

2354. Action to enjoin and restrain the interstate shipment of a drug known as "Dr. Haller's Prescription 5,000" or "Dr. Haller's Prescription 2,000," or "Rx 2,000" or "Rx 5,000." U. S. v. Walter Kurt Max Hassenstein (Hassenstein Co.). Consent decree granting injunction. (Inj. No. 189.)

COMPLAINT FILED: On or about March 10, 1948, Southern District of California, against Walter Kurt Max Hassenstein, trading as the Hassenstein Co., Hollywood, Calif.

NATURE OF CHARGE: That the defendant was engaged in the interstate distribution of a drug preparation designated as "Rx 5,000"; that prior to the time the defendant began trading as the Hassenstein Co., he had under various trade names and styles, and as the responsible official of Lewyn Drug, Inc., of Hollywood, Calif., caused to be introduced and delivered for introduction into interstate commerce the same drug under the designations "Dr. Haller's Prescription 2,000," "Dr. Haller's Prescription 5,000," "Rx 5,000," or "Rx 2,000," under representations that the preparation was an efficacious treatment for delayed menstruation, and that its use would have no ill effects; that such representations were false, in that the use of the preparation did not constitute an efficacious treatment for delayed menstruation and might be dangerous to health if used in the presence of heart trouble, kidney disease, or high blood pressure, or if used in cases of impending accidental termination of pregnancy or advanced stages of pregnancy; that by reason of the defendant's unlawful activities a preliminary injunction was issued on April 7, 1939, and a cease and desist order was issued by the Federal Trade Commission on June 6, 1939, against Lewyn Drug, Inc.; that a post office fraud order was issued on February 27, 1939, against Lewyn Drug, Inc., and others; and that the defendant was convicted on December 1, 1941, upon charges of using and causing the use of the mails to defraud.

The complaint alleged further that the defendant was at the time the complaint was filed, trading as the Hassenstein Company and had been and was causing to be introduced and delivered for introduction into interstate commerce the same drug under the designation "Rx 5,000"; that the boxes containing the drug were labeled, in part: "Rx 5000 White Tablets Each Contains: Extract Cotton Root Bark * * * 1 grain, Extract Black Hellebore 1 grain, Ergotin 1 grain, Aloes 1 grain, Iron Sulphate 1 grain, Oily Pennyroyal 1/2 minim * * * Oil Savin * * * 1/4 minim 6 Capsules, Each Contains: Ergotin 1 grain, Oil Savin * * * 1/2 minim, Aloin 1/8 grain, Apio Green 3 minims 3 Ampuls, Each Contains: Solution Posterior Pituitary U. S. P. 1/2 cc Chlorobutanol 0.5% * * * 3 cotton rolls, 1 glass rod, 1 file"; and that enclosed in each of the boxes was a certain circular headed "Rx 5000 Important," which contained, among others, the following statement, "Ampules should not be used in cases of nephritis, myocarditis, arteriosclerosis."

The complaint alleged further that the article so labeled, and introduced, and delivered for introduction into interstate commerce by the defendant was misbranded as follows:

Section 502 (f) (1), the labeling failed to bear adequate directions for use by reason of the failure of the labeling to state any condition, disease, or function for which the preparation was to be used, and for which it would be effective when used in accordance with the dosage, methods, and duration of administration set forth in the labeling. Section 502 (f) (2), the labeling failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form as are necessary for the protection of users, since it contained a solution of posterior pituitary, and the statement in the labeling "should not be used in cases of nephritis, myocarditis and arteriosclerosis" was not adequate to warn against use of the product in kidney disease, heart disease, and hardening of the arteries; and since the use of a product containing posterior pituitary may be dangerous to the health of persons with high blood pressure, and the labeling of the product bore no warning against use by persons with high blood pressure.

The complaint alleged also that the product was intended for use in the treatment of delayed menstruation, but that labeling statements representing or suggesting it for such use would be false and misleading, since it was not efficacious in the cure, mitigation, treatment, or prevention of delayed menstruation; that any labeling statements representing or suggesting the use of the preparation as a drug would be false and misleading, since the preparation was without value in the cure, mitigation, treatment, or prevention of disease, or to affect any function of the human body except to induce severe purgation; and that its prime physiological effect was to induce labor when administered near term in the pregnant female, in which case it was

dangerous to health when used in the amounts, and with the frequency and duration directed, because the posterior pituitary ingredient would cause spastic contractions of the uterus with possible rupture and consequent death to the mother and injury or death to the child.

PRAYER OF COMPLAINT: That the defendant be perpetually enjoined from shipping in interstate commerce in violation of Section 301 (a), the said drug preparation under the above-mentioned designations, or under any other designation, which would be misbranded within the meaning of Sections 502 (a), or (f) (1) and (2).

DISPOSITION: June 7, 1948. The defendant having consented to the entry of a decree, judgment was entered perpetually enjoining the defendant from directly or indirectly causing to be introduced or delivered for introduction in interstate commerce, in violation of Section 301 (a), the drug preparation under the designation of "Dr. Haller's Prescription 2,000," "Dr. Haller's Prescription 5,000," "Rx 5,000," or "Rx 2,000," or under any other designation, which would be misbranded within the meaning of Sections 502 (a), or (f) (1) and (2).

2355. Alleged misbranding of Rx 5,000. U. S. v. Walter Kurt Max Hassenstein (Hassenstein Co.). Motion granted for dismissal of information. (F. D. C. No. 20946. Sample Nos. 15984-H, 47152-H.)

INFORMATION FILED: November 13, 1946, Southern District of California, against Walter Kurt Max Hassenstein, trading as the Hassenstein Co., Hollywood, Calif.

ALLEGED SHIPMENT: On or about July 25, 1945, and March 28, 1946, from the State of California into the States of Colorado and Illinois.

PRODUCT: Examination disclosed that each package of the product consisted of 22 white tablets, 6 capsules, and 3 ampoules, together with 3 cotton rolls, 1 file, and 1 glass rod. Analyses indicated that the products contained the ingredients declared on the label, i. e., (tablets) extract of cotton root bark, extract of black hellebore, ergotin, aloes, iron sulfate, oil of pennyroyal, and oil of savin; (capsules) ergotin, oil of savin, aloin, and apiol green; and (ampoules) solution of posterior pituitary and chlorobutanol.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use, since the directions contained in the labeling were not adequate, because the labeling failed to reveal the reason for using the article. Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form as are necessary for the protection of users, since the article contained a solution of posterior pituitary, and the statement in the labeling "should not be used in cases of nephritis, myocarditis and arteriosclerosis" was not adequate to warn against use of the article in kidney disease, heart disease, and hardening of the arteries; and since the labeling of the article bore no warning against use by persons with high blood pressure.

DISPOSITION: May 8, 1947. A motion for dismissal of the information was filed on behalf of the defendant, and after consideration of the briefs and arguments of counsel, the court granted the motion and handed down the following decision:

HALL, *District Judge*: "The statement on the label 'IMPORTANT To be used as directed by physician,' is in my judgment an 'adequate direction' for the use of the product. It is not to be used at all unless a physician directs it. To put more on the label would be to suggest it could be used without the direction of a physician which would be more apt to be false and misleading than the simple statement as used.

"The words 'nephritis, myocarditis, and arteriosclerosis' are dictionary words which are commonly understood to mean certain types of kidney, heart or arterial diseases. The warning that the product should not be used in such cases appearing under the word 'IMPORTANT' together with the statement, 'To be used as directed by physician' is an 'adequate warning' sufficient to comply with the statute as to all except children, and is not false or misleading.

"As to the 'adequate warning against its use by children' I do not know how a more adequate warning could be given on a label than the statement 'Not to be used by children.'

"The motion to dismiss is granted."