

eating. Children—1 teaspoonful to a tablespoonful as above. General Directions. Wittone is full-strength, with a pure, sharp taste. Adults should take About two tablespoonfuls twice a day in a glass of water before eating. Please note we say 'about' two tablespoonfuls. We say this because we do not believe it is possible to prepare directions which will fit all people. Perhaps you should take a trifle more than two tablespoonfuls as your dose. Or, you may find that less than two tablespoonfuls is your proper dose. You can easily determine this soon after you start using the medicine and should then continue to take your proper dose twice daily. Laxatives should not be used continuously so that the bowels may resume their normal action. For Children up to 10 years of age, two teaspoonfuls more or less, two times a day as for adults, later reducing to one dose per day for a sufficient period," were not appropriate for the product and were not adequate.

It was alleged to be misbranded further in that the labeling failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health and against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users since there was no warning against the administration of the medicine to young children to whom its use might be dangerous nor against frequent or continued use of the article which might result in the establishment of dependence upon laxatives.

On August 16, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

CRIMINAL PROSECUTIONS

345. Adulteration and misbranding of Heron's Pure Eucalyptus Oil. U. S. v. Norman C. Heron (N. C. Heron Co.). Tried to the court and jury. Verdict of guilty. Fine, \$300. (F. D. C. No. 2091. Sample No. 97364-D.)

This product did not meet the requirements of the United States Pharmacopoeia for eucalyptus oil. Its labeling also bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter.

On September 12, 1940, the United States attorney for the Southern District of California filed an information against Norman C. Heron, trading as N. C. Heron Co., Los Angeles, Calif., alleging shipment on or about November 23, 1939, from the State of California into the State of Idaho, of a quantity of Heron's Pure Eucalyptus Oil which was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia but its strength differed from, and its quality and purity fell below, the standard set forth in that compendium in that it contained not more than 68 percent of eucalyptol and was not soluble in 5 volumes of 70 percent alcohol; whereas the United States Pharmacopoeia provides that eucalyptus oil shall contain not less than 70 percent of eucalyptus and shall be soluble in 5 volumes of 70 percent alcohol, and the difference in strength, quality, and purity of the article from the standard for eucalyptus oil set forth in the said compendium was not stated plainly on its label.

The article was alleged to be misbranded in that the statements borne on the bottle label were false and misleading since they represented that it was pure eucalyptus oil; that it was an all-around family remedy, and was efficacious for internal or external use from the youngest to the oldest; that said article, when used alone or in connection with Heron's Liver Regulator, had no equal in the treatment of Bright's disease and diabetes; that it was the only remedy without an enemy, implying that it was a remedy approved by everyone; that it was efficacious in the treatment of anything that originated from a cold; that it was efficacious in the treatment of cough, whooping cough, croup, sore throat, diphtheria, pleurisy, pneumonia, fever, stomach and kidney troubles, diabetes, catarrh, asthma, bronchitis, headache, earache, toothache, neuralgia, burns, poison oak, wounds of all kinds, consumption in its first stages, fever of all kinds, rheumatism, gravel, dyspepsia, kidney disease, and cuts; whereas it was not pure eucalyptus oil and was not efficacious for the said purposes.

On October 25, 1940, the defendant having entered a plea of not guilty, the case came on for trial before the court and jury. The trial was concluded

on October 28, 1940, on which date the court delivered the following instructions to the jury:

HARRISON, *District Judge*. "You have listened to counsel on both sides, and now you will have to listen to the court for a few moments as I read the instructions to you.

"By the filing of an information, no presumption whatsoever arises to indicate that a defendant is guilty, or that he has had any connection with, or responsibility for, the act charged against him. A defendant is presumed to be innocent at all stages of the proceeding until the evidence introduced on behalf of the Government shows him to be guilty beyond a reasonable doubt. And this rule applies to every material element of the offense charged. Mere suspicion will not authorize a conviction. A reasonable doubt is such a doubt as you may have in your minds when, after fairly and impartially considering all of the evidence, you do not feel satisfied to a moral certainty of the defendant's guilt. In order that the evidence submitted shall afford proof beyond a reasonable doubt, it must be such as you would be willing to act upon in the most important and vital matters relating to your own affairs.

"Reasonable doubt is not a mere possible or imaginary doubt or a bare conjecture; for it is difficult to prove a thing to an absolute certainty.

"You are to consider the strong probabilities of the case. A conviction is justified only when such probabilities exclude all reasonable doubt as the same has been defined to you. Without it being restated or repeated, you are to understand that the requirement that a defendant's guilt be shown beyond a reasonable doubt is to be considered in connection with and as accompanying all the instructions that are given to you.

"In judging of the evidence, you are to give it a reasonable and fair construction, and you are not authorized, because of any feeling of sympathy or other bias, to apply a strained construction, one that is unreasonable, in order to justify a certain verdict when, were it not for such feeling or bias, you would reach a contrary conclusion. And whenever, after a careful consideration of all of the evidence, your minds are in that state where a conclusion of innocence is indicated equally with a conclusion of guilt, or there is a reasonable doubt as to whether the evidence is so balanced, the conclusion of innocence must be adopted.

"You are the sole judges of the credibility and the weight which is to be given to the different witnesses who have testified upon this trial. A witness is presumed to speak the truth. This presumption, however, may be repelled by the manner in which he testifies; by the character of his testimony, or by evidence affecting his character for truth, honesty, and integrity or his motives; or by contradictory evidence. In judging the credibility of the witnesses in this case, you may believe the whole or any part of the evidence of any witness, or may disbelieve the whole or any part of it, as may be dictated by your judgment as reasonable men. You should carefully scrutinize the testimony given, and in so doing consider all of the circumstances under which any witness has testified, his demeanor, his manner while on the stand, his intelligence, the relations which he bears to the Government or the defendant, the manner in which he might be affected by the verdict and the extent to which he is contradicted or corroborated by other evidence, if at all, and every matter that tends reasonably to shed light upon his credibility. If a witness is shown knowingly to have testified falsely on the trial touching any material matter, the jury should distrust his testimony in other particulars, and in that case you are at liberty to reject the whole of the witness' testimony.

"There is nothing peculiarly different in the way a jury is to consider the proof in a criminal case from that by which men give their attention to any question depending upon evidence presented to them. You are expected to use your good sense, consider the evidence for the purposes only for which it has been admitted, and in the light of your knowledge of the natural tendencies and propensities of human beings, resolve the facts according to deliberate and cautious judgment; and while remembering that the defendant is entitled to any reasonable doubt that may remain in your minds, remember as well that if no such doubt remains the Government is entitled to a verdict. Jurors are expected to agree upon a verdict where they can conscientiously do so; you are expected to consult with one another in the jury room and any juror should not hesitate to abandon his own view when convinced that it is erroneous. In determining what your verdict shall be you are to consider only the evidence before you. Any testimony as to which an objection was

sustained, and any testimony which was ordered stricken out, must be wholly left out of account and disregarded. The opinion of the judge as to the guilt or innocence of a defendant, if directly or inferentially expressed in these instructions, or at any time during the trial, is not binding upon the jury. For to the jury exclusively belongs the duty of determining the facts. The law you must accept from the court as correctly declared in these instructions.

"Should you believe that Heron's Pure Eucalyptus Oil contains some ingredient which you believe to have a therapeutic or curative value in the treatment of the disease for which it is recommended, then there is no misbranding as to such disease.

"You are charged that to establish the fact that Heron's Pure Eucalyptus Oil is misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act and as charged in the information, the Government must prove beyond a reasonable doubt:

"That the labeling carries some statement regarding the contents of Heron's Pure Eucalyptus Oil which is false and misleading in some particular; and

"That the statements made on the labeling regarding the curative or therapeutic effects of Heron's Pure Eucalyptus Oil are false and misleading; and

"Such false and misleading labeling must be established by competent proof and by credible and convincing evidence.

"You are instructed that, among other things, before you can find the defendant guilty of count I, you must find that Heron's Pure Eucalyptus Oil is a drug that is recognized in the United States Pharmacopoeia and that the strength of Heron's Pure Eucalyptus Oil differed from, and its quality and purity fell below, the standard set forth in the United States Pharmacopoeia in that Heron's Pure Eucalyptus Oil contained only 68 percent eucalyptol and that Heron's Pure Eucalyptus Oil is not soluble in 5 volumes of 70 percent alcohol; and should you so find as I have above instructed you, before you can find the defendant guilty you must find further that the fact that Heron's Pure Eucalyptus Oil contains but 68 percent eucalyptol and is not soluble in 5 volumes of 70 percent alcohol as the test prescribed by the United States Pharmacopoeia to test the strength, quality, and purity of Heron's Pure Eucalyptus Oil and unless you so find, you must find the defendant not guilty of count I.

"If the evidence in this case, as to any particular count, is susceptible of two constructions or interpretations, each of which appears to you to be reasonable, and one of which points to the guilt of the defendant, and the other to his innocence, it is your duty under the law to adopt that interpretation which will admit of the defendant's innocence, and reject that which points to his guilt.

"You are further instructed that if any material claim or statement on either the label, carton, or circular is false or misleading then, regardless of the intent of the mind of the defendant, you are to find the defendant guilty.

"You are instructed that it is against the law of the United States for any person to introduce or deliver for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

"You are further instructed that a drug or device shall be deemed to be adulterated if it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium.

"You are further instructed that the Pharmacopoeia of the United States, Volume XI, is an official compendium.

"You are further instructed that a drug or device shall be deemed to be misbranded if its label is false or misleading in any particular.

"You are further instructed that the term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers or (2) accompanying such article.

"You are further instructed that if you find, from the evidence in this case, that Norman C. Heron did on or about November 21, 1939, deliver a package of Heron's Pure Eucalyptus Oil to an agent of the Railway Express Co. in Los Angeles, Calif., addressed to Nelson Drug Co. at Gooding, Idaho, and that said Railway Express Co. did send said package to Gooding, Idaho, you are to find that said package was introduced or delivered for introduction into interstate commerce.

"You are further instructed that if you find, from the evidence introduced in this case, beyond a reasonable doubt, that Norman C. Heron did on or about November 23, 1939, introduce into interstate commerce, a package of Heron's Pure Eucalyptus Oil at Los Angeles, Calif., consigned to Nelson's Drug Store, Gooding, Idaho, that said eucalyptus oil fell below the standards required for oil

of eucalyptus as set forth in the Pharmacopoeia of the United States, Volume XI, then you are to find the defendant Norman C. Heron guilty as charged in count I of the information.

"You are instructed that if you find, from the evidence introduced in this case, beyond a reasonable doubt, that Norman C. Heron did on or about November 23, 1939, introduce into interstate commerce a package of Heron's Pure Eucalyptus Oil at Los Angeles, Calif., said package being consigned to Nelson's Drug Store, Gooding, Idaho; that in said packages were labels, cartons, and circulars containing false and misleading statements as to the curative and therapeutic efficacy of said Heron's Pure Eucalyptus Oil, then you are to find the defendant Norman C. Heron guilty as charged in count II of the information.

"I have advised you that the defendant is charged with having violated certain provisions of what is known as the 'Food and Drugs Act,' the purpose of which was and is to protect consumers against impure and adulterated food and drugs, and also against the use of food or drugs which do not show what they contain by the brands on the packages; or which are misbranded or which contain misleading claims pertaining to the therapeutic and curative efficacy of the product. The prohibition of this act is directed only against the introduction into interstate commerce of any article of food, drink, or of any drug either adulterated or misbranded. In arriving at your decision in this case you are not concerned with the wisdom of this act of Congress in passing the Food and Drugs Act. You are only concerned with the facts in this case. You must determine what the facts are in relation to the issue which is formed by the information filed and the plea entered by the defendant.

"Ordinarily, in the trial of cases in court, witnesses are confined in their testimony to facts within their personal knowledge and they are not permitted to draw conclusions or express opinions. That is the general rule, but there is an exception to that rule where the points in issue arise out of a particular science or art concerning which there are trained minds who have special knowledge, learning, or schooling in that particular field. Such persons are called experts and because of that special training or learning they are entitled to express opinions concerning the matters at issue. You will, of course, weigh and evaluate the testimony of the expert witnesses in this case precisely as you weigh the testimony of any nonexpert witnesses; that is to say, you will take into account the probability and reasonableness of the matters to which they have testified, the schooling of the person giving it, the learning that he has in his profession, or the want of it, and the breadth of his experience in the field which would enable him to arrive at a correct conclusion. In other words, his testimony should be given such weight as you believe it is entitled to receive.

"Under the Federal Food and Drugs Act the term 'drug' includes any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease 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 or therapeutic effect of an article of drugs which will not deceive. Those which are ambiguous and likely to mislead should be read favorably to the accomplishment of the purposes of the act and, if you find the labels used by the defendant, Norman C. Heron, describing the curative and therapeutic effect of the article or drug, Heron's Pure Eucalyptus Oil, contain statements that are likely to mislead, you should find the defendant guilty of misbranding.

"If you find that the circulars introduced in evidence in this case were contained in the packages admitted to have been shipped in interstate commerce by the defendant, and if you further find that said circulars contain statements describing the curative and therapeutic effect of the article or drug, Heron's Pure Eucalyptus Oil, and if you further find that such statements are likely to mislead, you should find the defendant guilty of misbranding.

"The Food and Drugs Act is plain and direct. Its comprehensive terms condemn every statement, design, and device which may mislead or deceive and which are false and fraudulently made. Deception may result from use of statements not technically false or which may be literally true. The law is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. It is not difficult for one making and distributing drugs in interstate commerce to choose statements, designs, and devices which will not deceive. That is his duty when engaged in such business. Too, statements which are ambiguous and likely to mislead should be read favorably to the accomplishment of the aims and purposes of the Food and Drugs Act.

"This is important legislation intended to protect the people so far as this case is concerned from the transportation and sale of misbranded medicines, experience having shown that men and women afflicted with disease are disposed to try a professed remedy, no difference how useless or even harmful it may be if it is strongly recommended, and it is to protect the sick and afflicted and people who are easily imposed upon, from fraudulent practices of the unprincipled and avaricious that this law was passed. It is a wise law and in proper cases should be rigidly enforced.

"If, after hearing the evidence in this case, you reach the conclusion that the drug or product known as 'Heron's Pure Eucalyptus Oil' was harmless, that does not excuse the defendant, if you find that he placed statements upon said drugs which were false, concerning the curative and therapeutic effects of said products, as the danger and injury to the public from representations of this type 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 ills which affect them.

"If, in these instructions, any rule, direction, or idea be stated in varying ways, no emphasis thereon is intended by me, and none must be inferred by you. For that reason, you are not to single out any certain sentence, or any individual point or instruction, and ignore the others, but you are to consider all the instructions and as a whole, and to regard each in the light of all the others.

"At times throughout the trial the court has been called upon to pass on the question whether or not certain offered evidence might properly be admitted. With such rulings and the reasons for them you are not to be concerned. Whether offered evidence is admissible is purely a question of law, and from a ruling on such a question you are not to draw any inference as to what weight should be given the evidence, or as to the credibility of a witness. In admitting evidence to which an objection is made, the court does not determine what weight should be given such evidence. As to any offer of evidence that was rejected by the court, you, of course, must not consider the same; as to any question to which an objection was sustained, you must not conjecture as to what the answer might have been or as to the reason for the objection.

"You are instructed that if the judge has said or done anything which has suggested to you that he is inclined to favor the claims or position of either party, you will not suffer yourself to be influenced by any such suggestion.

"I have not expressed, nor intended to express, nor have I intimated nor intended to intimate, any opinion as to what witnesses are, or are not, worthy of credence; what facts are, or are not, established; or what inferences should be drawn from the evidence adduced. If any expression of mine has seemed to indicate an opinion relating to any of these matters, I instruct you to disregard it.

"The verdict to be rendered must represent the considered judgment of each juror.

"In order to return a verdict it is necessary that each juror agree thereto. Your verdict must be unanimous.

"When you retire to your jury room to deliberate, you will select one of your number as foreman and he will sign your verdict for you when it has been agreed upon. You will then return into court with the verdict and your foreman will represent you as your spokesman in the further conduct of this case in this court.

"Forms of verdicts have been prepared for your convenience, and when you have agreed upon a verdict, the foreman will sign the verdict upon which you agree and return it into court.

"Are there any exceptions on any of these instructions?"

Mr. COTTER. "No, your honor."

THE COURT. "The clerk will now swear the officers to take charge of the jury."

(Whereupon the officers were duly sworn to take charge of the jury.)

THE COURT. "The court will hand you the form of verdict, and you will now retire to the jury room for your deliberations.

"Is it stipulated that the jury may have the exhibits?"

Mr. COTTER. "So stipulated."

Mr. LAW. "So stipulated."

The jury thereupon retired and after due deliberation returned a verdict of guilty. The court suspended the sentence on the first count for a period of 2 years, and sentenced the defendant to 6-months' imprisonment on the second count, which was also suspended for 2 years and the defendant was placed on probation for that period. The court also imposed a fine of \$300.