

colored urine, pale countenance, confused sensation in the head, weariness and irritable and discontented state of mind, sense of fullness and oppression in the region of the stomach, feeble circulation on the surface; that it was efficacious from the simplest first symptoms to the most aggravated type of the disease; that it should be used in conjunction with Cotec Laxative Pills to prevent a return of piles; that if used regularly it would effect a cure; that it would cure quickly and permanently; that it was the best pile remedy, which representations were false and misleading since the article was not an adequate treatment for the conditions mentioned in the labeling but was a filthy mixture unfit for medicinal use.

On January 24, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS LABELED WITH FALSE AND MISLEADING THERAPEUTIC CLAIMS¹

96. Misbranding of Booth's Mentholated Cough Drops, Cough and Cold Remedy, La Grippe & Cold Tablets, Liniment, and Liver Pills; and adulteration and misbranding of Booth's Camphorated Oil and Carbollic Salve. U. S. v. 1,128 Boxes of Mentholated Cough Drops, et al. Default decree of condemnation and destruction. (F. D. C. Nos. 466 to 473, incl. Sample Nos. 53819-D to 53826-D, incl.)

The labeling of these products bore false and misleading representations regarding their medicinal properties as shown hereinafter. The Camphorated Oil did not conform to the standard prescribed for such product in the United States Pharmacopoeia, and the carbollic salve contained a smaller proportion of carbollic acid than that declared on the label. The liniment contained alcohol, which was not declared on the label.

On August 23, 1939, the United States attorney for the Western District of Michigan filed a libel against 1,128 boxes of mentholated cough drops, 168 bottles of camphorated oil, 114 bottles of cough and cold remedy, 264 boxes of la grippe and cold tablets, 426 tins of carbollic salve, 80 bottles of liniment, and 108 packages of liver pills at Harbor Springs, Mich., consigned by J. F. Booth, alleging that the articles had been shipped in interstate commerce on or about March 13 and June 21, 1939, from Springfield, Ill.; and charging that they were misbranded and that the camphorated oil and carbollic salve were also adulterated.

Analyses showed that the Mentholated Cough Drops were sugar lozenges flavored with menthol. The article was alleged to be misbranded in that statements in the labeling representing that one of the drops put into the mouth before going to bed would cause the patient to enjoy a comfortable night's sleep; that it was excellent for coughs, colds, hoarseness, etc.; that persons troubled with coughs, hoarseness, sore throat, etc., would find immediate relief by using the product, were false and misleading as applied to sugar lozenges flavored with menthol.

Analyses showed that one shipment of the Camphorated Oil contained not more than 12.6 percent of camphor and that the other shipment contained not more than 9.8 percent of camphor. It was alleged to be adulterated in that it was represented as a drug, the name of which is recognized in the United States Pharmacopoeia but its strength differed from the standard set forth in that compendium since the pharmacopoeia provides that camphorated oil shall contain not less than 19 percent of camphor. It was alleged to be misbranded in that the representations in the labeling of one lot that it was efficacious as an anodyne embrocation in rheumatic affection of the joints, and in the labeling of the second lot that it was useful in rheumatism, pains, and swellings of the breasts or joints and in colds on the chest, were false and misleading in that the article was not efficacious for the purposes recommended.

Analyses of the Cough and Cold Remedy showed that it consisted essentially of small proportions of extracts of plant material, ammonium chloride, and menthol, and sugar, alcohol and water. It was alleged to be misbranded in that statements in the labeling representing that it was a cough and cold remedy and was efficacious for recent chronic coughs, consumption, hoarseness, bronchitis, loss of voice and all inflamed conditions of the lungs and bronchial tubes, were false and misleading, since the article was not efficacious for the purposes recommended.

Analyses showed that the La Grippe & Cold Tablets contained acetanilid (1 grain per tablet), a small proportion of salol, a quinone compound, a bromide,

¹ See also N. J. Nos. 80, 85, 90, and 95.

capsicum, calcium carbonate, and starch. The article was alleged to be misbranded in that statements in the labeling representing that it was the best remedy for la grippe and was efficacious to arouse the liver and the secretions to perfect action, were false and misleading since it was not efficacious for the purposes recommended.

Analyses of the Carbollic Salve showed that it contained 2.9 percent of carbollic acid. It was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess since it was labeled "Contains 5% Carbollic Acid." It was alleged to be misbranded in that representations in the labeling that it was efficacious for ulcers, salt rheum, tetter, boils, piles, felons, etc., sores, and cold sores, were false and misleading since it was not efficacious for such purposes.

Analyses of the Liniment showed that it consisted essentially of volatile oils (including oil of peppermint, oil of mustard, and methyl salicylate), alcohol (36.1 percent by volume), and chloroform (10.8 percent). It was alleged to be misbranded in that statements in the labeling representing that it was efficacious in rheumatism, gout, lameness, weak joints, backache, sore lungs, etc., that it was efficacious in removing pain and taking out inflammation and could not be beaten for chronic rheumatism, were false and misleading since the article was not efficacious for the purposes recommended. It was alleged to be misbranded further in that its label failed to bear a declaration of the quantity, kind, and proportion of alcohol that it contained.

Analyses of the Liver Pills showed that they contained extracts of plant drugs including capsicum, nux vomica, and a laxative drug. The article was alleged to be misbranded in that statements in the labeling representing that it was efficacious for headache, dizziness, torpid liver, biliousness, dyspepsia, etc., were false and misleading since it was not efficacious for the purposes recommended.

On September 8, 1939, Jacob F. Booth, Harbor Springs, Mich., having authorized and requested that the products be destroyed, judgment of condemnation and destruction was entered.

97. Misbranding of Dormalgin. U. S. v. 100 Packages and 450 Packages of Dormalgin. Default decree of condemnation and destruction. (F. D. C. No. 275. Sample No. 67359-D.)

This product contained butyl-bromallylbarbituric acid and aminopyrine. It was labeled to indicate that it was an appropriate and harmless medicament, whereas it was a dangerous drug. Its labeling bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter.

On or about July 10, 1939, the United States attorney for the District of Connecticut filed a libel against 100 packages, each containing 10 tablets, and 450 packages, each containing 5 tablets of Dormalgin, at Darien, Conn., alleging that the article had been shipped in interstate commerce on or about December 10, 1935, by Lawson M. Luth from Geneva, N. Y.; and charging that it was misbranded.

It was alleged to be misbranded in that representations in the labeling that it had been submitted to the most severe laboratory and clinical tests; that the most rigid research examinations had been conducted by prominent clinics and medical men in private practice; that its effectiveness and harmlessness had been repeatedly emphasized by physicians qualified to judge such a preparation; that it vanished with the pain leaving no after effects; that it was completely split up when it had finished its appointed work; that it was burned up in the body leaving no disagreeable after effects such as benumbed head, lassitude, fatigue, or drowsiness; that it was an effective and nonpoisonous analgesic free from cumulative, concurrent, and after effects and was indicated for all painful diseases; that there was no danger of habit forming as is the case with alkaloids containing analgesics; that it would agree with patients even in large doses and had the advantage of being free from hypnotic concurrent and after effects; that experiments had proved its harmlessness; that it would not produce the slightest detrimental effect on heart and kidneys even when administered in large doses; that it had been developed by a concern which enjoys an international reputation as a manufacturer of the highest grade pharmaceuticals and which maintained a pharmaceutical laboratory world famous for its products; that many preparations are on the market to relieve pain but many are ineffective and many of these which will relieve pain are actually harmful, in that they contain narcotics and other dangerous habit-forming drugs or ingredients which affect the heart and kidneys and that even preparations with salicylic acid as a base, such as aspirin, are not easily tolerated by a large group of people, but that the Dormalgin contained no habit-