ing that the article had been shipped in interstate commerce on or about April 25, 1941, by the Voltamp Electric Manufacturing Co. from Baltimore, Md.; and charging that it was misbranded.

The article was alleged to be misbranded in that it would be dangerous to health when used with the frequency or duration prescribed, recommended, or suggested in the labeling for the following diseases: Amaurosis; aphasia, apoplexy, atrophy and non-development, muscular atrophy, backache, lame back, lameness, Bell's palsy, paralysis of bladder; blindness; cramps in bowels, catalepsy, trance; cramps, myalgia, cramps in muscles; general debility; difficulty of speech, dysphagia; paralysis of eye muscles, facial paralysis, fainting, syncope; hemiplegia; infantile paralysis, poliomyelitis; soreness, tired feeling; languor, listlessness, ennui; lockjaw, tetanus; loss of sensation, loss of voice, aphonia; meningitis, spinal meningitis; muscular contractions; neuralgia, sciatica, tic douloureaux; neuralgia of scalp; neuritis; numbness, general pain, shaking palsy, facial paralysis, paraplegia, throat paralysis, ptosis, falling of the eyelids; facial spasm, spasm of eyelid; vertigo, dizziness.

It was alleged to be misbranded further in that statements in the labeling which represented that it would be efficacious in the treatment of the above-named and the following disease conditions—pendulous abdomen; abscess, boils, furuncles, inflammation; alopecia, baldness, falling hair, dandruff, seborrhea sicca, other troubles of the scalp, acne, blackheads, comedones, pimples, chloasma, eczema, herpes zoster, shingles, hives, urticaria, nettle rash, itch, face wrinkles, amblyopia, failing sight, blindness, cataract, conjunctivitis, inflammation of eyes, spasm of eyelid, paralysis of eye muscles; amenorrhea, retention of the menses, dysmenorrhea, painful menstruation, menorrhagia, excessive menstruation, falling of the womb, prolapsus uteri, ulceration or inflammation of uterus; anemia, poverty of the blood, chlorosis; aphonia, hoarseness, stammering; paralysis; ascites, dropsy, asphyxia, asthma, hay fever; atrophy and non-development, soreness, lumbago; poor circulation of blood, cold feet, cold extremities, corns, bunions, irritable bladder, cystitis, urinary calculus, enlarged prostate, prostatitis, spasm of bladder, stone in the bladder, hyperaesthesia urethra, retention of urine, incontinence of urine; brain fag, cephalalgia, headache, headache accompanied by distress in the region of the stomach, liver and bowels, hypochondriasis and melancholia, hysteria, nervousness, insomnia, sleeplessness, tired feeling, migraine, nerves, neurasthenia; Bright's disease, kidney disorders; catarrhal jaundice, liver spots, cirrhosis of the liver, congestion of the liver, jaundice, hardening of the liver, torpid liver, liver troubles; cholera morbus, colic, nausea, sea sickness, constipation, enteralgia, cramps in bowels, chronic diarrhea, dysentery, flatulence, gastralgia, pain in the stomach, gastritis, indigestion, dyspepsia, loss of appetite, hysterical vomiting, vomiting of pregnancy, chorea, St. Vitus' dance, dysphagia, dizziness, vertigo; cold in the head, coryza, catarrh; consumption, coughs, croup, bronchitis, pleurisy; myalgia, cramps in muscles, crick in the neck, wry neck, torticollis; deafness, earache; diabetes; diphtheria; seminal emissions; spermatorrhea, functional sexual impotence, loss of vitality of the organs; enlarged glands, glandular tumors; epilepsy, catalepsy, trance; exophthalmic goiter; fever; frostbite, chilblains; hemorrhoids, piles, rectal prolapsus; hernia, rupture; persistent hiccough; enlarged, sprained joints, rheumatism, sprains, stiff joints, weak ankles, gout; lockjaw, tetanus; locomotor ataxia; malaria, ague, enlarged spleen; nose bleed, epistaxis; obesity; quinsy, sore throat, tonsillitis, enlarged tonsils; sunstroke; toothache, dontalgia; varicocele, varicose veins; whooping cough, pertussis; that it possessed a wonderful power to alleviate pain, cure disease, and save life; that it would increase the supply of mother's milk; would relieve afterpains, remove superflous hair, and rid one of all kinds of skin blemishes, that it would produce local anesthesia, would develop the bust and other shrunken parts, and would relieve constipation permanently, were false and misleading, since the device would not be efficacious for the purposes recommended.

On July 31, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to the Food and Drug Administration.

**659. Misbranding of No. 48511–C Tablets and Goodwin's Laxative Cold Tablets. U. S. v. 81,600 No. 48511–C Tablets in bulk containers and 6,330 Packages of Goodwin's Laxative Cold Tablets. Consent decree of condemnation. Product ordered released under bond to be repackaged and relabeled.** (F. D. C. No. 4883. Sample Nos. 50244–E, 50245–E.)

This case covered shipments of tablets in bulk containers, a portion of which had been repackaged and relabeled "Goodwin's Laxative Cold Tablets" by the con-

signee. The repackaged tablets would be dangerous to health when used according to directions. The labeling of both lots of tablets failed to bear adequate warning statements and satisfactory ingredient statements. Furthermore, the labeling of the bulk tablets failed to bear directions for use, and that of the repackaged tablets also bore false and misleading therapeutic claims.

On June 7, 1941, the United States attorney for the District of Maryland filed a libel against the above-named products at Baltimore, Md., alleging that they had been shipped on or about February 24 and 26 and March 4 and 10, 1941, by Sharp & Dohme from Philadelphia, Pa., and that having been so shipped, they remained in interstate commerce on the premises of the Read Drug & Chemical Co. at Baltimore, Md.; and charging that they were misbranded. The bulk tablets were labeled in part: (Container) "Sharp & Dohme Philadelphia, Pa. * * * No. 48511–C Made for Read Drug & Chemical Co. Baltimore, Md."

Analyses of samples taken from the bulk containers and the retail cartons showed that each tablet contained acetanilid (approximately 2 grains), quinine sulfate (¼ grain), podophyllin, capsicum, and belladonna extract.

The repackaged tablets were alleged to be misbranded: (1) In that they would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, namely, "Adults: 1 tablet every 4 hours until bowels move freely, then 1 tablet 2 or 3 times daily," since if taken in accordance with such directions they might result in the patient's ingesting amounts of acetanilid that would be dangerous to health. (2) In that the name "Goodwin's Laxative Cold Tablets" and the statements "Effective in the Treatment of Colds. Relieves the Feverish Condition which Accompany Colds," and "Keeps the Bowels Active," appearing in the labeling, were false and misleading since they gave the impression that the article was an effective treatment for colds; whereas it was not an effective treatment for colds and would not fulfill the promises of benefit made and implied by such statements. (3) In that a quantity of belladonna alkaloids was present in the article and the labeling did not bear a statement of the quantity or proportion of the belladonna alkaloids present.

Both lots of tablets were alleged to be misbranded in that the labeling did not bear adequate warnings against use in those pathological conditions or by children where their use might be dangerous to health and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users, since said labeling bore no warnings that their use should be discontinued if a skin rash appeared; that they should be used cautiously if dryness of the throat occurred; that their use should be discontinued if rapid pulse or blurring of the vision resulted; that the preparation should not be taken by children; that frequent or continued use might be dangerous to health by causing serious blood disturbances, anemia, collapse, or dependence on the drug; that the preparation should not be taken by elderly people except on competent advice; that frequent use of the preparation might lead to dependence upon laxatives to move the bowels; and (bulk tablets only) since said labeling did not carry a warning against use of the article in the presence of abdominal pain, nausea, vomiting, or other symtoms of appendicitis.

The bulk tablets were alleged to be misbranded further (1) in that the label failed to bear adequate directions for use since it did not bear any directions for use; and (2) in that the labeling did not bear the common or usual name of each active ingredient, namely, acetanilid, quinine sulfate, podophyllin, capsicum, and belladonna extract, and in that it did not bear a statement of the quantity or proportion of acetanilid and belladonna extracts.

On August 6, 1941, the Read Drug & Chemical Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond conditioned that it be repackaged and relabeled under the supervision of the Food and Drug Administration.

## DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS[1]

**660. Misbranding of acetylsalicylic acid and colchicine compound capsules. U. S. v. Sam Frank Drug Co. Plea of guilty. Fine, $10.** (F. D. C. 6430. Sample No. 65040–E).

In addition to failure to bear adequate warning statements, the label of this product failed to bear the required ingredient statement.

On March 13, 1942, the United States attorney for the District of Colorado filed an information against the Sam Frank Drug Co., a corporation at Denver,

[1] See also Nos. 657, 659.