4980. Adulteration and misbranding of fluid extract cinchona. U. S. * * * v. The G. F. Harvey Co., a corporation. Tried to the court and a jury. Verdict of guilty. Fine, $200. (F. & D. No. 5388. I. S. No. 1649-e.)

On February 19, 1914, the United States attorney for the Northern District of New York, 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 G. F. Harvey Co., a corporation, Saratoga Springs, N. Y., alleging shipment by said company, in violation of the Food and Drugs Act, on or about November 8, 1912, from the State of New York into the State of New Jersey, of a quantity of an article labeled, in part, "Fluid Extract Cinchona," which was adulterated and misbranded.

Analysis of a sample of the article by the Bureau of Chemistry of this department showed the following result:

Anhydrous ether-soluble alkaloids (grams per 100 cc) _____ 2.97

Adulteration of the article was alleged in the information for the reason that it was sold under and by a name recognized in the United States Pharmacopœia, to wit, fluid extract of cinchona, and differed from the standard of strength, quality, and purity as determined by the test laid down in the said Pharmacopœia, official at the time of the investigation and shipment of said article, in that said Pharmacopœia specifies that fluid extract of cinchona shall contain 4 grams of anhydrous ether-soluble alkaloids from cinchona per 100 cc, whereas said article did not contain said amount of anhydrous ether-soluble alkaloids from cinchona per 100 cc, but did contain a less amount of said alkaloids, to wit, 2.97 grams per 100 cc.

Misbranding was alleged for the reason that the statement, to wit, "Fluid Extract Cinchona," borne on the label, was false and misleading, in that it purported and represented to purchasers that said article was fluid extract of cinchona, a product well known to contain 4 grams of anhydrous ether-soluble alkaloids from cinchona per 100 cc, whereas, in fact, it was not, but was a so-called fluid extract of cinchona containing a less amount of anhydrous ether-soluble alkaloids from cinchona per 100 cc, to wit, 2.97 grams of said alkaloids per 100 cc.

On June 21, 1916, the case having come on for trial before the court and jury, after the submission of evidence and arguments by counsel, the following charge was delivered to the jury by the court (Ray, *D. J.*):

Gentlemen of the jury, this trial has occupied many days and I have allowed to the defendant considerable latitude to the end that every question involved might be fully and fairly presented to the court and to the jury. However, the questions involved are narrowel so far as you are concerned to one, and that question is, Did the defendant, The G. F. Harvey Co., on or about the 8th day of November, 1912, deliver for shipment in interstate commerce from the city of Saratoga Springs in the State of New York consigned to C. B. Smith & Co. at Newark, in the State of New Jersey, three 1-pint bottles containing an article designed and intended to be used as a drug and which was labeled, marked, and branded as described in the information, viz, "This preparation contains not more than 68 per cent alcohol by volume. Assayed. Fluid extract cinchona, yellow cinchona calisaya, Weddell. 12312, 88405. Dose, 15 to 60 minims. The G. F. Harvey Co.," and did this fluid extract so offered for shipment in interstate commerce by the defendant differ from the standard of strength, quality, or purity as determined by the test laid down in the United States Pharmacopœia or National Formulary official at the time of shipment, when the offense, if any, was committed?

It is conceded by the defendant by stipulation in writing and in evidence that the defendant is a corporation organized and existing under by virtue of the laws of the State of New York and that its office and principal place of business is Saratoga Springs in the Northern District of New York. That on or

about the 8th day of November, 1912, the defendant did ship from the city of Saratoga Springs in the State of New York to C. B. Smith & Co. of Newark, N. J., a consignment consisting of three 1-pint bottles containing a liquid designed and intended to be used as a drug and which bottles were then and there designated as to the contents thereof and labeled, marked, and branded as set forth in the information in this case and which label and brand I have already recited. It is also stipulated and conceded and admitted by the defendant that the samples of this consignment consisting of the three bottles taken were sold by the said C. B. Smith & Co. to Herman Lind, an inspector of the United States Department of Agriculture, after being properly marked and identified by him with the marks, "I. S. No. 1649-e," and that no change was made in said samples of three bottles from the time the same was sold and shipped in interstate commerce by the defendant to said C. B. Smith & Co. up to the time the same was sold and delivered by that company to said Lind.

The evidence shows without contradiction, so far as any evidence has been given on the subject, that Lind, an inspector of the United States Department of Agriculture, turned these three bottles of this mixture, fluid extract of cinchona over to the Department of Agriculture at Washington, D. C., with seals, etc., unbroken, except as to one bottle which was assayed or tested by Mr. Darling, another employee of the Department of Agriculture, in the State of New York, for the purpose of determining whether or not it was up to standard. The evidence also shows that one of the bottles of fluid extract so purchased of C. B. Smith & Co. and shipped to that company by the defendant was returned with the seal, etc., unbroken to the defendant here so as to enable it to make an examination as to its strength, quality, etc. The other two bottles were retained by the United States and one of same has been produced in court. The evidence shows or tends to show that both bottles retained by the Government were examined and tested by it and that one of them has been broken, lost, or destroyed without fault on the part of anyone. On being tested and examined in the manner prescribed and pointed out by law the Government contends that the two bottles examined, tested, and assayed by it shows that the composition or fluid extract contains only, in round numbers, three-quarters of the essential ingredients of such a mixture and that it was therefore far below the required standard and was adulterated within the meaning of the Pure Food and Drugs Act of June 30, 1906, as subsequently amended and as in force at the time of the sale and shipment mentioned. Two different chemists of experience and connected with the Department of Agriculture at Washington, D. C., Mr. Darling and Mr. Wright tested and analyzed these two bottles and they have given the contents as to the essentials as follows: Darling, first trial, 2.97 grams, second trial, 2.95 grams; Mr. Wright, first sample, 2.87 grams; second sample, 2.99 grams; third sample, 2.84 grams per 100 cubic centimeters, when under the law it should have contained 4 grams per 100 cubic centimeters of the anhydrous ether soluble alkaloids from cinchona.

The standard required by the law is 4 grams for the ingredients to which attention has just been called.

The third bottle which was returned to the defendant was examined and analyzed it is claimed by Mr. Ellery, a chemist of the Union College at Schenectady, N. Y., and he found that it contained the following of the essentials referred to, viz, first sample, 3.786 grams; second sample, 3.902 grams; third sample, 3.766 grams per 100 cubic centimeters.

He says he took three samples from the bottle and made three separate tests and that the results were as stated.

This test made by this professor of chemistry employed by the defendant company shows, as you will readily see, that the samples or bottle of this compound or fluid extract tested by him contained less of the essential substances than is required by the standard set up in the statute. Prof. Grose says he tested the contents and found: First test, 3.9 grams, and second test, 4.1 grams. But this was made last Wednesday, the 14 of this month, and that the fluid extract had undergone changes.

The Government further contends that this bottle or these bottles of fluid extract so sold and shipped by the defendant, and which were but a part of a larger quantity, were not manufactured, compounded, and put up as they should have been to insure the required and necessary degree of strength as pertains to the essential ingredients and that the result was necessarily an inferior quality which differed considerably from the standard. The Government further contends that when this fluid extract had been run through the percolator at the factory of the defendant it was found by the defendant itself and known to it

that the fluid extract fell short of the standard and that offering it for sale and shipping it in interstate commerce at that strength would have been a plain violation of the statute and would have subjected the defendant to the fines and penalties prescribed by law.

The Government contends that thereupon the defendant undertook to remedy the defect by putting into the mass of fluid extract in one receptacle or container a quantity of quinine and cinchonidine in powdered form and stirring it in with a stick and that this mode of manufacture, thereby attempting to bring the fluid extract up to the standard required, was not sufficient and did not, in its results, bring the fluid extract up to the required standard. The Government says that even if the requisite amount of powdered quinine and cinchonidine was put in in the powdered form and stirred in with a stick that it was not properly distributed through the mass and dissolved and that while some portions thereof might contain enough, other portions would be liable to be deficient, and that, therefore, the fluid extract of cincohona put upon the market and sold in interstate commerce by the defendant at the time mentioned was adulterated within the meaning of the law in that it failed to come up to the standard; that is, that this drug was sold under or by a name recognized in the United States Pharmacopœia and differed from the standard of strength, quality, and purity as to ingredients mentioned, as determined by the test laid down in the United States Pharmacopœia official at the time of investigation or shipment. That it also lacked some of the anhydrous ether soluble alkaloids, as only two were added when several were required.

The law itself, gentlemen of the jury, determines what shall be deemed a drug within the meaning of the law, and also determines when a drug shall be deemed to be adulterated.

By section 2 of the act of Congress referred to it is provided that the introduction into any State from any other State of any drug which is adulterated or misbranded within the meaning of the act is hereby prohibited; and that any person who shall ship or deliver for shipment from any State to any other State any such adulterated or misbranded drug shall be guilty of a misdemeanor and fined not exceeding $200 for the first offense.

By section 6 of the act to which attention has been called it is provided that the term "drug" as used in this act shall include all medicines and preparations recognized in the United States Pharmacopœia for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals. There is no question, gentlemen, or dispute that this fluid extract in question here is a drug within the meaning of the law.

By section 7 of the law to which I have called your attention it is declared when and under what circumstances an article or drug is deemed to be adulterated, and section 7 declares in express terms that "for the purposes of this act an article shall be deemed to be adulterated; Drugs. In the case of drugs; difference from recognized standard; statement on bottle, box, etc., as to different standard.

"First, if, when a drug is sold under or by a name recognized in the United States Pharmacopœia or National Formulary, it differs from the standard of strength, quality, or purity, as determined by the test laid down in the United States Pharmacopœia or National Formulary official at the time of investigation: *Provided*, That no drug defined in the United States Pharmacopœia or National Formulary shall be deemed to be adulterated under this provision if the standard of strength, quality, or purity be plainly stated upon the bottle, box, or other container thereof, although the standard may differ from that determined by the test laid down in the United States Pharmacopœia or National Formulary.

"Below professed standard.

"Second, if its strength or purity shall fall below the professed standard or quality under which it is sold."

In this case, gentlemen of the jury, there is no pretense or claim that the standard of strength, quality, or purity was plainly stated upon the bottles, boxes, or other containers of this fluid extract, and for that reason, as it was not made known what the standard of strength, quality, or purity was, it becomes a simple question in this case whether or not, as determined by the test laid down in the United States Pharmacopœia, this fluid extract did differ essentially from the standard of strength, quality, and purity as to the essentials to which I have called your attention as determined by that test. That this fluid extract was up to the quality required by law when or as determined

by some other test than that laid down in the United States Pharmacopœia would constitute no defense if not up to the standard required by the test prescribed by law. The law is somewhat exacting, but it is the law nevertheless and provides in express terms that this fluid extract cinchona, yellow cinchona calisaya, must not differ from the standard of strength, quality, or purity required, as determined by the test laid down in the United States Pharmacopœia or National Formulary official at the time of the investigation, meaning time of shipment. That is, the one that was official at the time these samples were taken and the shipment was made.

This law, gentlemen, was enacted for a purpose, or for purposes, and one of the purposes was to keep adulterated drugs out of interstate commerce and to insure to the purchaser and user of the drug shipped in interstate commerce an article that was up to and which complied with the standard prescribed by law. This would insure the purchaser and user of these drugs shipped in interstate commerce against fraud and imposition and would give to the purchaser that which he purchased and which he understood he was purchasing, and it would insure to the physician who prescribed it to a patient, or who would use it in other compounds that he was giving to the patient, or putting into the medicinal compound just what he supposed he was putting in and just what the needs and conditions of the patient required. When an article of this kind, like fluid extract of cinchona, is purchased in the market, having been shipped in interstate commerce, with this law in force the purchaser has the right to assume that he is receiving a preparation of a certain well-defined strength, quality, or purity, as the case may be, and neither he as a user, nor the physician, nor the druggist who gives it to others is under any obligation to make tests for themselves but may rely to an extent at least upon the article being of the strength, quality, or purity fixed by this standard. The manufacturer who compounds them and puts them on the market in interstate commerce is bound at his or its peril to see to it that they are up to the standard fixed by law not only when made and shipped but are so compounded and put up for sale that they will be of the required standard when shipped in interstate commerce for sale to the consumer or user.

This law, gentlemen, assures to the user and consumer and to the physician in a degree not only a safeguard in the respects to which I have called your attention, which may affect the health of the patient and have to do with his proper treatment, but that he gets his money's worth; that is, what he pays for. It is not for you, gentlemen of the jury, or for this court to question either the propriety or the wisdom of this law. It is the law of the land, and if violated by this defendant, and you are so satisfied beyond a reasonable doubt, then it is your duty to so say by your verdict. The court has no alternative. It is its duty to instruct you as to the law as it finds it. In the opinion of this court this was and is a wise and a necessary law, and, gentlemen, it is not necessary for the Government to show the adulteration here complained of was deleterious and injurious to the health of the user and consumer.

There is no question of intent, gentlemen, involved in this case. No question, necessarily, of evil mind or purpose. It is not a question whether or not the defendant *intended* to comply with the law, but whether it *did* comply with the law. It is no defense to the charge contained in this information that this defendant intended to bring this fluid extract of cinchona up to the required standard and supposed and honestly believed it had done so when it sold and shipped the same in interstate commerce, if you find that it was in fact below the standard required—that is, not up to the standard required by the law. In this case, as in all cases of this character, it being a criminal charge, the defendant is presumed to be innocent until proven guilty beyond a reasonable doubt. Hence the burden of proof was upon the Government to establish that this fluid extract of cinchona in question here was below the standard. If it has done this and you are satisfied of that fact under this proof beyond a reasonable doubt, then that presumption of innocence, of course, would be overcome and would disappear, and it would be your duty to say "Guilty." If, on the other hand, you have a reasonable doubt whether or not this fluid extract was below the standard and are not satisfied beyond a reasonable doubt that it was below the standard when shipped, then, of course, it would be your duty to find the defendant not guilty. But, gentlemen, you are to take the evidence as it is and not surmise, guess, or speculate or theorize that this fluid extract may have been up to the standard if the evidence proves it was not. A reasonable doubt, gentlemen, is not a surmise, a guess, a speculation, or a speculative theory that a thing may not be so. A reasonable doubt is not

a speculative theory. A reasonable doubt is just what the term implies—a doubt founded in reason, and for which a reason can be given by the jury if called upon to do so. It may arise from the lack of evidence or from the uncertainty of that presented. It may arise from the character or quality of the evidence given; that is, the character of the witnesses giving it may be such that the jury does not give credence to the testimony. The witnesses may be impeached in some one of the modes known to the law, or the witness may be so uncertain or unreliable or contradictory or unreasonable in his statements that the jury fails to place reliance on what he says. However, gentlemen, a jury has no right to disregard the testimony of an unimpeached witness who knows whereof he speaks, who has the facts within his knowledge, and who is disinterested and fair and consistent in giving his statements, and whose testimony is consistent with the other known and proved and conceded facts in the case.

In a criminal case the evidence must exclude every reasonable hypothesis except that of guilt, and if just as consistent with the innocence of the defendant as with its guilt, then the case is not made out.

Considerable has been said here about allowances, variations, and tolerances, meaning, I assume, that allowances and tolerations may be made for differences in results obtained when the formula or mode of procedure pointed out by law is followed in making an analysis of the article being analyzed. Of course, you, gentlemen of the jury, on this evidence and from this evidence, are to determine and say on your oaths as jurors, whether or not this fluid extract of cinchona compounded and sold and shipped in interstate commerce; that is, from one State into another State of the United States—from New York to New Jersey—did contain, when so shipped and sold, 4 grams per 100 cubic centimeters of the anhydrous ether soluble alkaloids from cinchona. If it did, then the statute was not offended against or violated in this respect. If it did not contain 4 grams of such anhydrous ether soluble alkaloids, but a lesser quantity of such alkaloids or ingredients, then the statute was violated by the defendant and your verdict should be "guilty," as charged in the first count of the information, irrespective of whether the defendant knew of the deficiency or intended the deficiency or not. The statute is imperative, as I have stated, and absolute in its requirements, and demands that this drug, or fluid extract of cinchona, shall contain when sold and shipped in interstate commerce—that is, from one State to another State—at least 4 grams per 100 cubic centimeters of these anhydrous ether soluble alkaloids from cinchona as determined by the process or analysis described in the work mentioned. That, gentlemen, is the standard fixed by law for determining the contents of the fluid extract, and no other analysis can be substituted and furnish evidence which will constitute a defense when the analysis made according to law and pursuant to the mode prescribed by law shows to your satisfaction that the article was not up to the standard required.

And, gentlemen, it will not do to say that a lesser quantity of these anhydrous ether soluble alkaloids from cinchona per 100 cubic centimeters is or may be just as good and just as efficient as the quantities of these ether soluble alkaloids required by the statute. Congress has the right in the interest of the general public and in the exercise of its control over interstate commerce to prescribe the standard up to which certain drugs when shipped in interstate commerce must come, and in this case it has done so. This drug, fluid extract of cinchona, is a drug sold under and by a name recognized in the United States Pharmacopœia or National Formulary, and the statute expressly declares that such drug "shall be deemed to be adulterated if it differs from the standard of strength, quality, or purity as determined by the test laid down in the United States Pharmacopœia or National Formulary official at the time of investigation" and neither the court nor the jury is at liberty to surmise, guess, theorize, or speculate that the drug would be just as good if it did differ from that standard of strength, quality, or purity and contain a lesser quantity of the ingredients to which I have repeatedly called your attention—those being the essential ingredients of the fluid extract. Of course the variation from the standard fixed by law must be real and not imaginary or the result of guesswork, but if it does vary to any substantial amount in strength, quality, or purity from the standard fixed by the statute, then the case is made out irrespective of intent, as I have already stated, and irrespective of the effect of such adulteration on the health of the consumer.

The credibility of the witnesses who have testified in this case as well as their accuracy is for the jury to determine. Were the tests or analyses made

carefully, honestly, and intelligently by competent persons who knew how to do that which they undertook to do? You are to consider the experience and skill and knowledge of the men who made these tests of these fluid extracts in question. You are to note and consider the fact that the Government's chemists expert in this business as well as Prof. Ellery, from Union College, agree that in the respects named as to these essential ingredients as shown by their tests the fluid extract fell below the standard fixed by law.

You are to consider the fact that the chemist from Union College concedes that he threw away the wrapper and marks and writing thereon on the bottle of fluid extract given to him by the defendant and from the contents of which he made his analysis. It is for you to say whether or not the bottle given him and from which he took the samples which he subjected to his analyses and from which Mr. Grose and Mr. Kirschberg took theirs was the same bottle or container returned to the defendant by the Department of Agriculture. If the wrapper with the writing put there by Mr. Lind had been preserved it would have been better, but, gentlemen, the force and effect of this evidence in view of all the evidence produced and circumstances in the case established to your satisfaction, is for your consideration and determination.

So you are to consider in determining what the strength of this fluid extract really was in the respects named; the mode and manner adopted for bringing it up to the standard when found, after coming from the percolator, to be below that standard which is required by the law. The law would not be complied with if the defendant adopted an improper method of bringing it up to the standard, one which by mixing in the powder in the manner described brought certain parts of the fluid extract up to the standard and left other parts of it below the standard. You have heard the evidence on that subject as well as a description of the mode and manner or process by means of which fluid extract of cinchona is properly made. You have heard the evidence as to the three essential anhydrous ether soluble alkaloids found in fluid extract of cinchona. Considering the method used to raise the standard of this fluid extract after it came from the percolator it is for you to say under this evidence, did this fluid extract on being bottled and shipped in interstate commerce contain the anhydrous ether soluble alkaloids from cinchona required, viz, 4 grams per 100 cubic centimeters? In short the methods pursued in the manufacture are to be considered as well as the method adopted for bringing it up to the standard when found deficient as well as what was done in the various analyses made by the several witnesses who have given testimony in this case.

One or more of the witnesses for the defendant was employed by it to make a test or analysis, and one said that he knew something was depending on the result of the analysis he made. Did or did not this induce him to take any measures which would cause his analysis to show more of these essential alkaloids than it really did? And did he in fact have the sample that came from the Department of Agriculture? The chemists who gave evidence for the Government are in the employ of the Government and it is for you to say whether or not this fact has in any way affected them in giving their testimony and induced them to vary the test or analysis to any extent or in any way favorable to the Government.

This case is one of importance not only to the Government but to the defendant, as it involves the imposition of a fine on the one hand and the maintenance of the law, if it has been violated, on the other hand.

You are to act fairly, fearlessly, and impartially, and if satisfied beyond a reasonable doubt that this fluid extract of cinchona offered and shipped in interstate commerce by the defendant on or about the 8th day of November, 1912, did not then contain 4 drams per 100 cubic centimeters of the anhydrous ether soluble alkaloids from cinchona, then say "Guilty," as charged in the first count of the indictment.

If, on the other hand, you find from the evidence that the fluid extract mentioned did in fact contain 4 or more grams of the anhydrous ether soluble alkaloids from cinchona per 100 cubic centimeters when shipped, then your verdict will be "Not guilty."

It may be of interest, gentlemen, for me to say to you that a centimeter is a measure of length and is the 100th of a meter, or 0.3937 of an inch, which is considerably less than one-half an inch, while a gram is the unit of weight in the metric system, or 15.43 grains troy weight. Cinchona is the name of a tree, and from its bark is extracted certain anhydrous alkaloids or ingredients which are soluble in ether, and one of these is what we know as quinine,

useful in medicine and especially in certain fevers. Ether soluble alkaloids include quinine, quinidine, and chinchonidine.

You take the law from the court, of which the court is the sole judge. This is your sworn duty. You are sole judge of all the disputed facts and of the inferences to be drawn from conceded or proved facts. Conceded facts you are not at liberty to question, but when the evidence conflicts you are to decide. This is your sworn duty, guided by the principles of law to which your attention has been called. The credibility of the witnesses—their truth and accuracy—is for you.

The following requests by the defendant for charge to the jury were refused by the court:

8. This method laid down was not followed by the witnesses who testified for the plaintiff.

No. It is for you to say, gentlemen, in this evidence what the process used by the Government experts was; and was it the process described in this law as I have read.

9. The assays made by the witnesses for the United States are therefore not to be relied upon as giving correct results.

No. It is for you to say did this process followed give correct results.

19. That the result obtained by analysis by the Government chemists is not entitled to any greater consideration or respect by the jury than is the result obtained by other chemists of acknowledged standing and ability in their profession.

No, as written, but yes with this addition: "For the reason they are Government employees of [or] Government chemists. You are to consider their interest, if any, their character, their knowledge and skill and experience, and the care exercised by them in making their analyses; and say whether or not they were correct in view of all the evidence in the case, including that of defendant and its witnesses, and whether the defendant's witnesses were incorrect and inaccurate in their results."

The jury thereupon retired, and after due deliberation returned a verdict of guilty, and the court thereupon imposed on the defendant company a fine of $200.

CARL VROOMAN, *Acting Secretary of Agriculture.*