

4086. Misbranding of various drugs. U. S. v. Arthur Cox. Plea of not guilty. Tried to the court and jury. Verdict of guilty on 1 count and not guilty on remaining 11 counts. Sentence of 1 year in jail. Appeal taken and subsequently dismissed. (F. D. C. No. 31254. Sample Nos. 10869-L, 10915-L, 10916-L, 11283-L, 12055-L, 32108-L, 32453-L, 32454-L, 32456-L.)

INDICTMENT RETURNED: August 31, 1951, Southern District of Indiana, against Arthur Cox, Sullivan, Ind.

ALLEGED SHIPMENT: On or about March 4, 19, 26, 27, and 28, and April 1, 1951, from the State of Indiana into the States of Arkansas, Illinois, and Ohio, of various quantities of drugs, some of which were accompanied by labeling consisting of circulars entitled "Cooking Instructions For Herbs" and "United States Patent Office."

NATURE OF CHARGE: Drug consisting of a large amount of leaves resembling sunflower leaves, a small amount of eupatorium leaves and flowers, a trace of mint and dogwood leaves, and unidentified leaf and stem fragments. Misbranding, Section 502 (a), a statement on the label of the article represented and suggested that the article was a tonic, and a statement appearing in the labeling accompanying a portion of the article represented and suggested that such portion would be effective in the treatment of cancer. Such statements were false and misleading since the article was not a tonic and would not be effective in the treatment of cancer. Further misbranding, Section 502 (f) (1), the labeling of a portion of the article failed to bear adequate directions for use in the treatment of cancer, which was the disease, symptom, and condition for which the article was prescribed, recommended, and suggested orally by the defendant; and the article failed also to bear adequate directions for use since the labeling failed to reveal the conditions for which the article was to be used.

Drug consisting of a large amount of leaves resembling sunflower leaves and a small amount of unidentified leaf and stem fragments. Misbranding, Section 502 (a), certain statements in the accompanying labeling of the article were false and misleading since they represented and suggested that the article would be efficacious in the treatment of diabetes, whereas it would not be efficacious for that purpose.

Drug consisting of a large amount of dogwood leaves, fruit, and bark, a small amount of eupatorium leaves and flowers, mint leaves, and unidentified leaf and stem fragments. Misbranding, Section 502 (a), certain statements in the accompanying labeling of the article were false and misleading since they represented and suggested that the article would be efficacious in the treatment of diabetes, whereas it would not be efficacious for that purpose.

Drug consisting of a muddy, black aqueous liquid containing plant extractives. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of psoriasis, which was the disease, symptom, and condition for which the article was prescribed, recommended, and suggested orally by the defendant, and the labeling of the article failed also to bear adequate directions for use since the labeling failed to reveal the conditions for which the article was to be used.

Drug consisting of a large amount of dogwood leaves, fruit, and bark, and small amounts of eupatorium leaves and flowers, leaves resembling sunflower leaves, and unidentified leaf and stem fragments. Misbranding, Section 502 (f) (1) the labeling of the article failed to bear adequate directions for use in the

treatment of cancer, which was the disease, symptom, and condition for which the article was prescribed, recommended, and suggested orally by the defendant; and the labeling of the article failed also to bear adequate directions for use since the labeling failed to reveal the conditions for which the article was to be used.

Drug consisting of a cloudy, aqueous liquid containing plant extractives and having an offensive odor. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of vaginal trouble, which was the disease, symptom, and condition for which the article was prescribed, recommended, and suggested orally by the defendant; and the labeling of the article failed also to bear adequate directions for use since the labeling failed to reveal the conditions for which the article was to be used.

Drug consisting of a large amount of leaves resembling sunflower leaves and small amounts of eupatorium leaves and flowers, dogwood leaves, and unidentified leaf and stem fragments. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of drawing of muscles, which was the disease, symptom, and condition for which the article was prescribed, recommended, and suggested orally by the defendant; and the labeling of the article failed also to bear adequate directions for use since the labeling failed to reveal the conditions for which the article was to be used.

Drug consisting of a large amount of dogwood leaves, fruit, and bark, and small amounts of eupatorium leaves and flowers, mint leaves, leaves resembling sunflower leaves, and unidentified leaf and stem fragments. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of drawing of muscles, which was the disease, symptom, and condition for which the article was prescribed, recommended, and suggested orally by the defendant; and the labeling of the article failed also to bear adequate directions for use since the labeling failed to reveal the conditions for which the article was to be used.

Drug consisting of petrolatum and tobacco. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of rectal fistula, which was the disease, symptom, and condition for which the article was prescribed, recommended, and suggested orally by the defendant; and the labeling of the article failed also to bear adequate directions for use since the labeling failed to reveal the conditions for which the article was to be used.

Drug consisting of a muddy, aqueous extract, flavored with peppermint and containing nicotine. Misbranding, Section 502 (a), the word "Sinuses" displayed upon the label of the article was false and misleading. The word represented and suggested that the article would be effective in the treatment of diseases of the sinuses, whereas the article would not be effective for that purpose.

Drug for use in the treatment of cancer (ingredients unknown). Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of cancer, which was the disease, symptom, and condition for which the article was prescribed, recommended, and suggested orally by the defendant; and the labeling of the article failed also to bear adequate directions for use since the labeling failed to reveal the conditions for which the article was to be used.

Further misbranding, Section 502 (b) (1) and (2), each of the articles failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and none of the articles bore a label containing statements of the quantity of the contents.

DISPOSITION: The defendant filed a motion for dismissal of the indictment and for an order subjecting the grand jurors, the district attorney, and the stenographers to examination under oath, in open court, as to the grand jury proceedings. This motion was overruled on February 12, 1952. The defendant then entered a plea of not guilty, and on September 22, 1952, the case came on for trial before the court and jury. The trial was concluded on September 30, 1952, with the return by the jury of a verdict of guilty on the count relating to the drug which consisted of a muddy, black aqueous liquid containing plant extractives, and a verdict of not guilty on the remaining 11 counts relating to the other drugs. On January 12, 1953, the court sentenced the defendant to 1 year in jail. An appeal was taken by the defendant to the United States Court of Appeals for the Seventh Circuit and was dismissed on April 22, 1953, because of the defendant's failure to perfect his appeal.

4087. Misbranding of amphetamine sulfate tablets and Seconal Sodium capsules. U. S. v. Thrifty Drug Stores Co., Inc., and Leonard Royce. Pleas of nolo contendere. Each defendant fined \$500 and placed on probation for 3 years. (F. D. C. No. 34317. Sample Nos. 19161-L, 35013-L.)

INFORMATION FILED: December 30, 1952, District of Minnesota, against Thrifty Drug Stores Co., Inc., Rochester, Minn., and Leonard Royce, vice president and pharmacist for the corporation.

ALLEGED VIOLATION: On or about May 14 and June 19, 1951, while a number of *amphetamine sulfate tablets* and *Seconal Sodium capsules* were being held for sale at Thrifty Drug Stores Co., Inc., after shipment in interstate commerce, the defendants caused various quantities of such drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged drugs failed to bear labels containing the common or usual name of the drugs; and, Section 502 (f) (2), the repackaged *amphetamine sulfate tablets* failed to bear labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: May 1, 1953. Pleas of nolo contendere having been entered, the court fined each defendant \$500 and placed each on probation for 3 years.