

Worm Powder in the package was efficacious in the cure or mitigation of all worms in hogs.

"The label in large type expressly states that it is 'Worm Powder for Ascaris Worms in Hogs' and designates it as 'Iowa Worm Powder.' The directions for the use of the powder refers to either 'the Worm Powder,' which certainly means the Worm Powder contained in the package, or 'Iowa Worm Powder,' which even more definitely refers to the Worm Powder in the package, and the worm powder in the package is labeled as clearly and distinctly as it could be as a Worm Powder for Ascaris Worms without any suggestion or inference that it could be used or was efficacious in any manner or degree in destroying other worms in hogs.

"The defendant's demurrer to Count 1 of the Amended and Substituted Information is sustained and said Count is dismissed as not stating an offense against the defendant. The United States of America excepts. Signed at Des Moines, Iowa, this 13th day of October, 1943."

On November 30, 1943, no appeal having been noted with respect to the ruling on the demurrer, the court imposed a fine of \$100 on each of counts 2 and 3, a total of \$200, together with costs.

**1011. Misbranding of Speagolax, Hunt's Salve, Triple-X Medicine, Booth's Balm, Booth's Pills, Liver-Cure, Fem-Re-Ills, Targosine, Jew David's or Hebrew Plaster, B. P. Stomach and Intestinal Corrective, Irogen, and Colonex Tablets; and adulteration and misbranding of Tansy. U. S. v. Allen Dobson and Matt H. Dobson, Jr. (Dobson & Co.). Pleas of nolo contendere. Fine, \$150 against each defendant. (F. D. C. No. 8766. Sample Nos. 59789-E, 59791-E to 59797-E, incl., 59799-E, 78301-E, 78302-E.)**

On February 18, 1943, the United States attorney for the Western District of North Carolina filed an information against Allen Dobson and Matt H. Dobson, Jr., trading as Dobson & Co., at Nashville, Tenn., and Rutherfordton, N. C., alleging shipment on or about April 16, 1942, from the State of North Carolina into the State of Virginia of quantities of the above-named products. The articles were labeled in part: "Speagolax \* \* \* Put up and Guaranteed by Speagolax Medicine Co., Durham, N. C.," "Hunt's Salve \* \* \* Manufactured by A. B. Richards Med. Co., Sherman, Texas," "Triple-X \* \* \* Medicine \* \* \* Triple X Laboratories Scotland Neck, N. C.," "Booth's Balm \* \* \* [or 'Booth's Pills'] \* \* \* Booth's Hyomei Co., Ithaca, N. Y.," "Tansy \* \* \* S. W. Gould & Bros. \* \* \* Malden, Mass.," "Liver-Cure Munyon's Homeopathic Home Remedies," "Fem-Re-Ills \* \* \* Guaranteed by the Henry S. Wampole Company \* \* \* Baltimore, Maryland," "Targosine \* \* \* Manufactured and Guaranteed by the Targosine Co. Monroe, N. C.," "Jew David's or Hebrew Plaster All Genuine. Signed E. Taylor Right Secured Comstock & Co. Rochester, N. Y.," "B. P. Stomach and Intestinal Corrective Burwell & Dunn Co. \* \* \* Charlotte, N. C.," "Irogen [or 'Colonex Tablets'] \* \* \* Guardian Health Products Co. Incorporated Atlanta, Georgia."

Analysis of the Speagolax showed that it was a brown liquid, having a bitter taste and consisting essentially of an iron salt, nux vomica extract, benzoates, cascara, iodides, alcohol, sugar, and water. It was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that the article would be efficacious as a tonic for the stomach and blood; that it would be efficacious in the cure, mitigation, treatment, or prevention of rheumatism, lumbago, indigestion, liver and kidney trouble, and diseases due to impure blood; and that it would aid digestion and restore tone to a run-down system. It was alleged to be misbranded further (1) in that its labeling failed to bear adequate directions for use, since the directions on the label, "Dose:—One tablespoonful three times a day before meals," suggested that the article should be used continuously, whereas it was a laxative and should not be used continuously, and the direction, "Children according to age," was not explicit, whereas directions should be explicit; (2) in that its labeling failed to bear adequate warnings against use in those pathological conditions wherein its use might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users, since the article contained a laxative, cascara, and its labeling did not warn that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present, and that frequent or continued use might result in dependence upon laxatives; and (3) in that its container was so made, formed, or filled as to be misleading since the container was larger than was necessary to contain the article.

Analysis of the Hunt's Salve showed that it was a greenish-brown ointment consisting essentially of sulfur, oil of sassafras, a mercury salt present as a

sulfide, and resins incorporated in a petrolatum base, together with small amounts of phenol, iodides, and chrysarobin. It was alleged to be misbranded in that the statements in its labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of itch, 7-year itch, barber's itch, itch in all of its various forms, eczema, scald head, piles, old sores, boils and all skin diseases, including skin diseases of babies and small children, were false and misleading since the product would not be efficacious for such purposes. It was alleged to be misbranded further in that it was not designated solely by a name recognized in an official compendium, and it was fabricated from two or more ingredients, one of which was a mercury salt, and the labeling failed to bear the common or usual name of each active ingredient, including a statement of the quantity or proportion of the mercury salt contained in the article.

Analysis of the Triple-X Medicine showed that it was a brown-colored emulsion of copaiba and cubeb oils and a sugar solution, emulsified with a water-soluble gum. It was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of acute and chronic discharges. It was alleged to be misbranded further in that it was not designated solely by a name recognized in an official compendium, and in that it was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient.

Analysis of the Booth's Balm showed that it was a green ointment consisting of chlorophyll containing plant extractives, a cresol-like substance, and a trace of eucalyptol, all incorporated in a base of petrolatum and fatty material. It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of many forms of skin diseases, such as dandruff, scalp irritation, pimples, blackheads, eczema, and itching skin; that it would be efficacious in the cure, mitigation, treatment, or prevention of bronchial catarrh, head colds, spasmodic croup, aching and tender feet, tender breasts, and sore nipples; and that it would be beneficial during pregnancy, were false and misleading since the article would not be efficacious or beneficial for such purposes.

Analysis of the Booth's Pills showed that they contained emodin-bearing drugs, apparently aloes.

The article was alleged to be misbranded in that its labeling failed to bear adequate warnings against use in those pathological conditions wherein its use might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users, since the article contained aloes, a laxative drug, and its labeling did not bear a warning that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present, and that frequent or continued use might result in dependence on laxatives.

Analysis of Tansy showed that it consisted of dried plant material containing the leaves and flower heads of the tansy plant. It was alleged to be adulterated in that it consisted in whole or in part of a filthy substance by reason of the presence therein of insects, insect fragments, and insect excreta, and because of fire or water damage. It was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that the article would be efficacious as a tonic, emmenagogue, and anthelmintic; and that it would be efficacious in the cure, mitigation, treatment, or prevention of amenorrhea and hysteria.

Analysis of the Liver-Cure showed that it consisted of small spherical sugar pellets with no other ingredient detected. It was alleged to be misbranded in that the statements in its labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of jaundice, and all diseases of the liver, including torpid liver, and all acute congested conditions of the liver, biliousness, constipation, bilious headache, and sick headache; and that it would be efficacious to relieve bad taste in the mouth, coated tongue, worn-out feeling, highly colored urine, soreness in the right side, dull spirits, and restless nights, were false and misleading since it would not be efficacious for such purposes.

Analysis of the Fem-Re-Ills showed that it was a white, sugar-coated elliptical pill, consisting essentially of ferrous sulfate, calcium carbonate, oil of savin, plant extractives including aloes, and sugar, together with small amounts of ergot alkaloids. It was alleged to be misbranded in that the statements appear-

ing in its labeling which represented and suggested that it would be efficacious as an ideal remedy for amenorrhea, dysmenorrhea, and menstrual disorders; that it would be efficacious in the cure, mitigation, treatment, or prevention of functional derangement of the reproductive organisms; that it would assist nature in its efforts to re-establish the menstrual flow at the regular period; and that it would prevent difficult, painful, over-profuse, and other morbid menstrual conditions, and would keep those important functions normal, were false and misleading, since it would not be efficacious for such purposes. It was alleged to be misbranded further in that it was not designated solely by a name recognized in an official compendium; and that it was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient.

Analysis of the Targosine showed that it consisted essentially of turpentine, kerosene, fatty material, a water-soluble gum, and water, together with a small amount of chloroform. It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that it would be efficacious as an instant relief for eczema, old sores, skin diseases, burns, scalds, and sunburn; that it would be efficacious in the cure, mitigation, treatment, or prevention of pains in the back, stiff neck, rheumatic pains, soreness in the chest, colds, croup, tonsillitis, sore throat, poison oak, itch, barber's itch, eczema, boils, old sores, ulcers, eruptions, pimples, vaccination sores, breastcane, and sore nipples, were false and misleading since it would not be efficacious for such purposes. It was alleged to be misbranded further in that it was not designated solely by a name recognized in an official compendium, and in that it was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient.

Analysis of the Jew David's or Hebrew Plaster showed it to be a brown, translucent and somewhat plastic mass having an agreeable terebinthinate odor, the odor, appearance, and physical properties resembling the oleoresin, Burgundy pitch. It was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of local inflammation, scrofulous affections, gout, inflammatory and chronic rheumatism, and lung and liver affections; and that it would be beneficial in cases of weakness, such as weakness and pain in the stomach and affections of the spine.

Analysis of the B. P. Stomach and Intestinal Corrective showed that it was a viscous mixture containing suspended solid material and a brown liquid, with a mint odor and taste, consisting essentially of bismuth subsalicylate together with a small amount of volatile oils including peppermint, sugar, and water.

It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that would be efficacious as an antiferment; that it would be efficacious for and would correct fermentation arising from improperly prepared and infected food; and that it would be efficacious in the cure, mitigation, treatment, and prevention of vomiting, diarrhea, dysentery, flux, and cholera morbus in children and adults were false and misleading since it would not be efficacious for such purposes. It was alleged to be misbranded further in that it was not designated solely by a name recognized in an official compendium; and in that it was fabricated from two or more ingredients and its labeling failed to bear the common or usual name of each active ingredient.

Analysis of the Irogen showed that it was a dark brown liquid containing considerable sediment and consisting essentially of alcohol, an iron salt, malt, manganese salt, cinchona alkaloids, nux vomica alkaloids, wild cherry, emodin-bearing drugs, phosphorus compounds, a sodium salt, sugar, and water. It was alleged to be misbranded because of the false and misleading statements in its labeling which represented and suggested that the article would be efficacious as a prompt aid for enriching the blood; that it would be efficacious in building up bodily strength and restoring impaired tissues; and that it would aid digestion and restore tone to the system. It was alleged to be misbranded further in that it was not designated solely by a name recognized in an official compendium; and in that it was fabricated from two or more ingredients, including the ingredient strychnine, and its labeling failed to bear the common or usual name of each active ingredient, including the quantity or proportion of strychnine contained in the article.

Analysis of the Colonex Tablets showed that the article consisted of sugar-coated tablets containing phenolphthalein and emodin drugs. It was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that the article would be efficacious as a stimulator

of the liver cells; that it would improve digestion and assimilation; and that it would be efficacious in the prevention of premature old age, rheumatism, high blood pressure, Bright's disease, diabetes, and constant headaches, and would produce normal bowel movements. It was alleged to be misbranded further in that its labeling failed to bear adequate directions for use since the directions suggested continuous use of the article, whereas laxative preparations should not be used continuously, and the directions were not explicit with respect to the dosage for children; and in that its labeling failed to bear such adequate warnings against use in those pathological conditions wherein its use might be dangerous to health, or against unsafe dosages or methods or duration of administration, in such manner and form as are necessary for the protection of users, since the article contained laxatives, phenolphthalein and emodin-bearing drugs, and its labeling failed to bear a warning that they should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present, and it did not bear a warning that frequent or continued use might result in dependence upon laxatives.

On November 8, 1943, the defendants having entered pleas of nolo contendere, the court imposed a fine of \$150 against each defendant.

### DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS\*

**1012. Adulteration and misbranding of salicylate soda, strychnine sulfate, Rheumatic No. 3, phenobarbital tablets, and acetanilid, caffeine and sodium salicylate compound tablets. U. S. v. Charles Killgore Co., Inc. Plea of guilty. Fine, \$1,000. (F. D. C. No. 7659. Sample Nos. 84880-E, 84881-E, 84943-E, 84944-E, 90441-E.)**

The Rheumatic No. 3 Tablets and the acetanilid, caffeine and sodium salicylate compound tablets differed from their own declared standards of strength and quality. The remainder of the products were sold under names recognized in the National Formulary and differed in strength from the standards prescribed in that compendium.

On April 5, 1943, the United States attorney for the Southern District of New York filed an information against the Charles Killgore Co., Inc., Yonkers, N. Y., alleging shipments on September 8 and December 1 and 4, 1941, from the State of New York into the States of Connecticut, New Jersey, and Rhode Island of quantities of the above-named drugs which were adulterated and misbranded.

The salicylate soda tablets were alleged to be adulterated in that they purported to be and were represented as a drug the name of which is recognized in the National Formulary, but their strength differed from the standard set forth in that compendium since each tablet contained the equivalent of not more than 89 percent of the labeled amount of sodium salicylate, whereas the National Formulary provides that tablets of sodium salicylate shall contain not less than 91 percent of the labeled amount; and their difference in strength from the standard was not plainly stated on the label. They were alleged to be misbranded in that the statement "Salicylate Soda 5 grains," appearing on the label, was false and misleading.

The strychnine sulfate tablets were alleged to be adulterated in that they purported to be and were represented as a drug the name of which, tablets of strychnine sulfate, is recognized in the National Formulary, but their strength differed from the standard set forth in that compendium since each tablet contained the equivalent of not more than 79.2 percent of the labeled amount of strychnine sulfate, whereas the National Formulary provides that tablets of strychnine sulfate of this size shall contain not less than 91 percent of the labeled amount of strychnine sulfate; and their difference in strength from the standard was not plainly stated on their label. They were alleged to be misbranded in that the statement "Strychnine Sulph 1-30 gr.," appearing on the label, was false and misleading.

The Rheumatic No. 3 Tablets were alleged to be adulterated in that their strength differed from and their quality fell below that which they purported and were represented to possess, since each tablet was represented to contain  $7\frac{1}{2}$  grains of soda salicylate, i. e., sodium salicylate, whereas each tablet contained not more than 6.18 grains of sodium salicylate. They were alleged to be misbranded in that the statement "Soda Salicylate  $7\frac{1}{2}$  grs.," appearing on the label, was false and misleading.

The phenobarbital tablets were alleged to be adulterated in that they purported to be and were represented as a drug the name of which is recognized in the

\*See also Nos. 1002, 1003.