that they were misbranded. On June 16, 1941, a libel was filed in the Northern District of Texas against 289 bottles of 10 percent and 28 bottles of 25 percent dextrose in physiological solution of sodium chloride at Dallas, Tex., which had been consigned by the Upjohn Co., alleging that it had been shipped within the period from on or about March 7 to on or about May 23, 1941, from Kalamazoo, Mich.; and charging that it was misbranded.

The articles were alleged to be misbranded 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, "For Parenteral Injection."

On June 17, 1941, the shipper having consented to the destruction of the dextrose seized at Dallas, judgment of condemnation was entered and the product was ordered destroyed. Between July 10 and November 14, 1941, no claimant having appeared for the remaining products, judgments of condemnation were entered and the products were ordered destroyed.

604. Adulteration and misbranding of Zerbst's Capsules. U. S. v. 12 Dozen Cartons, 387 Dozen Cartons, 47 Dozen Cartons, 141 Dozen Cartons and 1,000 Sample Envelopes of Zerbst's Capsules. Consent decree of condemnation and destruction. (F. D. C. Nos. 4834, 4835. Sample Nos. 43426-E, 43427-E).

These capsules were found to consist essentially of acetanilid (4 samples examined contained 1.132, 1.282, 1.125, and 1.289 grains, respectively), together with caffeine, asafoetida, camphor, capsicum, and plant materials including aloin. They would be dangerous to health when used in the dosage or with the frequency or duration prescribed in the labeling, which failed to reveal the consequences which might result from their use. The labeling was further objectionable, as indicated below.

On June 11, 1941, the United States attorney for the Western District of Oklahoma filed a libel against 528 dozen small cartons, 59 dozen large cartons and 1,000 sample envelopes of Zerbst's Capsules at Oklahoma City, Okla., alleging that the article had been shipped in interstate commerce within the period from on or about January 28 to on or about February 18, 1941, by Zerbst Pharmacal Co. from St. Joseph, Mo.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess, namely, (label) "Each Capsule contains as active ingredients, Acetanilid 1 Grain," whereas each capsule contained materially more than 1 grain of acetanilid in each capsule.

It was alleged to be misbranded (1) in that the directions for use, namely, "Adults—To allay the discomfort in breaking up a common head cold, simple headache or neuralgia, take one capsule every half hour until three are taken, then one capsule in two or three hours until three more are taken. Children—12 years old, one capsule, repeated in three hours," were not appropriate for an article of the composition disclosed by the analysis, and were therefore inadequate; (2) in that the label failed to bear adequate warnings against its use by children or in those pathological conditions where its use might be dangerous to health, and against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of users; and (3) in that it was dangerous to health when used according to the directions appearing on the label as set forth above.

On October 1, 1941, the claimants having withdrawn their answers and having admitted the allegations of the libel and consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

605. Misbranding of Mrs. Moffat's Shoo Fly Powders for Drunkenness. U. S. v. 11¼ Dozen Packages of Mrs. Moffat's Shoo Fly Powders. Case tried to the court. Judgment for the Government. Decree of condemnation and destruction. (F. D. C. No. 3444. Sample No. 19574-E.)

This product contained tartar emetic and would be dangerous to health when used according to directions; and it would not be an effective and appropriate treatment for drunkenness as suggested in the labeling.

On November 27, 1940, the United States attorney for the Western District of New York filed a libel against the above-named product at Buffalo, N. Y., alleging that it had been shipped on or about November 2, 1940, by M. F. Groves' Son & Co. from Philadelphia, Pa.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted of antimony and potassium tartrate (tartar emetic).

The article was alleged to be misbranded (1) in that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed,

recommended, or suggested in the labeling, namely, "Directions—one of the powders may be given in beer, coffee, tea, or any other liquid"; and (2) that the statement "For Drunkenness" was false and misleading.

On April 28, 1941, M. F. Groves' Son & Co., claimant, having filed an answer denying the material allegations of the libel, the case came on for trial before the court. Evidence was introduced on behalf of the Government and the claimant, and on June 17, 1941, the court handed down the following opinion:

KNIGHT, *District Judge.* "The libelant seeks condemnation of certain articles of alleged drug products described as '11-¼ Dozen Packages of an article labeled in part: "Mrs. Moffat's Shoo Fly Powders for Drunkenness."' Libel is brought under the provisions of the Federal Food, Drug and Cosmetic Act of June 25, 1938, Title 21 U. S. C., and is based upon the claim that the aforesaid articles are misbranded under subdivision (a) and (j) of Section 352 of Title 21 U. S. C.

"It is admitted that the articles in question were shipped in interstate commerce, that is, from the State of Pennsylvania to the Ellicott Drug Co., at Buffalo, N. Y., on November 2, 1940, by the intervenor, M. F. Groves' Son & Co., who concededly is the owner and manufacturer of the articles in question, and that a representative of the libelant during said month purchased a quantity of the articles in question from the last-named company. The articles contained on the average 3.2 grains of potassium antimony tartrate (tartar emetic) and no other constituents.

"Section 321 (g) Title 21 U. S. C. provides, among other things, that a drug means '(2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals'; and '(3) articles (other than food) intended to affect the structure or any function of the body of man * * *'; and (k) (same section) defines a label as 'a display of written, printed or graphic matters upon the immediate container of any article.' The label on the article in question clearly purports the content to be for use in the 'diagnosis, cure, mitigation, treatment or prevention' of drunkenness.

"The label in question is as follows: (Trade Mark) 'Mrs. Moffat's Shoo Fly Powders for Drunkenness 6 Powders—18 GM. Each Antimony & Potassium Tartrate In use 60 Years Use according to directions M. F. Groves' Son & Co. Since 1832 803 South Front Street Philad'a, Pa. Sold to Druggists only Price, 50 Cents a Box 19574 E Nov 14 1940 Directions.—One of the Powders may be given in Beer, Coffee, Tea or any other liquid. *Never give more than one Powder a day.* These powders are intended to be used by adults only, and should be kept from children.'

"Section 352, Title 21, supra, provides: 'A drug or device shall be deemed to be misbranded—(a) If its labeling is false or misleading in any particular' and '(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.' Such misbranded article is liable to condemnation 'when introduced into or while in interstate commerce * * * or at any time thereafter, * * *.' Section 334, Title 21, supra.

"The questions at issue are (1) whether the labeling of the article aforesaid is false and misleading, and (2) whether the drug is dangerous to health when used in the dosage prescribed on the label. The libel must be sustained on the determination of either question in the affirmative.

"On behalf of the Government five physicians testified with respect to the effect of the use of antimony and potassium tartrate (tartar emetic) 'for drunkenness,' and with respect to the danger to health in its use in the dosage prescribed. On behalf of the claimant an officer of the intervenor gave testimony as to the amount of the article in question sold over a period of years.

"The proceeding is in rem. The burden rests upon the Government to establish its case only by a fair preponderance of the evidence. *U. S.* v. *Five 1-Pint Bottles*, etc., 9 F. Supp. 990; *U. S.* v. *23½ Dozen Bottles*, etc., 44 F. (2d) 831.

"A contention made by the intervenor is that it is necessary for the Government to show intent to deceive and defraud. While this was held to be the law under the Act of June 30, 1906, sec. 8 as amended by the Act of August 23, 1932, such is not the law under the Act of June 25, 1938, supra. The former statutes provided that an article should 'be deemed to be misbranded in case of drugs; * * * If its package or label shall bear * * * any statement * * * regarding the curative * * * effect * * *, which is false and fraudulent.' *Chichester Chemical Co.* v. *United States*, 49 F. (2d) 516, held that the

Government must prove actual intent to deceive. Under the present statute a drug is deemed to be misbranded 'if its labeling is false or misleading in any particular.' Intent is not necessary to be proved. Further, the aforesaid act of 1906, sec. 8, required that the misbranding must be 'false and misleading.' These are the words of the present statute. Under the act of 1906 numerous cases held that it was not necessary to show intent. In this circuit we find *U. S.* v. *Scaduto*, S. D. N. Y. decided January 16, 1920; *Von Bremem et al.* v. *United States*, 192 F. 904.

"It is urged that merely stating that the article is 'for drunkenness' is not sufficient to constitute offense of misbranding. The use of the words 'for drunkenness' is the equivalent of saying that it is a 'cure, mitigation, treatment or prevention' of drunkenness. The necessary implication is that it is for relief from drunkenness to at least some extent. In *U. S.* v. *Natura Co.*, 250 F. 925, cited by the intervenor, the indictment charged misbranding where the label stated that the drug was 'a natural remedy for certain specified diseases, and that it had proved effective in the treatment of such diseases.' There it was claimed that the word 'remedy' was synonymous with 'cure.' This was a criminal case, and it was held that the plaintiff had not established beyond a reasonable doubt that the statements on the label were both 'false and fraudulent.' This has no controlling bearing here.

"The physicians testifying on behalf of the Government were, one a pharmacologist, one an internist, one a neuropsychiatrist, one a specialist in therapeutics. Each testified that antimony and potassium tartrate (tartar emetic) is not a curative for drunkenness, that it is a drug not properly usable in the treatment of drunkenness, and that its use in the dosage shown on the label herein is dangerous to health. Each of these physicians had had extensive practice in his specialty. Each testified that the medical profession had long recognized that tartar emetic was a drug dangerous to be administered through the mouth; that its use through the mouth has been abandoned in the teaching field; and that the standard textbooks treat it as a poison. The testimony of these physicians is to the effect that tartar emetic taken through the mouth irritates the lining of the stomach and intestines, produces various injurious effects on various other organs of the body; that it is cumulative in its effect; that when taken in increased doses it causes nausea, vomiting, diarrhea and retching; and after absorption affects the liver and kidneys and increases the heart rate; that through the loss of the control of the muscles of the stomach the vomitus may be swallowed causing pneumonia. They say the medical profession for many years has not prescribed it to be taken through the mouth, except as it is so used in so-called brown mixture, which contains 1/70 of a grain of this drug, and that its present use is almost entirely intravenous or intramuscular as a treatment for numerous tropical diseases. Brown mixture is used as a carrier with other drugs to make a cough syrup. They have given many other details pointing out the other effects from the use of this drug in the dosage prescribed.

"The pharmacopeia (ed. 1936) states the average dosage when taken internally as 1/20 of a grain. The National Standard Dispensary (ed. 1907) gives it as 1/2 to 1 grain taken every 15 minutes until several doses are taken or till emesis occurs. I find on reference to the edition of 1938 no reference is made to any repetition of the dose and that the dosage 'usually is about 1/2 grain (.03 gm.).' The National Standard Dispensary (ed. 1907) also states that tartar emetic at one time was largely employed as an 'expectorant, diaphoretic, emetic, sedative, antiphlogistic, and counter-irritant, but at present its use has become greatly limited.' It states it is an irritant and that continued application causes 'a pustular eruption followed by deep sloughing'; that 'antimony depresses the sensory side of the spinal cord; * * * lowers * * * the pulse-force'; and blood pressure; that it is an irritant to the stomach and intestines and in toxic dose produces violent gastro-enteritis; that the purging following overdose of the drug 'is an effort made by the intestines to eliminate the poison, and is due also to the intense intestinal inflammation'; that it is very slowly absorbed and slowly eliminated; that as an emetic this drug causes great prostration and muscular relaxation, it is badly borne by children, by the aged, and by those who are enfeebled by disease; and never should be used when 'gastro-intestinal irritation or inflammation is present'; and that chronic poison sometimes results from the frequent administration of this drug.

"The edition of 1937 of the National Standard Dispensary further states this: 'Its emetic action is very certain, powerful, prolonged, but accompanied by much depression. * * * although because of the promptness of its emetic action recovery may occur after very large amounts one case is on record in which 2

grains proved fatal.' This work gives the dosage when used intravenously or intramuscularly at ½ to 2 grains given every alternate day and as a dosage internally 'as a diaphoretic or expectorant it may be given in quantities of from 1/40 to ⅛ grain. If used as an emetic the dose usually is about ½ grain.'

"The conclusion here is inescapable both that the label in question is false and misleading and that the drug is dangerous to health when used in the dosage prescribed on the label. While it may seem that the use of this emetic in some amount may be beneficial in cases of drunkenness because of the fact that it clears the stomach, the fact is that alcohol is absorbed into the blood stream within 20 minutes to half an hour after being taken into the stomach and, therefore, the emetic could not usually affect the action of the alcohol.

"The only evidence offered by the intervenor was that given by an official of the claimant to the effect that the powders in question have been sold for upwards of 60 years; that over 50,000 of the powder packages have been sold yearly for the last 10 years and that not a single case of harm or injury has ever been reported by an one to the manufacturers. Objection was raised to the reception of all this testimony. It was received subject to be stricken, if the court later so decided. It is believed that the testimony as to the number of packages of the powder that had been sold and the period of years over which it had been sold is competent and the ruling as made stands. However, the testimony that no complaints had been received is incompetent. *Goldstein* v. *United States*, 63 F. (2d) 609. It is clearly hearsay.

"The intervenor urges that the testimony on behalf of the intervenor is not outweighed by the testimony given by the experts called by the Government. We are to bear in mind in this connection that the only testimony now in the record offered by the intervenor is with reference to the number of packages sold and the period of time over which they were sold. While the intervenor cites numerous cases in which consideration had been given to the weight of expert testimony, none of these hold that it is to be given no weight. The weight of such testimony is for the court to determine. These cases present somewhat comparable situations where physicians have testified as experts: *U. S.* v. *Lee*, 107 F. (2d) 522, cert. denied 309 U. S. 654; *U. S.* v. *Dr. David Roberts Vet. Co.*, 104 F. (2d) 785; *U. S.* v. *American Laboratories*, 222 F. 104; *U. S.* v. *W. B. Wood Mfg. Co.*, D. C. E. D. Mo., decided May 12 1921; *Eleven Gross Packages etc.* v. *United States*, 233 F. 71; *Chichester Chemical Co.* v. *United States*, supra; *Hall* v. *United States*, 267 F. 795. The testimony of these physicians is largely based on their studies as physicians but not upon the actual use of the article in question. Certain of these physicians have testified to personal observation of the use of the drug in question. Testimony of these men is not to be entirely disregarded because they testified as experts. As against the testimony that a large number of packages of this drug have been sold during many years, we have the testimony of all of the five physicians that the drug itself is not a cure for drunkenness and that its use in the dosage prescribed is dangerous to health. Each of these physicians went into great detail in explaining the nature of the drug and its reactions upon the human system when taken internally.

"It is not necessary to decide whether the drug when taken in the dosage of any specific number of grains less than 3.2 may properly be taken in the treatment of drunkenness or whether such dosage would be dangerous to health. I do decide that the articles in question are misbranded, since the labels thereon are false and misleading, because antimony and potassium tartrate in the dosage of 3.2 grains (the average in the articles analyzed) is not a 'cure, mitigation, or treatment' for drunkenness as purported to be and also that it is misbranded, because the use of the drug in the dosage of 3.2 grains is dangerous to health.

"Libelant is entitled to an order adjudging and decreeing that the articles of drug product aforesaid be condemned according to the provisions of the statute."

On August 12, 1941, judgment of condemnation was entered and it was ordered that the product be destroyed, with the exception of 3 dozen boxes that were ordered turned over to the Food and Drug Administration for official use. Through inadvertence, the entire lot of seized goods was destroyed.

606. Misbranding of Alcoban. U. S. v. 7 Packages of Alcoban and 8 other seizures of Alcoban. Decrees of condemnation and destruction. (F. D. C. Nos. 3832, 4097, 4794, 4795, 5266, 5274, 5445, 5793 to 5797, incl., 5875. Sample Nos. 22375-E, 23106-E to 23109-E, incl., 44738-E, 44770-E, 44771-E, 55721-E, 60189-E, 60545-E, 61741-E, 65083-E, 73420-E.)

This product contained emetine hydrochloride and would be dangerous to health when used as directed or suggested in the labeling. Furthermore, its