

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

3881. Misbranding of Seconal Sodium capsules, phenobarbital tablets, capsules of pentobarbital sodium and aspirin, and methamphetamine hydrochloride tablets. U. S. v. Edward J. Lotz, Jr. (Eddie's Drug Store). Plea of nolo contendere. Fine, \$260. (F. D. C. No. 32733. Sample Nos. 16048-L to 16051-L, incl., 16053-L, 16063-L, 16064-L, 16066-L.)

INFORMATION FILED: October 16, 1952, Eastern District of Oklahoma, against Edward J. Lotz, Jr., trading as Eddie's Drug Store, Ardmore, Okla.

ALLEGED VIOLATION: On or about September 29 and October 10, 12, 15, and 16, 1951, while a number of *Seconal Sodium capsules, phenobarbital tablets, capsules of pentobarbital sodium and aspirin, and methamphetamine hydrochloride tablets* were being held for sale at Eddie's Drug Store, after shipment in interstate commerce, the defendant caused various quantities of the 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) (2), the repackaged drugs failed to bear labels containing 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 (b) (1), the repackaged *phenobarbital tablets, capsules of pentobarbital sodium and aspirin, and methamphetamine hydrochloride tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged drugs, with the exception of the *methamphetamine hydrochloride tablets*, contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the labels of these drugs failed to bear the name, and quantity or proportion of each such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (2), the repackaged *methamphetamine hydrochloride 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: On December 4, 1952, the defendant filed a motion to dismiss the counts involving the dispensing of the *Seconal Sodium capsules* and entered a plea of nolo contendere to the counts charging the dispensing of the other drugs involved. On December 22, 1952, the court overruled the motion to dismiss, after which the defendant entered a plea of nolo contendere to the counts involving the *Seconal Sodium capsules*. On December 22, 1952, the court imposed a fine of \$260 against the defendant.

3882. Misbranding of Seconal Sodium capsules, tablets of phenobarbital and mannitol hexanitrate, methamphetamine hydrochloride tablets, and liquid mixture of phenobarbital and thiamine. U. S. v. James E. Martin (Martin Drug Co.). Plea of nolo contendere. Fine, \$210. (F. D. C. No. 32736. Sample Nos. 15599-L to 15602-L, incl., 15609-L, 15613-L, 15614-L.)

INFORMATION FILED: October 16, 1952, Eastern District of Oklahoma, against James E. Martin, trading as the Martin Drug Co., Ardmore, Okla.

ALLEGED VIOLATION: On or about September 29 and October 10, 12, and 15, 1951, while quantities of *Seconal Sodium capsules, tablets of phenobarbital and mannitol hexanitrate*, and a *liquid mixture of phenobarbital and thiamine* were being held for sale at the Martin Drug Co., after shipment in interstate commerce, the defendant caused quantities of such drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded; and, on or about October 15, 1951, while a number of *methamphetamine hydrochloride tablets* were being held for sale, after shipment in interstate commerce, the defendant caused one bottle of such tablets to be dispensed in the original bottle in which the tablets had been shipped in interstate commerce, without the prescription of a physician, which act resulted in such tablets being misbranded.

NATURE OF CHARGE: *Methamphetamine hydrochloride tablets*. Misbranding, Section 502 (f) (1), the labeling of the tablets bore no directions for use. (The bottle in which the tablets were shipped in interstate commerce bore no directions for use since it was exempted from such requirement by the label statement "Caution: To be dispensed only by or on the prescription of a physician." The act of the defendant in dispensing the drug without a physician's prescription, however, caused the exemption to expire.)

Seconal Sodium capsules, tablets of phenobarbital and mannitol hexanitrate, and a *liquid mixture of phenobarbital and thiamine*. Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents. Further misbranding, Section 502 (d), the repackaged drugs contained chemical derivatives of barbituric acid, which derivatives have been 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 each derivative and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

DISPOSITION: On December 4, 1952, the defendant filed a motion for dismissal of counts 1 through 4 of the information relating to the *Seconal Sodium capsules* and for a plea of nolo contendere to the remaining 3 counts of the information involving the other drugs described above. On December 22, 1952, the motion to dismiss was overruled, and the defendant entered a plea of nolo contendere to counts 1 through 4. On the same day, the court imposed a fine of \$210 against the defendant.

3883. Misbranding of methyltestosterone tablets, thyroid tablets, ergot and apiol capsules, dextro-amphetamine sulfate tablets, tablets of phenobarbital and mannitol hexanitrate, and tablets of caffeine and ergot alkaloids. U. S. v. Fred C. Blalock (Corner Drug Store). Plea of nolo contendere. Fine, \$600. (F. D. C. No. 32738. Sample Nos. 16070-L, 16072-L, 16074-L, 16076-L, 16078-L, 16080-L.)

INFORMATION FILED: October 16, 1952, Eastern District of Oklahoma, against Fred C. Blalock, trading as the Corner Drug Store, Madill, Okla.

ALLEGED VIOLATION: On or about October 10, 12, 15, and 16, 1951, while quantities of *methyltestosterone tablets, thyroid tablets, ergot and apiol capsules, dextro-amphetamine sulfate tablets, tablets of phenobarbital and mannitol*