the efficacy of its drug preparation will not occur again, it is of primary importance to consider the segment of the public which is most likely to be particularly affected by these misrepresentations.

Our mandate under the law was graphically expressed by Judge Clark when he emphasized that "the law is not 'made for the protection of experts, but for the public—that vast multitude which includes the ignorant, the unthinking and the credulous.'" *Charles of the Ritz Distributing Corporation* v. *Federal Trade Commission*, 143 F. 2d 676, 679 (2nd Cir. 1944).

The need for protection of the public becomes particularly acute where misrepresentations are made with respect to health

---

after use of this product these symptoms had disappeared or improved. There are certain fundamental weaknesses in each of these studies: (a) in each, the patients were instructed to use other conservative measures along with Preparation H, thus making it impossible to determine whether the results achieved were attributable to Preparation H or the other measures; (b) the Epstein-Isaacson studies did not use any control, thus failing to eliminate the psychological effect derived from the use of a placebo; the Berkowitz and Lieberman study did use a control—the prescription drug "Anusol"—but there was apparently no significant difference between the results obtained from said control and Preparation H and no evidence was introduced concerning the value of "Anusol"; (c) the symptoms of hemorrhoids have a tendency to remit within a period of from several days to two weeks which coincides with the time periods covered by the clinical studies. Furthermore, in the case of bleeding a showing made by respondent cannot be regarded as probative of any significant therapeutic effect in view of respondent's agreement some 12 years ago not to make the claim that its product will stop bleeding. It is significant that respondent never asked its own medical experts about their opinion as to the therapeutic effects of Preparation H on these specific symptoms nor did any of its medical experts testify that these symptoms would be affected, (with the sole exception of Dr. Burt, who testified that "simple mild bleeding" would be relieved (Tr. 1540)). Beyond their testimony on the specific symptoms of itching, pain and shrinking, respondent's other witnesses confined their opinions respecting the general efficacy of Preparation H to such observations as Preparation H "is an efficacious agent in the conservative management of patients with mild to moderate hemorrhoidal diseases" and "*can* render a patient with symptomatic hemorrhoids symptom free" (Dr. Epstein, Tr. 1569; emphasis added), or "that treatment with Preparation H *could* definitely render the primarily initially symptomatic hemorrhoid to a status where it was no longer a problem" (Dr. Berkowitz, Tr. 1113; emphasis added).

claims and the efficacy of drugs since the appeal of such representations falls most poignantly on those persons who are in distress, frequently the aged and the infirm. Moreover, today, with Medicare a reality, many people may be consulting doctors for the first time in their lives. They will be learning that aches and pains and discomforts of all kinds may be symptoms of diseases which they had never heard of before or never before associated with their own distress. Consequently, advertised claims of drug efficacy will have increasing relevance to this segment of our population and will offer hope of relief to millions in our population who may have previously ignored such advertising not realizing their possible application to their own conditions. Accordingly, it becomes of even greater importance today to make sure that representations respecting health claims and relief of distress are absolutely accurate and do not contain promises, impressions, or even highly veiled suggestions of efficacy which are in any sense false or misleading. It is with these basic principles in mind that we must fashion the type of prohibitive provisions which are necessary to be included in the order in this case.

A. *Product Application of the Order*

The order entered by us applies to representations made by respondent with respect to both Preparation H and to any medication sold by respondent in the future for the treatment of hemorrhoids. Certain of its prohibitions apply additionally to any drugs sold by respondent.

The order proposed by complaint counsel provided that it was to be applicable to Preparation H "or any other preparation or preparations *of substantially similar composition or possessing substantially similar properties*" (emphasis added). In our judgment, making the application of the order turn on a determination of whether or not a future preparation of respondent contains "substantially similar ingredients" or possesses "substantially similar properties" would be extremely difficult of enforcement and would only be productive of controversy and probably litigation.

The Commission is empowered to enter an order of sufficient breadth to ensure that respondent will not engage in violations of the law in the future. *Jacob Siegal* v. *F.T.C.*, 327 U.S. 608, 611 (1946); *F.T.C.* v. *Ruberoid Co.*, 343 U.S. 470, 473 (1952). Moreover, in the field of drug advertising we have special responsibility to avoid ambiguity in our orders so that their prohibitions

against misleading claims with respect to the efficacy of a medication are clear and easily understood and will in fact ensure that such claims will not be repeated in the future. Furthermore, the Commission must make sure that the effect of its orders cannot be evaded or avoided by a simple change in the ingredients of the products to which the order applies. *Erickson Hair & Scalp Specialists* v. *F.T.C.*, 272 F. 2d 318, 322 (7th Cir. 1959), *cert. denied*, 362 U.S. 940 (1960).

In the instant case respondent made five specific claims about the therapeutic effects of its products, each one of which was found to have been false. The pharmacological evidence with respect to respondent's products indicates that it has three basic ingredients: a "live yeast cell derivative," shark liver oil and phenylmercuric nitrate, a bacteriostatic agent having certain germ-arresting properties (Tr. 463–464), plus various lubricating agents. It is apparent that it would not be too difficult for respondent to replace these ingredients with others and put on the market another hemorrhoidal preparation which might have no different effect on hemorrhoids than its present Preparation H and yet be wholly outside the order if the order applied only to Preparation H or to other preparations containing similar ingredients. Accordingly, in our judgment it is essential that the order entered against respondent be sufficiently broad to cover any hemorrhoidal preparations sold by respondent regardless of whether their ingredients are the same or different from those contained in Preparation H.

If respondent should in the future develop a truly efficacious remedy for hemorrhoids, which would enable it to represent truthfully properties of its product which it could not now represent under this order, it can petition the Commission for an amendment of the order to permit such truthful representations with respect to such product.[32] (See Section 3.28(b)(2) of the Commission's Rules of Practice.) Thus, respondent is not restricted under this order from developing new hemorrhoidal remedies. The only limitation which this order places upon respondent is the obligation to petition the Commission for an amendment of this order if in fact respondent succeeds in developing a hemor-

[32] We are aware that under the provisions of Section 355 of the Federal Food, Drug & Cosmetic Act if respondent develops a "new drug" within the meaning of that section, it would be required prior to introducing it in commerce to obtain the approval of the Secretary of Health, Education and Welfare for all efficacy claims made for such drug in its labeling. Our order accordingly makes provision for this situation by providing that the Commission will take such approval into account in respondent's application for modification of the within order.

rhoidal preparation which heals or cures hemorrhoids or has any one or more of the properties which respondent is prohibited under this order from representing. We are of the view that any burden which is thereby placed on respondent in having to seek an amendment of this order before placing such new product on the market is far outweighed by the importance of protecting the public in advance against possible misrepresentations involving public health and safety. The gravity and widespread nature of respondent's misrepresentation with respect to Preparation H require no less.

Finally, we believe that it is essential not only to prohibit specific representations with respect to hemorrhoidal preparations sold by respondent, but also to cover misrepresentations as to the efficacy of any other drug product marketed by respondent. Respondent is hardly a stranger to Commission proceedings. In 1939 respondent's wholly owned subsidiary, Wyeth Chemical Co., was the subject of a Commission order proscribing future use of claims which it had made falsely representing the efficacy of the drug "Freezone" to remove corns (*Wyeth Chemical Co.*, Dkt. 3754, 29 F.T.C. 281). Only two years ago respondent was prohibited by order from continuing to misrepresent that their "Outgro" would restore ingrown toenails to normal (*American Home Products Corporation*, Dkt. 8478 (1963) [63 F.T.C. 933].[33] In both of these cases, as in the case before us, the gravamen of the violations which respondent and its subsidiary were found to have engaged in was the making of misleading exaggerations and misstatements in advertisments with respect to the efficacy of the drugs which each was selling.

The law is clear that an order issued by the Commission need

[33] In addition to the two litigated proceedings referred to above, respondent and its subsidiaries have been named in no less than six other Commission complaints, each of which also charged misrepresentations as to the efficacy of proprietary drugs. Of these, two were dismissed on the ground that the subsidiary involved had been dissolved (*Whitehall Pharmacal, Inc.* alleging misrepresentations as to the efficacy of the drug "Aspertaine," an analgesic [Dkt. 4718, 44 F.T.C. 1099 (1947)] and *Anacin Co.*, charging misrepresentations as to the efficacy of "Anacin," another analgesic [Dkt. 5213, 44 F.T.C. 1130 (1948)]); one was dismissed on the ground that the respondents therein had filed a petition asserting discontinuance and agreeing that if the same claims were again made, "then they agree that the facts in this case are as alleged in the complaint" (*Whitehall Pharmacal Co., et al.*, charging misrepresentations as to the efficacy of "Hill's Cold Tablets," a cold remedy [Dkt. 5038, 44 F.T.C. 1197 (1948)]); one was dismissed on a stipulation of discontinuance (*Whitehall Pharmacal Co.*, charging misrepresentations as to the efficacy of the drug "Kriptin," another cold remedy [Dkt. 5754, 47 F.T.C. 1450 (1950)]); one terminated in a consent order (*American Home Products Corp.*, charging misrepresentations as to the efficacy of the drugs "InfraRub" and "Heet," two remedies sold for the treatment of the pains of arthritis and other disorders (Dkt. 6755, 54 F.T.C. 1464 (1958)]); and one, again charging misrepresentations with respect to the drug "Anacin," was dismissed due to the lapse of time since the issuance of the complaint (*American Home Products Corp.* [Dkt. 8318 (1965)] [67 F.T.C. 430]).

not be confined to the particular product or even type of products sold by a respondent, particularly where the respondent has, by past conduct, demonstrated that the misrepresentations with which it has been charged are not isolated examples of its practices. Thus, in *Carter Products* v. *F.T.C.*, 323 F. 2d 523, 532 (5th Cir. 1963), the allegations in the complaint were limited to specific misrepresentation of the product "Rise," a shaving cream; but the order issued by the Commission prohibiting respondents from making such representations extended to "any other merchandise" sold by respondent in commerce which included a deodorant, "Arrid," and a drug, "Little Liver Pills." In affirming the order the court noted that the Commission had twice "litigated orders dealing with similar offenses" with respect to other products sold by Carter. In *Niresk Industries, Inc.* v. *F.T.C.*, 278 F. 2d 337, 343 (7th Cir. 1960), *cert. denied*, 364 U.S. 883 (1960), the court also affirmed with approval an order of the Commission covering all products sold by respondent, which consisted of a line of kitchenware, although respondent's misrepresentations constituting the subject-matter of the proceedings concerned only one product, an electric cooler-freezer. In rejecting respondent's argument that the order should be limited to the particular product in question, the Court stated:

> We do not agree with that contention. The Commission has a large discretion in its choice of a remedy which it deems necessary to cope with the unlawful practices found, * * *. Commission orders are not designed to punish for past transgressions, but are designed "as a means for preventing illegal practices in the future." * * * Petitioners marketed a large number of products in commerce. They stand adjudged guilty of the use of illegal practices in the advertisement and sale of one product. We think it is entirely reasonable for the Commission to frame its orders broadly enough to prohibit petitioner's use of identical illegal practices for new purposes or in conjunction with the sale of any and all of its products.

See also to the same effect *Albert Lane* v. *F.T.C.*, 130 F. 2d 48 (9th Cir. 1942) (misrepresentations found to have been made in two publications were prohibited in any similar publication); *Consumer's Sales Corp.* v. *F.T.C.*, 198 F. 2d 404 (2nd Cir. 1952) (misrepresentations found with respect to aluminum cookware, dinner and silverware, were also prohibited in connection with the sale of "other merchandise"); and *Benrus Watch Co.* v. *F.T.C.*, 352 F. 2d 313 (8th Cir. 1965), *cert. denied*, 384 U.S. 939 (1966) (misrepresentations found with respect to watches also prohibited in connection with the sale of all Benrus products whether or not related to the watch industry).

In the field of drug advertisements it is particularly important that the Commission's orders be sufficiently broad to ensure that the public will be fully protected against any future misrepresentations made by respondents with respect to the entire line of proprietary preparations which it sells and that it not be limited to just one type of preparation.

Accordingly, it is our judgment that in the circumstances of this case and of this respondent, it is essential that the order which we are entering cover all drug products sold by respondent.

B. *Respondent's Representations Respecting Curative Powers of Preparation H*

The order which we are entering prohibits respondent from making any general representations which in any way imply that use of its products will cure, remove or heal hemorrhoids or hemorrhoidal tissue. In this connection we have also prohibited respondent from representing that its product will shrink hemorrhoids or hemorrhoidal tissue. We have done so because of our view that any member of the public who reads a representation that a product will shrink hemorrhoidal tissue is unlikely to distinguish between this representation and the representation that the product will shrink hemorrhoids. Thus, even if it could be literally true under certain circumstances the representation is likely to mislead.

In addition, we have specifically prohibited respondent from referring in its advertising to Bio-Dyne or to any other ingredients, either singly or in combination, unless each such ingredient is effective in the treatment or relief of hemorrhoids or any of its symptoms and unless its specific effect is expressly and truthfully set forth.

The evidence establishes conclusively that Bio-Dyne, which respondent heralded so conspicuously in its advertisement as the "secret" of Preparation H, the "magical healing agent" in Preparation H and like representations, had no therapeutic qualities at all so far as hemorrhoids are concerned. The only effect claimed for "Bio-Dyne" was to "heal" hemorrhoids. Respondent admits that its product does not in fact heal hemorrhoids and it is clear, therefore, that any representations as to Bio-Dyne's healing effects are untrue and must be prohibited absolutely. Not only does Bio-Dyne not heal hemorrhoids but the record is devoid of any evidence that it has any therapeutic effect on hemorrhoids.

For the purposes of this litigation respondent arranged to have

performed a series of laboratory studies for the purpose of demonstrating that "Bio-Dyne" stimulates the growth of mouse fibroblast cells in vitamin-deficient media and increases the metabolic rate of tissue cells and explants from rat abdominal tissue (RX 70). However, respondent made no attempt to demonstrate that "Bio-Dyne" would have any effect on cellular respiration of cells attached to a living organism. As Dr. Sarner testified:

> * * * [T]here are many agents that work fine in the laboratory, but because of inhibiting agents encountered in the human body or in any animal body, these results do not follow on clinical examination (Tr. 443).

Even if it were assumed that this ingredient could increase the oxygen uptake of attached body cells, complaint counsel's witnesses unanimously testified that this would have no beneficial effect upon hemorrhoids (Tr. 113, 114, 195, 196, 259, 346, 416, 544, 545, 610, 611, 711, 712). Respondent attempted to counter this evidence through Dr. Arthur Grollman, a leading pharmacologist. However, after testifying that, if it were assumed that a substance could be demonstrated to increase the oxygen uptake of body cells, it could "conceivably" have a beneficent effect on hemorrhoids (Tr. 1764), Dr. Grollman conceded that hemorrhoids were not characterized by lack of oxygen (Tr. 1769).

Furthermore, the originator of Preparation H, Dr. Sperti, made it very clear in his testimony for respondent that the only effect of adding "Bio-Dyne" to the formula was to offset the depressing effect which phenylmercuric nitrate would have on cellular respiration and proliferation and thus that it would have no positive therapeutic value when used in Preparation H (Tr. 956, 981).

In view of this evidence, it is clear that any continued reference by respondent to Bio-Dyne in its advertising would be highly misleading and would imply to the public that the presence of this ingredient conveys some therapeutic properties to the product beyond those specifically claimed.

It is not too much to assume that a member of the public will believe that specific reference in an advertisement to a specific ingredient must mean that that ingredient is of particular importance to the efficacy of the product. For this reason we believe it is vital in the discharge of our responsibilities to eliminate all misleading representations, particularly in the case of drugs, to prohibit a respondent from singling out a particular ingredient in a medication and by such singling out, without more, convey an impression to the public of the therapeutic importance of such an

ingredient when in fact the ingredient is of no therapeutic value or of such minimal value as to be virtually worthless.

This is of particular importance in the instant case where respondent's advertisements have accorded major prominence to the presence in its Preparation H of Bio-Dyne and to its healing properties. To prohibit respondent from representing that Preparation H has any healing characteristics and to permit it to continue to represent that its products contain Bio-Dyne would be to nullify in major part the prohibition respecting the curative properties of its products.

C. *General Representations of Therapeutic Benefits*

The order entered by us prohibits respondent from making the specific representations respecting itch and pain which we have found to have been false and misleading. The order originally proposed by complaint counsel would have permitted respondent to make these representations provided it limited them to affording this relief temporarily and in situations where the itching or burning was of a "minor" nature. We believe that an order couched in these terms would be ambiguous and difficult both to comply with and to enforce. Moreover, any distinctions existing between major and minor pain or itch may be definable by medical experts, but it is highly unlikely that such distinctions would ever be realistically appreciated by the hemorrhoidal sufferer experiencing the itch or pain. Accordingly, the order entered by us simply permits respondent to represent what we have found to be supported by the evidence—that use of Preparation H may in some cases afford some temporary relief against some types of itch or some types of pain.

We have set aside that portion of the initial decision which is inconsistent with this opinion and our Findings of Fact and Conclusions which we are entering herein, and have adopted the findings of fact and conclusions of the examiner which are not inconsistent with our opinion and our Findings of Fact and Conclusions.

FINDINGS OF FACT, CONCLUSIONS AND ORDER

FINDINGS OF FACT

A. *Respondent and Its Product*

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 (C., Par. 1; A., Par. 1).

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 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).

3. The designations used by respondent for said preparations, the formulae [1] thereof and directions for use are as follows:

(1) 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 base composed of petrolatum, lanolin, falba, mineral oil and oil of thyme.

Directions: Remove new protective cover. 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. CAUTION: In case of bleeding, a physician should be consulted. Keep all medicines out of the reach of children.

(2) 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 in a base made up of cocoa butter, beeswax, polyethylene glycol 600 dilaurate, and glycerin.

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

(C., Par. 2; A., Par. 2; CX 5–8; RX 9–10; Stipulation, Tr. 68; Tr. 1017–19.)

4. 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, Hammonton, 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 maintains, and at all times mentioned herein has maintained, a course of

[1] The quantitative formulae for Preparation H are trade secrets and were received in evidence as *in camera* exhibits (CX 7, 8; Tr. 92–93, 97).

trade in said preparations in commerce, as "commerce" is defined in the Federal Trade Commission Act. The volume of business in such commerce has been and is substantial (C., Par. 3; A., Par. 3).

B. *Representations Made*

5. In the course and conduct of its said business, respondent 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 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, advertisements 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 purchase of said preparations in commerce, as "commerce" is defined in the Federal Trade Commission Act (C., Par. 4; A., Par. 4).

6. Among and typical of the statements and representations contained in the advertisements disseminated as set forth in the foregoing paragraph 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 hospitals.

Yes, doctors report a new healing medication . . . Preparation H . . . actually 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 Preparation H (optional: Ointment or Suppositories). Preparation H . . . shrinks hemorrhoids without surgery!

TV Commercial

VIDEO	*AUDIO*
OPEN MS MAN SEATED AT DESK. HE REACHES FOR BOOK FROM BOOK-SHELF BEHIND HIM.	ANNCR., DIRECT: These are doctors' reports on hemorrhoids . . . revealing a new medication that relieves pain and itching promptly, heals injured tissue . . .
OPENS BOOK TOWARD AUDIENCE, RESTS IT VERTICALLY ON DESK BEFORE HIM.	
CUT TO OPEN BOOK. SEE CHAPTER TITLE: "SHRINKS HEMORRHOIDS WITHOUT SURGERY."	ANNCR., OVER. . . . and actually shrinks hemorrhoids without surgery.
PKG. OF PREPARATION H MOVES FORWARD OUT OF TEXT TO MAXIMUM WIDTH SO PRODUCT NAME, CHAPTER HEADLINE BOTH ARE LEGIBLE.	It's the new medical discovery, Preparation H. Clinically tested, hospital tested, Preparation H.
CUT BACK TO MAN. HE REFERS TO BOOK.	ANNCR., DIRECT: Yes, hospital tests and clinical tests now show prompt relief of pain . . . healing and shrinking of swollen, injured tissue.
PAN AS MAN TURNS TO HIS RIGHT. TAKES PIPETTE OUT OF RACK, HOLDS IT UP OVER EMPTY TEST-TUBE.	The secret? Only Prepartion H contains Bio-Dyne . . .
CUT TO ECU GLISTENING DROP HANGING FROM PIPETTE. SUPER TITLE: "BIO-DYNE" AT BOTTOM SCREEN.	ANNCR., OVER: . . . the remarkable substance that draws the body's own healing oxygen to the painful area.

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.

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

Every Claim Verified By Doctors and Proved By 4 Leading Clinics.

For the first time science has found a new healing substance with the as-

tonishing ability to shrink hemorrhoids, stop burning rectal itch and relieve pain—without surgery or painful injections.

In one hemorrhoid case after another prompt relief was reported—also a "striking improvement" in from 2 to 4 days. These reports were verified by a doctor's observations and proved by four leading clinics.

Pain and itching were promptly relieved. And while gently relieving this distress—actual reduction (shrinking) of hemorrhoids took place. Most amazing of all—this improvement was maintained in cases where a doctor's observations were continued over a period of many months!

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 where 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. The secret is a new healing substance (Bio-Dyne)—the discovery of a world famous research institute. 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.

Magic Healing Power
Discovered by Accident

Like many great discoveries—the effectiveness of Preparation H was also discovered quite by accident. In the laboratories of a famous research institution in Cincinnati, Ohio—renowned scientists were conducting advanced medical tests.

During an ether-extracting procedure, there was a sudden explosion. An assistant was severely burned. As an emergency measure, large quantities of an ointment (still in an experimental stage) were smeared on. To everyone's amazement—pain ceased immediately and the skin healed remarkably fast without scarring.

Later tests revealed this ointment was 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 and helps prevent infection of hemorrhoids.

Every claim made for Preparation H has been verified by doctors. This is the *only* hemorrhoidal remedy containing Bio-Dyne. Just ask for Preparation H at any drug counter in ointment or suppository form.

(CX 9–14; RX 21, 22; Tr. 1917).

C. *Meaning of Representations Made*

7. Through the use of advertisements set forth in paragraph 6 hereof and others similar thereto not specifically set out therein, 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:

(a) Reduce or shrink hemorrhoids;[2]

(b) Avoid the need for surgery as a treatment for hemmorrhoids;

(c) Eliminate all itch due to or ascribed to hemorrhoids;

(d) Relieve all pain attributed to or caused by hemorrhoids;

(e) Heal, cure or remove hemorrhoids, and cause hemorrhoids to cease to be a problem.

D. *Evidence Pertaining to Truthfulness of Claims Made*

8. The following medical experts, all of whom were proctologists, or specialists in diseases affecting the anus, rectum and lower colon, including hemorrhoids (Tr. 102, 185–186, 248, 336, 409–410, 478, 536–537, 601, 695), testified on the basis of their experiences in their practices with the treatment of hemorrhoids and on the basis of their general knowledge in the the field of their specialty:

(a) *Dr. Richard Hopping:* formerly Chief of Proctology, Bethesda Naval Hospital and presently President of the Medical Board and Chief of Proctologic Services, Saint Barnabas Medical Center, Newark, New Jersey; author or a number of articles on disorders of the anus, rectum and lower colon (CX 28).

(b) *Dr. Sylvan Manheim:* formerly chief of the Rectal Clinic, Mount Sinai Hospital, New York, New York and Clinical Professor of Surgery for Rectal Diseases, New York Medical College; presently, Consulting Proctologist, Mount Sinai Hospital. Author of the book "Proctology," published by Oxford University Press in 1943; co-author of a number of articles in the field (CX 29).

(c) *Dr. W. Martin Marino:* Chief, Department of Surgery, Division of General Surgery, Division of Proctology, The Brooklyn-Cumberland Medical Center (CX 30).

(d) *Dr. Samuel W. Eisenberg:* Clincial Professor of Proctology, Temple University Medical Center (CX 31).

(e) *Dr. Joseph B. Sarner:* Senior Attending Proctologist, Einstein Medical Center, Philadelphia; instructor in proctology at Graduate School of Medicine, University of Pennsylvania (CX 32).

(f) *Dr. Andrew J. McAdams:* Chief of Department of Proctology, Division of Surgery, Western Pennsylvania Hospital (CX 33).

(g) *Dr. Karl Zimmerman:* formerly President of the Ameri-

[2] The words "hemorrhoids" and "piles" are synonymous (See Finding 15, *infra*) and will be used interchangeably herein.

can Protologic Society, author of over 30 articles and papers in the field (CX34).

(h) *Dr. Charles Evans Pope:* Head of the Proctologic Department, St. Francis Hospital, Evanston, Illinois; author of 30 papers and articles in the field (CX 35).

(i) *Dr. Durand Smith:* Chief of the Surgical Rectal-Proctoscopy Clinic at Northwestern University Medical School (CX 37).

9. The following medical experts testified for respondent with respect to clinical studies which they had conducted of Preparation H and on the basis of their experiences in their medical practices with Preparation H, other ointments and suppositories and other methods of treating hemorrhoids:

(a) *Dr. Robert E. S. Young:* General surgeon; instructor in surgery at Ohio State University; director of the Institute of Medical Research, Inc. of Columbus, Ohio (RX 79).

(b) *Dr. Olin Burt:* Obstetrician and gynecologist; Fellow of the American College of Obstetricians and Gynecologists (Tr. 1514–1517).

(c) *Dr. Jerome Epstein:* Specialist in internal medicine and gastroenterology; Assistant Clinical Professor of Medicine at George Washington University School of Medicine; formerly a "New Drug officer" with the federal Food and Drug Administration (Tr. 1540–1541; RX 80).

(d) *Dr. Norman H. Isaacson:* Surgeon, who, according to his testimony had a "special interest in Proctology:" Clinical Instructor at George Washington University Medical School (Tr. 1653, RX 81).

(e) *Dr. Donald Berkowitz:* Specialist in gastroenterology; Associate Professor of Medicine at Hahnemann Medical College; attending in Gastroenterology at the Albert Einstein and Sidney Hillman Medical Centers in Philadelphia; holder of Master of Science and Master of Arts Degrees in biochemistry; author of numerous articles on a variety of medical subjects (Tr. 1075–1080; RX 76).

(f) *Dr. William Lieberman:* Proctologist; Director of Department of Proctology, Unity Hospital, Brooklyn, New York; Fellow and President Elect of International Academy of Proctology; author of numerous articles in the field of proctology (Tr. 1219–1224; RX 77).

(g) *Dr. Harold S. Feldman:* General practitioner, with emphasis on internal medicine and psychosomatic medicine; holder of Doctorate in Philosophy on Medicine Sciences with Major in

Pharmacology; Clinical Instructor at New York Medical College and instructor in Psychopharmacology at Seton Hall Medical School (RX 72; Tr. 887–891).

(h) *Dr. Fred J. Phillips:* General practitioner; associate with two other general practitioners and a surgeon at Quakertown, Pa. (Tr. 835–843).

(i) *Dr. Frederick Steigman:* Specialist in internal medicine and gastroenterology; Associate Clinical Professor of Medicine at University of Illinois College of Medicine and Professor of Gastroenterology of Cook County Graduate School of Medicine (RX 71; Tr. 808–813).

The following medical expert testified for respondent on the basis of his knowledge as a pharmacologist:

Dr. Arthur Grollman: Professor of Medicine and Chairman of the Department of Experimental Medicine at Southwestern Medical School of the University of Texas; author of "Pharmacology and Therapeutics" (6th Ed. 1965 [Tr. 1769]), a leading text, and numerous other books and publications (RX 83).

10. Evidence was submitted by respondent pertaining to three clinical studies, each of which had been conducted at the request of respondent:

(a) Dr. Robert Young, who, assisted by Dr. Olin Burt, conducted a clinical study of Preparation H with 127 patients during 1958 and 1959.

(b) Dr. Jerome Epstein and Dr. Norman Isaacson, who, working independently of each other, each conducted a clinical study of Preparation H with 119 of their hemorrhoid patients during 1961–62.

(c) Dr. Donald Berkowitz and Dr. William Lieberman who conducted separate clinical studies during 1963–54 on 196 patients, approximately half of whom used "Anusol," an ethical hemorrhoidal preparation, as a control.

These clinical studies are described in Findings 11, 12 and 13.

11. *Young-Burt Study*

Of the 127 patients in the study, 19 were pregnant women who were treated in whole or in part by Dr. Burt, and the balance were treated by Dr. Young. Each patient participating in the study was told by Dr. Young or Dr. Burt that it was a clinical investigation and that he did not know whether the product would be of value or not. The patients were not told what the product was although the doctors did know that they were testing

Preparation H (Tr. 1456). The patients were instructed to use the medication after each bowel movement and at night when they went to bed. They were also instructed not to use any other type of medication or treatment. After the initial visit, the patient was seen again in three or four days and at intervals thereafter until there was no further need for observation. The report forms were broken down into various items: "Chief Complaint," "Diagnosis," "Follow Up," "Reactions" or "Sensitivity" and "Comments." No information was recorded respecting the patients' medical histories, previous medication used, the types of examinations performed or the size or state of the patient's hemorrhoids. No control was used. Of the patients who participated, 13 did not have hemorrhoids but had some other anal or rectal disorder (RX 5C, 5P, 5V, 5Z8, 5Z10, 5Z13, 5Z18, 5Z28, 5Z31, 5Z33, 5Z35, 5Z57 and 5Z74). The study could not be completed on 13 cases due to failure to contact or death (RX 5L, 5Z12, 5Z15, 5Z17, 5Z25, 5Z32, 5Z36, 5Z37, 5Z38, 5Z41, 5Z42, 5Z63, 5Z69). Twenty-nine of the patients were examined by other doctors (Tr. 1489).

12. *Epstein-Isaacson Studies*

Dr. Epstein's study involved 33 subjects who were patients in his private practice. Each patient was told that the doctor was evaluating some hemorrhoidal preparations which were completely safe, but were not informed as to the name of the drug; he was put on the doctor's usual, conservative program and was instructed by the doctor to use the preparation morning, evening, and following each bowel movement. The records show that each patient made either two or three visits after the initial examination, usually about a week apart (RX 6A–6Z7). No control was used in the study. Dr. Epstein reported that of the 33 cases, 1 was referred for surgery (RX 6N); 6 did not have hemorrhoids (RX 6J, 6K, 6L, 6M, 6Z2, 6Z3); 7 were free from symptoms on the fourth visit (RX 6A, 6C, 6–O, 6X, 6Z, 6Z1, 6Z5); 12 still had symptoms on the fourth visit (RX 6B, 6D, 6G, 6H, 6I, 6P, 6Q, 6R, 6S, 6V, 6Z4, 6Z6); 5 did not complete the test (RX 6F, 6T, 6U, 6X, 6Z7); 2 others with hemorrhoids did not complete the test since they claimed they were cured (RX 6E, 6W).

Dr. Isaacson's study consisted of 86 cases. The patient was not told the name of the ointment or suppositories which he was given but was advised that the medication was "reported to be pretty good" (Tr. 1661). The patient was instructed to apply the medication morning, evening, and after each bowel movement

(Tr. 1662) ; Dr. Isaacson also prescribed a diet and bowel softener (Tr. 1675). The records show that each subject was treated two to four times following the initial visit, such visits usually being spaced three to seven days apart (RX 6Z8–RX 6Z93). No control was used in the study. Of the 86 cases Dr. Isaacson found that 26 (RX 6Z8, 6Z10, 6Z13, 6Z18, 6Z19, 6Z21, 6Z23, 6Z24, 6Z29, 6Z35, 6Z41, 6Z42, 6Z43, 6Z45, 6Z46, 6Z49, 6Z55, 6Z58, 6Z60, 6Z62, 6Z64, 6Z66, 6Z69, 6Z71, 6Z78, 6Z80) required surgery. In addition, 4 patients reported "no improvement" in their symptoms (RX 6Z9, 6Z16, 6Z20, 6Z28) and 5 others still had some symptoms at the end of the study (RX 6Z31, 6Z36, 6Z37, 6Z40, 6Z47).

13. *Berkowitz-Lieberman Studies*

Dr. Berkowitz and Dr. Leiberman were requested by respondent and paid a fee of $7,500 each to conduct a test comparing Preparation H ointments and suppositories with "Anusol," another preparation for hemorrhoids. The study was said to be "double blind," in that the doctors were not told which of the applications were Preparation H and which were Anusol and the patients were not given any information as to the identity of the items. The products, however, differed in color (Tr. 1105–1106). In Dr. Berkowitz' study 54 patients were treated with Preparation H, and 42 treated with Anusol. In Dr. Lieberman's study 48 were treated with Preparation H and 52 were treated with Anusol. Dr. Berkowitz also prescribed "other therapeutic measures, such as hygiene, diet, sitz baths, stool softeners" (Tr. 1107). Dr. Lieberman told each patient to continue with whatever course of treatment he had previously been giving himself.

Each of the doctors was requested to observe the patients during 3 visits. In Dr. Berkowitz' study the visits generally covered a 14-day period. In Dr. Lieberman's study the span of the study generally exceeded this period; the total period was in every case except one less than 30 days, although one case spanned 4 months.

The results obtained from the use of Anusol were similar to those obtained from the use of Preparation H (I.D., p. 1590). Of the 48 patients in Dr. Lieberman's group who used Preparation H, 9 received surgical treatment (RX 80, 8Z75, 8Z81, 8Z95, 8Z101, 8Z107, 8Z123, 8Z145, 8Z149), and 3 more needed it but did not receive it (RX 8Z66, 8Z133, 8Z143), and all but 5 (RX 85, 8Z31, 8Z35, 8Z73, and 8Z93) still had some symptoms at the end of the study.

E. *General Medical Facts Pertaining to Hemorrhoids and their Treatment*

14. "Hemorrhoids" are masses of dilated weak-walled veins located underneath the mucous membrane of the lower portions of the rectum and under the skin of the anal canal and the peri-anal area (Tr. 193, 255, 340, 413–414, 478, 543, 606, 709, 817, 838, 867, 892).

15. The terms "hemorrhoids" and "piles" are synonymous (Tr. 117, 193, 255, 340, 414, 478–479, 543, 607 and 709).

16. "Internal hemorrhoids" are hemorrhoids occurring above the pectinate line and are covered by mucosa. "External hemorrhoids" are hemorrhoids occurring below the pectinate line and are covered by skin (Tr. 110, 193, 199, 232, 236, 255–257, 262, 342, 420, 421, 486, 548, 549, 608, 609, 817, 838, 867 and 892).

17. An "external thrombotic hemorrhoid" is a blood clot under the surface of the skin located in the immediate vicinity of the anal opening (Tr. 117). It is also referred to as an "anal hematoma" (Tr. 719) or a "perianal thrombosis" (Tr. 549).

18. A "prolapse" or "prolapsing hemorrhoid" is an internal hemorrhoid which, due to laxity of the rectum is enabled to fall outside the anal canal and protrudes to the surface (Tr. 199).

19. Hemorrhoids develop in a human being largely because of the fact that he stands in an upright position. In such a position a column of blood is formed from the splenic to the superior hemorrhoidal vein. The hemorrhoidal veins do not have valves to support the weight of this column of blood. The resulting pressure causes the hemorrhoidal veins to dilate (Tr. 594, 231). Hemorrhoids tend to be hereditary (Tr. 144, 231). Other factors leading to the development of hemorrhoids are abnormally long periods of standing, straining, difficulty with bowel movement, impacted stool, pregnancy and cirrhossis of the liver (Tr. 231–232, 144).

20. The most common symptom of internal hemorrhoids is bleeding (Tr. 256, 393, 479). The other principal symptom of internal hemorrhoids is prolapse (Tr. 256). Pain rarely occurs in internal hemorrhoids since the sympathetic nervous system which services the region above the pectinate line where hemorrhoids are located does not contain sensory nerve fibers (Tr. 266, 294, 342–343). Pain, however, may occur in infrequent cases of severe complicated internal hemorrhoids as the result of spasm or strangulation caused by prolapse or as the result of the involvement of tissues beyond the pectinate line (Tr. 342, 415, 631–632, 723).

21. The most common symptoms of external hemorrhoids are pain and swelling (Tr. 256, 742). Pain in external hemorrhoids is frequently caused by an external thrombotic hemorrhoid (Tr. 503). Other causes of pain in external hemorrhoids are inflammation, swelling and ulceration (Tr. 174, 267, 358, 519). Pain may also result from infection. However, this cause of pain is a relatively infrequent occurrence since the rectal and anal area is relatively highly resistant to infection (Tr. 520) and thus infection occurs very rarely as a symptom of hemorrhoids (Tr. 315).

22. Swelling, as distinguished from the dilation of the hemorrhoidal veins, may be a symptom of hemorrhoids as well as a possible cause of pain in external hemorrhoids. Swelling usually results either from a blood clot or thrombosis, which causes distension in the tissue overlying the hemorrhoid, or from edema, which is the accumulation of serous fluid in the interfibrillar spaces in such tissue (Tr. 144,550).

23. Itching is not a common symptom of internal or external hemorrhoids (Tr. 129, 265, 618–619, 727). The itching thought to be caused by hemorrhoids is usually the result of some other condition such as fungus infection or idiopathic pruritis (Tr. 326, 502, 504, 347, 618–619, 727). The itching which is caused by hemorrhoids is usually the result of discharge from a prolapsed internal hemorrhoid (Tr. 318, 425, 618–619), or healing of an external hemorrhoid (Tr. 265, 502).

24. The symptoms of hemorrhoids can be confused with other conditions such as fissure, fistula, perianal or peri-rectal abcess, hypertrophic papillae, papillitus, cryptitis, polyps, proctitis, ulcerative colitis, pruritis ani and carcinoma (cancer). Any of these conditions can co-exist with hemorrhoids and it is not uncommon to find such a situation (Tr. 114–115, 196–197, 205, 259–260, 347–349, 483–484, 545–546, 612–613, 714–715).

25. The symptoms of hemorrhoids often disappear spontaneously within short periods of time, which may range from several days to two weeks (Tr. 119, 264, 324, 255, 361, 424, 875, 1613). However, the underlying pathology, namely, the vascular dilation, will persist unless corrected and will be subject to recurring episodes of symptoms (Tr. 516, 214).

26. Surgical removal is the only means by which hemorrhoids can be permanently cured (Tr. 118–119, 195, 200–202, 262–263, 352, 422, 487, 550, 554, 623, 719–723, 830). However, surgery does not effect a complete cure in every case (Tr. 150). Surgery may not be advisable or necessary in every case. Surgery may be

contra-indicated in cases in which the patient's general medical condition is such that the danger of anesthesia and surgery outweigh the possible benefits to be derived (Tr. 226). Surgery is also not advisable for a simple, uncomplicated hemorrhoid (Tr. 169). Although hemorrhoids may be uncomfortable they are rarely a very serious medical problem, so that a patient, if he chooses to avoid surgery or should avoid it for medical reasons, can go through life without having his hemorrhoids removed (Tr. 135).

27. The symptoms of simple, uncomplicated, internal hemorrhoids of small size can frequently be ameliorated by injectional therapy. This consists of the injection of a schlerosing solution into the hemorrhoid itself which causes scar tissue to form which cuts off the blood vessel feeding the hemorrhoid (Tr. 145, 200, 262–263, 353). A further treatment which has been used within the last several years is the baron ligation method whereby a ligature of rubber is placed around internal hemorrhoids as another means of cutting off blood circulation to the hemorrhoid (Tr. 200–201, 488).

28. In cases in which surgery, injectional therapy or the baron ligation method are not used, a so-called "conservative" course of treatment may be prescribed. The measures used in such a course of treatment include cleanliness, altering of the diet to eliminate irritative foodstuffs, control of the bowels to ensure a smooth, soft stool, warm baths, witch hazel, boric acid, local anesthetic, ointments, suppositories, avoidance of standing and manual reinsertion of prolapse (Tr. 120, 202, 306, 356–357, 684–686). Ointments and suppositories contain lubricants which may protect the anal and rectal canal against the passage of hard, dry stool. Such lubricants may also serve to relieve dryness and soften the skin as well as provide a psychological advantage; many people derive mental relief from the fact that some sort of treatment is applied (Tr. 203–204, 279, 313, 355, 358, 362–363, 525, 555, 557).

F. *Ingredients in Preparation H*

29. The active ingredients set forth in the Preparation H formula consist of (a) a "live yeast cell derivative supplying 2,000 units Skin Respiratory Factor (Bio-Dyne) per ounce" of ointment or suppository base; (b) Shark Liver Oil and (c) Phenylmercuric Nitrate 1:10,000, in a base composed of various lubricants and other materials which were included in the formula to make it possible to incorporate the other ingredients in the formula (F. 3; Tr. 953–954).

(a) *"Live Yeast Cell Derivative" ("Bio-Dyne")*

The substance "Bio-Dyne" was first isolated in the 1930's in the laboratories of the Institutum Divi Thomae of Cincinnati in the course of research directed by Dr. George Sperti. Later it was incorporated in a topical ointment—identical to the Preparation H ointment—which was patented in 1943 and subsequently marketed for the treatment of burns and wounds.

"Bio-Dyne" consists of amino acid, mineral salts and pantothenic acid (RX 70A). It was added to the formula for the purpose of offsetting the depressing effect which, it was felt, that phenylmercuric nitrate would otherwise have on cellular respiration and proliferation (Tr. 956, 980–981, 988). Laboratory experiments have demonstrated that when applied in pure form in test tubes it may under certain conditions increase the oxygen uptake and the cellular growth of mouse and rat cells in vitamin deficient media (RX 70A). However, neither oxygen deficiency nor vitamin deficiency plays a part in the causation or aggravation of hemorrhoids (Tr. 111, 194, 257–258, 345, 416, 480, 543–544, 609, 711, 1767–1769). Furthermore, hemorrhoids are not caused by a deficiency in the body cells of pantothenic acid, amino acids or nutrition (Tr. 1767).

(b) *Shark Liver Oil*

Shark liver oil was added to Preparation H as another source of "Bio-Dyne" (Tr. 953; F. 29(a)). It is also a source of Vitamins A and D (Tr. 1762). However, vitamin deficiency does not play a part in the causation or aggravation of hemorrhoids (F. 29(a), *supra*). This ingredient may also serve as a lubricant and tends to have an antiseptic action (Tr. 1762).

(c) *Phenylmercuric Nitrate*

This substance is a bacteriostatic agent which is not recognized as a potent antiseptic (Tr. 298). It may perhaps assist in protection against infection (Tr. 464) although due to the fact that the substance is mixed with other fluids in the rectal tract, it may be diluted to the point where it has no effect (Tr. 463–464).

30. Preparation H Ointment and Suppositories do not contain an astringent, anesthetic or anti-pruritic (itch relieving) agent (CX 5C; Tr. 278).

G. *Conclusions re Effect of Preparation H on Hemorrhoids and Its Symptoms and Manifestations*

31. Preparation H will not avoid the need for surgery where it is indicated, or heal, cure or remove hemorrhoids, or cause hemorrhoids to cease to be a problem (F. 25, 26, 28, 29; I.D., p. 1602; conceded by respondent on appeal herein).

32. Preparation H cannot reduce the size of hemorrhoidal veins (Tr. 128–129, 173–174, 212–213, 276, 369–370, 436–437, 500, 563–564, 629–630, 740, 1497, 1668).

33. Preparation H may possibly, through the lubricants which it contains, temporarily protect inflamed surface areas from the passage of hard, dry stool and thereby have some effect upon edema or swelling in the tissue overlying hemorrhoids (Tr. 202, 1471, 1570, 1668. *But cf.* Tr. 128–129, 463, 684, 742–143). However, where swelling is due to thrombosis (Tr. 264), it will have no beneficial effect (Tr. 503).

34. Preparation H may in some cases afford some temporary relief against some types of pain associated with hemorrhoids (Tr. 131, 207, 279, 372–373, 439–440, 503, 566, 632–633, 744). Through the lubricants which it contains, this medication may protect inflamed surface areas against the passage of hard, dry stool and thereby temporarily relieve some pain caused by ulceration or from edema or swelling resulting from such inflammation (Tr. 174, 212–213, 358, 493, 525. *But cf.* Tr. 128–129, 463, 684, 742–743). Preparation H can, however, have no effect upon pain due to thrombosis (Tr. 295, 358, 503) or due to spasm or strangulation caused by prolapsing internal hemorrhoids (Tr. 631–632).

35. Through the lubricants which it contains, Preparation H may possibly relieve dryness and surface irritation and thereby provide some temporary relief from some types of itching associated with hemorrhoids (Tr. 131, 215, 279–280, 373–374, 439–440, 503–504, 566, 633–634, 741).

36. Except for the effects set forth in F. 33, 34, 35, as well as possible psychological effects (see F. 28), Preparation H will not have any beneficial effect in the treatments or relief of hemorrhoids or any of its symptoms (Tr. 131, 215, 279, 315–316, 372–373, 424, 439–440, 503–504, 566, 632–633, 682–683, 744; Answer, Par. 3).

CONCLUSIONS RE ALLEGATIONS IN COMPLAINT

1. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of respondent.

2. Through the use of the advertisements set forth in paragraph 6 hereof and others similar thereto not specifically set out therein, 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:

(a) Reduce or shrink hemorrhoids;

(b) Avoid the need for surgery as a treatment for hemorrhoids;

(c) Eliminate all itch due to or ascribed to hemorrhoids;

(d) Relieve all pain attributed to or caused by hemorrhoids;

(e) Heal, cure or remove hemorrhoids, and cause hemorrhoids to cease to be a problem.

3. Preparation H Ointment or Suppositories will not:

(a) Reduce or shrink hemorrhoids;

(b) Avoid the need for surgery as a treatment for hemorrhoids;

(c) Heal, cure or remove hemorrhoids and cause hemorrhoids to cease to be a problem;

(d) Eliminate all itch or pain due to or ascribed to hemorrhoids or afford any relief from pain or itching associated with hemorrhoids in excess of affording some temporary relief in some cases of pain and itching associated with some types of hemorrhoids; or

(e) Afford any other type of relief or have any other therapeutic effect upon hemorrhoids or upon any of the symptoms or manifestations thereof.

4. Therefore, the advertisements referred to in paragraph 6 hereof 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; and the dissemination of said false advertisements constituted, and now constitutes, unfair and deceptive practices in commerce, in violation of Sections 5 and 12 of the Federal Trade Commission Act.

ORDER

I. *It is ordered,* That respondent American Home Products Corporation, a corporation, and its officers, representatives, agents and employees, directly or through any corporate or other device, do forthwith cease and desist from disseminating or causing the dissemination of any advertisement by means of the United States mails or by any means in commerce, as "commerce" is defined in the Federal Trade Commission Act:

A. In connection with the offering for sale, sale or distribution of Preparation H Ointment or Suppositories or any other product offered for sale for the treatment or relief of hemorrhoids or piles or any of its symptoms which:

1. Represents directly or by implication that the use of such product will:

(a) Reduce or shrink hemorrhoids or hemorrhoidal tissue or membranes or reduce or shrink swelling associated with hemorrhoids;

(b) Avoid the need for surgery as a treatment for hemorrhoids or hemorrhoidal symptoms;

(c) Heal, cure or remove hemorrhoids or eliminate the problem of hemorrhoids;

(d) Afford any relief from pain or itching attributed to or caused by hemorrhoids in excess of affording some temporary relief in some cases of pain and itching associated with some types of hemorrhoids;

(e) Afford any other type of relief or have any other therapeutic effect upon the condition known as hemorrhoids or upon any of the symptoms or manifestations thereof.

2. Contains any reference (a) to the word "Bio-Dyne"; (b) to any word which implies that said product will shrink hemorrhoids; or (c) to any word which implies that said product will provide any relief from pain or itching associated with hemorrhoids in excess of affording some temporary relief in some cases of pain and itching associated with some types of hemorrhoids.

3. Contains any reference to any other ingredient either singly or in combination unless each such ingredient is effective in the treatment or relief of hemorrhoids or any of its symptoms and unless the specific effect thereof is expressly and truthfully set forth.

B. In connection with the offering for sale, sale or distribution of any "drug" within the meaning of the Federal Trade Commission Act, including without limitation any product referred to in Paragraph I(A) hereof, which misrepresents directly or by implication the efficacy of such drug.

C. Disseminating, or causing to be disseminated, by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of respondent's

preparation or preparations, in commerce, as "commerce" is defined in the Federal Trade Commission Act, any advertisement which contains any of the representations prohibited in Paragraphs I(A) and I(B) hereof.

II. In the event that respondent at any time in the future markets any preparation for the treatment or relief of hemorrhoids or any of its symptoms for which it desires to make any of the representations now prohibited under Paragraph I(A) of this order, it may petition the Commission for a modification of the order. Such petition shall be accompanied by a showing that the representation is not false or misleading within the meaning of the Federal Trade Commission Act, and, if such has been the case, that the specific representation has been approved by the Secretary of the Department of Health, Education and Welfare under the provisions of the Federal Food, Drug and Cosmetic Act as it is presently constituted or as it may hereafter be amended.

It is further ordered, That respondent shall, within sixty (60) days after service upon it of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which it has complied with this order to cease and desist.

FINAL ORDER

This matter having been heard by the Commission on an appeal by complaint counsel from the initial decision of the hearing examiner, and upon briefs and argument in support thereof and in opposition thereto and the Commission having issued its Opinion herein; it is hereby

Ordered, That the findings of fact and conclusions in the initial decision of the hearing examiner which are inconsistent with the Commission's Opinion and the Findings of Fact and Conclusions hereby entered be and hereby are set aside; and it is further

Ordered, That the attached Findings of Fact and Conclusions, as supplemented by the additional facts set forth in the Commission's Opinion herein and the findings of fact and conclusions in the initial decision not hereby set aside, be and hereby are adopted and entered as the findings of fact and conclusions of the Commission; and it is further

Ordered, That the order proposed by the hearing examiner be and hereby is set aside and that the attached Order be and hereby is entered as the order of the Commission.