

3855. Misbranding of amphetamine citrate tablets, pentobarbital sodium capsules, and apiol and ergot. U. S. v. Charles Pizinger and Donald White. Pleas of nolo contendere. Defendant Pizinger fined \$1,500, plus costs, and placed on probation for 3 years; Defendant White fined \$500 and placed also on probation for 3 years. (F. D. C. No. 31252. Sample Nos. 70181-K, 70182-K, 70188-K, 89805-K.)

**INFORMATION FILED:** November 28, 1951, District of Nebraska, against Charles Pizinger, pharmacist and manager of the City Drug Store at 2823 Leavenworth Street, Omaha, Nebr., and Donald White, an employee of the store.

**ALLEGED VIOLATION:** On or about July 14, 17, and 25, 1950, while quantities of *amphetamine citrate tablets, pentobarbital sodium capsules, and apiol and ergot capsules* were being held for sale at the above-mentioned City Drug Store after shipment in interstate commerce, various quantities of the drugs were repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

Defendant Pizinger was charged with causing the repacking and dispensing of each of the drugs involved in three different counts of the information, and Defendant White was charged with causing such acts to be done with respect to a quantity of *pentobarbital sodium capsules* as alleged in an additional count in the information.

**NATURE OF CHARGE:** Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing accurate statements 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 (b) (1), the repackaged *pentobarbital sodium capsules* and *apiol and ergot capsules* failed to bear labels of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *pentobarbital 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 repackaged capsules failed to bear a label containing 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 *amphetamine citrate tablets* failed to bear a label containing the common or usual name of the drug; Section 502 (e) (2), the repackaged *apiol and ergot capsules* were fabricated from two or more ingredients, and they failed to bear a label containing the common or usual name of each active ingredient; and, Section 502 (f) (2), the repackaged *apiol and ergot capsules* 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:** A motion for a bill of particulars was filed by the defendants on January 3, 1952, and was overruled by the court, with the exception of that part in which the Government was requested to show how the defendants "caused" the various drugs to be repacked and dispensed. In accordance with such ruling, the Government filed a bill of particulars on April 23, 1952. Thereafter a motion for dismissal of the information was filed on behalf of the defendants, and after consideration of the arguments of counsel, it was overruled by the court on May 29, 1952. Pleas of nolo contendere subsequently

were entered on behalf of the defendants, and on October 30, 1952, Defendant Pizinger was fined \$1,500, plus costs, and Defendant White was fined \$500. Each defendant also was placed on probation for 3 years.

**3856. Misbranding of apiol and ergot capsules, dextro-amphetamine sulfate tablets, methamphetamine hydrochloride tablets, capsules of pentobarbital sodium and aspirin, and methyltestosterone tablets. U. S. v. Clarence L. Fedler (Fedler's Pharmacy), and Ollie Gilmer. Pleas of nolo contendere. Fine of \$300 against Defendant Fedler and \$50 against Defendant Gilmer. (F. D. C. No. 32732. Sample Nos. 16082-L, 16083-L, 16085-L, 16087-L, 16088-L, 16090-L, 16092-L.)**

**INFORMATION FILED:** October 16, 1952, Eastern District of Oklahoma, against Clarence L. Fedler, trading as Fedler's Pharmacy, Ardmore, Okla., and Ollie Gilmer, a pharmacist.

**ALLEGED VIOLATION:** On or about October 12 and 15, 1951, while quantities of *apiol and ergot capsules, dextro-amphetamine sulfate tablets, methamphetamine hydrochloride tablets, capsules of pentobarbital sodium and aspirin, and methyltestosterone tablets* were being held for sale at Fedler's Pharmacy after shipment in interstate commerce, Defendant Fedler caused 1 box of *apiol and ergot capsules* to be dispensed in the original box in which the capsules had been shipped in interstate commerce, without the prescription of a physician; and Defendant Fedler caused various quantities of the other drugs, and Defendant Gilmer caused a number of *dextro-amphetamine sulfate tablets*, to be repacked and dispensed without prescriptions, which acts resulted in the drugs being misbranded.

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (1), the labeling of the *apiol and ergot capsules* failed to bear adequate directions for use. (The box in which the capsules had been shipped in interstate commerce bore no directions for use since it was exempted from such requirement by a statement on the label "Caution: To be dispensed only by or on the prescription of a physician." The act of Defendant Fedler in dispensing the drug without a physician's prescription caused the exemption to expire.)

Further misbranding, Sections 502 (b) (1) and (2), all of 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.

Further misbranding, Section 502 (d), the repackaged capsules of *pentobarbital sodium and aspirin* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the capsules failed to bear a label containing 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) (2), a portion of the repackaged *dextro-amphetamine sulfate tablets* failed to bear a label containing the common or usual name of the active ingredient of the tablets; Section 502 (f) (1), the labeling of all of the repackaged drugs failed to bear adequate directions for use; and, Section 502 (f) (2), the repackaged *methamphetamine hydrochloride tablets* and a portion of the *dextro-amphetamine sulfate tablets* failed to bear 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.