

On November 6, 1934, the defendant entered a plea of nolo contendere and the court ordered that sentence be withheld for 12 months. On November 5, 1935, the defendant was sentenced to pay a fine of \$2,000. Sentence was suspended and defendant was placed on probation for 2 years.

W. R. GREGG, *Acting Secretary of Agriculture.*

24628. Adulteration and misbranding of compound tincture of cinchona. U. S. v. John Wyeth & Bro., Inc. Tried to the court and a jury. Verdict of guilty. Fine, \$250. (F. & D. no. 30172. Sample no. 8280-A.)

This case was based on an interstate shipment of compound tincture of cinchona, which differed from the standard prescribed by the United States Pharmacopoeia, and which was not labeled to show its own standard.

On February 9, 1934, the United States attorney for the Eastern District of Pennsylvania, acting upon a report by the Secretary of Agriculture, filed in the district court an information against John Wyeth & Bro., Inc., trading at Philadelphia, Pa., alleging shipment by said company in violation of the Food and Drugs Act, on or about April 22, 1932, from the State of Pennsylvania into the State of New Jersey of a quantity of compound tincture of cinchona which was adulterated and misbranded. The article was labeled in part: "Compound Tincture Cinchona U. S. P. 10th Revision * * * John Wyeth & Brother Incorporated Philadelphia."

The article was alleged to be adulterated in that it was sold under a name recognized in the United States Pharmacopoeia and differed from the standard of strength, quality, and purity as determined by the test laid down in the said pharmacopoeia official at the time of investigation in that it yielded not more than 0.376 gram of the alkaloids of cinchona per 100 cubic centimeters; whereas the pharmacopoeia provides that compound tincture of cinchona shall yield not less than 0.4 gram of the alkaloids of cinchona per 100 cubic centimeters; and the standard of strength, quality, and purity of the article was not declared on the container. Adulteration was alleged for the further reason that the strength and purity of the article fell below the professed standard of quality under which it was sold, in that it was represented to be compound tincture of cinchona which conformed to the standard prescribed by the United States Pharmacopoeia, tenth revision; whereas it was not compound tincture of cinchona which conformed to the standard prescribed by that authority.

Misbranding was alleged for the reason that the statement, "Compound Tincture Cinchona U. S. P. 10th Revision", borne on the label, was false and misleading.

On June 17, 1935, a plea of not guilty having been entered on behalf of the defendant company, the case came on for trial before the court and a jury. Evidence on behalf of the Government and defendant company was introduced, and arguments of counsel heard at the conclusion of which the court delivered the following charge to the jury:

DICKINSON, *Judge:* Members of the jury: You have something to decide, a question to answer, and the suggestion that I am in the habit of making to all juries is before you; answer that question; get clearly in your mind what the question is which you are answering. I commend that to you in this case.

Now, what is the question in this case which you will answer by your verdict? It is a question which arises out of what are known as the Pure Food and Drug Laws of the United States. You all understand the general purpose of those laws, you all appreciate the importance of them. Different concerns and individuals are in the business of selling drugs to what we call the consumer, the ultimate person who buys them for use. You all know a term used in medical science. It is toxic. They say things are toxic. What do they mean by that? What they mean by that is what we understand in the vernacular of every day life as poison. Yet, although they are poisonous, they may be very valuable medicinal drugs. Take arsenic, for instance, or strychnine. They are poisonous. One a mineral poison and the other a vegetable poison. But each a poison; if taken in undue quantities they will cause damage, even the death of a person who takes them into his or her system. Used in less quantity, they may be very effective in restoring us to health.

You see the importance when you go to buy something to get what you are buying and not something else. Now, that is the general purpose of these laws, to require dealers in these drugs, some of which as I have said, may be in themselves poisonous, that they shall be supplied in such proportions as

they may be a remedial agent instead of a lethal agent. The same thing applies to other things, to the food we take in our stomach. We want to be assured that it is pure and unadulterated, and safe to take.

Well, you can run the whole gamut of all these things in which people deal. Therefore, I say you will appreciate the importance of this law.

Now, somebody must determine what the proper proportion of ingredients in any drug as administered is, and the United States has published what is called the United States Pharmacopoeia which gives the relative quantities of these different ingredients which should be used and administered in any drug that is medicinally used. Now, of course, this feature of the case enters the picture. These drugs are intended to produce or intended to have a certain result. In order to produce that result there must be a certain proportionate quantity of a particular drug in the medicine that is sold. If it is less than that required to accomplish the purpose; it won't accomplish it and our money is thrown away. Our hopes are blasted. Perhaps we may succumb to a disease from which we might have recovered if the proper medicine were administered. You have also the other element, if there is more of the drug than is required, instead of it being remedial, the thing may have the most disastrous consequences. So you will appreciate that it is necessary that the law should specify definitely what these relative quantities are, and with respect to this particular drug or medicine it has prescribed it and given a limit as to the contents, relative contents of this remedial agent which is known as cinchona bark, or, what in ordinary language is commonly called quinine, and we all understand what that is. The United States Pharmacopoeia sets down the limits of those quantities and they are represented—you can carry them in your minds better by the figures five and four. There must be a quantity which is represented by the figure five, and not more than that, because more than that may be injurious to the human system. We put down the other figure which you can carry in your minds as four. There must be at least that much of the particular drug in question or it won't have the effect upon the system which it is expected to have. So you get those limits which you can carry in your minds as five and four. Not more than five and not less than four.

The charge against these defendants, is that they sold this medicine which did not conform with the requirements of the United States Pharmacopoeia for that medicine. We will first turn to the maximum requirement, which you will call five, and determine whether or not it was within that limit. Under all the evidence in this case, the medicine sold by the defendants did not exceed five. Now, you will go to the other question, the minimum, the least quantity, relative quantity which can be used in this medicine, which we have represented for the purposes of this case, by the figure four. The next charge against these defendants is that they put out a medicine with less than the required quantity. Now, of course, you will have in mind the importance of this law; the value to all of us in its enforcement and the value to all the people of its enforcement, and, of course, it is your duty as a jury to render your aid, as it is the duty of the trial judge to render his aid to the enforcement of that law.

You also have in mind the importance to these defendants and to any manufacturer of any medicine. There is their reputation in the trade. That would be involved. Their profits would be involved. Therefore, you can see the importance to them that they should not unjustly be condemned as having been guilty of an infraction of the law, unless the evidence justifies the jury in reaching that conclusion.

I think out of this you will see what the real question before you is. Did this medicine contain less than the quantity specified in the United States Pharmacopoeia? This law is perfectly fair. It does not require any dealer to put forth a medicine which conforms with the United States Pharmacopoeia, but if they label it under a name which purports to say that it does comply with the United States Pharmacopoeia, then it must comply. If there is less in its ingredients or if there is more in its ingredients, all the dealer has to do is to say so on his label; say what it does contain so that the person who buys it and pays the price knows precisely what he is to get, and knows whether or not he gets it. That is all they have to do. If they depart from the required standard, they merely have to indicate that on their labels by saying the figure is not in accordance with the United States Pharmacopoeia, but it is something else, and setting forth what that something else is. So, you can see the law is perfectly fair in its requirements.

Therefore, direct your attention to this, for it is the only question before you, and the answer to which governs your verdict. Did this medicine, which was put out under a name recognized and used in the United States Pharmacopoeia, contain the ingredients which the law requires it to contain? The law requires a quantity not less than what we have called the figure four. You are to determine whether or not the proportion of this ingredient we have called cinchona bark was a proportion represented by less than the figure four. Now, if it was less, I charge you that under the evidence you may find a verdict of—what will we call it, guilty? What is the form of the verdict?

Mr. CURTIN. In this type of case it is just a guilty verdict.

The COURT. When you are asked whether or not you have agreed upon your verdict, you can say that your finding is guilty. If this evidence has not convinced you that the relative proportion of the ingredient is represented by less than the figure four, then your verdict would be not guilty. Now, did it contain less than the quantity which I have referred to for convenience by the figure four?

You will want to know under the evidence in this case, when is the test to be applied, when it is manufactured? When it is sold to the ultimate consumer? When it is sold to what we call the retail dealer, the druggist, or when is the test to be applied. That is a question of law, and I charge you that the test is to be applied at the time when this drug was sold by the manufacturer, and under the evidence in this case I charge you that you may find that it was sold at the time when it was shipped in interstate commerce. Not at the time it was manufactured, but when it was sold.

There is evidence in this case that this particular product or medicine deteriorates. It may have at one time a certain relative quantity of the particular drug and it may have at a later time a less quantity. That is due in part to precipitation. You all know that any liquid may hold other things in solution. If that liquid is set down, or, in a bottle stood up on a druggist's counter, it may be that those ingredients which are in what we call solution, suspended in the liquid, may be precipitated. That is, they may drop to the bottom of the vessel or bottle in which they are contained, and you can all understand that. A very familiar illustration of it is the liquid we know as water. It may be taken from a stream or spring and shortly after stored and it may be what we call muddy. If you put it in a vessel and allow it to stand, that mud will fall to, or be precipitated to the bottom, and you look at it and you see a layer of mud at the bottom and what you would call pure water above it.

Of course, if anybody would take a siphon and be careful to take only that part of the contents from this bottle which is represented by what I have called the pure water, and analyze it, he would without doubt get a very different result from the man who took the sample which he assayed from the bottom of the bottle where this precipitate was. You can all understand that. That enters into this case. What we are concerned with in this case, is the accumulated contents of the whole mixture, not the part of it which was precipitated to the bottom, not the part which was unprecipitated, but the relative contents of the whole mixture. You have heard all the evidence.

I may say that there is evidence in the case that aside from this precipitate or incrustation, there may be a chemical change which results, and there may be a loss of what you might call the strength of the medicine, independently of this precipitate, but it means this, as far as you are concerned; you are to find what the contents of this medicine were, when it was sold, and that means when it was shipped in interstate commerce from the factory by the manufacturer. Direct your whole attention to that, and determine that question according to your best judgments.

That is really all there is in this case. Let me repeat, if you find under all the evidence that this medicine was put out by the manufacturer and shipped in interstate commerce and it contained less of this ingredient which we have called cinchona than what would be represented by the figure four, then you would be justified in rendering a verdict of guilty. If under all the evidence you are unconvinced of that, and unwilling to make that verdict, then, when you are asked the question, your response would be that you find the defendants not guilty.

Is it the desire of counsel that I should charge the jury upon the question of reasonable doubt?

Mr. PHILLIPS. I should like a word on that subject, yes.

The COURT. Members of the jury, this is a penal statute. You all understand that there is a difference, more than formal, it is substantial, in the verdict that you render in so-called criminal cases than what you render in other cases. The lawyers know that under the name or doctrine of reasonable doubt. That doctrine applies in criminal cases but does not apply to civil cases.

I have been advised that jurors sometimes have a little difficulty in grasping just what is meant by that doctrine of reasonable doubt. I will try to make that clear to you. If you are trying what we will call a civil case, where the question to be decided is where a man owes a bill which he is asked to pay or not, or, if you are trying a case to determine whether a man is guilty of negligence to find out who caused the injury to another, or any question of that kind, that belongs to the division of the law which we call the civil branch as distinguished from the criminal. The evidence is heard by the jury pro and con. It may be clear, it may be contradictory, it may leave your minds in a more or less of an unsettled state as to the verdict you should render. In a civil case, you render a verdict according to your judgment on what is called the weight of the evidence. In other words, you ask yourselves the question, "Now, under this evidence what should the verdict be? Should the verdict be for the plaintiff or for the defendant?" and you reach the best judgment you can, undisturbed by any thought of reasonable doubt. If you are asked after you render your verdict whether or not you are sure that you were right, you would be fully justified in answering "No, we were by no means sure"; and if you were asked, "But there was some doubt about whether the verdict should be for the plaintiff or the defendant?" you would say, "Yes, we were all troubled with this doubt, there was a good deal of doubt, but that was the best judgment to which we could come under all the evidence in the case", and that would be a sound verdict.

In a criminal case, the law requires something more than that. It requires a jury really to answer two questions, first, "What do you think under all the evidence in this case, and the weight of the evidence, is this man guilty or not guilty?" and your judgment may be, "We think he is guilty", but before you render that verdict you ask yourselves the second question, and that is, "Well, we all think he is guilty, but is there a reasonable doubt as to the correctness of that judgment?" and you take up that second question and answer it.

You want to know what the law means by a reasonable doubt. It means precisely what that indicates, a doubt that rises out of your reason. It must be founded upon something. It is not any mere whim of unbelief or disbelief. That is not reasonable, and it is not a reasonable doubt. If a doubt is suggested, then you take up the question, "What is a reasonable doubt?" Is there any good reason why you should render a different verdict from that which you would otherwise render? You answer that as you answer every other question and you determine whether or not under all the evidence in the case you reasonably should refuse to render the kind of a verdict which you would have otherwise rendered under what I call the weight of the evidence.

I think you appreciate the distinction between those two things. Ask yourselves the first question, "Under all the evidence in this case did the defendants put out upon the market a product of less medicinal value than what the law requires?" That, you may present to your minds under the figure four. Under all the evidence in the case, how does your judgment incline on that question? If it inclines in favor of the defendants, then, of course, that is the end of it and your verdict is not guilty. If it, however, inclines against the defendants, then, you ask yourselves the second question, "Is there any reasonable doubt—reasonable doubt—as to the correctness of that conclusion to which we have come?" If your answer is that there is no reasonable doubt, your verdict would be one of guilty. If in answer to that second question your minds are disturbed by a reasonable doubt, after considering all the evidence in the case you are unable to remove that doubt from your minds and it still continues in the case, then under the law your duty would be to render a verdict of not guilty.

The points submitted I have covered, I think, in the general charge. Insofar as they are affirmed, they are affirmed and insofar as they are not so affirmed, they are disaffirmed, with an exception allowed to the respective parties.

I assume you will enter into the usual stipulation of rendering the verdict—

Mr. PHILLIPS. I will move that the record be transcribed and filed.

The COURT. Members of the jury, you may retire to your room to deliberate on your verdict. You will have to stay together until you have rendered

your verdict. You need not wait for the Court to be in session. Under the agreement of counsel, whenever you have agreed upon your verdict, you may announce it to the officer in charge, and the clerk will take your verdict.

The jury retired.

The following points for charge were submitted by the Government:

(1) If the jury believes as a matter of fact that interstate shipments, all of which are included in the Government's samples, was below the minimum United States Pharmacopoeia, then the jury must bring in a verdict of guilty. (2) The standards of the United States Pharmacopoeia as defined in section 7, in the case of drugs, paragraph 1, are to all intents and purposes parts of the law, and such drug products shipped in interstate commerce should not be deviated in any degree from these standards.

CHARLES D. MCAVOY, *United States Attorney.*

The following points for charge were submitted by the defendants:

The Learned Trial Judge is respectfully requested, on behalf of the defendant, to charge the jury as follows:

- (1) On all the evidence your verdict should be for the defendant on the first count.
- (2) On all the evidence your verdict should be for the defendant on the second count.

C. RUSSELL PHILLIPS, *Attorney for Defendant.*

On June 18, 1935, the jury returned a verdict of guilty and the court imposed a fine of \$250.

W. R. GREGG, *Acting Secretary of Agriculture.*

24629. Misbranding of Espiritu Water. U. S. v. Doris E. Lame (The Espiritu Water Co.). Plea of guilty. Fine, \$200. Sentence suspended and defendant placed on probation for 1 year. (F. & D. no. 30219. Sample no. 38888.)

This case was based on an interstate shipment of mineral water which contained smaller amounts of certain minerals than declared on the label. The labeling contained unwarranted curative and therapeutic claims.

On September 10, 1934, the United States attorney for the Southern District of Florida, acting upon a report by the Secretary of Agriculture, filed in the district court an information against Doris E. Lame, trading as the Espiritu Water Co., Safety Harbor, Fla., alleging shipment by said defendant in violation of the Food and Drugs Act as amended, on or about October 26, 1931, from the State of Florida into the State of Massachusetts of a quantity of Espiritu Water which was misbranded.

The article was alleged to be misbranded in that certain statements regarding its curative and therapeutic effects, borne on the bottle label and in a leaflet shipped with the article, falsely and fraudulently represented that it was effective as a treatment, remedy, and cure for diseases of the stomach, liver, and kidneys, rheumatism, neuritis, kidney stones, and other kidney irregularities; effective as a cure for Bright's disease, bladder troubles, diabetes, dropsy, high blood pressure, gout, stomach and bowel troubles, eczema, psoriasis, cystitis, calculus, sciatica, and all other forms of rheumatism, catarrh of the stomach, digestive troubles of the stomach and bowels, chronic skin disease, chronic skin disease of the squamous varieties and chronic conditions due to malarial infections; and effective as beneficial for many kidney and rheumatic conditions. Misbranding was alleged for the further reason that the statements "Spring No. 2 * * * Peroxide Iron and Alumina .1692 Sodium Chloride 137.8520 Magnesium Chloride 25.8768 Potassium Sulphate 3.4815 Calcium Sulphate 19.7172 Calcium Carbonate 12.6145 Silica .9972 Total Solids by Evaporation 254.9195", appearing in the leaflet, were false and misleading in that the said statements represented that the article consisted of mineral water containing certain specified quantities of the said ingredients; whereas it contained less than the stated quantities of the said ingredients.

On June 11, 1935, the defendant entered a plea of guilty and the court imposed a fine of \$200, and ordered that sentence be suspended and the defendant placed on probation for 1 year.

W. R. GREGG, *Acting Secretary of Agriculture.*

24630. Adulteration and misbranding of fluidextract of squill. U. S. v. 21 Pint Bottles of Fluidextract Squill. Default decree of condemnation and destruction. (F. & D. no. 31264. Sample no. 55785-A.)

This case involved a shipment of fluidextract of squill, samples of which were found to have a potency of less than two-fifths of that required by the United States Pharmacopoeia.

On October 23, 1933, the United States attorney for the Northern District of Illinois, acting upon a report by the Secretary of Agriculture, filed in the district court a libel praying seizure and condemnation of 21 bottles of fluid-