

502 (a)—the labeling of the device was false and misleading since it represented and suggested—

(a) That the device was effective for increasing the size of the breasts, for providing shape, growth, and expansion for underdeveloped breasts so that they would become full, round, and firm, and for improving the tone of the breast tissue, whereas the device was not effective for such purposes;

(b) That the device could be used safely without the supervision of a physician, whereas it could not be used safely without the supervision of a physician;

(c) That the directions for the use of the device would assure its safe use without medical supervision, whereas the labeling failed to reveal the material fact that the contraindications suggested in the labeling, including symptoms which were signs of early cancer, could only be detected by a competent physician and that the device should therefore never be used except upon the prescription of a physician;

(d) That physicians and surgeons commonly prescribed the use of the device in the regular course of their practice, whereas physicians and surgeons do not commonly prescribe the use of the device in the regular course of their practice; and

(e) That a number of physicians and surgeons whose letters were quoted in the labeling had approved the device as safe for use by women without the supervision of a physician, whereas such physicians and surgeons had not approved the device as safe for use by women without the supervision of a physician; and

502 (f) (1)—the labeling of the device failed to bear adequate directions for use, and the device was not eligible for an exemption from the requirement that its labeling bear adequate directions for use.

DISPOSITION: On 3-11-55, the court issued a temporary restraining order enjoining the defendants against the commission of the acts complained of. On 4-1-55, the defendants having given notice that they would not contest the case, the court entered a default decree of permanent injunction enjoining the defendants (1) from introducing into interstate commerce the *Voluptae device*, any similar device, or any device or drug offered for similar purposes, which would be misbranded as alleged in the complaint, and (2) from causing the association of labeling with any such device or drug while held for sale by a distributor after shipment in interstate commerce which would result in such device or drug being misbranded as alleged in the complaint.

DRUGS FOR VETERINARY USE

4669. Master Liquid (6 seizure actions). (F. D. C. Nos. 36060/2, 36144/8. S. Nos. 20-447/9 L, 83-856 L, 84-047/50 L.)

QUANTITY: 8 5-gal. cans and 172 1-gal. jugs at Belle Plaine, Carroll, Cherokee, Denison, George, Humbolt, Onawa, and Orange City, Iowa.

SHIPPED: Between 5-19-53 and 9-2-53, from Omaha, Nebr., by Master Laboratories.

LABEL IN PART: "Master Liquid * * * Ingredients: Sodium Thio-Sulphate; Beechwood Creosote; Guaiacol; Powdered Extract of Licorice; Sodium Hydroxide, 9%; Sodium Bicarbonate; Betanaphthol; Oil of Anise; Sodium Phenosulfonate; Solution of Potassium Arsenite, (Arsenic as Arsenous Oxide, 0.75%); Nicotinic Acid."

ACCOMPANYING LABELING: Mimeographed letters entitled "Dear Friend and Dealer" and "Dear Dealers" and a leaflet entitled "Antibiotics Sulphas."

LIBELED: 10-28-53, 10-30-53, 11-23-53, and 11-30-53, N. Dist. Iowa; libels amended 10-29-54.

CHARGE: 502 (a)—the labels of the article when shipped contained misleading representations that the article was an effective remedy for diseases of swine; the label statement "Alkalinizes Slops composed of Oats, Barley or Grain Mixtures" was misleading in that it failed to reveal the material fact that such alkalinization was of no value or importance; and the labeling accompanying portions of the article contained false and misleading representation that the article was an adequate and effective treatment for disease in suckling pigs, "necro," scours, bacterial growth in the intestines, or conditions producing runty, unthrifty, and poor doing swine.

502 (f) (1)—the labeling of the article failed to bear adequate directions for use in the treatment of "necro," scours, and general unthriftiness in pigs and hogs, which were the conditions for which the article was intended.

DISPOSITION: John E. von Dorn, the receiver of Master Laboratories, appeared as claimant in all six seizure actions. Upon motion of the claimant and with the consent of the United States attorney, the court, on 12-14-53, ordered the actions consolidated. On 9-16-54, the claimant filed an answer, admitting that the article was labeled as alleged in the libel but denying that the article was misbranded. Thereafter, the Government filed a motion for summary judgment on the grounds that there was no genuine issue of material fact.

On 1-6-55, the court, after consideration of written briefs and argument, handed down the following opinion sustaining the Government's motion:

GRAVEN, District Judge: "On December 14th, 1954, at the Federal Court House at Sioux City, Iowa, there came on for hearing the motions of the Libelant for summary judgment in the above entitled actions. F. E. Van Alstine, United States District Attorney appeared as attorney for the Libelant in support of said motions. John E. von Dorn appeared as attorney for the Claimant in resistance thereto. It was there agreed between the attorney for the Libelant and the attorney for the Claimant that the said motions be submitted on written briefs and arguments. The attorney for the Libelant thereupon submitted a written brief and argument on its behalf. On December 21st, 1954, the attorney for the Claimant submitted a written brief and argument on behalf of the Claimant, and the said motions were thereupon submitted to the Court and by it taken under advisement. The Libelant submitted affidavits in support of its motion for summary judgment. The Claimant submitted affidavits in connection with its resistance thereto.

"The Court now being fully advised in the premises finds:

1. The Master Laboratories was and is a co-partnership consisting of John E. von Dorn and Agnes C. von Dorn. John E. von Dorn is the liquidating trustee of said partnership which is the Claimant herein. The principal place of business of said partnership is in the City of Omaha, Douglas County, Nebraska.

2. For a number of years the Claimant has been engaged in selling in interstate commerce a liquid preparation styled and known as 'Master Liquid' or 'Master Liquid Hog Medicine.' The labels of the preparation contained claims or representations to the effect that the preparation would be beneficial and efficacious in the prevention or cure of a swine ailment commonly referred to as 'Necro.' The preparation is directed to be used in slop feed for swine.

3. On March 18th, 1949, the United States of America instituted an action in the Cedar Rapids Division of this District which action was Civil Action No. 325 in that Division. For convenience in reference that action will be referred to as Civil Action 325. That action was entitled as follows:

UNITED STATES OF AMERICA,

Libelant,

vs.

7 cans, more or less, 3 gallons each, and 3 cans, more or less, 5 gallons each of an article of drug labelled in part: "Master Liquid Hog Medicine"; and 43 leaflets entitled "Master Treatment For Brood Sows,"

Libelee.

4. In Civil Action 325 the Libelant claimed that the 'Master Liquid' preparation which was the subject matter of the action had been shipped in interstate-commerce. The Libelant further claimed that the said liquid preparation was misbranded under the provisions of that portion of 21 U. S. C. A. Section 352 which provides: 'A drug . . . shall be deemed to be misbranded—(a) If its labelling is false or misleading in any particular.' The Libelant asked for the seizure and condemnation of the liquid preparation which was the subject matter of the action under the provisions of 21 U. S. C. A. Section 334. The Claimant in the present actions intervened as a Claimant in the action and contested the claims of the Libelant in regard to the liquid preparation. Starting on May 9th, 1950, a Court trial of substantial length was had as to the matters in issue between the Libelant and Claimant. The Libelant presented the testimony of eight expert witnesses. The Libelant's evidence included the results of tests of 'Master Liquid' in connection with 'Necro.' The Claimant presented the testimony of seven expert witnesses. The testimony of the expert witnesses covers over 400 pages of the transcript of the evidence. It was the claim of the Libelant that the swine ailment commonly referred to as 'Necro' was of bacterial origin. It was the claim of the Claimant that 'Necro' was 'caused primarily or that it follows at least from a nutritional deficiency.' (Transcript p. 4). It was the claim of the Claimant that alkaline solutions were of benefit in remedying the claimed nutritional deficiency and that the 'Master Liquid' was a preparation which would increase the alkalinity of the slop feeds fed to swine, and thereby prevent or cure 'Necro.' The evidence of the Libelant was to the effect that the Claimant's claim that 'Necro' was caused by nutritional deficiency was not well founded. The evidence of the Libelant was to the effect that the Claimant's claim that an alkaline solution would be of benefit in the prevention or cure of 'Necro' was not well founded. The evidence of the Libelant was to the effect that adding 'Master Liquid' to slop feed had the effect of decreasing the alkalinity of the feed.

"On May 20th, 1950, the Court filed its Findings of Fact, Conclusions of Law and Order for Judgment in Civil Action No. 325. In its Findings, the Court among other Findings made the following Findings:

Finding 11. * * * In common speech, swine are said to be suffering from "Necro" when they are afflicted with Necrotic Enteritis. Necrotic Enteritis is a disease caused by bacteria known as Salmonella Cholerasuis.

Finding 14. There is no credible or adequate scientific or medical foundation for any claim or representation that the use of Master Liquid Hog Medicine will prevent Necrotic Enteritis in swine.

Finding 15. There is no credible, adequate, scientific or medical foundation for any claim or representation that the use of Master Liquid Hog Medicine will cure Necrotic Enteritis in swine.

Finding 16. It clearly and satisfactorily appears that Master Liquid Hog Medicine is without efficacy or benefit in the treatment of Necrotic Enteritis in swine.

Finding 17. It clearly and satisfactorily appears that Master Liquid Hog Medicine is without efficacy or benefit in the prevention of Necrotic Enteritis in swine.

Finding 18. It clearly and satisfactorily appears that the ingredients of Master Liquid Hog Medicine, whether used separately or in combination, are without efficacy or benefit in the treatment or prevention of Necrotic Enteritis in swine however used or administered.

The Court further found that the Claimant in connection with the sale and shipment of the said liquid preparation made the claim or representation that:

the same was of efficacy or benefit in the prevention of 'Necro' and that said claims or representations were both false and misleading.

5. The Court held that the said liquid preparation was misbranded under the provisions of 21 U. S. C. A. Section 352. On May 20th, 1950, the Court entered a decree condemning said liquid preparation and assessing the taxable costs in the sum of \$1,503.73 against the Claimant. The Claimant then appealed the case to the United States Court of Appeals for the Eighth Circuit. On May 21st, 1951, there was certified to this Court by the Clerk of that Court a mandate of that Court docketed May 2d, 1951 (189 F. 2d 967), dismissing the appeal of the Claimant.

6. The present six actions were instituted in this District. Each of them relates to 'Master Liquid' shipped in interstate commerce to points in this District. In each action the Libelant claims that the particular shipment is misbranded under the provisions of 21 U. S. C. A. Section 352. In each action the Libelant asks that the particular shipment be seized and condemned under the provisions of 21 U. S. C. A. Section 334.

7. It is the claim of the Libelant in the present actions that the issues in these actions are the same as the issues in Civil Action No. 325 and that these issues were adjudicated adversely to the Claimant in that action and such adjudication is binding upon the Claimant in the present actions.

8. On page 11 of the brief and argument of the Claimant in the present actions the Claimant states as follows:

The question of prior proceedings against the preparation "Master Liquid Hog Medicine" in the case tried at Cedar Rapids, Iowa, is not open to argument. That was a trial upon the merits between the same parties and would amount to an adjudication of the issues there presented. It is admitted that the parties are the same, the ingredients in the preparation are the same, but the label is not agreed to be the same or are the issues the same. The amended answer of claimant alleges new medical opinion and that inference made by claimant was to the extent that the product was of value in Nutritional "Necro" which is not the same as Necrotic Enteritis and points to a particular type of "Necro" (enteritis) to-wit: an enteritis from purely nutritional causes.

On page 2 of its amended answer in the present actions the Claimant states:

Claimant further alleges that the article in question is an aid in the treatment of so-called "Necro" due to purely nutritional causes.

"In its resistance to the motions of the Libelant in the present actions the Claimant submitted the affidavits of three veterinarians. In their affidavits the affiants express the view that 'Necro' is also caused by nutritional deficiency and that 'Master Liquid' will be of benefit or aid in 'Nutritional Necro.' Two of the affiants testified at length and similarly in Civil Action No. 325. The Claimant claims that the theories as to the cause of 'Necro' change from time to time and the more modern theory is that 'Necro' is due to nutritional deficiency. In Civil Action No. 325 the evidence of the Libelant was to the effect that the theory that 'Necro' is due to nutritional deficiency was an older and discredited theory.

9. It is the finding and holding of the Court that the issue as to whether 'Necro' was due to bacteria as claimed by the Libelant or due to nutritional deficiency as claimed by the Claimant was presented and adjudicated adversely to the Claimant in Civil Action No. 325.

10. It is the finding and holding of the Court that the issue as to whether 'Master Liquid' has value or aid or benefit in the prevention or cure of 'Necro' was presented and adjudicated adversely to the Claimant in Civil Action No. 325.

11. In the present actions the labelling by the Claimant's admission does make the claim or representation that it is of value or aid or benefit in connection with 'Necro.'

12. It is the finding and holding of the Court that the present labelling makes the same claim or representation that was adjudicated to be false and misleading in Civil Action No. 325.

13. It is the finding and holding of the Court that the Claimant in the present action is attempting to relitigate and re-try the same issues that were litigated and adjudicated in Civil Action No. 325. It is not permissible for the Claimant to do so. *George H. Lee Co. v. Federal Trade Commission* (8th Cir. 1940) 113 F. 2d 583; *George H. Lee Co. v. United States* (9th Cir. 1930) 41 F. 2d 460; *Lee v. United States* (10th Cir. 1951) 187 F. 2d 1005; *United States v. 14 105 Pound Bags* (D. C. Idaho 1953) 118 F. Supp. 837.

14. It is the finding and holding of the Court that there is no genuine issue of material fact in any of the present actions which is now subject to being litigated or tried.

15. It is the finding and holding of the Court that the Libelant is entitled to judgment in each of the present actions as a matter of law.

"It is hereby ordered that the motions of the Libelant for summary judgment in the present actions be and the same are hereby sustained and judgment shall be entered accordingly."

Pursuant to the above opinion, the court, on 1-6-55, entered decrees condemning the article and ordering its destruction. The claimant filed a motion for rehearing on 1-17-55 and a motion to amend findings and decrees on 1-28-55, both of which were denied by the court on 2-1-55.

4670. Hog Tabs. (F. D. C. No. 37529. S. No. 8-621 M.)

QUANTITY: 11 drums containing a total of 136,400 tablets and 21 250-tablet cans at Omaha, Nebr., in the possession of Standard Chemical Mfg. Co.

SHIPPED: 6-17-54, from Cleveland, Ohio, by Strong, Cobb & Co., Inc.

LABEL IN PART: (Can) "Standard Hog Tabs An Intestinal Astringent Contain Potassium Permanganate and Copper Sulphate * * * Directions Dissolve one tablet in each gallon of water. * * * Give in the drinking water night and morning, * * * Feed hogs a milk of mill feed slop until they are well on the road to recovery."

RESULTS OF INVESTIGATION: The tablets had been shipped in bulk, and upon receipt by the consignee, a number of the tablets were repackaged into cans.

Analysis showed that the tablets contained approximately 27 grains of copper sulfate and 3.6 grains of potassium permanganate per tablet.

LIBELED: 12-14-54, Dist. Nebr.

CHARGE: 502 (a)—the label of the article while held for sale contained false and misleading representations that the article was effective as an intestinal astringent for the treatment of "sick" hogs; and, 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

DISPOSITION: 2-8-55. Default—destruction.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

4671. Bulk tablets. (F. D. C. No. 37404. S. No. 42-170 L.)

QUANTITY: 4 15,000-tablet drums at San Francisco, Calif.

SHIPPED: 8-24-54, from Cleveland, Ohio.

RESULTS OF INVESTIGATION: Examination showed that the tablets were contaminated with petroleum oil and were brownish in color and obnoxious in odor. It was assumed that the tablets became contaminated with petroleum oil while in transit.

LIBELED: 11-10-54, N. Dist. Calif.