

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

7926-8100

FOODS

The cases reported herewith were instituted in the United States District Courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

MAURICE COLLINS, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., December 7, 1945.

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BEVERAGES AND BEVERAGE MATERIALS*

7926. Adulteration of beer and ale. U. S. v. Commonwealth Brewing Corporation and Leo Kaufman. Pleas of not guilty. Tried to the court and jury. Verdict of guilty. Fines, \$5,000 against both defendants. Individual defendant also given suspended sentence of 6 months in jail and placed on probation for 3 years. (F. D. C. No. 14309. Sample Nos. 63580-F, 63585-F, 63588-F, 63600-F, 63929-F, 79691-F, 79740-F to 79744-F, incl.)

INDICTMENT RETURNED: March 7, 1945, District of Massachusetts, against the Commonwealth Brewing Corporation and Leo Kaufman, treasurer and manager, Springfield, Mass.

ALLEGED SHIPMENT: Between the approximate dates of August 30 and September 29, 1944, from the State of Massachusetts into the States of South Carolina, Florida, Virginia, and West Virginia.

LABEL, IN PART: "Gold Medal Tivoli Beer," "Worcester Stock Ale," "Bay State Beer," "Oxford Brand Beer," "Dartmouth Cream Ale," and "New England Ale." VIOLATION CHARGED: Adulteration, Section 402 (a) (2), the product contained an added poisonous or deleterious substance, fluorine, which was unsafe within

*See also Nos. 8089, 8097.

the meaning of the law since it was not required in the production of the product and could have been avoided by good manufacturing practice.

DISPOSITION: Pleas of not guilty having been entered on behalf of the defendants, the case came on for trial before a jury on May 22, 1945, at the conclusion of which the court delivered the following instructions to the jury:

FOOD, DISTRICT JUDGE: "Before I explain to you what a reasonable doubt is, it has been explained to you in more or less detail by one of the counsel—before I come to that, gentlemen, I want to say to you what our different provinces are. Counsel has explained them to you.

"The facts are for you. You, as has been said by counsel, are the sole arbiters of the facts, to decide the facts. I give you the law, and you must take your law from me. If I make an error with respect to the applicable principles of law, then of course I can be corrected by a higher court. The credibility of the witnesses is for you. Do you believe the witnesses? Do you believe them in whole or do you believe them in part? The credibility of the witnesses is for you, as I have said.

"Now, when you pass upon the credibility of a witness decide whether or not he is telling the truth, deciding what part, if any, of the evidence is credible, then of course you can take into consideration his appearance on the stand, the manner in which he answered the questions, whether he has any bias or prejudice with respect to the case itself, and generally decide how much of his evidence—*any* witness in *any* case—how much of his evidence you will believe in looking at him, hearing him. That is your province exclusively.

"There is one other principle here that is applicable. Failure of the defendant here, the individual defendant, Kaufman, to take the stand and testify in his behalf, raises no presumption against him. No prejudice must arise against him for not taking the stand. That applicable rule and principle is expressed in a United States case which reads as follows: 'In the trial of all indictments against persons charged with the commission of crimes in the United States Court, the person so charged shall of his own request be a competent witness and his failure to make such request shall not create any presumption against him.' That is, he is not obliged to testify, gentlemen, unless he desires to. He may testify if he wishes, and if he does not he cannot be prejudiced because of that fact.

"Now, I said to you that the burden is upon the Government to prove every essential element of the offence charged beyond a reasonable doubt, and later I shall go on and tell you what the Government charges, what the essential elements of the charges are in detail.

"Counsel has described to you, has defined what a reasonable doubt is, proof beyond a reasonable doubt, and I like to read what has been said by, if not the Supreme Court, one of the other courts, in deciding what a reasonable doubt is, the quantum of proof, how much proof the Government must adduce before you would be warranted in finding a defendant in any case guilty. 'Reasonable doubt is such a doubt as would affect the mind and judgment of the ordinary reasonable and prudent person in making decisions on important matters. Proof beyond a reasonable doubt has been defined correctly as 'not beyond all possible or imaginary doubt. * * * but such proof as precludes every reasonable hypothesis except that which it tends to support. It is proof to a moral certainty as distinguished from an absolute certainty.'

"It is said in other cases and at other times that it is proof beyond a probability but not an absolute certainty. The term 'reasonable doubt' means a doubt which is substantial, not shadowy. It does not mean a doubt born of reluctance on the part of a juror to perform an unpleasant duty or a doubt arising out of sympathy for a defendant or out of anything other than a candid consideration of all the evidence presented. 'While it is a requisite to a verdict of guilty that the prosecution prove the guilt of the accused beyond reasonable doubt, the doubt to the benefit whereof the accused is entitled must be the doubt that a rational sensible person may fairly entertain; not the doubt of a vacillating mind that has not the moral courage to decide.'

"Now, gentlemen, with those principles in mind, applicable to all criminal cases—and in all criminal cases the duty is imposed upon the Court to lay down those principles before proceeding to the charge, and it would be error on the part of the Court if those instructions were not presented to you—this brings us to the present indictment, Mr. Foreman and gentlemen, and the indictment with which we are concerned here is an indictment in eight counts, eight differ-

ent shipments, and each count charging a separate shipment in violation of Section 301a of the Food, Drug and Cosmetic Act. The indictment simply charges that these defendants introduced and delivered and caused to be introduced and delivered for introduction into Interstate Commerce the aforesaid certain food which was then and there adulterated within the meaning of said Act of Congress, and then defines the Act which I shall refer to in more or less detail. This is the charge in the indictment, and here is where you take it from, the indictment, the charge made in accordance with the applicable section of the statute. Here is where we find the essential elements of the charge which I shall point out to you and which the Government is required to prove beyond a reasonable doubt, in that it contained an added poison or deleterious poison, flourine, which was unsafe within the meaning of the statute, the particular section of the statute, since it was a substance not required in the production of this beer and could have been avoided by good manufacturing practice.

"Now, we all know it generally, but there is a history back of the Food, Drug and Cosmetic Act. I think it was shortly after the turn of the century, some time if I am correct, but I am sufficiently correct in saying, in 1906 I know, the Food and Drug Act was passed by Congress, and at that time Congress wanted to scrape out the evils that were present in the United States of America, with respect to the adulteration of foods, the presence of poisonous and deleterious and impure substances in food, and also to protect the public against fraud with respect to food products, misbranding by having labels misbranded where the public were being cheated.

"In 1906 Congress passed the Pure Food and Drug Act and with various amendments we come down to the Act, I think the date of this Act is 1938. It is now called the Pure Food, Drug and Cosmetic Act. Well, pure is not in there, it is called the 'Food, Drug and Cosmetic Act.' We always find what the name of the Act is in the Act itself, and this designates it. It may give you some idea in the sections of this statute what Congress was going to do, in the sections where it defined an adulterated food. It said, 'A food shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substances which may render it injurious to health.' I will have occasion to refer specifically to this question later. And note this also: 'but in case the substance is not an added substance,' and it becomes here a question of an added substance. Congress provided in this particular section, (a) (1) of 242 of 21 U. S. C. A.—that is not the exact section of the Act itself, I am reading Section 402—Congress said, 'In case the substance is not an added substance—that is not our case, as I will point out to you later, 'but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.' And the clause with which we are here concerned, the section of the statute under which this prosecution is brought, refers to food which may contain any added poison or added deleterious substance. Here we have the added aspect of substance where we did not have it in the first section which is 'unsafe within the meaning of Section 346,' because that is the section of the statute as I say under which this prosecution proceeds.

"Then it provides a section with respect to the presence of filthy, putrid or decomposed substances in the food, and then protected the public by the passage of this statute which Congress made as to food under unsanitary conditions so that the food would be rendered contaminated.

"I read those sections to you to show the purpose that Congress had in passing these food and drug acts. This act itself is denominated 'Food, Drug and Cosmetics.' It went along and protected the public in the same direction with reference to the adulteration and misbranding of cosmetics as well as food and drugs.

"Now, the section of the Act which the defendants are charged with violating here among those sections that I have just read is Section 301 of the Act. Section 301 of the Act prohibits the introduction or delivery into Interstate Commerce of any food that is adulterated, and since Congress here and the Act itself have defined food as meaning articles used for food or drink for man or other animals, the beer with which we are concerned here is a food.

"Congress further defined the meaning of 'adulterated food' as follows in Section 402, Subdivision (2), of the Act: 'A food shall be adulterated: If it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of Section 406,' and Section 406 of the Act

with which we are concerned here said that any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice, shall be deemed to be unsafe for purposes of the application of this clause I have just read to you.

"With these pertinent clauses of the food and drug act in mind, we return to the indictment, as I said to you before, and find out what the Government charges and what are the essential elements that the Government must prove. The essential elements of the charge that the Government must prove beyond a reasonable doubt in order to warrant a conviction of the defendant corporation and the defendant Kaufman are: First, the Government must prove beyond a reasonable doubt that the defendant corporation, as I have already read to you from the indictment, these defendants with making eight separate interstate shipments of beer. With respect to the corporation it is admitted here that the corporation actually shipped the beer. With respect to the defendant Kaufman I understand it is agreed that he was the treasurer of the corporation, its general manager, and I don't know that there has been any agreement that he actually participated or shared in the responsibility of shipping the beer. Is that disputed?"

MR. LEWIS: "Yes, your Honor."

THE COURT: "In view of the fact that it is disputed the burden is upon the Government to prove that Kaufman shared the responsibility of shipping this beer interstate. Even though it has appeared that the corporation actually shipped the beer, the corporation through its duly authorized agents, the burden is upon the Government to show that Kaufman himself individually participated in the shipment or he shared in the responsibility for the shipment, and when you decide this fact as to whether Kaufman shared in the responsibility of these shipments, you will take into consideration the fact—and I think it has been testified to here—that he owned all the stock in the corporation, that he was treasurer and clerk and general manager, and then take into consideration the evidence with respect to his control of the affairs of the brewery that have been testified to here and described to you by the Government inspector Hannigan, who interviewed him at the brewery and furnished to him the different ingredients or pieces of evidence that have been introduced here. Take that all into consideration in deciding the fact as to whether or not Kaufman himself individually, as treasurer of the corporation or general manager of the corporation shared in the responsibility of these shipments interstate, Mr. Foreman and gentlemen. That fact is for you to decide."

"Now we will proceed from the interstate aspect of this charge to the next essential element, that the Government charges—and I want you to have in mind that it must prove beyond a reasonable doubt—the Government charges and will have to prove to warrant a conviction of the defendants that fluorine in some form was added to the beer by the corporation, acting through its duly authorized agents, or by Kaufman, and I mean Kaufman through himself or his authorized agents or employees."

"I want to point out to you that it is entirely unimportant and irrelevant how much the quantity of fluorine was which was added to the beer. The issue is, Was fluorine in some form added as an ingredient? If, as one of the Supreme Court cases say, it is an added deleterious ingredient, the statute denounces that. It is an added deleterious ingredient, the statute denounces that. It is an added deleterious ingredient, the statute denounces that. It is an added deleterious ingredient."

"Thus the gravamen or material charge in the section of the statute with which we are concerned is the addition of the deleterious substance and the quantity of the deleterious substance is of no moment. Hence, with respect to this element of the offence charged, if you find fluorine in any form was added,—and I say beyond a reasonable doubt,—then the Government has sustained its burden in that connection."

"To emphasize the fact—and I want to make this plain—that the quantity of fluorine added to the beer has no relevancy here, I think I might point out to you that there is a section of the Food and Drug Act—I have already read it—where the quantity contained in a food may be of considerable importance, and that is where it has been charged under Section 402 (a) (1) of the statute which deals with adulterated foods where the deleterious substance has not been added. That section reads as follows: 'A food shall be deemed to be adulterated (a) (1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health.'

"Quantity is of course important in determining whether or not it may be harmful, and quantity would be the test under this section, but not by any means under the section of the statute with which we are concerned here."

"Congress recognized that nature's products such as grain, salt, hops, water, contained poisonous substances in small amounts and that they were not a danger or evil so long as the poisonous substance was not extracted by artificial process and added, and the users of these substances in their product are not punishable provided the quantity of such substances in the food does not ordinarily render it injurious to health."

"To repeat, in this latter section that I have just read to you as to quantities, and the only question involved where it is added is, was it added? Was it deleterious? Was it unsafe?"

"There are some other considerations and some other matters of importance in this case that I want to point out to you at this point so that you will have these issues clearly before you and so that you will have an intelligent and a knowing idea of just what you are to decide here."

"It is of no importance under the section of the statute under which these defendants are being prosecuted that no evidence has been introduced to show someone drank this beer and was harmed. The question here is, not whether the beer was harmful—'deleterious' is the word in the statute, but whether the fluorine if it was added was harmful."

"It is of no importance that an expert witness who took fluorine into his system said he was not harmed as far as he knew. In fact, though he said he felt no harmful effects, yet he still may have been harmed, according to the evidence. What did he say? As I remember the testimony—and remember although I had a right to comment and give my opinion on the testimony, yet the testimony is for you in the last analysis—this witness said, as I remember, that he was not in a position to know whether he was harmed or not, but he felt no ill effects himself."

"The Government does not have to show in this case how much beer would have to be drunk to harm a person."

"It is of no importance in this case that tea or salt contain fluorine in quantities not harmful to health if ordinarily used."

"It is of no importance that one bottle of this beer or five or fifty would or would not be harmful if drunk. The question to keep before you is whether fluorine itself is harmful and poisonous, and if so the statute says it cannot be added in any form to a food product without running afoul of the law."

"Now, we pass on to the essential elements of the Government's charge. Is fluorine a poisonous or deleterious substance? You have heard the testimony of all the experts with respect to this particular issue as to whether or not fluorine is deleterious or harmful. You heard the testimony, I think it was of Professor Carlsson, how he described it. I think he said that eight parts in a million were harmful, that it was harmful if it contained, or anything containing eight parts in a million. And then you heard the testimony of other experts with respect to whether or not this fluorine was a poisonous or deleterious substance."

"These words in the statute, 'poisonous and deleterious' have their plain, natural meaning, Mr. Foreman and gentlemen, and 'poisonous' defined by Webster's New International Dictionary is, 'Any agent which introduced into an organism, may chemically produce an injurious or deadly effect'. And 'deleterious' is defined as 'hurtful or destructive'."

"Take into consideration—I am not going to repeat it in detail—all the evidence you have heard here. Take into consideration the fact that fluorine would kill rats, take into consideration the testimony of the Professor, Dr. McNally, for the defendant, who said, I believe, that if he drank enough fluorine, assuming that it contained 45.2 parts per million, if he drank about 15 bottles of this beer he would be apprehensive at that point because he had given about that amount of fluorine to rats and killed rats with it."

"Now, taking into consideration the plain meaning of the word 'poison', that poison in any agent which, introduced in an organism, may chemically produce an injurious effect, and taking again into consideration, keeping in mind 'deleterious', its plain meaning, natural meaning in the statute, that it means hurtful or destructive, on all the evidence you have heard here, answer the question in your own minds."

"The Government must prove beyond a reasonable doubt, of course, that

"I cannot impress upon you too much but to point out to you again, to repeat, that the issue is whether this beer that these defendants put out, that the corporation put out, that Kaufman put out, and sent interstate is deleterious. The question is, is fluorine itself deleterious?"

"The next element the Government must prove is that the fluorine was unsafe within the meaning of the statute, and what is unsafe has been defined, so I charge you that if the Government has proved beyond a reasonable doubt that the fluorine was not required and could be avoided by good manufacturing practice, you would be warranted in finding that the beer was unsafe, the food here or beer was unsafe within the meaning of the statute.

"We have had with respect to that particular issue the testimony of the brewer from the Boston Brewing Company. There was no other evidence in the case on that point. He said categorically, as I remember, that fluorine was not necessary in the production of beer and it could be avoided by good manufacturing practice.

"I have outlined all the essential elements charged, and if you can find that the Government has proved them all beyond a reasonable doubt you will find both the defendants guilty. On the other hand, if the Government has failed to prove any one of the essential elements of the charge, you will find the defendants not guilty.

"There is just one other matter and I am done. In many offences that we try here in the criminal court, intent, knowledge or conscious wrong-doing is an essential element of the offence. This is referred to generally and commonly as 'criminal intent'. However, the Government does not have to establish any criminal intent here. Kaufman, if he shipped beer or shared in the responsibility or participated in the shipping of this beer interstate, did so at his own risk. The Government does not have to prove he knew it contained fluorine. If he shared in the responsibility of the shipments, the beer contained added fluorine and that fluorine was poisonous and deleterious and unsafe within the meaning of the statute, that is, it was adulterated, it would be of no consequence whether or not the beer was adulterated through his intention or negligence, or that he had knowledge of it or that he was acting in good faith. As Mr. Lewis pointed out here good faith is no defense, and as I said before, the defendants, if they shipped adulterated beer, they did so at their own risk.

"There is just one other matter to point out to you. In a criminal case verdicts are rendered orally. When you return to this court room you will be asked to give me your verdict with respect to each separate count and you will be asked whether or not you find the defendants guilty or not guilty, with respect to Count One right through to Count Eight.

"I will see counsel now."

(After a conference with counsel, the court further charged the jury):

THE COURT: "Just one additional thing, Mr. Foreman and gentlemen. You will take the case and retire to your jury room and decide it. It is not incumbent upon the Government to show specifically how the fluorine, if you find it was added, was put into the beer. There has been no testimony as I understand it, and the Government experts could not determine the exact form in which it was put into the beer, so that I charge you that it is not incumbent on them to show specifically how the added substance, if it was added, was added. The burden is on them to show it was added. There is no burden upon them to show how it came into the beer."

The jury returned a verdict of guilty on all counts against both defendants, and on June 6, 1945, the court imposed fines of \$5,000 against each defendant, and further imposed a suspended sentence of 6 months in jail upon the individual defendant and placed him on probation for 3 years.

7927. **Adulteration of beer and ale.** U. S. v. 1,160 Cases of Beer (and 30 other sets ordered destroyed. Cases and bottles in a number of instances ordered destroyed. (F. D. C. Nos. 13806, 13875, 13979, 14020, 14051, 14052, 14063, 14377, 14397, 14074, 14087 to 14090, incl., 14095, 14097, 14118, 14326, 14530, 14571, 15101, 15404, 14432, 14621, 14666, 14875, 14876, 14904, 15470, 15471, Sample No. 15475-F, 61385-F, 61384-F, 63594-F to 63600-F, incl., 63752-F, 63753-F, 63754-F, 63755-F, 63756-F, 64201-F, 79687-F to 79691-F, incl., 79735-F, 79740-F, 80143-F, incl., 83778-F, 83929-F, 84201-F, 85247-F, 88559-F, 88562-F, 88569-F, 92918-F, 30830-H, 31508-H, 31509-H.)

LABELS FILED: Between the approximate dates of October 7, 1944, and March 5, 1945, Middle and Western Districts of North Carolina, Eastern District of North Carolina, and Middle and Western Districts of West Virginia.

District of Massachusetts, Southern District of California, and Western District of South Carolina.

ALLEGED SHIPMENT: Between the approximate dates of July 21 and November 2, 1944, in most instances by the Commonwealth Brewing Corporation, from Springfield and Boston, Mass. A number of lots which had been originally shipped by this firm were returned to Springfield during this period by the consignees from Jacksonville, Fla., Fayetteville, N. C.; Richmond, Va., Shenectady, N. Y., Norfolk, Va., Raleigh, N. C.; Charleston, W. Va., and Greenville, N. C. Two lots were shipped by the Manhattan Distributing Co., from Springfield, Mass., during the same period.

PRODUCT: Beer or ale: 17,628 cases at Springfield, Mass., 3,687 cases at Rock Hill, S. C., 2,158 cases at Norfolk, Va., 1,157 cases at Charlotte, N. C., 188 cases at Greenville, S. C., 494 cases at Gastonia, N. C., 1,298 cases at Aberdeen, N. C., 1,100 cases at Beaumont, Tex., 1,728 cases at Hattiesburg, Miss., 1,999 cases at Fort Fairfield, Maine, 96 cases at Jacksonville, Fla., 1,600 cases at Richmond, Va., 228 cases at Graham, N. C., 2,177 cases at Greensboro, N. C., 1,102 cases at Los Angeles, Calif., 680 cases at Ingleswood, Calif., and 2,000 cases at Charleston, W. Va.

LABEL, IN PART: "Gold Medal Tivoli Beer for 'Bay State Beer,' 'Dartmouth Cream Ale,' 'Oxford Brand Beer,' 'Oxford Brand Ale,' or 'Victory Extra Rich Old Stock Beer.' Commonwealth Brewing Corporation, Springfield, Mass., 'New England Ale,' or 'Ace-Hi Brand Deluxe Beer' Bottled Exclusively for Schaefer Distributing Co. Little Rock, S. C. By Commonwealth Brewing Co. Springfield, Mass."

VIOLATION CHARGED: Adulteration, Section 402 (a) (2), the product contained an added poisonous and deleterious substance, fluorine, which was unsafe within the meaning of the law since it was a substance not required in the production of the product and could have been avoided by good manufacturing practice.

DISPOSITION: Between October 17, 1944, and May 4, 1945. The Commonwealth Brewing Corporation, Springfield, Mass.; Ben Hefner, Beaumont, Tex.; Louis R. F. Murrad, trading as the Central Distributing Co., and Lee Cassis, Charleston, W. Va.; the Charlotte Wine and Beer Distributing Co., Charlotte, N. C.; James Ingram, Los Angeles, Calif.; and Charles Ehrlich, Los Angeles, Calif., having appeared as claimants for respective lots, judgments of condemnation were entered and the products were ordered released, conditioned upon the destruction of the beer and ale. The bottles and cases were returned to the claimants or the shipper. No claimant having appeared for the remaining lots, judgments of condemnation were entered and the products were ordered destroyed. In some instances, the court ordered the cases and bottles salvaged.

"ORDERED, ADJUDGED AND DECREED that the allowable claims that may be made as to the need for, or usefulness of, Nutrilite Food Supplement XX, Nutrilite Food Supplement X, and Nutrilite Food Supplement Junior, shall be limited to the following:

"1. These articles, when taken as directed, will supply to the user's diet the vitamins and minerals stated on the labels in the amounts and proportions of the minimum daily requirements stated on their labels.

"2. The need in human nutrition has been established for the following vitamins and minerals contained in Nutrilite Food Supplement:

Vitamin A	Calcium
Vitamin D	Phosphorus
Vitamin B-1 (Thiamin)	Iodine
Vitamin B-2 (Riboflavin)	Copper
Vitamin C (Ascorbic Acid)	Iron
Vitamin K	
Vitamin B-6	
Niacinamide	
	Manganese
	Zinc
	Cobalt
	Nickel
	Fluorine

but the need in human nutrition has not been established for the following vitamins and minerals contained in Nutrilite Food Supplement: