

IN THE MATTER OF
HATO COMPANY, INC., ET AL.

COMPLAINT, DECISION, FINDINGS, ORDER, AND OPINION IN REGARD TO THE
ALLEGED VIOLATION OF SEC. 5 OF AN ACT OF CONGRESS APPROVED SEPT.
26, 1914

Docket 5087. Complaint, Sept. 6, 1950—Decision, Oct. 6, 1952

Diabetes is incurable and cannot be self-diagnosed or self-treated by the layman, and the sale of a preparation therefor to the lay public under representations and claims which are false is a public danger to the several million diabetics in the United States.

As respects the treatment of such conditions as retinopathy or retinitis, and increased capillary fragility, which accompany diabetes, treatment of the former is still in the research field, and cause or cure of the latter is unknown, so that it is inimical to the health of a large and unfortunate segment of the public to offer relief for such conditions through the purchase of a preparation calculated to lull the taker into a false sense of security which may, notwithstanding the wrapper and its directions, lead him to throw off the onerous diet restrictions and use of insulin, and thus inevitably hasten his death.

With regard to the authority of the Commission in a proceeding under Section 5 to direct its orders to the officers, agents, representatives, and employees of a named corporate respondent in the absence of any findings other than those directed solely at the corporate respondent: the Commission was of the opinion that the decision in *R. J. Reynolds Tobacco Co. v. F. T. C.*, 192 F. (2d) 535, 539-540, to the effect that the Commission was without such authority was erroneous in the light of that of the Supreme Court in *Regal Knitwear Co. v. N. L. R. B.*, 325 U. S. 9, there relied on, and in the light of other pertinent holdings of the courts including those in six other circuits, and that the earlier decision of the same court, overruled by it in the *Reynolds case*, in *Sebrone Co. et al. v. F. T. C.*, 135 F. (2d) 676, 678, was right.

It has long been the practice of the Commission to make its orders run against the officers, agents, representatives, and employees of corporate respondents and against their agents, etc., as individual respondents, such phrasing being regarded by it as a proper method of advising respondents that they are forbidden to undertake the interdicted act indirectly through some representative or subordinate, and the Commission has always understood that it not only had the right but the duty of making such inclusion in its orders.

A representation in an advertisement that a certain medicinal preparation would relieve "certain conditions often accompanying diabetes" was false, misleading and deceptive in its breadth and lack of qualification where it appeared that there was no claim that the product would relieve any except two of said conditions, and there was indirect evidence that the product would not relieve any of the others including acidosis, leg ulcers, cataracts, kidney complications and gangrene.

Where a corporation and its president, engaged in the offer and sale of a drug tablet designated "Celparux", in advertising in newspapers—

Falsely represented that said "Celparux" would control diabetes and would relieve certain conditions and complications thereof;

The facts being that no drug or combination of drugs presently known will cure or remedy diabetes; and neither said product, taken as directed, nor its ingredient rutin, will prevent the development, arrest the progress of, or serve as an adequate, competent treatment, remedy, or cure for diabetic retinitis or retinopathy; or prevent the development or increase of, or diminish, restore to normal, or correct increased capillary fragility in diabetics; or prevent, cure, treat, remedy, or relieve any symptom or complication of diabetes per se:

Held, That said acts and practices were false, misleading, and deceptive, and were all to the prejudice and injury of the public, and constituted unfair and deceptive acts and practices in commerce.

In reviewing and appraising the expert medical testimony of both parties in the foregoing proceeding, the Commission was of the opinion that the greater weight of the evidence in the record as to the therapeutic value of rutin for increased capillary fragility or retinitis resulting from or concomitant with diabetes, or hypertension, was that it had none.

In so deciding the determinative fact was not the greater number of the experts who so testified, but an analysis of the testimony as a whole, including the facts that respondent's expert did not specialize in diabetes, and that the benefits of rutin therapy for hypertensive retinitis and increased capillary fragility which he found may be accounted for by a difference in causation, namely, that while capillary fragility accompanying diabetes and hypertension is the same, the cause and treatment are different, and hypertensive retinitis is quite different from diabetic retinitis, and there is no relationship between increased capillary fragility and retinopathy in diabetes.

As respects public interest involved in respondent's advertising and selling to the lay public, it was significant that said expert testified that correction of increased capillary fragility would not aid or repair hemorrhage which had already taken place, that capillary fragility is certainly not the sole cause of retinal hemorrhage and may not even be a contributing part, that patients who had suffered said conditions had passed the point of no return so far as their retinal blood vessels are concerned, and that treatment of retinal hemorrhage is still in the research field and that neither rutin nor anything else can be offered to the general clinician as a remedy, cure, or relief therefor.

The reopening of the proceeding in question as a result of which additional evidence of qualified experts, including actual experience with rutin, the techniques employed, and the results obtained were detailed, and the standards of judgment and professional opinion were set out, largely cleared up prior uncertainties in the record and thus furnished a broader and sounder basis on which to judge and decide, weigh the evidence, and resolve conflicts and draw conclusions.

As respects the offer of the aforesaid preparation, whether the seller might make a profit out of the operation or give it away was beside the point.

In the aforesaid proceeding it was immaterial that reputable and leading drug houses offered the rutin compound for sale to the medical profession, since

Complaint

49 F. T. C.

that was no evidence of its therapeutic value; and the deduction therefrom that a substantial number of physicians were prescribing it for the very "conditions" advertised by respondents was likewise immaterial, and certainly so as any defense or justification; and the fact that a segment of the medical profession may be misleading diabetics is no excuse for respondents' likewise doing so, and no evidence on the record that neither of respondents' claims was misleading.

Before *Mr. Frank Hier*, hearing examiner.

Mr. R. L. Banks and *Mr. Jesse D. Kash* for the Commission.

Henican, James & Cleveland, of New Orleans, La., for respondents.

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 Hato Company, Inc., a corporation, and Charles W. Thomas, individually and as an officer of Hato Company, Inc., hereinafter referred to as respondents, have violated the provisions of the 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, Hato Company, Inc., is a corporation chartered and existing under the laws of the State of Louisiana, having its office and principal place of business at 150 Baronne Street, New Orleans, Louisiana.

Respondent, Charles W. Thomas, is president of Hato Company, Inc. The said Charles W. Thomas is responsible for and has control of and formulates the advertising policies and practices of the said corporate respondent, including the acts and practices hereinafter described. The address of the said individual respondent is the same as that shown for the corporate respondent.

PAR. 2. The respondents are now and have been for more than one year last past, engaged in the business of offering for sale and selling a drug preparation, as "drug" is defined in the Federal Trade Commission Act. The said preparation is compounded and sold as a tablet.

The designation used by respondent for the said drug, its formula and directions for use thereof are as follows:

Designation: "Celparux"

Formula: Each tablet contains:

Rutin-----	20 MG.
Parsley-----	180 MG.
Celery-----	60 MG.
Ascorbic Acid-----	20 MG.

Directions :

One tablet three times a day and one at bed time.

Use : Diuretic.

The labeling for said preparation sets out certain suggestions with respect to diet.

PAR. 3. In the course and conduct of their business, respondents have disseminated, and caused the dissemination of, certain advertisements concerning their said drug, Celparux, by the United States mails and by various means in commerce, as "commerce" is defined in the Federal Trade Commission Act, for the purpose of inducing and which were likely to induce directly or indirectly, its purchase, including, but not limited to advertisements in the "New Orleans Item" issues of December 18, 21, and 31, 1948; the New Orleans "Times Picayune" issues of December 8, 12, 15, 19, 22, 26, and 29, 1948; the "New Orleans States" issue of December 8, 1948; and the Monroe, Louisiana "News Star" issues of May 1 and 2, 1949; and respondents have disseminated and caused the dissemination of advertisements including, but not limited to those referred to above, for the purpose of inducing and which were likely to induce, directly or indirectly, its purchase in commerce, as "commerce" is defined in the Federal Trade Commission Act.

PAR. 4. Among the statements and representations contained in said advertisements, disseminated and caused to be disseminated, as hereinabove set forth, are the following:

Do you have diabetes? Celparux tablets are especially compounded to control your diabetes.

DO YOU HAVE DIABETES MELLITUS? CELPARUX TABLETS—
Especially compounded as an aid in the relief of certain conditions often accompanying DIABETES MELLITUS.

PAR. 5. Through the use of the advertisements containing the statements and representations hereinabove set forth, respondents have represented, directly and by implication, that the use of said preparation "Celparux" will control diabetes, and relieve certain conditions and complications of diabetes.

PAR. 6. The said advertisements are misleading in material respects and are "false advertisements" as that term is defined in the Federal Trade Commission Act. In truth and in fact, the use of the said preparation, as directed or otherwise, will not control diabetes, relieve any condition or complication of diabetes or have any therapeutic or other value in the treatment of said disease or its symptoms or complications.

PAR. 7. The use by respondents of the said advertisements has had the capacity and tendency to mislead and deceive a substantial portion of the purchasing public into the erroneous and mistaken belief that

the statements and representations are true, and to induce a substantial portion of the purchasing public, because of such erroneous and mistaken belief, to purchase said preparation.

PAR. 8. The aforesaid acts and practices of the respondents, as herein alleged, are all to the prejudice and injury of the public and constitute unfair and deceptive acts and practices in commerce within the intent and meaning of the Federal Trade Commission Act.

DECISION OF THE COMMISSION AND ORDER TO FILE REPORT OF COMPLIANCE

Pursuant to the provisions of the Federal Trade Commission Act, the Federal Trade Commission on September 6, 1950, issued and subsequently served its complaint in this proceeding upon respondents Hato Company, Inc., a corporation, and Charles W. Thomas, individually and as an officer thereof, charging them with the use of unfair and deceptive acts and practices in commerce by disseminating false advertisements in violation of said Act. After the issuance of said complaint and the filing on October 25, 1950, of respondents' answer thereto, hearings were held at which testimony and other evidence in support of and in opposition to the allegations of said complaint were introduced before a hearing examiner of the Commission theretofore duly designated by it, and said testimony and other evidence were duly recorded and filed in the office of the Commission. Thereafter, on April 9, 1951, the hearing examiner filed his initial decision, which was duly served upon the parties. Thereafter, counsel in support of the allegations of the complaint moved the Commission to order the proceeding reopened and remanded to the hearing examiner for the taking of additional evidence, which motion, though opposed by respondents, was granted by the Commission on August 23, 1951. Pursuant to such order, hearings were held for the receipt of additional evidence tendered by counsel in support of the complaint and for the receipt of evidence in opposition thereto tendered by respondents. Neither side having anything further to offer, the taking of evidence was closed by the hearing examiner on April 9, 1952. Thereafter, the proceeding regularly came on for final consideration by the hearing examiner upon the complaint, answer thereto, testimony and other evidence, before and since prior decision, and proposed findings of fact and conclusions presented by counsel for respondents; and said hearing examiner, on May 14, 1952, filed his initial decision therein.

Within the time permitted by its Rules of Practice, the Commission, having reason to believe that said initial decision did not constitute an adequate disposition of this proceeding, issued an order placing this

case on its docket for review, and served on all parties its tentative order to cease and desist proposed in lieu of the order contained in the initial decision, together with an order granting respondents leave to file any objections they might have to the proposed changes in the initial decision as embodied in said tentative order. The Commission having denied respondents' objections to said tentative order, this proceeding regularly came on for final consideration by it upon the record herein; and the Commission, being now fully advised in the premises, finds that this proceeding is in the interest of the public and makes this its findings as to the facts and its conclusions drawn therefrom and order based thereon, the same to be in lieu of the initial decision of the hearing examiner.

FINDINGS AS TO THE FACTS

PARAGRAPH 1. Respondent Hato Company, Inc., is a corporation chartered and existing under the laws of the State of Louisiana, having its office and principal place of business at 150 Baronne Street, New Orleans, Louisiana.

Respondent Charles W. Thomas is, and since its organization has been, president of Hato Company, Inc., and is and has been responsible for and in control of the advertising policies and practices of the corporate respondent, he having formulated such policies and practices, including the acts and practices herein described. His address is the same as that of the corporate respondent.

PAR. 2. Respondents are now and since 1948 have been engaged in offering for sale and selling a drug tablet, as "drug" is defined in the Federal Trade Commission Act. Such tablet is designated Celparux and its formula is:

Rutin.....	20 mg.
Parsley.....	180 mg.
Celery.....	60 mg.
Ascorbic Acid.....	20 mg.

Directions for use are one tablet three times a day and one at bedtime as a diuretic. The labeling of said preparation sets out certain dietary suggestions.

PAR. 3. In the course and conduct of their business, respondents have disseminated, and caused the dissemination of, advertisements of Celparux, by the United States mails and by various means in commerce, as "commerce" is defined in the Federal Trade Commission Act, for the purpose of inducing and which were likely to induce, directly or indirectly, its purchase, including advertisements inserted in the "New Orleans Item," "New Orleans States," "Times Picayune" news-

Findings

49 F. T. C.

papers in 1948 and the Monroe, Louisiana, "News Star" newspaper in 1949; and respondents have disseminated and caused the dissemination, by various means, of advertisements 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. 4. Among the statements and representations in said advertisements, disseminated and caused to be disseminated as hereinabove found, are the following:

Do you have diabetes? Celparux tablets are especially compounded to control your diabetes.

Do you have diabetes mellitus? Celparux tablets—especially compounded as an aid in the relief of certain conditions often accompanying diabetes mellitus.

PAR. 5. Through the use of the advertisements containing the statements and representations hereinabove set out in Paragraph Four, respondents have represented that Celparux tablets will control diabetes, and will relieve certain conditions and complications of diabetes.

PAR. 6. Diabetes to the public is synonymous with diabetes mellitus, and is an incurable disease of metabolism in which the pancreas fails to produce and pour into the blood stream enough of the hormone insulin to metabolize glucose sugar in the blood to substances which can be utilized by the tissues. This failure results in an excess of sugar in the blood stream, which spills over into the urine. Uncorrected or uncompensated acidosis, vascular disease, leg ulcers, retinitis, cataracts, kidney complications, increased capillary fragility, and gangrene may ensue, resulting in death. At least several million people in the United States have diabetes.

PAR. 7. Diabetes is characterized symptomatically at the onset by increased thirst and appetite, loss of weight, excessive urination, itching of the skin, often infections of the skin and weakness. While all of these are objectively discernible to the patient himself, they are not indicative of diabetes alone, but characterize other physical disturbances or diseases also. Furthermore, they are merely the outward manifestations of the metabolic fault which is undeterminable without facilities and the knowledge of their use, not possessed by a layman. Self diagnosis of diabetes is impossible. The victim must be given a thorough physical examination by a competent and experienced physician including extensive laboratory tests, such as urinalyses, glucose blood level and glucose tolerance tests. While urinalyses may be performed by an instructed layman or patient, the other tests cannot be. From these tests the physician must determine the extent of metabolic fault—just how much blood sugar the impaired pancreas

can metabolize. If the breakdown be slight, restriction of sugar and starches in the diet may be adequate to prevent complications and death. If the breakdown be extensive, then in addition to diet restriction, insulin must be injected parenterally at various intervals. Fifty percent of diabetics need insulin as well as diet restriction. Victims of diabetes vary greatly in their ability to utilize blood sugar, diets must be fitted to the individual exigency, and dosages of insulin vary widely as to the kind of insulin, the unit dose and frequency of the injection. Self-treatment, in the sense of halting or delaying the disease, is therefore impossible also.

PAR. 8. There exists no drug or combination of drugs, presently known, which will cure, correct or remedy diabetes. Since there likewise exists no drug, or combination of drugs, presently known, which, when taken by mouth, will control or adequately and effectively treat diabetes, the question of whether the disease can be controlled or treated at all by diet and/or insulin, in one sense of those verbs, is immaterial. Respondents' representation, therefore, that Celparux tablets "are especially compounded to control your diabetes," is misleading and deceptive on its face and false in its implication that they will control the disease.

PAR. 9. The evidence on respondents' second representation: "Celparux tablets—especially compounded as an aid in the relief of certain conditions often accompanying diabetes," is in conflict on one point. The "conditions" accompanying diabetes are hereinabove set out in Paragraph Six. There is no claim by respondents that their product will relieve any of these conditions except retinitis and increased capillary fragility. There is indirect evidence in the record that Celparux will not. Therefore, the representation is false, misleading and deceptive in its breadth and lack of qualification as to the other conditions which frequently accompany diabetes—acidosis, leg ulcers, cataracts, kidney complications, gangrene. The only serious dispute in this proceeding is whether rutin, with or without ascorbic acid, in the amounts contained in Celparux, taken as directed, will relieve retinitis and increased capillary fragility. Forty percent of all diabetics have increased capillary fragility, of which seven to eight percent have retinitis.

PAR. 10. On this issue, two specialists in internal medicine, the orbit of which includes diabetes, who had treated many diabetics and who were currently doing so, testified that neither Celparux tablets, nor any of the ingredients therein, alone or in combination, in the dosage prescribed, or in any dosage, would "relieve," treat, cure, or alleviate either diabetes or its accompanying retinitis or increased capillary fragility. Neither had had any experience with Celparux

Findings

49 F. T. C.

or rutin, experimental or clinical. Both were aware of reported research and experimental and clinical work done by others with rutin on both animals and humans in the treatment of retinitis and increased capillary fragility, whether concomitant to diabetes, hypertension or some other disorder, and were aware that some of this work indicated success. They testified that other work done produced neutral or negative results. Both rejected the findings of success, on the ground that the results were inconclusive.

PAR. 11. One of these experts was of the opinion that rutin was not absorbed into the blood stream in appreciable amounts, with or without the other ingredients of Celparux; that insulin does not cure increased capillary fragility or retinitis but that diet restriction will limit and prevent retinitis; that the clinical reports on the use of rutin in decreasing increased capillary fragility and retinitis have been equivocal, that is, that there have been comparatively as many failures as successes; that the tests for increased capillary fragility are not completely satisfactory but open to a number of valid criticisms; that the work of others on this subject has shown positive, neutral and negative results (some of it shows rutin does decrease capillary fragility and retinitis, some of it shows rutin to have no effect whatever and some of it shows increased capillary fragility and retinitis in spite of rutin therapy). Therefore, she rejects it all as inconclusive and does not believe that rutin in the dosage of Celparux, with or without the other ingredients, will relieve increased capillary fragility or retinitis.

PAR. 12. The second of these experts was of the opinion that Celparux is not an adequate treatment for diabetes; that there is no conclusive proof that Celparux, taken as directed, will prevent or relieve any symptom, condition or complication of the disease; that there is evidence that rutin will, and evidence that it will not, but that it is in the experimental stage at this time and, therefore, he did not believe that it would. He had great doubt that rutin was absorbed through the intestinal tract when taken orally and was not aware of any research showing that combining ascorbic acid with rutin increased the absorbency of the latter. He was of the opinion that there was conclusive evidence that rutin would not relieve increased capillary fragility in the majority of patients treated with it, although he had never used it himself, experimentally or clinically; that there is evidence that rutin will relieve increased capillary fragility in a few cases but that such evidence was inconclusive in his opinion; that there were some experts in the field who believe that rutin deserves further clinical trial, who advocate its use and believe it to be effective. He was further of the opinion that ascorbic acid has an effect on

increased capillary fragility where associated with scurvy; that the tests to discover increased capillary fragility are all subject to criticism for validity; that his acceptance of experiments with rutin would depend upon how well the experiments and the increased capillary fragility were controlled and how long the experiments were run; that he knew of no experiments with rutin where these factors were satisfactorily demonstrated. He testified that insulin does not decrease capillary fragility and does not correct or control retinitis, that diabetes may be under control but the patient will still have increased capillary fragility. He testified he was reluctant to recommend, accept or use a drug until it is proved to his satisfaction to be and to do what it is supposed, because he is not sure it will do the patient the good it is supposed to, because some harm may befall the patient from taking it and because of the added expense to the patient.

PAR. 13. Opposing this medical opinion evidence, respondents produced a medical expert in the field of hypertension. Hypertensives, however, frequently have increased capillary fragility as a concomitant to their hypertension. This witness had first used rutin, experimentally and clinically. He was the author or co-author of some eight published articles describing its use and the results thereof. He was of the opinion that rutin is of definite value in correcting increased capillary fragility and retinitis in the amount contained in, and the dosage directed for, Celparux, with which product as such he was entirely unfamiliar. He did not know whether ascorbic acid increased the effect of the rutin but testified that rutin therapy was successful in reducing increased capillary fragility to normal in 88 percent of 300 to 500 patients, all of whom were the patients of the witness, all of whom he treated himself, and all of whom he saw. Very few of them had diabetes. His experience with rutin therapy for increased capillary fragility and retinitis covers eight years. He was of the opinion that a tablet containing the rutin in Celparux would have therapeutic value in the treatment of capillary fragility and retinitis, but would not testify as to the other ingredients in Celparux since he was unfamiliar with the product. He was of the opinion that diabetes was not due to a deficiency of ascorbic acid, that celery and parsley would have no therapeutic value in the treatment of diabetes.

PAR. 14. There was no dispute in the medical opinion testimony that increased capillary fragility and retinitis cannot be discovered or diagnosed by a layman; that Vitamin C, celery and parsley have no therapeutic effect whatever on diabetes or any symptom or condition thereof; that rutin preparations are sold by leading pharmaceutical houses for the treatment of increased capillary fragility, usually

under the supervision of a physician; that Celparux is not dangerous to the human body in many times the dosage recommended by respondents.

PAR. 15. Celparux never has been and is not sold or given away except with a pamphlet prepared by respondents containing express directions to the user to follow his diet and see his physician. Selparux is sold in bottles of 100 tablets formerly for \$3.50 each, now for \$2.50 at the rate of from 150 to 300 bottles per month, twenty-five percent of which are given away by respondents to those who can't afford to pay for them.

PAR. 16. In addition to the medical testimony it was stipulated that if a pharmacologist were called, he would testify that he had made an extensive study of rutin, was familiar with the bibliography on the subject, and had prepared a thesis thereon; that in his opinion, it was of definite therapeutic value in treating increased capillary fragility and retinitis in the dosage recommended by respondents; that it is sold by reputable drug manufacturers for this purpose; that its effectiveness is increased by the addition of ascorbic acid. Such were the facts as revealed by the record when the proceeding was first closed and decided. After being reopened and remanded by the Commission, the following facts were adduced.

PAR. 17. Four specialists in internal medicine, which specialty includes diabetes mellitus, hypertension and their complications—two in Cleveland, Ohio, one in New York City and one in Philadelphia—all conferees of numerous academic and scientific degrees, all having served as instructors in medicine, both graduate and undergraduate, all of them authors of scientific articles, all of them having held hospital and clinical appointments of importance and responsibility and all of them having actively practiced medicine with private patients and in clinics for from 15 to 25 years and otherwise well qualified as experts in their field, testified they had administered rutin to patients suffering from retinopathy or retinitis, whether caused by or a concomitant of diabetes mellitus or hypertension, with completely negative results. One of these specialists had taken a group of 19 diabetics with retinopathy, all of whom were tested for increased capillary fragility by standard methods, and had given half of them placebos and the other half rutin in a dosage of 60 milligrams three times a day for a period of from 1 month to 3 months. He had also taken another group of 12 with hypertension and had similarly divided this group and treated one-half thereof with a similar dosage. Results were completely negative for both groups. Some of the patients in the control group showed improvement in capillary fragility; some in the treated group showed a worsening. There was no distinguishable

change in the retinopathy. The second expert had made a study of the use of rutin for the relief of capillary fragility, retinitis or retinopathy in conjunction with a leading ophthalmologist, giving a dosage of 50-60 milligrams three times a day to 75 patients who were observed over a period of from 6 months to a year, and he was unable to detect any objective evidence of improvement. The third specialist had treated more than 100 diabetics with a dosage of 20 milligrams three times a day which was increased up to 80 milligrams three times a day over a minimum period of 2 to 3 months and a maximum of 6 months without evidence of improvement. In fact, two patients developed blindness due to hemorrhage while on the rutin therapy. The fourth specialist prescribed it in dosages ranging from 20 milligrams to 100 milligrams four times a day to 150 to 200 patients over a period of from 3 months to 3 years and he has not seen a single patient where rutin had any effect on the progress of the retinitis. All of these men were of the professional opinion that the periods of time over which they administered the drug were amply sufficient to demonstrate whether it had any therapeutic effect on the disorder for which it was administered. In addition to the above, an equally well qualified ophthalmologist testified that he had tried rutin in dosages of from 20 milligrams three times a day to 400 milligrams daily over a period of from 6 months to 2 years on 50 diabetics and 25 to 30 hypertensives having retinopathy without beneficial result.

PAR. 18. Based on their experience, as detailed, and their scientific knowledge and experience as a whole, these men gave it as their collective expert opinions that rutin does not and will not arrest the progress of, correct, relieve or cure retinitis or retinopathy in either diabetics or hypertensives; nor does it diminish or restore to normal the increased capillary fragility from which diabetics or hypertensives frequently suffer; and that it is not an adequate, competent or effective treatment or remedy for diabetic or hypertensive retinitis or increased capillary fragility. They were further of the unanimous opinion that the respondents' preparation Celparux, when taken as directed, would not prevent the development of diabetic retinitis or retinopathy nor arrest the progress of these disorders; that it will not prevent capillary fragility from increasing nor will it correct or restore to normal increased capillary fragility in diabetics; that it will not correct, prevent or relieve any symptoms, conditions or complications of diabetes, nor will it cure diabetes, diabetic retinitis or increased capillary fragility, nor would the drug rutin alone accomplish any of these desired results.

PAR. 19. Respondents thereupon recalled as a witness the same specialist in hypertension who had previously testified, as set out

Findings

49 F. T. C.

supra, in Paragraph Thirteen hereof. This witness, as well qualified to testify as an expert on hypertension as any in this proceeding, criticized the testimony of the first of the Cleveland, Ohio, internists on two principal grounds: that the tests used to determine increased capillary fragility were neither medically established nor reliable, and that too few patients were tested over too short a time to determine whether rutin has or has not any therapeutic value. It was conceded that where a drug is toxic, 3 months is an adequate time, but he insisted that rutin is nontoxic and is allied to vitamins where results are frequently not demonstrable for many more months. Further criticism was made of the selection of patients with retinal hemorrhages already occurred on the ground that this amounted to restricting the testing to the worst cases where calamity had already occurred, and the negative results from such a restricted field did not necessarily indicate a drug had no beneficial or preventative effect on patients who had not retrograded so far. He testified further that some 11 reputable drug houses make and sell rutin under license from the U. S. Government, which holds the patent for its manufacture. He admitted that this is no evidence of the therapeutic value of rutin but simply evidence that there is a demand for it and use of it by the medical profession. As to the other testifying experts, he was of the opinion that their conclusions were too sweeping. He testified that he was convinced that correcting capillary fault would not help a hemorrhage which has already occurred; that capillary fragility is certainly not the sole cause of retinal hemorrhage and may not even be a contributing cause; that those who have had retinal hemorrhage have passed the point of no return so far as their retinal blood vessels are concerned; and that treatment of retinal hemorrhage is still in the research field and neither rutin nor anything else can be offered to the general clinician as a fait accompli. He did not know whether diabetics got any benefit from rutin dosage, having had too many diabetics suffer progressive failure of vision during the past few years while on adequate rutin therapy, frequently with normal capillary fragility, to have any illusions that rutin is the final answer for diabetic retinopathy and he had never claimed that it was. He was of the opinion that it had a subsidiary place, however.

PAR. 20. The greater weight of the evidence in this record as to the therapeutic value of rutin for increased capillary fragility, retinitis or retinopathy resulting from or concomitant with diabetes mellitus or hypertension is that it has none—not because there were a greater number of experts expressing such opinion but for the following reasons. It is most significant that identical results were obtained from usage of rutin, experimentally and clinically, by a

number of well qualified specialists in different parts of the country, unanimously opposite to the results obtained by respondents' experts. If the other experimenters or users had obtained varying or spotty results, the extensive and positive results of respondents' expert might well prevail because of the number of cases and the number of years followed. Opposing results were not all obtained in just 3 months—two observers followed patients taking rutin for 2 and 3 years, respectively. It seems impossible for five well qualified specialists, anxious to find some drug which would relieve or help the distressing conditions of their patients, separately to try out this drug without a single positive result, if the substance has the value and produces the results described by respondents' expert. There is no animus to discredit reflected on this record—the urge would naturally be to the contrary. Furthermore, there is credible and uncontradicted testimony in the record that, although the capillary fragility accompanying diabetes and hypertension is the same, the cause is different and the treatment is different, that hypertensive retinitis is quite different from diabetic retinitis or retinopathy, and there is no relationship between increased capillary fragility and retinopathy in diabetes. Respondents' expert does not specialize in diabetes, has limited experience with it, makes no claim to expertise in that field. The benefits of rutin therapy for hypertensive retinitis, retinopathy and increased capillary fragility which he found may, for all any expert testified, be accounted for by this difference in causation. This deduction is supported by his statement that he had seen too many diabetics suffer progressive failure of vision, although on adequate rutin therapy and frequently with normal capillary fragility, to have any illusions that rutin is the final answer for diabetic retinopathy. He admits he does not know whether diabetics get any benefit from rutin therapy. Rutin could be effective for vascular and retinal degenerative conditions accompanying hypertension and yet be entirely ineffective for the same conditions accompanying diabetes because of different causation. In any event, it is incorrect to assume, as was done on the previous record, that beneficial results claimed for rutin dosage on hypertensive concomitant indicated relief for the same conditions accompanying diabetes with the same treatment. Respondents' advertising, under attack in this proceeding, is confined to diabetes or "certain conditions often accompanying diabetes mellitus," for the relief or control of which respondents' nostrum is offered for sale.

PAR. 21. Accordingly, the finding of fact is that neither respondents' product Celparux, taken as directed, nor its ingredient, rutin, in any dosage, will prevent the development, arrest the progress of,

or serve as an adequate, competent, or effective treatment, remedy or cure for diabetic retinitis or retinopathy; nor prevent the development or increase of, nor diminish, restore to normal, or correct increased capillary fragility in diabetics; nor prevent, cure, treat, remedy, or relieve any symptom, condition or complication of diabetes, nor of diabetes per se. Respondents' representation, therefore, that its product Celparux, per se, or because of any ingredient, is "especially compounded as an aid in the relief of certain conditions often accompanying diabetes mellitus" is false, misleading and deceptive.

PAR. 22. On the question of the public interest in respondents' so advertising and selling to the lay public, it is significant that respondents' expert testified that correction of increased capillary fragility will not aid or repair a hemorrhage already taken place, that increased capillary fragility is not the sole, and may not even be a contributing cause of retinal hemorrhage, that patients who have had retinal hemorrhage have passed the point of no return so far as aid to their retinal blood vessels is concerned and that the treatment of retinal hemorrhage is still in the research field, and neither rutin nor any other substance is a reliable cure, remedy or relief therefor. According to another expert, diabetic retinopathy is a most serious complication, blinding one out of every six diabetics in spite of insulin, and increased capillary fragility occurs in 25 to 50 percent of all diabetics.

CONCLUSIONS

1. The uncertainties existing in the record in this proceeding prior to its having been reopened for the reception of additional evidence have been largely cleared up by the additional testimony of qualified experts. Actual experience with rutin has been presented, the techniques employed and results obtained have been detailed and the standards of judgment and professional opinion have been set out, thus furnishing a broader and sounder basis on which to judge and decide, weigh the evidence, resolve the conflicts and draw conclusions.

2. The sale of respondents' product to the lay public, under the representations and claims made is a public danger to the several million diabetics in the United States. Diabetes is incurable, cannot be self-diagnosed or self-treated by a layman. Even insulin and diet restriction do not prevent, control, arrest or relieve various degenerative "conditions" accompanying it, such as retinopathy or retinitis, which blinds one out of six, or increased capillary fragility, which attacks 25-50 percent of the unfortunate. With the treatment of the former condition still in the research field, and the latter unknown as to cause or cure, it is certainly inimical to the health of this very large

and unfortunate segment of the public to offer relief for these conditions through the purchase of respondents' pills, and lull the taker into a false sense of security which may, in spite of the wrapper around the pill bottle, lead him to throw off the onerous diet restriction and insulin treatment, thus inevitably hastening his death. Whether the respondents make a profit out of the operation or give the pills away is beside the point. It is likewise immaterial that reputable and leading drug houses offer the rutin component for sale to the profession. That is no evidence of its therapeutic value. The deduction therefrom that a substantial number of physicians are prescribing it as a treatment for the very "conditions" advertised by respondents is likewise immaterial, certainly as any defense or justification to respondent. That a segment of the medical profession may be misleading diabetics is no excuse for respondents' likewise doing so, and no evidence on this record that neither is misleading.

3. The acts and practices of respondents as herein found to be false, misleading and deceptive, are all to the injury and prejudice of the public and constitute unfair and deceptive acts and practices in commerce within the intent and meaning of the Federal Trade Commission Act.

ORDER

It is ordered, That respondents Hato Company, Inc., a corporation, its officers, representatives, agents, and employees, and Charles W. Thomas, individually and as an officer thereof, his representatives, agents, and employees, directly or through any corporate or other device, in connection with the offering for sale, sale, or distribution of Celparux, or any product of substantially similar composition, or possessing substantially similar properties, whether sold under the same or any other name, do forthwith cease and desist from directly or indirectly—

1. Disseminating, or causing to be disseminated, by means of the United States mails or by any means in commerce, as "commerce" is defined in the Federal Trade Commission Act, any advertisement, which represents, directly or through inference, that Celparux does or will control diabetes or does or will relieve or have any therapeutic value in the treatment of any symptoms, complication or condition of diabetes, including retinitis, retinopathy and increased capillary fragility.

2. 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 in commerce, as "commerce" is defined in the Federal Trade Commission Act, of Celparux, any advertisement

which contains any of the representations prohibited in Paragraph 1 of this order.

It is further ordered, That the respondents shall, within sixty (60) days after service upon them of this order, file with the Commission a report in writing setting forth in detail the manner and form in which they have complied with this order.

Commissioner Mason not participating.

OPINION OF THE COMMISSION

SPINGARN, COMMISSIONER: The Commission's complaint in this matter charges that respondents' advertising of their drug preparation Celparux as possessing therapeutic value in the treatment and control of diabetes and its symptoms is false, misleading and deceptive and constitutes unfair and deceptive acts and practices in commerce within the intent and meaning of the Federal Trade Commission Act.

After consideration of testimony and other evidence in the matter, the hearing examiner issued an initial decision in which he sustained the material allegations of the complaint and ordered respondents to cease and desist from the practices challenged by the complaint.

No appeal from the initial decision was filed. However, the Commission, being of the opinion that the hearing examiner's initial decision did not constitute an appropriate disposition of the matter, placed the matter on its own docket for review and has issued its findings as to the facts, conclusion, and order to cease and desist substantially as issued by the hearing examiner, except for adding to the order language making the order applicable to "officers, representatives, agents, and employees" of the corporate respondent Hato Company, Inc., and to "representatives, agents, and employees" of the individual respondent, Charles W. Thomas. Such alterations of the initial decision present the sole issue in this matter.

For years it has been the practice of the Commission to make its orders run against the officers, agents, representatives, and employees of corporate respondents, and also against the agents, representatives, and employees of individual respondents. The Commission has always understood that it not only had the right but the duty to make such inclusion in its orders. It regarded this phrasing as a proper method of advising respondents that they were forbidden to undertake the interdicted act indirectly through some representative or subordinate. Authority apparently sustained this inclusion. *Regal Knitwear Co. v. National Labor Relations Board*, 325 U. S. 9 (1945); *Southport Petroleum Co. v. National Labor Relations Board*,

315 U. S. 100 (1942); *Sebrone Co., et al. v. Federal Trade Commission*, 135 F. (2d) 676, 678 (C. A. 7, 1943). The Commission feels that the inclusion serves a worthwhile purpose because, as a practical matter, it tends to prevent and discourage evasion.

The present question was squarely raised by the Court of Appeals for the Seventh Circuit in its decision in *R. J. Reynolds Tobacco Co. v. Federal Trade Commission*, 192 F. (2d) 535, 539-540 (1951). That Court held the Commission was without authority in a proceeding under section 5 of the Federal Trade Commission Act to direct its order to the officers, agents, representatives and employees of the named corporate respondent in the absence of any findings other than those directed solely at the corporate respondent. In the course of its opinion the Court did concede that "under the cases there may be room for differences of opinion" but, nevertheless, overruled its own prior decision on the precise point as expressed in *Sebrone Co., et al. v. Federal Trade Commission*, 135 F. (2d) 676, 678 (C. A. 7, 1943), because it felt "the opinion discloses the question received scant consideration."

In *Regal Knitwear Co., supra*, the Supreme Court had refused to strike from the Labor Board's order the somewhat broader phrase "officers, agents, successors and assigns." In the *R. J. Reynolds Tobacco Co.* case the Seventh Circuit Court found it necessary to distinguish that decision. It pointed out that violations of Commission orders, unlike those of the Labor Board, might be the subject matter of civil penalty actions instituted in the district courts, 15 U. S. C. § 45 (1). It understood that the Supreme Court's approval of the inclusion of "officers, agents, successors and assigns" in Labor Board orders rested on the premise that enforcement of such orders "was lodged with a court of equity, which had ample facilities on a citation for contempt for protecting a person or party improperly brought before the court." And further said with regard to Commission orders:

"Thus, the unnamed 'officers, agents, representatives and employees' are not only subject to a contempt proceeding for the violation of a court's enforcement decree *where equitable considerations prevail*, but they are likewise subject to a severe penalty, to be recovered in a civil action." [Emphasis supplied.]

The Commission does not understand that the Supreme Court's approval in *Regal Knitwear Co., supra*, rested on the premise that enforcement of Labor Board orders was lodged with a court of equity. Instead it notes that in the course of the opinion the court pointed out that Rule 65 (d) of the Federal Rules of Civil Procedure provides that:

"Every order granting an injunction and every restraining order * * * is binding upon the parties to the action, their officers, agents, servants, employees and attorneys, and upon those persons in active concert or participation with them who receive actual notice of the order by personal service or otherwise."

The Court then stated:

"* * * This is derived from the common law doctrine that a decree of injunction not only binds the parties defendant but also those identified with them in interest, in 'privity' with them, represented by them or subject to their control. In essence, it is that defendants may not nullify a decree by carrying out prohibited acts by aiders and abettors, although they were not parties to the original proceeding."

The reasoning of the Seventh Circuit Court would be persuasive if the propriety of including the phrase in question rested on some power peculiar to and inherent in an equity court, or if the force and effect of such inclusion was to fix and determine responsibility for future acts without adequate notice and hearing, but since neither alternative appears correct, the Commission is of the opinion that the distinction sought to be made is unwarranted and not within the current of authority.

The Commission well recognizes that its orders cannot be "so broad as to make punishable the conduct of persons who act independently and whose rights have not been adjudicated according to law." *Regal Knitwear Co.*, *supra*, at p. 13. However, orders directed to the "officers, agents, representatives and employees" of a named corporate respondent do not seek any such result, nor is the Commission appropriating any powers peculiar to courts of equity for, "* * * no court can make a decree which will bind anyone but a party; a court of equity is as much limited as a court of law. * * *" *Alemite Mfg. Corporation v. Staff*, 42 F. (2d) 833 (C. A. 2, 1930).

The common law has long sanctioned the inclusion of "officers, agents, representatives and employees" of a named party. This inclusion has never been considered to be in derogation of the rights of the members of the class to have their day in court, because to the extent they are bound by the order they have had complete and adequate representation. It is well established that no restraint is laid on such "officer, agent, representative and employee" personally but merely as the "officer, agent, representative and employee" of the named party. Notwithstanding the order and notice of it, he, upon ceasing to be the officer, agent, representative or employee is free to act for himself in the protection of his own rights and the prosecution of his own interest even though it may involve his doing the very thing prohibited his former master. The order is a personal matter to the

party against whom it is directed and to those persons who occupy a subordinate relation to such party while they occupy that relationship. The object of the generalization is to advise the named party that he may not do indirectly, through representatives and subordinates, the act which he is directly forbidden to do. The act prohibited by the order is the act of the respondent and if respondent is not involved in the violation, the officer, agent, representative and employee could not be involved. *Chase National Bank v. Norwalk*, 291 U. S. 431 (1934); *Alemite Mfg. Corporation v. Staff*, 42 F. (2d) 832 (C. A. 2, 1942); *Dadirrian v. Gullian, et al.* 79 Fed. 784 (Circuit Court, D. New Jersey, 1897); *Kean v. Bailey, et al.*, 82 F. Supp. 260-262 (D. C. Minn., 1949); *Harvey v. Bettis, et al.*, 35 F. (2d) 349, 350 (C. A. 9, 1929); *Swetland v. Curry*, 188 F. (2d) 841, 843 (C. A. 6, 1951). See also 28 Am. Juris. Injunctions, sec. 331, 332

For further reasons, close study of the *Regal Knitwear Co.* decision affords small comfort for the Seventh Circuit's decision on this question in the *R. J. Reynolds Tobacco Co.* case. The *Regal Knitwear Co.* case involved a National Labor Relations Board order running against "officers, agents, successors and assigns" of a particular respondent. The issue seems to have been confined to the propriety of including "successors and assigns" in the order. Both the court and appellant apparently assumed that inclusion of "officers" and "agents" was entirely proper.

In delivering a 6 to 3 decision of the Court, Justice Jackson pointed out that the Seventh Circuit has consistently disagreed with other Circuits on this issue (pages 10-11):

"* * * Not only have circuit courts of appeals, except the Seventh Circuit, generally enforced orders containing this provision, but this Court has several times done so."

Then, after a discussion as to legal precedent for inclusion of the words in question (pages 12-15) it is stated that respondents' objection to the words of the order is "merely as words" and that:

"* * * No successor or assign appears before us complaining that these words put him in jeopardy. No one can be punished for contempt because of these words until after a judicial hearing in which their operation could be determined on a concrete set of facts" (page 16).

Finally, most significant to the determination of the issue in the instant matter and future similar Commission matters, is the fact that the Supreme Court noted with approval and as precedent for its decision in the *Regal Knitwear Co.* case that this Commission had long incorporated similar provisions in its orders. The Court stated:

"* * * Before the enactment of the Labor Relations Act, the Federal Trade Commission issued orders containing these familiar provisions" (page 12).

A footnote to this last statement cites in support thereof three Commission cases: *Matter of Superior Woolen Mills*, 8 F. T. C. 283, 288 (1924); *Matter of American Snuff Co.*, 11 F. T. C. 144, 160 (1927); and *Matter of Sherwin-Williams Co.*, 36 F. T. C. 25, 72, 74 (1943). The first two cases involve orders for violations of section 5 of the Federal Trade Commission Act, enforceable alternatively through contempt proceedings or penalty actions. The third case involves an order for violations of section 2 of the amended Clayton Act, enforceable only through contempt proceedings. It thus appears that the Supreme Court intended no such distinction as was made by the Seventh Circuit in the *Reynolds Tobacco Co.* case and that there is a fundamental disagreement between the two courts on the issue herein. If the Commission should follow the Seventh Circuit's decision, it would find itself in the somewhat inconsistent position of inserting the questioned words in Clayton Act orders, as authorized by the Seventh Circuit's interpretation of the *Regal Knitwear Co.* decision, but being expressly forbidden by the Seventh Circuit to use similar phraseology in Federal Trade Commission Act orders.

There are other considerations which have moved the Commission to follow the course outlined in this matter. As the Seventh Circuit has stated in *Steelco Stainless Steel, Inc., et al. v. Federal Trade Commission*, 187 F. (2d) 693, 697 (1951):

"* * * A corporation can act or speak only through its authorized officers or agents."

The Supreme Court was unmoved by the consideration that unnamed officers and agents might some day find themselves named and at bar for violations of orders of administrative agencies, so long as they then had their day in court. The Commission recognizes that it must both plead and prove before the appropriate courts any violations alleged against offenders, whether such violations be adjudicated in contempt proceedings or in penalty actions. In this connection, it may be observed that a possible advantage accrues to offenders in the penalty actions for the reason that such actions involve the right of trial by jury rather than trial by the court as in contempt proceedings.

The Commission is of the opinion that the Seventh Circuit's decision in the *Sebrone Co.* case was right, as are similar decisions emanating from six other circuits. The Commission is of the further opinion that the Supreme Court's decision in the *Regal Knitwear Co.* case fully disposes of the issue in this matter, until such time as the Supreme Court shall speak further on the question.

Syllabus

IN THE MATTER OF
DEAN MERCHANDISING COMPANY, INC. ET AL.

COMPLAINT, FINDINGS, AND ORDERS IN REGARD TO THE ALLEGED VIOLATION
OF SEC. 5 OF AN ACT OF CONGRESS APPROVED SEPT. 26, 1914

Docket 5950. Complaint, Jan. 24, 1952—Decision, Oct. 6, 1952

Articles of wearing apparel made from the chemical fiber rayon have the appearance and feel of wool, and many members of the purchasing public are unable to distinguish between such articles and those made from the latter substance, so that such rayon articles are readily accepted by some of the purchasing public as wool products.

Products made from wool have for many years held and still hold great public esteem and confidence because of their outstanding qualities, and in said connection camel's hair is a type of wool and is a highly desirable material for sweaters.

Where a corporation and its two officers, engaged in the manufacture and interstate sale and distribution of brushed rayon sweaters—

- (a) Falsely represented through the labeling on the boxes containing said sweaters that they were hand tailored; when in fact they were machine made;
- (b) Falsely represented through the depiction of a camel on the said boxes that the sweaters were made of camel's hair;
- (c) Offered and sold said sweaters without informing the purchasing public of the fact that they were made of rayon and not wool; and
- (d) Sold and distributed said sweaters—which they thus represented, and impliedly warranted through the labeling, sale and distribution thereof, as suitable and safe for wearing as sweaters ordinarily are—without revealing on the containers or otherwise that said products, by reason of the length of the fibers on the brushed-up surface, were highly inflammable and dangerous and unsafe to wear;

With tendency and capacity thereby to mislead and deceive a substantial portion of the purchasing public into the purchase of substantial quantities of such sweaters, and with result of placing in the hands of retailers a means whereby members of the purchasing public might be thus misled and deceived:

Held, That such acts and practices, under the circumstances set forth, were all to the prejudice and injury of the public, and constituted unfair and deceptive acts and practices in commerce.

Before *Mr. William L. Pack*, hearing examiner.

Mr. Joseph Callaway for the Commission.

Mr. Benedetto A. Cerilli, of Providence, R. I., for respondents.