

4834. Misbranding of Athlophoros. U. S. v. The Athlophoros Co., a corporation. Tried to the court and a jury. Verdict of guilty. Fine, \$25 and costs. (F. & D. No. 6042. I. S. No. 2852-e.)

On May 14, 1915, the United States attorney for the District of Connecticut, acting upon a report by the Secretary of Agriculture, filed in the District Court of the United States for said district an information against the Athlophoros Co., a corporation, New Haven, Conn., alleging shipment by said company, in violation of the Food and Drugs Act, as amended, on or about December 19, 1912, from the State of Connecticut into the State of California, of a quantity of Athlophoros which was misbranded. The article was labeled: (On bottle) "Athlophoros. Trade Mark. Searles' Remedy for Rheumatism, Neuralgia, Sciatica, Lumbago, Internal Pains, Gout, Sick Headache and Disorders of the Kidneys and Liver. Prepared only by the Athlophoros Company, New-Haven, Conn., U. S. A. Price One Dollar. Directions. Dose.—One teaspoonful in a wine glass of water, every three hours, is an ordinary dose. In acute cases, two teaspoonfuls until relieved; then one. In case of nausea add one tablespoonful of whisky. Follow carefully the full directions accompanying every bottle. Important.—If the bowels are constipated, take 'Athlo Tablets.' The bowels must be kept open. Notice—If the use of Athlophoros should cause an unpleasant feeling in the head, a ringing in the ears, or deafness, it is no cause for alarm; on the contrary, it shows the medicine has taken hold of the disease. The unpleasant symptoms will soon pass off, leaving the patient free from Rheumatism, Neuralgia and kindred ailments." (Directions in German, French, and Spanish.) (On carton) "Guaranteed under The Food and Drugs Act, June 30, 1906. Athlophoros. Trade Mark. Searles' Remedy for Rheumatism, Neuralgia, Sciatica, Lumbago, Internal Pains, Gout, Sick Headache and Disorders of the Kidneys and Liver. Prepared only by The Athlophoros Company, New-Haven, Conn., U. S. A. Price One Dollar. This style of wrapper adopted April 1891. Robt. N. Searles." The following appears on the carton in German, French and Spanish: "Athlophoros. Trade Mark. Searles' Infallible Remedy for Rheumatism, Neuralgia, Internal Pains, Sciatica, Lumbago, and Derangements of the Kidneys and Liver. Prepared only by The Athlophoros Company, New Haven, Conn., U. S. A. Price One Dollar." The circular or pamphlet accompanying the article contained, among other things, the following: "Athlophoros * * * It reaches the liver and kidneys, cleansing them from irritating substances, and restoring the organs to regularity and health." "Should the use of Athlophoros cause an unpleasant feeling in the head, a ringing in the ears, or deafness, it is no cause for alarm; on the contrary, it shows that the medicine has taken hold of the disease. The unpleasant symptoms will soon pass off, leaving the patient free from rheumatism, Neuralgia and kindred ailments." "For sick headache—Athlophoros has proved an absolute specific—especially among ladies—for this prevalent complaint." "Our observation and experience warrant the positive claim that Athlophoros is an absolute cure for Rheumatism and Neuralgia wherever and whenever these diseases alone exist."

Analysis of a sample of the article by the Bureau of Chemistry of this department showed that it was essentially a solution of glycerin, sodium salicylate, oil of cinnamon, and water.

Misbranding of the article was alleged in the information for the reason that the following statements regarding the therapeutic or curative effects thereof appearing on the label aforesaid, to wit, (on label of bottle and on carton) "Athlophoros, * * * Remedy for * * * Sciatica, * * * Gout, sick headache * * *," (on carton, in German, French, and Spanish) "Athlophores * * * Infallible Remedy for * * * Sciatica * * *," and in-

cluded in the circular or pamphlet aforesaid, to wit, "It reaches the liver and kidneys, cleansing them from irritating substances, and restoring the organs to regularity and health. The unpleasant symptoms will soon pass off, leaving the patient free from * * * neuralgia * * *. For sick headache—Athlophoros has proved an absolute specific * * *. Our observation and experience warrant the positive claim that Athlophoros is an absolute cure for * * * Neuralgia wherever and whenever these diseases alone exist," were false and fraudulent in that the same were applied to the article knowingly and in reckless and wanton disregard of their truth or falsity, so as to represent falsely and fraudulently to the purchasers thereof and create in the minds of purchasers thereof the impression and belief that it was, in whole or in part, composed of, or contained, ingredients or medicinal agents effective, among other things, as a remedy for sciatica, gout, and sick headache, for cleansing the liver and kidneys from irritating substances and restoring those organs to regularity and health, for curing neuralgia, and as a specific for sick headache, when, in truth and in fact, it was not, in whole or in part, composed of and did not contain such ingredients or medicinal agents.

On May 19, 1916, the case having come on for trial before the court and a jury, after the submission of evidence and arguments by counsel, the following charge was delivered to the jury by the court (Thomas, *D. J.*):

On the 14th of May, 1915, the learned district attorney for the United States for this district filed a criminal information against the defendant, the Athlophoros Company, charging it with a violation of what is known as the Pure Food and Drugs Act. To this information the accused has pleaded not guilty. This puts in issue every material allegation contained within the information, and the burden of proof rests upon the Government to establish the truth of all those allegations beyond a reasonable doubt.

Section 8 of the Food and Drugs Act, as amended by the act of August 23, 1912, provides, with respect to the misbranding of drugs, as follows:

That the term "misbranded" as used herein shall apply to all drugs, the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular. That for the purposes of this act an article shall also be deemed to be misbranded, in case of drugs, if its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent. (The court here reviewed the charges in the information.)

Those are all of the important allegations of this information. As I stated, the defendant's plea of "Not guilty" puts the burden of proof upon the Government to establish the truth of all of those allegations beyond a reasonable doubt.

The jurisdiction of the Federal court is invoked because the act of Congress is intended to reach an interstate shipment, and there is no question raised in this matter of the interstate shipment. The object of the act under which this prosecution is brought is to prevent the carrying in interstate commerce, that is, from one State to another, of drugs which are worthless and injurious when they are transported with false and fraudulent statements as to their curative or therapeutic effects, the object being to prevent credulous and ignorant people, and to protect the public generally, from having imposed upon them as medicine, things to be used as medicines, drugs which will not perform the functions which it is claimed they will perform, and to prevent people being injured by the use of harmful drugs. In this case it is claimed by the Government that this article is misbranded because the packages contain certain statements as to their curative or therapeutic properties which the Government claims are false and fraudulent.

Now, gentlemen, you have given very patient consideration to the extended arguments of able counsel in behalf of the Government and for this defendant, to both of whom you and I are indebted for their courtesy and their efforts to expedite this trial. Each one of them has, with much ability and free from the personalities which sometimes enter the trial of a long case, presented the evidence and their respective claims. Of course, it is now my duty to give you

the principles of law which are applicable, and which you must carefully apply to that state of the case which you find true from the evidence. You are aware, doubtless, that your verdict, as does the verdict of every other jury, consists of two things—first, the truth as you find it; and second, the principles of law applicable to that truth. In that way you reach the result which we call a verdict. These principles of law affect either the whole or some particular feature of the case, and in any instance you are to bear them carefully in mind and diligently apply them wherever they are applicable.

Courts are established to administer the law and enforce its execution. The law is the only standard by which judges and jurors can be governed, and in considering your verdict you should be governed by the law as it is given you by the court, and by the evidence as you hear it from the witness stand. You have heard the evidence offered on both sides of this controversy. From that evidence you must decide what the facts are and what the truth is.

The attorneys have had a wide range of discussion. They have had complete freedom of argument before you upon all questions of fact and have asked you to draw certain inferences and conclusions from either conceded or proven facts. It is their privilege in the argument to criticize the evidence, the attorney for the Government to criticize the conduct of this defendant, and the attorney for the defendant to criticize the conduct of the Government and its witnesses, to attack the credibility of the witnesses. Arguments of counsel are not evidence, however, and only in so far as their respective claims are, in your opinion, supported by the evidence in the case should their claim receive consideration. You should arrive at your verdict only after a cool, calm, careful, and scrutinizing consideration of all the evidence in the case.

In all criminal cases a person charged with crime, as is charged here by virtue of the provisions of this act, starts out at the threshold of the trial with the presumption in his favor that he is innocent of the crime with which he is charged. It is a humane provision of law, and it is based upon the theory that neither a jury nor the court shall presume that a person is guilty simply because he is charged with a violation of a criminal statute, but, on the contrary, the law presumes that all persons are honest and righteous in their dealings with their fellow men. So that if a criminal information has been filed by the district attorney, yet that information does not take away from this defendant the presumption of innocence; that presumption remains with it throughout the trial and it is only removed when you, as a result of the conscientious consideration which you are required to give to the evidence in this case, conclude that the defendant is guilty of the crime with which it is charged. Moreover it is a fundamental rule of law that the Government which makes this charge shall satisfy you of the guilt of the accused beyond a reasonable doubt.

Before we come to the questions particularly involved in this case I ought to and do remind and charge you that you, and you alone, are the sole judges of all questions of fact which arise here, and you are to determine those questions upon a careful consideration of all the evidence before you without direction or suggestion from the court as to what weight or value you should give to all or any part of the testimony, nor are you in any way to be governed in your conclusions by any opinion the court may express or even seem to express.

In analyzing testimony and drawing conclusions from it a juror must use all of his experience, his knowledge of human nature, his knowledge of human events, his knowledge of the motives which influence and control human action and test the evidence in the case according to such knowledge and render his verdict accordingly.

It is properly within your province, in listening to the testimony of witnesses, to observe their manner and bearing, their intelligence, their character, their means of knowledge, and to take into consideration any interest or bias or prejudice any witness may have or entertain, and reconcile so far as possible any conflicting testimony. In weighing the evidence and determining the credibility of the witnesses, and each of them, you should look to the manner and demeanor of each witness, to the readiness and willingness, or tardiness or unwillingness, if any, in answering; to the consistencies or inconsistencies of his testimony; to the interest or want of interest, if any, upon the one side or the other; to the witnesses' means of knowledge and opportunity for knowing the facts he testified to and professes to know and understand; to the reasonableness or unreasonableness, the probability or improbability of the facts and circumstances related by the witnesses when considered in connection

with all the facts and circumstances in evidence before you, and having thus carefully considered all of these matters you must fix the weight and the value of the testimony of each and every witness and the evidence as a whole.

In considering this case and in drawing your conclusions, you may be guided to some extent by the testimony of expert witnesses. I therefore deem it necessary to instruct you with reference to the evidence of such witnesses. An expert witness is one who is skilled in any particular art, trade, or profession, being possessed of peculiar knowledge concerning the same, acquired by study, observation, and practice. The jury is not necessarily bound by expert testimony, but such testimony should be considered by you in connection with all the other evidence in the case. Their evidence is subject to your consideration, to your supervision, and to your judgment. Such testimony is to be taken and treated by you like the evidence of other witnesses; and their testimony, their opinions, are subject to the same rules of credit or discredit as the testimony of other witnesses, and are not necessarily conclusive upon you. Whether the matters testified to by them are facts, whether they are true or false, and the value of their opinions, is to be determined by you and you alone; and you will carefully consider and examine their testimony in this case, subject to the same rules of credit and disbelief as the testimony of other witnesses.

The only issue of fact in controversy in this case, gentlemen, which must be determined by you, is whether the product described in the information was misbranded. The test of this misbranding is what the statements appearing on the label mean to the ordinary man, and when I refer to the label I mean likewise the circular or pamphlet which was inclosed in the package as it was transmitted in interstate commerce. In other words, what the ordinary man reading the label would understand as to what properties Athlophoros had or the curative or therapeutic effects it had. I will not attempt to define or set out the various ailments or physical disabilities which it is claimed the statements contained that this drug would cure, but these diseases or physical ailments you will understand to be such diseases or ailments as the public generally understood and the generally accepted meaning of these drugs by the public, and you are not confined in your deliberations in applying to these diseases the technical medical definition or term which has been scientifically limited by some of the witnesses. I have indicated the generally accepted understanding of the public as to what these terms mean and what physical disabilities they include, and you will apply the curative or therapeutic effect of the drug to the definition as generally understood. And you will also understand that it is not only necessary for the Government to show beyond all reasonable doubt that the statements that were made were false in fact and that the drugs did not have the curative or therapeutic effects that the statements attributed to them, but the Government must further prove beyond a reasonable doubt, that the statements are fraudulent and that the defendant knew them to be false, and that they were falsely made with the intent to deceive the public. If you find they were not false, then your inquiry is ended; if you find they were false, you have to go on further and find they were fraudulently—that they were fraudulently made with intent to deceive the public or induce the purchaser to buy them because of such statements. If you believe that these statements were false and the defendant knew they were false and made them with the intent to deceive the purchaser, or if, acting as an ordinary prudent man would act under like circumstances, he should have known that the statements were false, then you will find that the statements were falsely made as charged in the information and under such circumstances your verdict would be guilty. On the other hand, if you have a reasonable doubt as to whether the statements were false or whether they were fraudulently made, then it would be your duty to acquit this defendant. So that the mere falsity of the statements would not be sufficient to justify you in returning a verdict of guilty, but in addition to that it requires the further proof that the defendant made them knowingly and with intent to deceive and defraud.

It will not be necessary for me to enter into any definition of these various terms, but suffice it to say that a fraudulent statement is a statement which is recklessly made without knowledge of its truth, but which is really false, and an unqualified statement of that which one does not know to be true, or has no reasonable ground to believe to be true, is equivalent to a statement of that which one knows to be false. This phrase "false and fraudulent" must be taken with its accepted legal meaning, and thus it must be found that the statement contained in the package was put there to accompany the goods with actual intent to deceive—an intent which may be derived from the facts and

circumstances, but which must be established. That false and fraudulent representations may be made with respect to the curative effect of substances is, of course, obvious. The owner has the right to give his views regarding the effect of his drugs. But state of mind is itself a fact, and may be a material fact, and false and fraudulent representations may be made about it; and persons who make or deal in substances, or compositions, alleged to be curative, are in a position to have superior knowledge and may be held to good faith in their statements.

In determining whether the defendant knew the statements were false and fraudulently made, you will take into consideration all of the evidence which was offered and admitted surrounding the placing of this drug on the market, which led to placing it in interstate commerce as charged in the information, and you will consider all of the testimony with regard to these statements that is before you from the inception, dealing or treating with this drug up to the time of the filing of this information, May 22, 1915, and from all of these statements as disclosed by the evidence bearing on the conduct of the defendant with relation to this drug, determine whether it acted as an honest, fair-minded, average man would act under like circumstances, and whether it had reason to believe, acting as a reasonably prudent man would act under such circumstances, and that Athlophoros did contain the curative or therapeutic effects which are attributed to it in the various statements. In this case a number of physicians have testified, among whom, if I remember correctly, are some specialists. A chemist or analyst testified regarding the ingredients, about which there has been no dispute. The testimony of the Government is confined largely to expert medical evidence, except the testimony of the chemist or analyst. They have testified with relation to the sodium salicylate contained in this drug as disclosed by the evidence and the curative and therapeutic effect of sodium salicylate, based upon their experience as practitioners and likewise upon their reading in medical journals and treatises by eminent doctors. The defendants claim to have established the value of sodium salicylate in rheumatism, and I take it there is no contention about its value in what is known as acute articular rheumatism. The defendant further claims in that connection that these various diseases that are enumerated on the carton and in the literature are what are known as kindred ailments. If you find from the evidence that these various diseases enumerated on this carton and bottle are kindred ailments, kindred to rheumatism—if you find that to be true, you may take that into consideration as bearing upon the question of good faith or bad faith.

Perhaps at this point I ought to call your attention to this question of testimonials. You will understand that I said to you yesterday that they were not entered as proof of the truth contained in those letters, but merely bearing upon this charge or question of fraud—question of intent. If they received such letters as those, assuming those letters to be true, it is claimed that it is an evidence of the fact that they were acting in good faith in continuing their business right down to the date of this information and labeling their article as they have labeled it.

It is not my purpose to go into an analysis of the testimony or give you a synopsis of my recollection of it. It has been reviewed by counsel for both sides, and while you are not bound by their recollection of it, you will give their statements, their version of it, such consideration as you think it is entitled to receive.

In this case, while the Government must prove beyond every reasonable doubt the material allegations of the information, this need not be done with relation to every disease which is named upon this label or in the statement which is included within this package as it was transmitted in interstate commerce. If you believe from the evidence that this drug will cure many of the diseases which are named on the label or package but will not cure others in which it is alleged that it would effect a cure, and believe beyond a reasonable doubt that there are some ailments named upon the label or the literature or statement inclosed with the package, as charged in the information, concerning which the statements were false and known to be false at the time they were made, and were made for the fraudulent purpose, as charged in the information—if you are so convinced beyond a reasonable doubt of the falsity of the statements with relation to one of the diseases—then it would be sufficient to support a verdict of guilty; and if you are so convinced, your duty would be to return a verdict of guilty. But if you have a reasonable doubt as to all of these, then your duty would be to return a verdict of not guilty.

Throughout the charge I have told you that the Government must prove the material allegations of the information beyond a reasonable doubt. By reasonable doubt it is not meant that the proof should establish this defendant's guilt to a certainty, but merely that you should not convict unless from the evidence you find the defendants guilty beyond a reasonable doubt. Speculative notions or possibilities arising upon mere conjecture, not arising nor deducible from the proof or from the want of it, should not be confounded with reasonable doubt. A doubt suggested by the ingenuity of counsel, or by your own ingenuity, not legitimately warranted by the evidence, or the want of it, or one born of merciful inclination to permit the defendant to escape the penalty of the law, or one prompted by sympathy, is not what is meant by reasonable doubt. It is an honest, substantial misgiving, generated by the proof or want of it; that is, such a state of the proof as fails to convince your judgment or conscience and satisfy your reason of the guilt of the accused. If the evidence, when carefully examined, weighed, compared, and considered, produces in your minds a settled conviction or belief of the guilt of the defendants—such an abiding conviction that you would be willing to act upon it in the most weighty and important affairs of your own lives—you may be said to be free from any reasonable doubt and may find a verdict in accordance with that conviction or belief.

I have been requested by the defendant to make certain charges. I will take them up by paragraphs.

First, I charge as requested. I think I have substantially covered it.

First. This offense is that the defendant misbranded its label and circular accompanying the remedy by statements as alleged in the information regarding the curative or therapeutic effects of the medicine which, it is claimed, were false and fraudulent. If, then, the statements were not false and fraudulent, no crime has been committed and the law has not been violated. In other words, the gist of this action is that the statements were both false and fraudulent.

Second. In deciding whether they are false and fraudulent, I would instruct you that the expression "false and fraudulent" has a well-defined meaning in the criminal law. The word "false" means untruthful in its ordinary sense. The word "fraudulent," as used in this criminal statute and as a very material word in the allegation in this information, which charges the defendant with fraudulently representing certain things, is given its legal meaning, and that is that the defendant deliberately planned, and it was its purpose and intent, to deceive the public. In other words, that it made such false statements regarding the curative or therapeutic effect of the remedy, well knowing that the remedy contained nothing in its ingredients which could operate beneficially and as a remedy for the various ailments it pretended to benefit, and this for the sole purpose of deceiving the public.

Third. That the statements as to the curative or therapeutic effects of this remedy must be both false and fraudulent, within the meaning I have described. And in this connection I would inform you that it is well recognized that the curative properties of articles purveyed as medicinal preparations are matters of opinion largely, and the contrariety of views among medical practitioners and the conflict between the schools of medicine are imperfectly described. If you should find from the evidence that the defendant made its statements based upon an honest opinion arising out of this contrariety of views of medical practitioners and this conflict between the schools of medicine regarding the curative and therapeutic effect of the ingredients, you may take those facts into consideration as bearing upon the good faith of the defendant and upon his honest intention to put out an article labeled with such statements as he honestly believed to be true, and as bearing upon the question of fraudulent intent. With these variations I charge paragraph three.

Fourth. In order for you to find this defendant guilty of the offense charged, you must find that the statements of the curative and therapeutic effects of this remedy were a false representation of a fact; in other words, that in labeling the article as a remedy or cure as alleged it was nothing of the sort from any point of view. If you find that there is honest diversity of opinion among the medical profession and among schools of medicine upon the curative or therapeutic effect of the ingredients of the medicine, with reference to the diseases named, and this defendant acted upon this honest opinion, this evidence will then bear upon the question of whether it made any false statements and which were made fraudulently for the purpose of deceiving the public. Of course, if you find that it did not make them fraudulently, it would then be your duty to acquit the defendant.

Further, that the use of the word "fraudulent" in this prosecution requires the Government to prove such a state of facts regarding the properties of the remedy sold as alleged, which imply a knowledge on the part of this defendant that the medicine will not do the thing that is asserted on the label or circular. In other words, it must show that the so-called remedy is absolutely worthless as to its curative or therapeutic effect upon the ailments for which it is claimed, and this the Government must prove beyond a reasonable doubt. If the Government has not proved to you, beyond a reasonable doubt by facts and circumstances, that the remedy is absolutely worthless as to its curative or therapeutic effects upon the ailments or diseases claimed for it, or any one of them set out in the information, then you must find that the defendant is not guilty and render your verdict accordingly.

Further that the word "fraudulent" is descriptive of the wrongful motive with which the statements are made, and it is the duty of the Government to satisfy you beyond a reasonable doubt that the statements were made with that wrongful motive for the purpose of deception. If, as I have said before, the motive was an honest motive, from all the facts and circumstances surrounding the preparation and sale of the remedy, due to the fact that there is a contrariety of views in the medical profession regarding the curative or therapeutic effect of the remedy, or due to any other fact in evidence, then your verdict must be for the defendant, for under such circumstances the statements can not be held to be false and fraudulent.

I further charge you that in considering the question as to whether the statements alleged in the information are false and fraudulent, you are to consider not only the statements upon the carton but upon the bottle and in the circular, and all of them, and from the entire context you are to draw your conclusions whether or not they can be said to be false and fraudulent within the meaning I have described. If the statements alleged as false and fraudulent are matters only of opinion, taking them all as I have stated, based upon the contrariety of views of practitioners and schools of medicine as to the curative or therapeutic effect of the remedy employed, you should take this seriously into consideration as bearing upon the good faith or the bad faith of the defendant, as bearing upon the defendant's honest belief that the statements on the carton and the literature were true and were not made with fraudulent intent.

Paragraphs eight and nine I must decline to charge. Eight I will charge in a modified form:

That you may take into consideration the statements upon the bottle and within the circular relative to the use of Athlo Tablets in connection with the Athlophoros, as an aid and as a part of the remedy, and when this bottle of Athlophoros was sold to the purchaser that Athlo Tablets was really an essential part of the remedy—all bearing again on its good intention.

COURT. If you wish, Mr. Webb, you may have an exception to refusal to charge paragraph nine.

Mr. WEBB. Exception to the modification.

Mr. SPELLACY. The Government has no requests.

Gentlemen, you may retire to the jury room and when you have arrived at your verdict you will make it known by your foreman,

The jury thereupon retired and, after due deliberation, returned into court with its verdict of guilty, and thereafter, on May 24, 1916, the court imposed a fine of \$25 and costs.

CARL VROOMAN,
Acting Secretary of Agriculture.