

903. Misbranding of Ju-Van capsules. U. S. v. 292 Boxes of Ju-Van Capsules. Consent decree of condemnation. Product ordered destroyed. (F. D. C. Nos. 1528, 1691, 1847, 1849, 1910. Sample Nos. 90103-D, 4003-E, 4119-E, 4437-E, 4442-E.)

Within the period from on or about February 29 to May 5, 1940, the United States attorneys for the Northern District of Illinois and the Eastern District of Michigan filed libels against the following quantities of Ju-Van capsules: 85 boxes at Chicago, Ill., 142 boxes at Detroit, Mich., 31 boxes at Flint, Mich., and 13 boxes at Lansing, Mich. The libel against the last-named shipment was amended on May 14, 1940, to include an additional 21 boxes of the product. The libels alleged that the article had been shipped in interstate commerce within the period from on or about February 8 to April 20, 1940, by the Mid-West Drug Company, Inc., from Ft. Wayne, Ind.; and charged that it was misbranded.

Examination of samples of the article showed that in 4 of the 5 shipments the capsules contained 1.5 grains of thyroid of United States Pharmacopoeia potency, and plant material, and that in the fifth shipment they contained thyroid equivalent to 1.3 grains of thyroid of the same potency, together with plant material.

The article was alleged to be misbranded in that the statements and designs appearing on the carton labels, "For Overweight Caused by Myxedematous Hypothyroidism (Advanced stage of thyroid deficiency) * * * DIRECTIONS: One capsule after each meal and before retiring, or as directed by physician. In the event distress such as nervousness, insomnia, palpitation, or increased pulse develop, decrease number of capsules taken until condition disappears. If these conditions persist, or if any symptoms of excess thyroid activity appear, or when normal weight is approached, discontinue taking capsules. Advisability of treatment should be determined by physician. WARNING: Not to be used by children nor by persons with Heart Defects, Kidney Diseases, Pregnancy, Diabetes, Goiter, Hyperthyroidism, or any disease or affliction other than overweight as mentioned above," together with further and similar statements contained in the circular shipped with the article, were false and misleading in that they created the impression that the article was a safe and appropriate remedy for overweight, whereas it was not such a safe and appropriate remedy for overweight, but was a dangerous drug, and its labeling failed to reveal the material fact that the use of the article might result in harmful consequences to the user.

It was alleged to be misbranded further in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, "One capsule after each meal and before retiring, or as directed by physician."

On April 29, 1940, no claim having been entered at that time, judgment of condemnation was entered with respect to 69 boxes of the product located at Chicago, and the product was ordered destroyed. However, on May 1, 1940, the Mid-West Drug Co., Inc., having entered an appearance, an order was entered to vacate the default order and the claimant was given further time to answer. On December 3, 1940, on motion of the claimant, the cases instituted in the Eastern District of Michigan were ordered transferred to the Northern District of Illinois for consolidation with the 2 libels filed in the latter District. On June 23, 1943, the claimant having consented to the entry of a decree in the consolidated case, judgment of condemnation was entered and the product was ordered destroyed.

904. Misbranding of Trens. U. S. v. 40 Packages of Trens. Default decree of condemnation and destruction. (F. D. C. No. 10171. Sample No. 32531-F.)

This product consisted of tablets, each containing essentially 1 grain of phenobarbital, 3 grains of aspirin and $\frac{1}{2}$ grain of caffeine.

On July 7, 1943, the United States attorney for the Northern District of Ohio filed a libel against 40 packages of Trens at Cleveland, Ohio, alleging that the article had been shipped in interstate commerce by Trens, Inc., from St. Louis, Mo.; and charging that it was misbranded.

The article was alleged to be misbranded (1) in that it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, "Dosage: Sleeplessness—For Adults, Two tablets 20 minutes before retiring. Other symptoms—One or two tablets as required," since it contained phenobarbital, a drug which cannot be administered with safety except under competent supervision, and the directions which appeared in the labeling did not provide for any limitation in the dosage, but

implied that it might be taken as frequently as desired with safety; (2) in that it was for use by man and contained a chemical derivative of barbituric acid, phenobarbital, which derivative has been found by the Federal Security Administrator, after investigation, to be, and by regulations designated as, habit-forming, and (a) its label failed to bear the statement: "Warning—May be habit forming" in juxtaposition with the name and quantity or proportion of such derivative of barbituric acid, and (b) its label failed to bear, as such regulations specify, the name and quantity or proportion of phenobarbital and the statement: "Warning—May be habit forming," immediately following, without intervening written, printed, or graphic matter, the name by which such drug was titled.

On August 17, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

905. Misbranding of Utra-Jel. U. S. v. 5 Boxes of Utra-Jel. Decree of condemnation and destruction. (F. D. C. No. 6621. Sample No. 54631-E.)

This product, in addition to being dangerous to health when used as directed, bore statements on its labeling which created the false and misleading impression that it was a safe and effective treatment for the conditions indicated below.

On December 29, 1941, the United States attorney for the Eastern District of Pennsylvania filed a libel against 5 boxes, each containing 4 tubes, of Utra-Jel at Philadelphia, Pa., alleging that the article had been shipped on or about November 29, 1941, from Chicago, Ill., by Pynosol Laboratories, Inc.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of a castor oil soap, water, pine oil, and combined iodine.

The article was alleged to be misbranded in that the following statements appearing on its labeling created the false and misleading impression that it was a safe and effective treatment for the conditions hereafter quoted, whereas it was not a safe and effective treatment, but was a dangerous drug: (Tube) "Indicated As An Aid—In Treatment of Minor Infections Of The Cervix And Cervical Canal. As a Uterine Evacuant," (carton) "Indicated as an aid . . . in the treatment of minor infections of the cervix and cervical canal. As a uterine evacuant," (circular) "Cervical Infections And Cervical Erosions (minor) * * * Infections Of The Cervical Canal (Minor) * * * Cystic Cervix * * * As A Uterine Evacuant."

It was alleged to be misbranded further in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof, as follows: (Circular) "take cotton applicator saturated with UTRAJEL and apply to infected parts. If cervix is extensively eroded, apply 1 cc. to 3 cc. on a wool tampon and place against cervix and leave in place about 12 hours. * * * In addition to the same procedure as outlined in the above paragraph, saturate a small gauze packing with UTRAJEL and insert into the cervical canal, leaving a loose end so that the patient may remove in about 12 hours. * * * Prepare field, gently insert sterilized applicator into the external os and pass it carefully along the canal and into the mouth of the uterus remembering the position of the uterus as determined by previous bimanual examination. DOSAGE: 5 cc. to 12 cc. the first month, 15 cc. the second month, 20 cc. to 30 cc. the third month and over. The dosages suggested may be varied slightly depending upon the individual case. In all cases treatment should be administered slowly to eliminate as much the possibility of shock * * *"

On November 10, 1942, an answer to the libel having been filed by Pynosol Laboratories, Inc., and later withdrawn, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS²

906. Action to enjoin and restrain interstate shipments of a drug designated as Korjena. U. S. v. Jerome V. Gladke (Korjena Medicine Co.). Permanent injunction granted. (Inj. No. 51.)

On March 1, 1943, the United States attorney for the Western District of New York filed a complaint for an injunction against Jerome V. Gladke, trading as the

² See also No. 902.