

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

3021. Misbranding of Metro-Vac. U. S. v. Charles A. C. Faiman (Physicians Rx Products), and Dr. F. H. Jordan. Pleas of not guilty. Tried to a jury; verdict of guilty as to defendant Faiman and not guilty as to defendant Jordan. Sentence of two years in prison against defendant Faiman. Judgment affirmed on appeal. (F. D. C. No. 25563. Sample Nos. 22351-K, 27247-K.)

INDICTMENT RETURNED: September 23, 1948, Northern District of Texas, against Charles A. C. Faiman, alias A. C. Faiman, alias C. A. C. Faiman, alias Dr. C. Andrew Faiman, and alias Dr. Charles C. Faiman, trading as Physicians Rx Products, and against Dr. F. H. Jordan, Dallas, Tex.

ALLEGED SHIPMENT: The indictment alleged in count 1 that both defendants, on or about January 24, 1948, willfully and unlawfully caused a quantity of *Metro-Vac* to be introduced and delivered for introduction into interstate commerce at Dallas, Tex., for delivery to Monroe, La. The indictment alleged in count 2 that the defendant Faiman, on or about January 27, 1948, willfully and unlawfully caused a quantity of *Metro-Vac* to be introduced and delivered for introduction into interstate commerce at Dallas, Tex., for delivery to Helena, Ark.

PRODUCT: Analysis showed that the product was a soft potassium soap containing 2.5% of potassium iodide and a crystal violet dye. It was represented to be a uterine evacuant.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the article bore no label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), it bore no label containing an accurate statement of the quantity of the contents; Section 502 (e) (2), it bore no label containing the common or usual name of each active ingredient; Section 502 (f) (1), it bore no labeling containing directions for use; and, Section 502 (f) (2), it bore no labeling containing warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration or application.

DISPOSITION: On September 30, 1948, the defendants entered pleas of not guilty, and the case immediately proceeded to trial before a jury. On October 1, 1948, the jury returned a verdict of guilty against defendant Faiman and a verdict of not guilty against defendant Jordan, and on the same day the court imposed a sentence of two years in prison against defendant Faiman. An appeal was taken to the U. S. Court of Appeals for the Fifth Circuit on behalf of defendant Faiman, and on March 20, 1950, a decision was handed down by that court, affirming the judgment of the lower court.

3022. Misbranding of Benadryl capsules, Hexital tablets, and Carbrital capsules. U. S. v. Thompson D. Adcock and John G. Malley. Pleas of guilty. Fines of \$125 against defendant Adcock and \$50 against defendant Malley. (F. D. C. No. 26710. Sample Nos. 26183-K, 27029-K, 27031-K, 27041-K, 27044-K, 27315-K, 27532-K.)

INFORMATION FILED: August 19, 1949, Western District of Missouri, against Thompson D. Adcock, a pharmacist for the McGreevy Drug Co. No. 2, a partnership, Springfield, Mo., and against John G. Malley, a partner in the partnership.

*See also No. 3039 (veterinary preparations).

INTERSTATE SHIPMENT: Between the approximate dates of April 18, 1945, and December 11, 1947, from the States of Michigan and New Jersey into the State of Missouri.

LABEL, WHEN SHIPPED: "Kapseals Benadryl Hydrochloride [or "Kapseals Carbrital"] * * * Caution—To be dispensed only by or on the prescription of a physician" and "Hexital Caution—To be used only by or on the prescription of a physician."

ALLEGED VIOLATION: On or about April 20, July 8 and 10, August 9 and 13, and September 20 and 23, 1948, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused a number of capsules and tablets of the drugs to be removed from the bottles in which they had been shipped and to be repacked and sold to various persons without a prescription, which acts of the defendants resulted in the repackaged drugs being misbranded. The repackaged drugs were labeled in part "Benadryl Capsules 50 MG," "Hexital," and "Carbrital Capsules."

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the labels of the repackaged drugs bore no statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (e) (2), the labels of the repackaged *Hexital tablets* and the repackaged *Carbrital capsules* failed to bear the common or usual name of each active ingredient of the drugs, namely, phenobarbital and Hexestrol, in the *Hexital tablets*, and pentobarbital sodium and carbromal, in the *Carbrital capsules*.

Further misbranding, Section 502 (d), the repackaged *Hexital tablets* and *Carbrital capsules* were drugs for use by man and contained chemical derivatives of barbituric acid, which derivatives had been, by the Administrator of the Federal Security Agency, after investigation, found to be, and by regulations designated as, habit forming; and the labels of the repackaged drugs failed to bear the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: November 18, 1949. Pleas of guilty having been entered, the court imposed a fine of \$25 on each of 5 counts against defendant Adcock, covering the sales personally made by him, and a fine of \$25 on each of 2 counts against defendant Malley, relating to the sales which he had made personally.

3023. Misbranding of Elodex. U. S. v. 3 Cases * * *. (F. D. C. No. 28039. Sample No. 48536-K.)

LIBEL FILED: On or about October 17, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about September 30, 1949, from New York, N. Y.

PRODUCT: 3 cases, each containing 28 10-ounce packages, of *Elodex* at Vine-land, N. J., in possession of the Neptune Health Products.

This product was represented by Rudy Holmberg, proprietor of the Neptune Health Products, during lectures delivered by him at the Trenton State Fair, Trenton, N. J., on September 30, 1949, to be effective in helping relieve the user of rheumatism and in preventing colds, rheumatism, lumbago, arthritis, and neuritis, for which no adequate directions for use appear in its labeling.