

labeling bore false and misleading claims regarding its efficacy in overcoming the liquor habit.

Between February 19 and September 23, 1941, the United States attorneys for the Districts of Oregon and Montana, and the Western District of Missouri, filed libels against 119 packages of Alcoban at Portland, Oreg., 12 packages at Missoula, Mont., and 9 packages at Kansas City, Mo., alleging that the article had been shipped in interstate commerce within the period from on or about July 10, 1940, to on or about August 25, 1941, by the Maffett Sales Corporation from Seattle, Wash.; and charging that it was misbranded. On May 23, August 2, and September 23, 1941, the United States attorneys for the District of Colorado and the Northern District of California filed libels against 123 boxes of Alcoban at Denver, Colo., and 229 packages of Alcoban at San Francisco, Calif., which had been consigned by the Maffett Sales Corporation, alleging that the article had been shipped in interstate commerce from Seattle, Wash., within the period from on or about November 19, 1940, to August 20, 1941; and charging that it was misbranded.

Analyses of samples of the article showed that it consisted of capsules containing emetine hydrochloride in amounts varying from 0.05 to 0.18 grain of ephedrine hydrochloride, pilocarpine hydrochloride, and milk sugar.

The article was alleged to be misbranded in that it would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the following labeling: "Dosage A. When Alcoban is dissolved in each Separate alcoholic drink—determination of correct dosage: 1. The contents of 1 capsule should be given every 15 to 20 minutes until 3 capsules are taken. If vomiting occurs, this should be regarded as the proper dose and the treatment may be so given at the rate of 6 capsules (6 drinks) every third day. 2. If no vomiting occurs on the 1 capsule per drink basis as above described, double the dosage to 2 capsules per drink. Wait one hour and administer only 2 such additional drinks. If vomiting occurs, then the correct dosage is 2 capsules per drink and this treatment may be given at the rate of 6 capsules (3 drinks) every third day. * * * B. When Alcoban is dissolved in bottles of alcoholic drink—determination of correct dosage: The bulk liquor should be prepared on the basis of 1 capsule per full size drink i. e., 2 capsules per pint of beer, 4 capsules per pint of wine or 6 capsules per pint of whiskey, gin, rum or other hard liquor. 1. Administer the drink at the equivalent of 1 capsule every 15 minutes until an amount of liquor containing 3 capsules of Alcoban has been consumed. If vomiting occurs, this should be regarded as the proper dose and the treatment may be so given at the rate of 6 capsules (6 drinks) every third day. 2. If no vomiting occurs on the 1 capsule per drink basis as above described, increase the dosage to 2 capsules per drink. Wait one hour and administer only 2 such additional drinks. If vomiting occurs, then the correct dosage is 2 capsules per drink and this treatment may be given at the rate of 6 capsules (3 drinks) every third day."

It was alleged to be misbranded further in that the statement on the carton "An aid in curbing the liquor habit" and statements in the circular which represented that it would be effective to curb the liquor habit were false and misleading since it would not be an appropriate or effective treatment for curbing the liquor habit.

Between April 17 and November 7, 1941, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

Nos. 607 and 608 report the seizure and disposition of drugs which would be dangerous to health when used in the manner recommended and suggested in the labeling, which recommended the introduction of the drug into the pregnant uterus.

607. Misbranding of Leunbach' Paste. U. S. v. 4 Packages of Leunbach' Paste, Complete Outfit; and 4 Packages of Leunbach' Paste Refill Tube (and 5 other seizure actions against Leunbach' Paste, Complete Outfit; and Leunbach' Paste Refill Tube). Default decree of condemnation and destruction with respect to one seizure. Remaining five seizure actions ordered removed and consolidated. Answers withdrawn and judgment of condemnation entered; product ordered delivered to Government. (F. D. C. Nos. 2668, 2674, 2676, 2826, 2827. Sample Nos. 5032-E, 5033-E, 20127-E, 28933-E, 28934-E, 32419-E, 32420-E, 33525-E.)

Between August 23 and December 30, 1940, the United States attorneys for the District of Columbia, the Southern District of Ohio, the Middle District of Pennsylvania, the Southern District of California, and the Northern District of Georgia filed libels against the following quantities of Leunbach' Paste

Complete Outfits and Leunbach' Paste Refill Tubes; 4 packages of the outfits and 4 packages of the refill tubes at Washington, D. C.; 4 packages of the outfits and 6 packages of the refill tubes at Cincinnati, Ohio; 1 package of the outfits and 7 packages of the refill tubes at Scranton, Pa.; 10 packages of the outfits and 16 packages of the refill tubes at Los Angeles, Calif.; and 10 packages of the refill tubes at Atlanta, Ga., alleging that the articles had been shipped in interstate commerce within the period from on or about March 7 to on or about August 16, 1940, by Merz & Co. Chemical Works, Inc., from Newark and East Orange, N. J.; and charging that they were misbranded.

Examination showed that the outfit contained a tube of paste and instruments for its application, and that the refill tubes contained the same paste. Analysis of the paste showed that it consisted essentially of soap, water, alcohol (approximately 2 percent) and potassium iodide (approximately 2 percent).

The articles were alleged to be misbranded in that they were dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the following labeling: (Circular found in complete outfit) "Technique of Injection Now carefully introduce rounded tip of cannula through external os. Gradually enter into canal by injecting smallest doses of paste ahead and following through with metal tip. In this way canal is naturally opened and small obstacles such as folds of mucosa pushed aside. No additional dilation is required. Guide $3\frac{1}{2}$ " metal tip through full length of canal until internal os has been passed. In the advanced stage of pregnancy, take special care to introduce metal tip only until internal os has been passed—avoid puncturing of ovisac, also avoid detaching of placenta with metal tip. If difficulty of retention of paste is anticipated in advanced cases, a firm and high vaginal pack may be made. Some physicians have successfully used a technique to inject Leunbach' Paste into the upper fundus by attaching to the metal tip a piece of soft rubber tubing (catheter) long enough to reach behind the fetus. In cases of bad cervical laceration slide cervical plug over cannula tip far enough down to provide an effective 'stop-cock', thus preventing reflux of paste during injection. Then plug external os with gauze or tampon as soon as cannula is withdrawn. In cases of cervical stenosis attach a 2" to 3" piece of soft rubber tubing (catheter) to metal tip which may thus be guided through canal. In all cases, Leunbach' Paste is to be deposited at the lowest point of the fundus. To inject Paste roll up tube with turn-key Very Very Slowly And Carefully, and With Frequent Intermissions. Note on tube scale the quantity being injected. During injection withdraw cannula slightly to make such of avoiding infiltration and employing the lowest possible pressure. Injection should be timed by the watch and should require an average of one minute per gm. of Paste, that is $\frac{1}{4}$ hour should be taken to inject 15 gms. of Paste. * * * Occasionally a Leunbach' treatment fails to produce results. In such cases the physician should check that the paste was actually deposited in the lower fundus with injection, and that it was not reexpelled during or shortly after injection. Another reason for failure to respond may be unusual inertia. Where the Leunbach' treatment has been followed by but a few cramps with little or no bleeding and with the cervix remaining closed, a repeat of Paste injection is suggested within one week from date of first injection. If the date of the next estimated period is near, it is always advisable to wait, as many cases will still respond at this time. To prepare most thoroughly for a repeat Leunbach' treatment, inject Paste at night up to the point of overflow while injecting as slowly as possible and avoiding high pressure;" (leaflet found both in complete outfit and refill) "1. To prepare for treatment warm tube to body temperature and sterilize cannula. Before inserting cannula, make sure that at least 2 Gms. of homogeneous paste have exuded from its tip. Air must not enter with injection. Do not boil tube. To sterilize posterior vagina any recognized antiseptic, except zephiran or related chemicals, may be used. 2. Guide cannula carefully and slowly through cervical canal while injecting small doses of paste ahead. Introduce cannula until metal tip rests in lower fundus, protruding a trifle beyond internal os. Be careful not to puncture ovisac or detach placenta. 3. In every case paste is deposited at the lowest point of the fundus. To inject paste, roll up tube with turn-key very very slowly and carefully, with frequent intermissions, thereby decreasing pressure on membranes. During injection withdraw cannula slightly. Injection should be timed by the watch, to require an average of one minute per Gm. of Paste, e. g. $\frac{1}{4}$ hour should be taken to inject 15 Gms. of paste. 4. If strong tension, much bleeding or a re-expulsion of paste occur during injection, treat-

ment should be stopped. Should a temperature of 100° F. persist for at least 24 hours, or in case of hemorrhage, the outside complicating factor causing this condition must at once be determined and treated accordingly. A temporary rise in temperature during paste treatment is no sign of danger. 5. In those rare cases where the first paste treatment fails to produce results, it may be repeated a week later provided there is no bleeding. 6. For cases up to and including six weeks of gestation the use of the modified strength of Leunbach' Paste (identified as package 'M') is suggested in an average dose of 15 Gms. 7. Spontaneous, and incomplete, as well as infected cases should be treated with a dose not exceeding 5 Gms. per month of gestation, up to a maximum of 25 Gms., injecting with but the slightest pressure. At term, Leunbach' Paste is contraindicated in the presence of placenta praevia and premature separation of placenta"; and (leaflet in both complete outfit and refill tube of lot seized at Los Angeles) "In those rare cases where the first paste treatment fails to produce results, it may be repeated a week later provided there is no bleeding. * * * For cases up to and including six weeks of gestation the use of the modified strength of Leunbach' Paste is suggested in an average dose of 15 Gms."

On October 7, 1940, no claimant having appeared for the lot seized at Atlanta, Ga., judgment of condemnation was entered and the product was ordered destroyed. On October 10, 1940, the decree was set aside, but on October 18, 1940, an order was entered reinstating the original judgment of condemnation and destruction.

Merz & Co. Chemical Works, Inc., appeared as claimant in the remaining seizures and filed answers denying the allegations of the libels. On March 24, 1941, the claimant filed a petition in the District Court for the District of Columbia praying removal of the case in that district and all other pending cases to the Eastern District of Pennsylvania for consolidation and trial. On March 25, 1941, an order was entered in the District Court for the District of Columbia in accordance with said prayer and the clerks of the various district courts were ordered to transmit to the Eastern District of Pennsylvania all records and papers in the proceedings pending in their respective jurisdictions.

On December 9, 1941, the answers filed by the claimant having been withdrawn by the receiver of the claimant corporation, which had filed a voluntary petition in bankruptcy, judgment of condemnation was entered and the products were ordered delivered to the Food and Drug Administration for its official use.

608. Misbranding of Leunbach' Paste. U. S. v. 1 Leunbach' Paste, Complete Outfit; and 7 Packages of Leunbach' Paste Refill Tube. Default decree of condemnation and destruction. (F. D. C. No. 7340. Sample No. 91220-E.)

On April 30, 1942, the United States attorney for the Northern District of Illinois filed a libel against the above-named drugs at Chicago, Ill., alleging that the articles had been shipped in interstate commerce on or about January 25, 1942, by the Doctors Pharmacy from Milwaukee, Wis.; and charging that they were misbranded. The articles were labeled in part: "Leunbach' Paste Complete Outfit"; or "Leunbach' Paste Refill Tube * * * Made in U. S. A. By Merz & Company Chemical Works, Inc., Newark, New Jersey."

The articles were alleged to be misbranded in that they were dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling. (The labeling accompanying the articles consisted of the circular and leaflet quoted in full in D. D. N. J. No. 607.)

On June 10, 1942, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

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

609. Adulteration and misbranding of Virgitalis, Rua-Balm, and Theobarb. U. S. v. Van Pelt & Brown, Inc. Plea of nolo contendere to first and second counts. Plea of guilty to remaining four counts. Total fines, \$300. (F. D. C. No. 4170. Sample Nos. 50070-E, 50095-E, 50129-E, 50130-E.)

The Virgitalis possessed a potency of approximately one-third of that declared. The Rua-Balm contained less alcohol than the amount declared and its labeling failed to bear such adequate warnings as are necessary for the protection of users. The Theobarb Tablets contained less phenobarbital than the amount declared.

On September 19, 1941, the United States attorney for the Eastern District of Virginia filed an information against Van Pelt & Brown, Inc., Richmond, Va., alleging shipment on or about September 12 and 21, 1940, and January 9, 1941,