

IN THE MATTER OF
HUMPHREYS MEDICINE COMPANY, INCORPORATED
ORDER, OPINION, ETC., IN REGARD TO THE ALLEGED VIOLATION OF
THE FEDERAL TRADE COMMISSION ACT

*Docket 8640. Complaint, Aug. 28, 1964—Decision, Dec. 16, 1966**

Order requiring a New York City manufacturer of "Humphreys Ointment" to cease falsely representing in its advertising that its product will 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 Humphreys Medicine Company, Incorporated, 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 Humphreys Medicine Company, Incorporated, is a corporation organized, existing and doing business under and by virtue of the laws of the State of New York, with its principal office and place of business located at 71 West 23rd Street, in the city of New York, State of New York.

PAR. 2. Respondent Humphreys Medicine Company, Incorporated, is now, and for some time last past has been, engaged in the sale and distribution of a 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.

*Modified on Dec. 15, 1970.

The designation used by respondent Humphreys Medicine Company, Incorporated, for said preparation, the formula thereof and directions for use are as follows:

Designation: "Humphreys Ointment."

Formula: The active ingredients for "Humphreys Ointment" are as follows:

Camphor; pyroligneous Acid; Benzocaine; Lanolin; Witch Hazel Extract; Oil of Rosemary, in a specially prepared base.

Directions: Remove the Cap and screw Rectal Tip in its place. Lubricate tip by spreading Humphreys Ointment on it. Insert tip into rectum and squeeze the tube. Also apply Ointment to the External parts. Repeat as desired.

In case of continued bleeding discontinue treatment and see a Doctor, since this may indicate a serious condition.

PAR. 3. Respondent Humphreys Medicine Company, Incorporated, causes the said preparation, when sold, to be transported from Newark, New Jersey, to purchasers thereof located in various other States of the United States and in the District of Columbia. This respondent maintains, and at all times mentioned herein has maintained, a course of trade in said preparation 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 business, respondent has disseminated, and caused the dissemination of, certain advertisements concerning said preparation by various means in commerce, as "commerce" is defined in the Federal Trade Commission Act, including, but not limited to, advertisements disseminated by means of radio broadcasts transmitted by stations located 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 preparation; and has disseminated, and caused the dissemination of, advertisements concerning said preparation 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 preparation 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:

WHY SUFFER! WHY TORTURE YOURSELF! WHEN
THE PAINFUL AGONY OF HEMORRHOIDS CAN BE HELPED

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QUICKLY AND SIMPLY WITH NEW IMPROVED HUMPHREYS OINTMENT THAT WORKS SIMPLY AND EFFECTIVELY 3 WAYS:—

1) ANESTHETIC ACTION EASES PAIN. 2) ASTRINGENT ACTION SHRINKS SWOLLEN MEMBRANES. 3) SOOTHING ACTION RELIEVES DISCOMFORT SO, WHY SUFFER WHY TORTURE YOURSELF, WHEN THIS HELPFUL MEDICATION IS AS NEAR AS YOUR DRUG STORE.

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 "Humphreys Ointment" will:

1. Shrink piles;
2. Relieve all pain attributed to or caused by piles;

PAR. 7. In truth and in fact the use of "Humphreys Ointment" will not:

1. Shrink piles;
2. Relieve all pain attributed to or caused by piles;
3. Afford any relief or have any therapeutic effect upon the condition 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.

OPINION OF THE COMMISSION

DECEMBER 16, 1966

BY JONES, *Commissioner*:

I

The complaint in this matter, issued on August 28, 1964, charged that respondent violated Sections 5 and 12 of the Federal Trade Commission Act by making false representations in advertising its ointment, sold under the name of "Humphreys Oint-

ment," for the treatment of hemorrhoids or piles.¹ The complaint alleged, and respondent in its answer admitted, that it maintained a course of trade in said preparation in commerce within the meaning of the Federal Trade Commission Act.

Paragraph Five of the complaint charged that the following were typical of the statements made by respondent in its advertising:

WHY SUFFER! WHY TORTURE YOURSELF! WHEN THE PAINFUL AGONY OF HEMORRHOIDS CAN BE HELPED QUICKLY AND SIMPLY WITH NEW IMPROVED HUMPHREYS OINTMENT THAT WORKS SIMPLY AND EFFECTIVELY 3 WAYS:—

1) ANESTHETIC ACTION EASES PAIN. 2) ASTRINGENT ACTION SHRINKS SWOLLEN MEMBRANES. 3) SOOTHING ACTION RELIEVES DISCOMFORT SO, WHY SUFFER WHY TORTURE YOURSELF, WHEN THIS HELPFUL MEDICATION IS AS NEAR AS YOUR DRUG STORE.

This charge was admitted by respondent in its answer.

Paragraph Six of the complaint charged that through the use of these advertisements and others respondent had represented that use of Humphreys Ointment will: (1) shrink piles and (2) relieve all pain attributed to or caused by piles.

In Paragraph Seven these representations are alleged to be false and it is further alleged that Humphreys Ointment will not "[a]fford any relief or have any therapeutic effect upon the condition 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 complaint concludes that respondent's advertisements were misleading in material respects and constituted "false advertisements" within the meaning of the Federal Trade Commission Act.

Respondent denied the allegations in both Paragraphs Six and Seven.

The complaint in this matter was issued simultaneously with four other complaints also charging misrepresentations in the advertising of hemorrhoidal preparations, namely: *American Home Products Corporation*, Docket No. 8641 [p. 1524 herein], *E. C. DeWitt & Co., Inc.*, Docket No. 8642 [p. 1647 herein], *Grove Laboratories, Incorporated*, Docket No. 8643 [71 F.T.C. 822] and *The Mentholatum Company*, Docket No. 8644 [p. 1671 here-

¹ The terms "hemorrhoids" and "piles" are synonymous (Finding of Fact 11) and will be used interchangeably herein. Hereinafter the paragraphs of the Findings of Fact in this case will be referred to as "F.——."

in]. Hearings in the *American Home Products* case took place in April and May 1965, and the initial decision in that case was rendered on October 22, 1965. Complaint counsel appealed. On January 12, 1966, before argument of his appeal, complaint counsel moved in each of the other four cases to suspend hearings pending the issuance of the Commission's decision in *American Home Products*. This motion was denied by the Commission on March 16, 1966, and respondents in each of these four cases moved for reconsideration. On April 26, 1966 [69 F.T.C. 1179], the Commission entered an order directing the examiner to proceed with the hearings in each of these cases unless the parties desired to enter into a stipulation providing essentially that their cases may be disposed of on the basis of the record and findings in the *American Home Products* case. On May 24, 1966, respondent and complaint counsel filed a stipulation in accordance with the provisions of the Commission's order of April 26, 1966.² The stipulation provided that the Commission may issue such order as it deems necessary in the public interest on the basis of the facts stipulated by the parties and that the respondent waived any intervening steps before the hearing examiner. The parties further stipulated 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*; that the effect of the use of respondent's preparation is not significantly different from the use of American Home Products' preparation; and 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.

Attached to the stipulation are five advertisements, stated in the stipulation to be "representative of respondent's advertising claims," consisting of radio announcements, two of which are Spanish translations of two of the remaining three advertisements. Among the statements made in these advertisements are the following:

Humphreys Ointment relieves almost immediately the pain of simple piles, reducing the swelling and soothing its hotness.

Live free of the troubles of piles with Humphreys Ointment.

For over 100 years, Humphreys Ointment has helped people suffering with piles, to relieve its pain.

² The terms of this stipulation (hereinafter referred to as "Stip.") are set forth in full in F.5.

YOU MUST GET RELIEF FROM PAINFUL DISCOMFORTS OR YOUR MONEY IS REFUNDED PROMPTLY.

On the basis of the pleadings, the stipulation of the parties and the attached advertisements, together with such portions of the record in *American Home Products* as are specified in the attached findings, we conclude that we have jurisdiction over respondent and the subject matter and that respondent was engaged in commerce and accordingly are entering our Findings of Fact and Conclusions in the matter.

II

DISCUSSION OF ISSUES

A. Representations Made by Respondents in Its Advertisements

Respondent is charged with representing that its product will (1) shrink hemorrhoids and (2) relieve all pain attributed to or caused by hemorrhoids.

In *American Home Products* we found that respondent had represented that its preparation would "reduce or shrink hemorrhoids" and "relieve all pain attributed to or caused by hemorrhoids" (F.8(a) and (d)). In Paragraph 2(a) of the stipulation executed by the parties, it is provided that the advertisements in the instant case "had no significantly different effect upon the readers or hearers from the effect of the advertisements in *American Home Products*." Accordingly, on the basis of this provision of the parties' stipulation alone, we could conclude that respondent's advertisements represent that its ointment will shrink hemorrhoids and relieve all pain. However, there is no need to rely exclusively on parties' stipulation for this conclusion since the advertisements speak for themselves and our own independent examination of them enables us to determine whether the complaint allegations as to the representations made in these advertisements may be sustained.

(1) Respondent's claims respecting shrinkage

Respondent's advertising claims that respondent's product "relieves almost immediately the pains of simple piles, *reducing the swelling*, and soothing its hotness" and that its "*astringent action shrinks swollen membranes*" (emphasis added).

We believe that the effect of respondent's representation that its ointment will reduce and will shrink swollen membranes is to create the impression in the minds of the hemorrhoid sufferer that his hemorrhoids will be shrunk. Respondent's use of the

word "astringent" underscores the importance which respondent places upon the claimed efficacy of its ointment to shrink hemorrhoids.³ In our opinion any member of the public who reads a representation that a product whose "astringent action shrinks swollen membranes" is unlikely to make any technical distinctions between this representation and the representation that the product will shrink hemorrhoids. Thus we conclude that respondent's claims in its advertising are the equivalent to direct representations that its product will shrink hemorrhoids.

(2) Respondent's claims respecting pain

Respondent states in its advertisements that its ointment "relieves almost immediately the pains of simple piles * * *"; and it "has helped people suffering with piles, to relieve its pain"; that its "anesthetic action eases pain"; that "you must get relief from painful discomforts or your money is refunded promptly"; and finally that one may "live free of the trouble of piles, with Humphreys Ointment." In our opinion these statements represent to the hemorrhoid sufferer that any and all pain which he suffers as a result of his hemorrhoids will be relieved. It would obviously be impossible for one to "live free of the trouble of piles" if *any* pain attributable to hemorrhoids persisted after use of Humphreys Ointment. Respondent's claims are unequivocal and do not permit even an inference that the relief actually afforded may be only partial or temporary. The obvious implication of the word "anesthetic," which is defined as an agent "capable of producing anesthesia" or the "entire or partial loss or absence of feeling sensation; a state of paralysis of the sensory apparatus" (Webster's New International Dictionary, Second Edition), is that all pain or other sensation resulting from hemorrhoids will be relieved by Humphreys Ointment. Accordingly, we conclude that the statements in respondent's advertisements constitute representations that its product will relieve all pain attributed to or caused by hemorrhoids.

B. Deceptive Nature of Respondent's Claims

The parties have stipulated that the facts applicable to this case support the stipulation that the effect of the use of respondent's preparation is not significantly different from the effect of American Home Products' preparations (Stip., Par. 2(b)). Ac-

³ An "astringent" is defined as a "medicine or other substance that astringes, or contracts, the soft organic textures, and checks discharges of blood, mucus, etc." (Webster's New International Dictionary, Second Edition).

cordingly, the findings of fact and conclusions reached in *American Home Products* with respect to the efficacy of Preparation H, drawn from the record and Findings of Fact in that case, are equally applicable to Humphreys Ointment. It is in the light of these findings and conclusions, therefore, that the allegations in Paragraph Seven must be analyzed.

(1) Ability of Humphreys Ointment to shrink hemorrhoids

Paragraph Seven (1) of the complaint alleged that, contrary to respondent's representations, Humphreys Ointment will not shrink piles.

Respondent's advertising representations are to the effect that Humphrey's Ointment will "reduce swelling" and shrink "swollen membranes." We have concluded that these representations amount to a claim, and will be understood by the hemorrhoidal sufferer as a claim, that his hemorrhoids will be reduced in size. Hemorrhoids are by definition veins located underneath the mucous membrane of the rectum and the skin of the anal canal (F.10). The evidence in the record is that hemorrhoidal preparations such as Humphreys Ointment may have some effect upon edema or swelling in the tissue overlying hemorrhoids (F.25(c), 26), but that it cannot reduce the size of the hemorrhoidal veins (F.25(b), 26). The record also demonstrates, however, that this product can have no beneficial effect when the swelling is due to thrombosis (F.25(c), 26). Thus, even if we were to assume that some reduction of swelling is effected by respondent's preparation, not all types of swelling will be affected in this way, and furthermore the reduction which will occur will not be of the hemorrhoid itself but only of the surrounding area and thus will not be of the type implicitly promised by respondent's advertising. Accordingly, we find that respondent's representations with respect to shrinkage of hemorrhoids are in all respects false and misleading.

(2) Ability of Humphreys Ointment to relieve all pain

It is alleged in Paragraph Seven (2) of the complaint that, in contrast to respondent's claims in its advertising, respondent's products will not "relieve all pain attributed to or caused by piles." The record applicable to this case demonstrates that Humphreys Ointment cannot in fact eliminate all pain of hemorrhoids (F.25(d), 26). Pain 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 (F.16). Pain in external hemorrhoids is frequently caused by an external thrombotic hemorrhoid or by inflammation, swelling, ulceration or infection (F. 17). Through the lubricants which it contains, Humphreys Ointment 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 (F.25(d), 26). Humphreys Ointment can, however, have no effect upon pain due to thrombosis or due to spasm or strangulation caused by prolapsing internal hemorrhoids (F.25(d), 26). Thus we conclude that respondent's claim that its ointment will relieve all pain is false. The most that can be concluded is that Humphreys Ointment may in some cases afford some temporary relief against some types of pain associated with hemorrhoids (F.25(d), 26).

C. Alleged Absence of Other Therapeutic Benefits of Humphreys Ointment

In addition to the allegations that respondent's affirmative representations with respect to its product are false, the complaint also alleged that Humphreys Ointment will not "[a]fford any relief or have any therapeutic effect upon any of the symptoms or manifestations thereof in excess of affording temporary relief of minor pain or minor itching associated with piles" (Complaint, Paragraph Seven (3)).

The record demonstrates that surgical removal is the only means by which hemorrhoids can be permanently cured (F.22) and that Humphreys Ointment will not heal, cure or remove hemorrhoids or cause them to cease to be a problem (F.25(a), 26). The record also demonstrates that while Humphreys Ointment may in some cases provide some temporary relief from two symptoms of hemorrhoids, namely pain and itching (F.25(d) and (e), 26), it will not afford any other type of relief or have any other therapeutic effect upon hemorrhoids or its symptoms or manifestations (F.25(f), 26).

Accordingly, we conclude that the allegation in Paragraph Seven (3) of the complaint must be sustained.

III

THE ORDER

The parties have stipulated that the Commission may issue such order as it deems necessary in the public interest, taking into con-

sideration any significant differences between respondent's advertising and those of *American Home Products* (Stip. Par. 3 and 6).

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 representations.

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 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 proposed by complaint counsel provided that it was to be applicable to Humphreys Ointment "or any other preparation of substantially similar composition or possessing substantially similar properties" (emphasis added). As we noted in our Opinion in *American Home Products* with respect to Preparation H, under such an order the respondent could easily replace the in-

gredients in its product with those that are not "substantially similar" or which did not possess "substantially similar properties" and be exempt from the order even though such substitute product may be equally ineffective in relieving symptoms of hemorrhoids (*American Home Products*, Opinion, pp. 1623-1625).⁴ And, as we further pointed out in *American Home Products*, determination of whether or not the new ingredients were "substantially similar" or possessed "substantially similar properties" "would be difficult of enforcement and would only be productive of controversy and probably litigation" (*American Home Products*, Opinion, p. 1623). Consequently, we are entering an order in the instant case, comparable to that entered in *American Home Products*, which is applicable to all preparations which may be sold by respondent for relief or treatment of hemorrhoids or its symptoms regardless of whether they contain the same or different ingredients from those contained in Humphreys Ointment. Finally, as we pointed out in detail in our opinion in *American Home Products* case, this provision in no way hinders respondent from developing a truly efficacious remedy for hemorrhoids which might enable it to make some of the claims which this order now prohibits it from making. In this situation respondent need only apply to the Commission for a modification of the order as specifically provided for in the order which we are entering.

*B. Respondent's Representations Respecting the Efficacy of
Humphreys Ointment*

The order which we are entering prohibits respondent from continuing to represent directly or by implication that its product will shrink piles or relieve all pain attributed to or caused by piles. In addition, we are specifically prohibiting respondent from using the word "astringent" in its advertising. Since this word implies shrinkage of hemorrhoids, its continued use would have the effect of negating the prohibition on claims of shrinkage and therefore must be disallowed. We have similarly specifically prohibited respondent from referring in its advertisements to the word "anesthetic" which respondent uses to emphasize the purported pain-relieving qualities of its medication. As we noted above, the term anesthetic is synonymous with total elimination

⁴It is apparent from the nature of the ingredients in respondent's preparation (F. 3) that they in all likelihood are replaceable by other ingredients which might have no different effect on hemorrhoids and yet be wholly outside the order if it applied only to Humphreys Ointment or other preparations containing similar ingredients.

of all pain. In view of our findings and conclusions that Humphreys Ointment will not relieve all pain, any use of the term "anesthetic" would therefore be wholly false and misleading. While we do not know whether or not respondent's product in fact contains any anesthetic ingredient,⁵ even if we assume that it does, we have found that respondent's product will at best only afford some temporary relief in some cases of pain associated with some types of hemorrhoids. If this temporary relief is due to an anesthetizing ingredient in respondent's product it would be redundant to permit respondent to single this ingredient out for special mention in its advertisement in addition to making the permitted disclosure respecting temporary relief for some cases of pain and would serve only to confuse and mislead the reader or hearer. To the extent singling such an ingredient out for special emphasis conveyed an impression different from this disclosure, it would be false and misleading. Accordingly, we have prohibited use of this word.

We have furthermore provided that respondents may not refer 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. While respondent has not in its advertisements stressed any particular ingredient it has referred to anesthetic action and astringent action thus implying efficacy of its product which typically is generated by particular ingredients having these properties. Moreover, under established case law, the Commission need not "confine its road block to the narrow lane the transgressor has traveled; it must be allowed effectively to close all roads to the prohibited goal, so that its order may not be by-passed with impunity." *Federal Trade Commission v. Ruberoid Co.*, 343 U.S. 470 (1952). It is particularly vital in the discharge of our responsibilities to prevent misrepresentations of the efficacy of drugs, to prohibit a respondent from singling out an ingredient in a medication, and thereby convey the impression that such ingredient is of therapeutic importance, when in fact such ingredient has no value or is of such nominal value as to be virtually worthless.

Respondent's advertisements promise that use of its ointment will enable the hemorrhoid sufferer "to live free of the troubles

⁵ It may be noted that we found in *American Home Products* that Preparation H does not contain an anesthetic (A.H.P. 30). Respondent has stipulated that the facts applicable to this case support the stipulation that the effect of the use of its product is not significantly different from use of Preparation H but the facts themselves have not been stipulated.

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of piles." The record applicable to this case indicates that the only cure for hemorrhoids is their removal by surgery (F.22) and that using Humphreys Ointment cannot effect a cure nor heal or remove hemorrhoids (F.25(a), 26). While respondent has made no specific claim for itching we find that the broad claims in its advertisements of overall efficacy encompass the representation that all itching will be eliminated.

Accordingly, the order which we are entering against respondent prohibits it from making any specific or generalized efficacy claims for its product which would include the specific claims mentioned above or any other of like effect. Respondent is specifically permitted to claim that in some cases of hemorrhoids its preparation may afford temporary relief of pain and itching.

FINDINGS OF FACT, CONCLUSIONS AND ORDER

FINDINGS OF FACT

A. Respondent and Its Product

1. Respondent Humphreys Medicine Company, Incorporated, is a corporation organized, existing and doing business under and by virtue of the laws of the State of New York, with its principal office and place of business located at 71 West 23rd Street, in the city of New York, State of New York (Complaint, Par. 1; Answer, Par. 1).

2. Respondent Humphreys Medicine Company, Incorporated, is now, and for some time last past has been, engaged in the sale and distribution of a 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 (Complaint, Par. 2; Answer, Par. 2).

3. The designation used by respondent Humphreys Medicine Company, Incorporated, for said preparation, the formula thereof and directions for use are as follows:

Designation: "Humphreys Ointment."

Formula: The active ingredients for "Humphreys Ointment" are as follows:

Camphor; Pyroligneous Acid; Benzocaine; Lanolin; Witch Hazel Extract; Oil of Rosemary, in a specially prepared base.

Directions: Remove the Cap and screw Rectal Tip in its place. Lubricate tip by spreading Humphreys Ointment on it. Insert tip into rectum and squeeze the tube. Also apply Ointment to the External parts. Repeat as desired. In case of continued bleeding discontinue treatment and see a Doctor,

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since this may indicate a serious condition.
(Complaint, Par. 2; Answer, Par. 2.)

4. Respondent Humphreys Medicine Company, Incorporated, causes the said preparation, when sold, to be transported from Rutherford, New Jersey, to purchasers thereof located in various other States of the United States and in the District of Columbia. Thus respondent maintains, and at all times mentioned herein has maintained, a course of trade in said preparation in commerce, as "commerce" is defined in the Federal Trade Commission Act. The volume of business in such commerce has been and is substantial (Complaint, Par. 3; Answer, Par. 3).

B. Stipulation Entered Into By Parties Hereto

5. The parties hereto entered into a Stipulation, filed on May 24, 1966, providing as follows:

1. The above entitled case will be submitted to the Commission on the record in Docket No. 8641, *AMERICAN HOME PRODUCTS CORPORATION*, and such other facts and records as provided for below;

2. (a) The facts applicable to this case support the stipulation that advertisements in the case had no significantly different effect upon the readers or hearers from the effect of the advertisements in American Home Products.

(b) The facts applicable to this case support the stipulation that the effect of the use of respondent's preparation is not significantly different from the use of American Home Products' preparations.

3. 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;

4. The advertisements attached to this stipulation are representative of respondent's advertising claims and are to be included in the record of this proceeding;

5. Respondent waives any intervening steps before the Hearing Examiner;

6. The Commission may, on the basis of this stipulation, the attached advertisements and the record in American Home Products, issue such order as it deems necessary in the public interest;

7. The Commission is to issue its order disposing of this proceeding concurrently with the order setting forth its final action in American Home Products; and

8. The record on which the Commission is to make its disposition of this proceeding and for the purpose of judicial review is limited to the record at the time this stipulation is filed, this stipulation with the attached advertisements and the record in American Home Products.

Attached to this stipulation (hereinafter referred to as "Stip.") are copies of five advertisements, two of which are translations of two of the other two advertisements.

C. Representations Made

6. In the course and conduct of its business, respondent has disseminated, and caused the dissemination of, certain advertisements concerning said preparation by various means in commerce, as "commerce" is defined in the Federal Trade Commission Act, including, but not limited to, advertisements disseminated by means of radio broadcasts transmitted by stations located 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 preparation; and has disseminated, and caused the dissemination of, advertisements concerning said preparation 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 preparation in commerce, as "commerce" is defined in the Federal Trade Commission Act (Complaint, Par. 4; Answer, Par. 4).

7. Among and typical of the statements and representations contained in said advertisements disseminated as hereinabove set forth are the following:

WHY SUFFER! WHY TORTURE YOURSELF! WHEN THE PAINFUL AGONY OF HEMORRHOIDS CAN BE HELPED QUICKLY AND SIMPLY WITH NEW IMPROVED HUMPHREYS OINTMENT THAT WORKS SIMPLY AND EFFECTIVELY 3 WAYS:—

1) ANESTHETIC ACTION EASES PAIN. 2) ASTRINGENT ACTION SHRINKS SWOLLEN MEMBRANES. 3) SOOTHING ACTION RELIEVES DISCOMFORT . . . SO, WHY SUFFER. . . . WHY TORTURE YOURSELF, WHEN THIS HELPFUL MEDICATION IS AS NEAR AS YOUR DRUG STORE.

Humphreys Ointment relieves almost immediately the pain of simple piles, reducing the swelling and soothing its hotness.

Live free of the troubles of piles, with Humphreys Ointment.

For over 100 years, Humphreys Ointment has helped people suffering with piles, to relieve its pain.

YOU MUST GET RELIEF FROM PAINFUL DISCOMFORTS OR YOUR MONEY IS REFUNDED PROMPTLY (Complaint, Par. 5; Answer, Par. 5; Stip. [attachments]).

D. Meaning of Respondent's Representations

8. In *American Home Products Corporation*, Docket 8641 [p. 1524 herein], we found that through the use of American Home Products Corporation's advertisement, said respondent has represented and is now representing, directly and by implication, that

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the use of Preparation H Ointment and Suppositories, and each of them, will:

- (a) Reduce or shrink hemorrhoids;¹
- (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.

(*American Home Products Corporation*, Docket 8641, Finding of Fact 7 [p. 1633 herein].²)

9. Through the use of the advertisements set forth in paragraph 7 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 Humphreys Ointment 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.

(Stip. Par. 2(a).)

E. General Medical Facts Pertaining to Hemorrhoids and Their Treatment

10. "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 (A.H.P. Tr. 193, 255, 340, 413-414, 478, 543, 606, 709, 817, 838, 867, 892³).

11. The terms "hemorrhoids" and "piles" are synonymous (A.H.P.Tr. 117, 193, 255, 340, 414, 478-479, 543, 607 and 709).

12. "Internal hemorrhoids" are hemorrhoids occurring above the pectinate line and are covered by mucosa. "External hemorrhoids" are hemorrhoids occurring below the pectinate line and

¹ The words "hemorrhoids" and "piles" are synonymous (See Finding 11, *infra*) and will be used interchangeably herein.

² The paragraphs of the Findings of Fact in *American Home Products* are hereinafter referred to as "A.H.P.——."

³ The references herein are to the transcript in *American Home Products*.

are covered by skin (A.H.P. Tr. 193, 199, 232, 236, 255-257, 262, 342, 420, 421, 486, 548, 549, 608, 609, 817, 838, 867 and 892).

13. An "external thrombotic hemorrhoid" is a blood clot under the surface of the skin located in the immediate vicinity of the anal opening (A.H.P. Tr. 117). It is also referred to as an "anal hematoma" (A.H.P. Tr. 719) or a "perianal thrombosis" (A.H.P. Tr. 549).

14. 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 (A.H.P. Tr. 199).

15. 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 (A.H.P. Tr. 594, 231). Hemorrhoids tend to be hereditary (A.H.P. 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 cirrhosis of the liver (A.H.P. Tr. 231-232, 144).

16. The most common symptom of internal hemorrhoids is bleeding (A.H.P. Tr. 256, 393, 479). The other principal symptom of internal hemorrhoids is prolapse (A.H.P. 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 (A.H.P. 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 (A.H.P. Tr. 342, 415, 631-632, 723).

17. The most common symptoms of external hemorrhoids are pain and swelling (A.H.P. Tr. 256, 742). Pain in external hemorrhoids is frequently caused by an external thrombotic hemorrhoid (A.H.P. Tr. 503). Other causes of pain in external hemorrhoids are inflammation, swelling and ulceration (A.H.P. 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 (A.H.P. Tr. 520) and thus infection occurs very rarely as a symptom of hemorrhoids (A.H.P. Tr. 315).

18. 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 (A.H.P. Tr. 144, 550).

19. Itching is not a common symptom of internal or external hemorrhoids (A.H.P. 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 (A.H.P. 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 (A.H.P. Tr. 318, 425, 618-619), or healing of an external hemorrhoid (A.H.P. Tr. 265, 502).

20. The symptoms of hemorrhoids can be confused with other conditions such as fissure, fistula, peri-anal or peri-rectal abscess, hypertrophic papillae, papillitis, 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 (A.H.P. Tr. 114-115, 196-197, 205, 259-260, 347-349, 483-484, 545-546, 612-613, 714-715).

21. The symptoms of hemorrhoids often disappear spontaneously within short periods of time, which may range from several days to two weeks (A.H.P. Tr. 119, 264, 324, 355, 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 (A.H.P. Tr. 516, 214).

22. Surgical removal is the only means by which hemorrhoids can be permanently cured (A.H.P. 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 (A.H.P. 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 (A.H.P. Tr. 226). Surgery is also not advisable for a simple, uncomplicated hemorrhoid (A.H.P. 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 (A.H.P. Tr. 135).

23. The symptoms of simple, uncomplicated, internal hemorrhoids of small size can frequently be ameliorated by injectional therapy. This consists of the injection of a sclerosing solution into the hemorrhoid itself which causes scar tissue to form which cuts off the blood vessel feeding the hemorrhoid (A.H.P. 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 (A.H.P. Tr. 200-201, 488).

24. In cases on 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 (A.H.P. 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 (A.H.P. Tr. 203-204, 279, 313, 355, 358, 362-363, 525, 555, 557).

F. *Conclusions re Effect of Humphreys Ointment*

25. In *American Home Products* we reached the following conclusions with respect to the effect of Preparation H Ointment and Suppositories on hemorrhoids and its symptoms based on citations set forth below:

(a) 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 (A.H.P. 25, 26, 28, 29; A.H.P. Initial Decision, p. 124; conceded by respondent on appeal) (A.H.P. 31).

(b) Preparation H cannot reduce the size of hemorrhoidal veins (A.H.P. Tr. 128-129, 173-174, 212-213, 276, 369-370, 436-437, 500, 563-564, 629-630, 740, 1497, 1668) (A.H.P. 32).

(c) 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

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edema or swelling in the tissue overlying hemorrhoids (A.H.P. Tr. 202, 1471, 1570, 1668. But *cf.* Tr. 128-129, 463, 684, 742-743). However, where swelling is due to thrombosis (A.H.P. Tr. 264), it will have no beneficial effect (A.H.P. Tr. 503) (A.H.P. 33).

(d) Preparation H may in some cases afford some temporary relief against some types of pain associated with hemorrhoids (A.H.P. 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 (A.H.P. 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 (A.H.P. Tr. 295, 358, 503) or due to spasm or strangulation caused by prolapsing internal hemorrhoids (A.H.P. Tr. 631-632) (A.H.P. 34).

(e) 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 (A.H.P. Tr. 131, 215, 279-280, 373-374, 439-440, 503-504, 566, 633-634, 741) (A.H.P. 35).

(f) Except for the effects set forth in A.H.P. 33, 34, 35, as well as possible psychological effects (see A.H.P. 28), Preparation H will not have any beneficial effect in the treatment or relief of hemorrhoids or any of its symptoms (A.H.P. Tr. 131, 215, 279, 315-316, 372-373, 424, 439-440, 503-504, 566, 632-633, 682-683, 744; Answer, Par. 3) (A.H.P. 36).

26. We hereby enter findings with respect to the effect of Humphreys Ointment on hemorrhoids and its symptoms and manifestations identical to the findings with respect to Preparation H set forth in paragraph 25 hereof (Stip., Par. 2(b)).

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 7 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 Humphreys Ointment will:

- (a) Shrink hemorrhoids;
- (b) Relieve all pain attributed to or caused by hemorrhoids.

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3. Humphreys Ointment will not:

- (a) Shrink hemorrhoids;
- (b) Eliminate all pain due to or ascribed to hemorrhoids; or
- (c) Afford any relief or have any therapeutic effect upon hemorrhoids or upon any of the symptoms or manifestations thereof, in excess of affording some temporary relief in some cases of pain and itching associated with some types of hemorrhoids.

4. Therefore, the advertisements referred to in paragraph 7 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 Humphreys Medicine Company, Incorporated, 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 Humphreys Ointment 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, eliminate the problem of hemorrhoids, or enable one to live free of the troubles 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 any word such as "astringent" which implies that said product will shrink hemorrhoids; or (b) to any word such as "anesthetic" which implies that said product will provide 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. 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 Paragraph I(A) 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

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.
