

Between March 29 and October 26, 1944, no claimant having appeared, judgments were entered condemning the product and ordering its destruction.

1325. Adulteration and misbranding of prophylactics. U. S. v. 19 Packages and 40½ Gross of Prophylactics. Decrees of destruction. (F. D. C. Nos. 12156, 13028. Sample Nos. 67053-F, 80829-F to 80831-F, incl.)

On or about April 11 and July 27, 1944, the United States attorney for the Western District of Missouri filed libels against 40½ gross of prophylactics and 19 packages, each containing 1 dozen, of the same product at Kansas City, Mo., alleging that the article had been shipped between the approximate dates of March 7 and June 6, 1944, by the Crown Rubber Sundries Co., from Akron, Ohio; and charging that it was adulterated and misbranded. The article was labeled in part: "Genuine Gold Beaters," "Tetratex Genuine Latex Prophylactics Mfd. By L. E. Shunk Latex Products Inc. Akron, Ohio," or "Genuine Latex * * * Apris Prophylactics Mfd. by The Killian Mfg. Co. Akron, Ohio."

Samples of the article were found to be defective because of the presence of holes.

The article was alleged to be adulterated in that its quality fell below that which it purported and was represented to possess.

It was alleged to be misbranded in that the statements in the labeling of one lot, "Prophylactics," and of the other lot, "for prevention of diseases" and "for the prevention of disease only," were false and misleading since the article contained holes. A portion of the product was further misbranded in that its label failed to bear the name and place of business of the manufacturer, packer, or distributor.

On July 28 and October 26, 1944, no claimant having appeared, judgments were entered ordering the product destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS FOR HUMAN USE

1326. Misbranding of Sugretus and Sunol. U. S. v. Elmer J. Dailey (Dailey's Laboratories). Plea of not guilty. Tried to the jury. Verdict of guilty. Fine of \$250 on count 1; imposition of sentence on count 2 suspended and defendant placed on probation for 5 years. (F. D. C. No. 11424. Sample Nos. 57639-F, 57640-F.)

On July 5, 1944, the United States attorney for the Southern District of California filed an information against Elmer J. Dailey, trading as Dailey's Laboratories, San Diego, Calif., alleging shipment of a quantity of the above-named products from the State of California into the State of Texas on or about August 14, 1943.

Analysis of a sample of the Sugretus disclosed that it consisted of dark gray, uncoated, compressed tablets with a slight aromatic odor, and that it contained plant material, probably cactus, together with an iron compound. It was alleged to be misbranded because of false and misleading statements on its label and in an accompanying circular letter headed "Dailey's Laboratories," which represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of diabetes, Buerger's disease, and pancreas, liver, and kidney troubles; that it would make diabetics sugar-free and keep them so; that its use would enable persons who were using insulin and dieting to live normal lives, i.e., give up insulin and dieting; and that it would build up the pancreas, liver, and kidneys.

Analysis of a sample of the Sunol disclosed that it consisted essentially of volatile oils including oil of eucalyptus, camphor, and thymol dissolved in a fatty oil. The article was alleged to be misbranded in that the statement, "For soreness in Bunions," borne on its label, was false and misleading since the article would not be efficacious in the cure, mitigation, treatment, or prevention of soreness in bunions; and in that its label failed to bear any statement of the quantity of the contents or of the active ingredients of the article.

On July 15, 1944, the defendant entered a plea of not guilty, and on September 5, 1944, the case came on for trial before a jury. The trial was concluded on September 7, 1944, on which date the court delivered the following instructions to the jury:

*See also Nos. 1301-1307, 1312-1315, 1324, 1325.

LING, *District Judge*: "It now becomes the court's duty, gentlemen, to instruct you with reference to the law that applies to this particular case.

"This criminal proceeding was brought under the provisions of the Federal Food, Drug and Cosmetic Act, which was intended to prevent the movement in interstate commerce of adulterated and misbranded foods, drugs, devices and cosmetics.

"The statute prohibits the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

"In this case the government in Count I charges defendant with unlawfully introducing and delivering for introduction into interstate commerce three bottles containing an article known as 'Sugretus.'

"The government alleges the article to be misbranded in violation of the statute and a drug within the meaning of the statute.

"Count II charges the same transaction with respect to another article known as 'Sunol.'

"The government alleges this article to be misbranded in violation of the statute and a drug within the meaning of the statute.

"In Count II the government further alleges that the label failed to bear an accurate statement of the quantity of the contents and further that the said label failed to bear the common or usual name of the active ingredients, in violation of the statute.

"The Food, Drug, and Cosmetic Act provides that an article can be misbranded in a number of different ways. In Count I of this Information, that is with respect to the article 'Sugretus,' the government has confined its charges to false and misleading statements. An article can be misbranded, however, in other ways.

"In Count II of this Information, the government has set forth three different ways in which this article is misbranded.

"First: It is alleged that the article is misbranded because of certain statements which it alleges are false and misleading.

"Second: It is alleged that the article is misbranded because the label fails to bear a statement as to the quantity of contents.

"Third: It is alleged that it is an article fabricated from two or more ingredients, and fails to bear a statement as to the common or usual name of each active ingredient.

"It is not necessary that you find from the evidence that the article is misbranded in all three of these ways. If you should find that the article is misbranded in any one of these three manners, then you must find the defendant guilty under Count II. If, for example, from the evidence you find that the article 'Sunol' fails to bear a statement on its label of the quantity of contents, or that it is fabricated from two or more ingredients and fails to bear a statement of the common or usual name of active ingredients, then you must find the defendant guilty with respect to Count II whether or not you believe that the statements alleged to be false and misleading are in fact false and misleading.

"If you find from the evidence that in any particular this drug is misbranded, then the law has been violated. It is not necessary that every misbranding be proved.

"There is no dispute that the articles set forth in the information were shipped in interstate commerce by the defendant as alleged.

"It has been stipulated that the articles were introduced and shipped in interstate commerce.

"I, therefore, charge you that the sole question for you to determine from the evidence in the case, is whether or not there was a misbranding in violation of the statute, as alleged by the government.

"If, after hearing the evidence in this case, you reach the conclusion as to Count I that the drug or product known as 'Sugretus' was harmless, that does not excuse the defendant if you find that he placed statements upon said article or drug which were false concerning curative, therapeutic, and mitigating effects of said product, as the danger and injury to the public from representations of this kind is considerable, in that it induces persons frequently to rely in serious cases upon preparations without healing virtue when, but for this reliance, they would no doubt secure proper advice and treatment for the illnesses which affect them.

"With respect to Count II of the Information, you are instructed that the

term 'relief' is not of definitive connotation or entirely free from ambiguity; in a common sense it connotes permanent removal of organic or functional disturbance as distinguished from alleviation of discomfort. The representation that an article or drug is 'for' or a 'treatment for' a disease is equivalent to labeling it as a cure or remedy.

"The statute under which this case has been tried condemns every statement in the labeling of the article 'Sugretus,' and the article 'Sunol' which may mislead or deceive. Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements that are false. It is not difficult to choose statements that will not deceive.

"If you find from the evidence that there are any false and misleading statements in the labeling involved in this case, your verdict should be for the government, as I have stated before.

"In determining whether or not any statements made in the labeling of 'Sugretus' and 'Sunol' are misleading, you should take into account, among other things, not only representations made or suggested by such statements, but also the extent to which the labeling may fail to reveal facts material in the light of such representations.

"If you find from the evidence that there is a material weight of medical and scientific opinion contrary to any of the representations made in labeling 'Sugretus' or 'Sunol,' you may find that said articles are misbranded.

"If you find that the circular introduced in evidence in this case, and contained in the package admitted to have been shipped in interstate commerce by the defendant, as alleged in Count I, contains statements describing the curative, therapeutic or mitigating effects of the article or drug, and find that such statements are likely to mislead in any particular, you should find the defendant guilty of misbranding on Count I.

"What these labels and circular mean, you are to test by taking the language of each of them and imparting to that language the meaning of the words singly and together that would be conveyed to you as ordinary men, not as men who are skilled in medical, chemical, or pharmaceutical science capable of making nice distinctions or nice discriminations, but rather the meaning that comes to you as ordinary men unskilled, but seeking, we will assume, some sort of remedy or remedial help from the afflictions that flesh is heir to. Now, in that connection, you should examine the language used in the light of the purpose of this law, which is to protect human kind against the consequence of human weakness, or human failing, or human credulity, or the disposition to believe, or of human gullibility. You should examine it in the light of the disposition of the ordinary human kind to wish to believe in the potency of remedial agents to relieve them of ills from which they are actually or conceivably suffering.

"Under the Food and Drug Act the term 'drug' includes any substance or mixture of substances intended to be used for the cure, mitigation or prevention of diseases of mankind. The aim of the Act is to prevent indirection and ambiguity in the labeling of drugs, as well as to prevent statements which are literally false. It is not difficult to choose statements, designs, or devices concerning the curative, therapeutic or mitigating effect of any article or drug which will not deceive. Those which are ambiguous or likely to mislead should be read favorably to the accomplishment of the purposes of the Act, and if you find the labels and circular used by the defendant, Elmer J. Dailey, describing the curative, therapeutic and mitigating effect of the articles or drugs 'Sugretus' and 'Sunol' contain statements that are likely to mislead, in any particular, you should find the defendant guilty of misbranding.

"Of course, if you do not so find, you should find the defendant not guilty.

"Witnesses, those who are supposed to know more than the ordinary person about such subjects, such as chemists and physicians, have been permitted to give their opinions as to various matters. Opinion evidence is not binding upon you, but should be considered in connection with all other evidence in this case. Should you believe it, you may accept and follow it. By an opinion, I mean a statement or a conclusion arrived at by the witness from experience or from knowledge, as distinguished from testimony concerning the direct fact.

"That is, I might say that this building was constructed of brick. That

would be a statement of fact. If I would say it was worth twenty thousand or a hundred thousand dollars, that would merely be my opinion.

"You are the sole judges of the value of opinion evidence. Of course, an opinion is worthless unless it is the honest opinion of the man who states it. If you deem it is his honest opinion, then its value depends upon how much he knows about the subject concerning which he is testifying. If he is fairly experienced, fairly grounded in his subject, if his opinion is the result of mature reflection, if he is a man of strong logical intellect, his opinion would be entitled to great value. If, on the other hand, he is incapable of logical thinking, or if he is not well grounded in his subject, nor familiar with the facts upon which his conclusion is assumed to be based, then, of course, his opinion would be of little or no value; and it is for you to decide what value you will give to the opinion evidence that you have heard.

"It is not necessary for the government to prove the defendant intentionally misbranded the articles in any particular. Intent is immaterial in a charge of misbranding as is charged in this case.

"So, if you find from the evidence that the labels and circular contained false and misleading statements in any particular, then you must render your verdict accordingly.

"Now, a great deal of the evidence of the witnesses who have testified concerning their own ailments is in the nature of opinion evidence. Those witnesses who testified that they had well-known, easily discernible diseases, or easily-told diseases, I will say, such as headaches and constipation, or something of that sort, of course, there will be very little reason to doubt that they knew what they had. But if one testified that he thought he had some more obscure disease, more difficult to diagnose, and his diagnosis of what he had depended entirely upon his own opinion, and he was unable to make such a diagnosis, his opinion would be of very little value. Those are matters for you to take into consideration in weighing the testimony of the witnesses.

"You are the sole judges of the facts of this case, also of the credibility of each and every witness who has testified before you, and the weight that you will give his testimony. In determining the credibility of any witness you have a right to take into consideration his or her manner and appearance while giving his or her testimony, his or her means of knowledge of the facts to which he or she has testified; any interest or motive he or she may have for his or her testimony, if shown, and the probability or improbability of the truth of his or her statements when measured in connection with all other evidence in the case. If you believe that any witness has wilfully sworn falsely as to any material fact, then you have a right to wholly disregard the testimony of such witness, except insofar as the same may be corroborated by other credible evidence or by facts and circumstances proven or admitted in the case.

"In order to convict the defendant of the crime charged in the indictment, it is incumbent upon the government to prove to you beyond a reasonable doubt and to a moral certainty the truth of each and every material allegation of the indictment. The law raises no presumptions against a defendant, but every presumption of law is in favor of his innocence.

"A reasonable doubt as applied to evidence in criminal cases, is such a doubt as you may entertain as reasonable men after a thorough review and consideration of all the evidence, a doubt for which a reason arising from the evidence, or from the want of evidence, exists. It is not, however, a fanciful conjecture of the mind, nor the mere possibility of a doubt, but it is a substantial, well-founded doubt. It is that state of the case which, after a full and fair review of all the evidence, leaves the mind of a juror in such condition that he cannot say he feels an abiding conviction to a moral certainty of the guilt of the accused. It is an actual, sincere mental hesitation caused by insufficient or unsatisfactory evidence.

"While it is true that the government is required to prove the guilt of the defendants beyond a reasonable doubt, it is not required to prove their guilt to a mathematical certainty. All that the court and the jury can act upon is belief to a moral certainty and beyond a reasonable doubt.

"Now, if, after fully and fairly considering all of the evidence in this case you entertain such a reasonable doubt as I have defined as to the guilt or innocence of this defendant, then it becomes your duty to resolve that doubt in favor of the defendant and to return a verdict of not guilty. On the

other hand, if, after so considering all of the evidence in the case you are satisfied beyond a reasonable doubt and to a moral certainty that the defendant has committed the acts as charged and constituting the crime set forth in the Information, then it becomes your duty to render a verdict of guilty.

"After you retire to the jury room you will select one of your number to act as foreman, and you will proceed with your deliberation. After you had agreed upon a verdict you will have it signed by your foreman and return it to open court. And any verdict rendered, of course, will be the unanimous verdict of the jury.

"A form of verdict has been prepared for your guidance."

The jury thereupon retired and, after due deliberation, returned a verdict of guilty. On September 15, 1944, the court imposed a fine of \$250 on count 1 and suspended the imposition of sentence on count 2, placing the defendant on probation for 5 years.

1327. Misbranding of Tesano Tea. U. S. v. Tesano Tea Co., Inc., and Elmer H. Baden. Pleas of guilty. Corporate defendant fined \$50, which fine was remitted. Individual defendant fined \$200, which fine was paid. (F. D. C. No. 7313. Sample Nos. 79774-E, 90432-E.)

On July 18, 1944, the United States attorney for the Southern District of New York filed an information against the Tesano Tea Co., Inc., New York, N. Y., and Elmer H. Baden, alleging shipment of quantities of Tesano Tea on or about February 13 and 16, 1942, from the State of New York into the States of Ohio and Connecticut.

Analysis of a sample of the article disclosed that it consisted essentially of plant material, including senna leaves, Vaccinium leaves, yarrow herb, sweet clover, Malva flowers, chamomile flowers, fennel seed, and anise seed.

The article was alleged to be misbranded because of false and misleading statements in its labeling which misrepresented and implied that the article would be efficacious in the treatment, mitigation, and relief of diabetes and kidney and bladder disorders; that it would aid the regenerative forces of the human body in bringing about a more normal condition; and that it would improve the health and bring about a general improvement in the conditions of persons suffering from diabetes and kidney and bladder disorders. The article would not be efficacious for the purposes claimed.

On August 11, 1944, a plea of guilty having been entered on behalf of the corporate defendant, the court imposed a fine of \$50. On October 13, 1944, the individual defendant entered a plea of guilty and was fined \$100 on each of 2 counts, a total fine of \$200. The fine imposed on the corporation was remitted.

1328. Misbranding of Doradil. U. S. v. 19 Bottles of Doradil. Default decree of condemnation and destruction. (F. D. C. No. 12478. Sample No. 35263-F.)

On or about June 12, 1944, the United States attorney for the Southern District of Florida filed a libel against 19 bottles of Doradil at Tampa, Fla., alleging that the article had been shipped on or about December 11, 1943, and January 6 and 18, 1944, by the Ulrici Medicine Co., Inc., from New York, N. Y.

Examination disclosed that the article consisted essentially of rhubarb extract; sodium phosphate, approximately 1.3 percent; potassium iodide, approximately 0.23 percent; alcohol, 7 percent; and water.

The article was alleged to be misbranded because of false and misleading statements, appearing in an accompanying circular entitled "Doradil of Ulrici," regarding its efficacy in treating liver complaints, hepatitis, congestion, biliousness, bilious diarrhea, and constipation, and its efficacy in maintaining the correct hepatic activity, stimulating the biliary secretion, toning the liver, regulating the digestive process, and combating many causes of obstruction and flatulence. The article was alleged to be misbranded further in that the common or usual name of each active ingredient in the article, required by law to appear on the label, was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, and devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, since the information did not appear in the English language on the carton and did not appear at all upon the bottle label, and the names of the active ingredients, which were given in the Spanish language, were intermingled with the names of inactive ingredients so as