30899. Misbranding of adhesive compress. U. S. v. 33,500 Envelopes of Adhesive Compress. Default decree of condemnation and destruction. (F. & D. No. 39093. Sample No. 28024–C.)

This product had been shipped in interstate commerce and remained unsold and in the original unbroken packages. At the time of examination it was found to be contaminated with viable micro-organisms.

On February 16, 1937, the United States attorney for the Northern District of California, acting upon a report by the Secretary of Agriculture, filed in the district court a libel praying seizure and condemnation of 33,500 envelopes of adhesive compress at San Francisco, Calif.; alleging that the article had been shipped on or about January 28, 1937, by the Bay Co. from Versailles, Conn., and charging misbranding in violation of the Food and Drugs Act. The article was labeled in part: "One Inch Adhesive Compressed E D Bullard Company * * * San Francisco."

Misbranding was alleged in that the statements on the label, "A protective dressing for minor injuries remove covering from plaster and place pad over wound," were false and misleading when applied to an article which was contaminated with bacteria.

On July 1, 1939, the case having been called and the default of all persons having been entered, judgment of condemnation was entered and the product was ordered destroyed.

M. L. WILSON, *Acting Secretary of Agriculture.*

30900. Misbranding of Dr. David Roberts Uterine Capsules, Dr. David Roberts Worm Powder, Dr. David Roberts Poultry Worm Capsules, Dr. David Roberts Poultry Tonic, Dr. David Roberts Dog Medicines (Blood Tablets, Liver Tablets, Kidney Tablets and Chorea Tablets), and Dr. David Roberts Absorbent. U. S. v. Dr. David Roberts Veterinary Co., Inc., and Dr. David Roberts. Tried to the court. Judgment of guilty. Fines of $1,300 imposed on corporation. Fine of $650 imposed on Dr. David Roberts. Judgment affirmed on appeal. (F. & D. Nos. 38588, 38618, 39769, 39839. Sample Nos. 63254–B, 5204–C, 5206–C, 5207–C, 14696–C, 19567–C, 19568–C, 19569–C, 49101–C, 49106–C, 49110–C, 49113–C, 49115–C.)

The labeling of these veterinary preparations bore false and fraudulent curative and therapeutic claims.

On June 21 and October 25, 1937, and May 9, 1938, the United States attorney for the Eastern District of Wisconsin, acting upon reports by the Secretary of Agriculture, filed in the district court four informations against the Dr. David Roberts Veterinary Co., Inc., Waukesha, Wis., and Dr. David Roberts, alleging shipment by said defendants in violation of the Food and Drugs Act as amended, within the period from on or about January 11, 1936, to on or about January 27, 1937, from the State of Wisconsin into the States of Minnesota and Indiana of quantities of the above-named veterinary preparations which were misbranded.

Analyses of samples showed that the Uterine Capsules consisted chiefly of sucrose, bicarbonate of soda, and ground plant material (corn); that the Worm Powder consisted essentially of cornstarch, boric acid, small proportions of iron oxide, potassium nitrate, rosin, charcoal, sugar, plant material including a nicotine-bearing drug, and anise oil; that the Poultry Worm Capsules consisted essentially of kamala, nicotine, sulfate, and thymol; that the Poultry Tonic consisted essentially of magnesium sulfate, calcium phosphate, bonemeal, sulfur, a fixed oil, iron compound, sodium chloride, and plant material including a nicotine-bearing drug, hominy, and wheat middlings; and that the Absorbent consisted of soap, water, glycerin, and fatty acids.

Analyses of the Dog Medicines showed that the Blood Tablets consisted essentially of sulfur; the Liver Tablets consisted essentially of plant material and a small proportion of calomel, coated with iron oxide and calcium carbonate; the Kidney Tablets consisted essentially of plant material and potassium nitrate, coated with calcium carbonate; and that the Chorea Tablets consisted essentially of extracts of plant drugs and small proportions of potassium bromide and zinc phosphide, coated with calcium carbonate.

The Uterine Capsules were alleged to be misbranded in that certain statements in the labeling regarding their curative and therapeutic effects falsely and fraudulently represented that they were effective as a treatment for slow breeding in cows, and to promote conception; effective as a treatment, remedy, and cure for acid secretions of the genital organs, germs of herd infection, retention of the afterbirth, and abnormal conditions; and effective to prevent acid secretions, to cleanse and soothe the inflamed parts, to serve to improve the breeding condition, to overcome an unnatural discharge, to freshen cows on time, and to cause cows to be with calf.

The Worm Powder was alleged to be misbranded in that certain statements in the labeling falsely and fraudulently represented that it was effective as a treatment, remedy, and cure for roundworms in livestock and bots in horses.

The Poultry Worm Capsules were alleged to be misbranded in that certain statements in the labeling falsely and fraudulently represented that they were effective as a treatment, remedy, and cure for tapeworms and large roundworms in poultry.

The Poultry Tonic was alleged to be misbranded in that certain statements in the labeling falsely and fraudulently represented that it was effective as a poultry tonic and stimulant to the appetite and as a treatment for wormy poultry.

The Absorbent was alleged to be misbranded in that certain statements in the labeling falsely and fraudulently represented that it was effective as an absorbent and effective as a treatment of removable enlargements and in the healing of wounds on livestock and effective as a treatment for old sores, thoroughpin, shoeboils, poll evil, fistulous withers, cold abscess, lameness, and enlarged glands.

The Blood Tablets for dogs were alleged to be misbranded in that certain statements in the labeling falsely and fraudulently represented (in the case of one shipment) that the article was effective as a treatment, remedy, and cure for blood ailments and all forms of skin diseases of dogs; and (in the case of the second shipment,) that it was effective as a treatment, remedy, and cure for blood ailments and all forms of skin diseases; effective as a treatment, remedy, and cure for every dog ailment; effective to prevent and overcome various ailments of dogs; and effective as a treatment for sickness and disease, and as a treatment, remedy, and cure for sore growth or injury, worms, running fits, skin disease, cough, running nose, and matter in the corner of the eyes.

The Liver Tablets for dogs were alleged to be misbranded in that certain statements in the labeling falsely and fraudulently represented (in the case of one shipment) that the article was effective as a treatment, remedy, and cure for liver ailments of dogs, and (in the case of a second shipment) that it was effective as a treatment, remedy, and cure for ailments of the liver; effective for inactive or sleepy condition due to liver trouble; effective as a treatment, remedy, and cure for every dog ailment; effective to prevent and overcome various ailments of dogs, and as a treatment for sickness and disease; and effective as a treatment, remedy, and cure for sore growth or injury, worms, running fits, skin disease, cough, running nose, and matter in the corner of the eyes.

The Kidney Tablets for dogs were alleged to be misbranded in that certain statements in the labeling falsely and fraudulently represented (in the case of one shipment) that the article was effective as a treatment, remedy, and cure for kidney ailments of dogs; and (in the case of a second shipment) that it was effective as a treatment, remedy, and cure for kidney diseases and kidney disorders, and every dog ailment; effective to prevent and overcome various ailments of dogs, and as a treatment for sickness and disease; and effective as a treatment, remedy, and cure for sore growth or injury, worms, running fits, skin disease, cough, running nose, and matter in the corner of the eyes.

The Chorea Tablets for dogs were alleged to be misbranded in that certain statements in the labeling falsely and fraudulently represented (in the case of one shipment) that the article was effective as a treatment, remedy, and cure for chorea of dogs; and (in the case of a second shipment,) that it was effective as a treatment, remedy, and cure for chorea and twitching of the muscles; effective as a treatment, remedy, and cure for every dog ailment; effective to prevent and overcome various ailments of dogs, and as a treatment for sickness and disease; and effective as a treatment, remedy, and cure for sore growth or injury, worms, running fits, skin disease, cough, running nose, and matter in the corner of the eyes.

Pleas of not guilty having been entered on behalf of the defendants, the cases came on for trial before the court without a jury on January 24, 1939. The trial was concluded on January 26, 1939, and resulted in a finding of guilty on all counts of the four informations. Sentence of $1,300 was imposed against the corporation and $650 against Dr. David Roberts. Appeal was perfected and on June 15, 1939, the Circuit Court of Appeals for the Seventh Circuit handed down the following opinion affirming the judgment of the district court:

Before MAJOR and KERNER, *Circuit Judges*, and BARNES, *District Judge*.

Opinion by Kerner. "Appellants, hereafter called defendants, were convicted of violations of the Food and Drugs Act of 1906 (U. S. C. A. 21, Secs. 2 and 10) under four informations involving nine articles, charging interstate shipments of drugs that were alleged to be misbranded, in that the labels, containers, and enclosures of each of the products were false and fraudulent regarding the curative or therapeutic effect of the drugs. The cases were tried by the court, a jury being waived, and resulted in the findings of guilty on all nine counts and the court imposed sentences in the form of fines. Defendants have appealed from these judgments.

"The principal assignment of error and the only one relied upon is that there is an insufficiency of competent evidence to establish guilt beyond a reasonable doubt.

"The informations allege violation of Section 2 of the Food and Drugs Act (Title 21 U. S. C. A. Sec. 2) which makes any person guilty of a misdemeanor who shall ship or deliver for shipment from any State to any other State 'any article of food or drugs which is adulterated or misbranded, within the meaning of Sections 1 to 15 * * *.' The term 'drug' is defined in the act as including 'all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use.' In section 10, an article is defined as misbranded 'if its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent.'

"The argument is made that before there can be a finding of guilty under this act the Government must prove, not only that the statements made concerning the article were false, but that they were also fraudulent. This is a correct statement of the law. We are therefore called upon to decide whether the statements were false and fraudulent.

"There was evidence that the defendant corporation was engaged in the manufacture and sale of medicines used in the treatment of ailments of dogs, livestock, and poultry, supplying its customers in the States of Minnesota and Missouri with the nine articles mentioned in the informations.

"Since we are of the opinion that the Government introduced evidence at the trial which justified the court in finding, as alleged in the nine counts of the informations, that certain of the statements appearing on the containers and labels regarding the curative or therapeutic effect of the articles were false and fraudulent, it will not be necessary to specifically discuss the evidence relative to each of the nine articles, as that would unduly lengthen this opinion. A discussion of several ought to suffice.

"The brandings complained of are as follows:

Dr. David Roberts Worm Powder

"Regarding this product, there appears on the label and enclosed leaflet the following: 'For Round Worms in Livestock,' 'For Bots In Horses.'

"In support of this count of the information, the Government called five witnesses, four of whom were doctors of Veterinary Medicine and one with a Master's degree from Georgetown University, majoring in zoology with special emphasis on parasitology, who testified in substance that this powder is worthless and has no value against any species of roundworms in livestock and bots in horses, and is not effective as a treatment or cure for worms in livestock or for bots in horses.

Dr. David Roberts Poultry Worm Capsules
For Tapeworms and Large Round Worms in Poultry
Worm Poultry Twice a Year

"Relative to this count, the testimony was in substance that this product was not effective as a treatment for or control of any kind of worm that infests poultry. Three of the doctors testified that they had made extensive critical and controlled tests of these capsules on chickens over a period of 6 weeks, and that at the conclusion of the tests the chickens were autopsied and it was found that the capsules were ineffective in the removal of roundworms or tapeworms.

Dr. David Roberts Dog Medicine

"Four of the counts involved the following dog medicines: Blood tablets, liver tablets, kidney tablets, and chorea tablets, contained in a metal package, holding small tin boxes, one for each dog medicine, sold as a unit. The outside package or box was labeled and carried a large circular, reading thus:

" 'Dr. Roberts Dog Medicines,' 'A Prescription For Every Dog Ailment,' 'Dr. David Roberts' Dog Medicines are Dependable—Try them,' Let Dr. David Roberts advise you about the various ailments of dogs, how to recognize such ailments and diseases by their symptoms, and how to prevent and overcome them in a simple, effective and economical manner right in your own home. Every dog owner can keep his pet reasonably healthy by proper care and feeding, and by administration of proper medicines when sickness or disease occurs. Dr. Roberts has a prescription for every dog ailment. Most of these medicines are conveniently put up in tablet form and easily administered; they have proven their worth and effectiveness for many years. The complete line is given below.' Thereafter are set forth the following products, in the following language: 'Blud Tablets, in case of skin diseases, Chorea Tablets for twitching muscles, Kidney Tablets for Kidney disorders, Liver Tablets for inactive or sleepy condition.'

"The informations charged that these statements, together with the language on the outer container and large circular, were applied to said articles knowingly and in a reckless and wanton disregard of their truth, so as to create in the minds of the purchaser the impression and belief that the articles were effective as a treatment, remedy, or cure for blood ailments, all forms of skin diseases, and all liver and kidney ailments in dogs.

"Dr. John V. LaCroix, a veterinary practitioner, journalist and teacher, testified that for 20 years his practice has been limited to the treatment of dogs: that these blood tablets have no beneficial influence on skin diseases, and are of no value in the treatment of any diseases of the blood; that the liver tablets contain no ingredient having any therapeutic value in connection with the treatment of liver trouble in dogs; that there is no drug or combination of drugs effective as a treatment, remedy, or cure of kidney ailments of dogs in general, and that to prescribe potassium indiscriminately would be harmful in more instances than helpful; and that the elements of calcium carbonate and potassium nitrate are of no assistance in the treatment of kidney ailments in dogs, and that this product has no value in the treatment of any kidney ailment in dogs.

"Dr. Henry E. Moskey, a veterinarian since 1920, in charge of the veterinary section of the Food and Drug Administration, corroborated Dr. LaCroix.

Absorbent

"The language complained of is as follows: 'Absorbent,' 'Apply Absorbent once daily with small brush to lameness,' 'Absorbent—useful in the treatment of removable enlargements and healing of wounds on livestock—old sores—thoroughpin—shoeboils—poll evil—fistulous withers—cold abscess—enlarged glands.'

"In support of this count the testimony disclosed that the product does not contain ingredients which would be effective as a treatment for shoeboils or poll evil; that it has no value in the treatment of enlarged glands; and that no drug or mixture of drugs is known to the profession generally, or agreed upon by the consensus of veterinary opinion, that can do all of the things claimed by this label.

"The record also discloses that the professional witnesses for the Government testified that the opinions expressed by them were in accord with the consensus of veterinary opinion.

"Dr. David Roberts testified that he arrived at the formula for the worm powder by experiments which were successful, and that it was his opinion the powder was effective in the elimination of bots in horses. As he stated it, 'I know that by having tested it out personally by giving it to horses and watching the feces.' He admitted that the powder did not contain ingredients effective as a cure for all forms of worms that infest livestock, and that the capsules were not an effective cure for tapeworms.

"He also testified that the blood tablets did not contain medicinal components effective as a cure for all blood ailments and all forms of skin diseases; that the liver tablets stimulate the liver and were helpful; and that the kidney tablets constituted a remedy, being helpful but not curative.

"Dr. Frederick H. Akin, a practising veterinarian since 1906, testified that the worm powder has two ingredients, both of which he prescribes in the treatment of roundworms, but that he does not use them for bots in horses; that for 32 years he has used kamala, one of the ingredients of the worm capsules in the treatment of chickens, and that the capsule would be effective for tapeworms, but not for large roundworms; that the blood tablet is beneficial, but not a remedy or cure for all diseases of the blood; that the ingredients of the liver tablets are not an effective remedy or cure for all diseases involving a dog's liver; that the ingredients of the kidney tablet have a therapeutic effect in the treatment of kidney troubles; and that the constituent elements of the absorbent are such as are used beneficially in relieving congestion and inflammation, it being his opinion that the absorbent had a remedial effect such as was described on the carton. Neither Dr. Roberts nor Dr. Akin testified that their opinions were in accord with the consensus of veterinary opinion.

"The point is made that a man should not be convicted because he advocates a theory of medicine which has not received the endorsement of the medical profession, and *United States* v. *American Laboratories*, 222 F. 104, is cited. That case is of no help to the defendants. There it was said, p. 106:

" 'The broad distinction between things which are frauds and things which are not frauds is clear. It would be difficult, and indeed seems to be impossible, to give a definition of such frauds in words. * * * The essential difference is a fact, and in the administration of the criminal law it is a fact to be found by a jury.

" '* * * There would seem to be no other way of dealing with the subject than to submit to the common sense judgment of a jury to find whether in a given case the acts of a defendant have been honest, however mistaken, or whether they have been false and fraudulent.'

"In the instant case, the question was reduced to one of fact, as distinguished from mere opinion, *Eleven Gross Packages* v. *United States*, 233 F. 71 and *Kar Ru Chemical Co.* v. *United States*, 264 F. 921, and, as defendants' testimony made for conflicting evidence, a question of weighing the evidence was presented. To weigh the evidence is not within the power of this court.

"It is insisted that there was no proof that any of the statements were fraudulently made. In *Seven Cases* v. *United States*, 239 U. S. 510, in speaking of the phrase 'false and fraudulent,' it was said, p. 517: 'This phrase must be taken with its accepted legal meaning, and thus it must be found that the statement contained in the package was put there to accompany the goods with actual intent to deceive,—an intent which may be derived from the facts and circumstances, but which must be established.'

"The owner has a right to give his views regarding the effect of his drugs, *Seven Cases* v. *United States, supra*, but he must be mindful that the statute condemns every statement which may mislead or deceive. If an article is not the identical thing that the statement indicates it to be, it is misbranded, *United States v. 95 Barrels of Vinegar*, 265 U. S. 438, and if the drugs are worthless, he cannot escape by hiding behind the phrase the 'doctors say,' *United States* v. *John J. Fulton Co.*, 33 F. (2) 506. Moreover, proof of the false and fraudulent character of any one of the various claims is sufficient, *Goodwin, et al.* v. *United States*, 2 F. (2) 200.

"There can be no doubt that enough was proved to justify an inference that the defendants knew the articles did not possess the curative or therapeutic qualities claimed for them in the statements appearing on the containers and labels, and that the court was justified in holding that they were made with a fraudulent purpose. See *Simpson* v. *United States*, 241 F. 841.

"Defendants assigned as further grounds for error rulings on the admission and exclusion of evidence. Counsel has failed to quote the evidence alleged to have been improperly admitted or excluded, or to present any argument or reason in support of this assignment. We have therefore assumed that it has been waived and we refrain from any special consideration of it.

"Finding no error in the proceeding below, the judgments are

"Affirmed."

M. L. WILSON, *Acting Secretary of Agriculture.*