DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

4301. Misbranding of vaginal suppositories. U. S. v. 22 Boxes * * *. (F. D. C. No. 36219. Sample No. 45306–L.)

LIBEL FILED: December 30, 1953. District of Rhode Island.

ALLEGED SHIPMENT: On or about July 3, 1953, by the Dr. J. A. McGill Co., from Chicago, Ill.

PRODUCT: 22 boxes of *vaginal suppositories* at Providence, R. I. Each box contained a copy of a leaflet entitled "Dr J. A. McGill Co.'s Suppositories." Examination showed that each suppository weighed approximately 5.47 grams and contained approximately 47 percent ammonium alum and 16 percent borax.

LABEL, IN PART: (Box) "Contents 6 Suppositories * * * Orange Blossom Suppositories * * * Alum–Borax–Petrolatum * * * Dr. J. A. McGill Co. * * * Chicago 16, Ill."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement on the box label and in the above-mentioned leaflet, namely, "For Simple Irritations Of The Vaginal Tract," was false and misleading. The statement represented and suggested that the article was an adequate and effective treatment for diseases of the vaginal tract which are manifested by irritation of the vaginal tract, whereas the article was not an adequate and effective treatment for these diseases.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Directions Remove tinfoil at bedtime, insert one suppository in vagina and with your finger push it up as far as you can. Let it remain there undisturbed for three days. Then at night take a douche of warm water, and on the evening of the second day apply again as above making the application every five days excepting at monthly periods, allowing four days for the periods, then apply the suppository every five days."

DISPOSITION: January 25, 1954. Default decree of condemnation and destruction.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4302. Misbranding of secobarbital sodium capsules. U. S. v. Walter M. Risch (Walter's Drug Store). Plea of not guilty. Tried to the court and jury. Verdict of guilty. Defendant fined $2,500 and placed on probation for 2 years. (F. D. C. No. 35195. Sample Nos. 69251–L, 69262–L, 69272–L, 69276–L, 69282–L, 69291–L.)

INFORMATION FILED: October 27, 1953, District of Colorado, against Walter M. Risch, trading as Walter's Drug Store, Denver, Colo.

NATURE OF CHARGE: On or about November 12 and December 2 and 22, 1952, and January 2 and 16 and February 5, 1953, while a number of *secobarbital sodium capsules* were being held for sale at the Walter's Drug Store, after shipment in interstate commerce, the defendant caused various quantities of the capsules to be dispensed upon requests for refills of a written prescription therefor without obtaining authorization by the prescriber. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: The defendant entered a plea of not guilty on November 18, 1953. Thereafter, a motion for a bill of particulars was filed, and on February 11, 1954, this motion was denied. The case subsequently came on for trial before the court and jury, and on February 26, 1954, the jury returned a verdict of guilty. On March 24, 1954, the court fined the defendant $2,500 and placed him on probation for 2 years.

4303. Misbranding of penicillin G potassium tablets, sulfadiazine tablets, and secobarbital sodium capsules. U. S. v. Harold L. Potter (Potter's Drug Store), and Robert W. Lawson. Pleas of nolo contendere. Each defendant sentenced to 1 hour imprisonment; sentence suspended. (F. D. C. No. 35203. Sample Nos. 76141–L to 76144–L, incl.)

INFORMATION FILED: November 13, 1953, District of Idaho, against Harold L. Potter, trading as Potter's Drug Store, at Boise, Idaho, and Robert W. Lawson, an employee.

NATURE OF CHARGE: On or about June 25 and 29 and July 1, 1953, while a number of *penicillin G potassium tablets*, *sulfadiazine tablets*, and *secobarbital sodium capsules* were being held for sale at Potter's Drug Store, after shipment in interstate commerce, various quantities of the drugs were dispensed without a prescription from a practitioner licensed by law to administer such drugs. Defendant Potter was charged with causing the acts of dispensing involved in each of the 4 counts of the information, and Defendant Lawson was joined as a defendant in 2 counts. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: February 8, 1954. The defendants having entered pleas of nolo contendere, the court imposed a sentence of 1 hour imprisonment against each defendant, but suspended this sentence.

4304. Misbranding of sulfathiazole tablets. U. S. v. Scott-Butler Drug Store, a partnership, Harry W. Scott, and Mayo Holman. Pleas of nolo contendere. Fine of $75 against Defendant Scott and $50 against Defendant Holman. Proceedings against partnership dismissed. (F. D. C. No. 35170. Sample Nos. 61882–L to 61884–L, incl.)

INFORMATION FILED: October 22, 1953, Eastern District of Oklahoma, against the Scott-Butler Drug Store, a partnership, Idabel, Okla., Harry W. Scott, a partner and manager of the partnership, and Mayo Holman, an employee of the partnership.

NATURE OF CHARGE: On or about May 19 and 22 and June 1, 1953, while a number of *sulfathiazole tablets* were being held for sale at the Scott-Butler Drug Store, after shipment in interstate commerce, various quantities of the tablets were dispensed without a prescription from a practitioner licensed by law to administer such drug. The partnership and Defendant Scott were charged with causing the acts of dispensing involved in each of the 3 counts of the information, and Defendant Holman was joined as a defendant in 2 counts. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed tablets being misbranded while held for sale.

DISPOSITION: February 19, 1954. Pleas of nolo contendere having been entered by the defendants, the court fined Defendant Scott $75 and Defendant Holman $50 and dismissed the proceedings against the partnership.