

* * * Enlarged, Capped and Injured Knee * * * Sprung Knee
 * * * Splint * * * Ringbone or 'Cling-Fast,' and 'Osslets' * * *
 Side-bone * * * Hoof-Bound and Founder * * * 'filled' Tendon
 * * * Bowed Tendon."

On November 1, 1934, no claimant appearing, judgment of condemnation was entered, and it is was ordered that the product be destroyed.

M. L. WILSON, *Acting Secretary of Agriculture.*

24037. Alleged adulteration and misbranding of thyroid gland capsules.
 U. S. v. George A. Breon & Co., Inc. Tried to the court. Judgment of guilty on one misbranding count; not guilty on remaining counts. Appeal to the Circuit Court of Appeals. Judgment reversed and case remanded. (F. & D. no. 31336. Sample nos. 13916-A, 13917-A.)

On January 12, 1934, the United States attorney for the Western District of Missouri, acting upon a report by the Secretary of Agriculture, filed in the district court an information against George A. Breon & Co., Inc., Kansas City, Mo., alleging shipment by said company in violation of the Food and Drugs Act as amended, on or about August 24, 1932, from the State of Missouri into the State of Ohio of quantities of thyroid gland capsules which were adulterated and misbranded. The article was labeled in part: "Capsules * * * Thyroid Gland Substance (Desiccated) 1-4 Gr. [or "1 gr."]" * * * Geo. A. Breon & Co., Inc., Kansas City, Mo."

The article was alleged to be adulterated in that its strength and purity fell below the professed standard under which it was sold in that the capsules were represented to contain $\frac{1}{4}$ grain and 1 grain, respectively, of desiccated thyroid, whereas the former contained more than $\frac{1}{4}$ grain and the latter contained less than 1 grain of desiccated thyroid.

The article was also alleged to be misbranded in that the statements "Capsules * * * Thyroid Gland Substance (Desiccated) 1-4 gr. [or "1 gr."]", borne on the bottle labels, were false and misleading.

On February 5, 1934, the defendant filed a motion to quash, and subsequently filed a demurrer and a motion for a bill of particulars, which were argued March 26, 1934, and overruled. On April 5, 1934, a jury having been waived, the case was tried to the court, and judgment was entered finding the defendant guilty on the count charging misbranding of the $\frac{1}{4}$ -grain capsules, and not guilty on the remaining counts. On April 19, 1934, motions in arrest of judgment and for a new trial were overruled, and on the same date the defendant filed its petition for appeal and assignment of errors. On November 19, 1934, the judgment of the lower court was reviewed in the circuit court of appeals for the eighth circuit, was reversed, and the case was remanded with the following opinion (Gardner, *circuit judge*):

"This is an appeal from the judgment of the lower court finding appellant guilty upon the second count of an information charging it with having shipped in interstate commerce a bottle containing one hundred capsules labeled, "one-quarter grain desiccated thyroid", and charging that the same was misbranded under the Food and Drugs Act (Title 21, U. S. C. A., secs. 1 to 25), in that said capsules contained more than one-quarter grain desiccated thyroid.

"We shall refer to the appellant as defendant.

"The information contained four counts. Trial by jury was waived, and the court, at the conclusion of the evidence, found the defendant not guilty on counts 1, 3, and 4, but found it guilty on count 2. Defendant interposed a demurrer to count 2, on the ground that unless the contents of the capsules fell below the indicated strength and purity, it was not a violation to ship them. The court overruled the demurrer, and also overruled defendant's demurrer to the evidence as to this count.

"On this appeal it is contended (1) that the court erred in overruling the demurrer to count 2 of the information; (2) that the evidence is insufficient to warrant a conviction; and (3) that the verdict is against the declaration of law given by the trial court.

"It is earnestly urged by defendant that furnishing an excess of the identical drug stated on the label, the drug being a harmless and wholesome one, is not a crime, and that the Pure Food and Drugs Act was intended to protect public health and prevent fraud, and hence, does not apply to a case where health is not endangered, and no fraud is committed. The Government, on the other hand, contends that the act was passed for the purpose of protecting the general public, to preserve their health, and to prevent their being deceived by

label or fraud as to the real character of the article offered for sale, and that where drugs are involved, the act requires a correct statement on the label.

"Section 9, of Title 21, U. S. C. A., provides:

The term "misbranded" as used in sections 1 to 15, inclusive, of this title, shall apply to all drugs, or articles of food, or articles which enter into the composition of food, 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, and to any food or drug product which is falsely branded as to the State, Territory, or country in which it is manufactured.

"Section 10, of Title 21, U. S. C. A., provides in part as follows:

For the purposes of sections 1 to 15, inclusive, of this title, an article shall be deemed to be misbranded;

Drugs. In case of drugs:

Imitation or use of name of other article.—First. If it be an imitation of or offered for sale under the name of another article.

Removal and substitution of contents of package, or failure to state on label quantity or proportion of narcotics therein.—Second. If the contents of the package as originally put up shall have been removed, in whole or in part, and other contents shall have been placed in such package, or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilid, or any derivative or preparation of any such substances contained therein.

False statement of curative or therapeutic effect.—Third. 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.

"It appears from the evidence in this case that the drug involved is not a potent, poisonous, or harmful one, and that no harm would result to a person from taking capsules containing approximately one third of a grain of thyroid, instead of a capsule containing one quarter of a grain of thyroid, nor, indeed, from the taking of a series of bottles of such capsules. This is not a case in which the defendant is charged with adulteration, but with misbranding, and a falsity of the label is not as to the ingredients or substances contained in the capsules, but as to the quantity contained therein. The Government contends that the label is false and misleading within the meaning of section 9, title 21, supra, and that it is not material that the drug was a harmless and wholesome one, nor that the label understated the amount of such drug. It is persuasively argued by defendant that the added strength or quantity of thyroid could not have been within the purpose of this statute, and that the statute was aimed at the giving of a less amount, rather than an excess, and by way of illustration it is said in counsel's brief:

If I sell a package of butter which is labeled "Pure Creamery Butter, net weight 1 Lb.," it is necessary to determine the strength, quality, and purity of the butterfat and other articles contained in this substance, in order to determine whether or not it is the identical thing stated, namely, pure creamery butter, but if it is pure creamery butter, and I sell in the package 18 ounces of the pure creamery butter instead of the 1 pound net weight declared on the label, there is no misbranding, because I have sold the identical thing or substance which the label declares. I have merely given the purchaser good measure, and I have violated no law.

"In the view we have taken of the other issues involved, however, we do not deem it necessary to pass upon this question.

"At the request of defendant, the court gave the following declaration of law:

The court declares the law to be that the burden is upon the Government to show beyond a reasonable doubt that the thyroid mentioned in counts one and two contained more than $\frac{1}{4}$ grain of thyroid, and in such quantity as not to permit a reasonable tolerance or variance, and if the court finds and believes from the evidence that the assay made by the Government chemists under the supervision of the Secretary of Agriculture, was not correct, or if there is a reasonable doubt as to the accuracy of such assay, if any, then the court should find the defendant not guilty as charged in the first and second counts of the information.

"The United States Pharmacopoeia prescribes a method for determining the iodine content of powdered thyroid. It also states that, 'Thyroid contains not less than 0.17 and not more than 0.23 percent of iodine in thyroid combination, and must be free from iodine in inorganic or any other form of combination than that peculiar to the thyroid gland.' The capsules in question contained in addition to thyroid: Calcium, phosphate, carbonate, and starch. One of the Government's experts testified that using the method of analysis prescribed by the United States Pharmacopoeia, he obtained a 53 percent excess in an analysis of 30 of the $\frac{1}{4}$ -grain capsules. On analyzing 10 more, the result was within 3 percent of the first analysis. Another of the Government's experts testified that using 20 of the quarter-grain capsules, he found a 42 percent excess.

"Counts 3 and 4, which were dismissed, charged violation of the act on the shipment of a bottle of thyroid capsules which were alleged to be adulterated,

and the bottle to be misbranded because the label stated the capsules contained 1 grain of thyroid, while they contained only a small percent of a grain. It is interesting to observe that one of the Government's chemists testified that the 1-grain capsule showed 0.12 grain of thyroid, while the other Government chemist found approximately only 0.032 grain per capsule. At the trial the Government produced six of the 1-grain capsules and offered to have the Government's chemist and the defendant's chemist analyze them. The analysis was thereupon made in the United States Pure Food and Drug Laboratory at Kansas City, in strict accordance with the United States Pharmacopoeia method. The result obtained showed 6.82 grain of thyroid per capsule. This was admitted by all the expert witnesses to be an impossible result, as each capsule was only a 4-grain capsule to begin with, consisting of 1 part thyroid powder and 3 parts filler.

"Defendant introduced in evidence the formula used in making the quarter-grain capsules, showing that the proper amount of filler was used to produce $\frac{1}{4}$ -grain thyroid per capsule. One of the Government's chemists testified, on cross-examination, that in the quarter-grain capsule, if the mathematical proportions were proper by weight, and the thyroid substance used was a proper thyroid substance, and the blending was properly done, each capsule should assay the $\frac{1}{4}$ -grain thyroid allowing for 100-percent efficiency in the mixture. This witness also testified, on cross-examination, that various contents mixed with thyroid powder might cause various results in analysis, depending upon the nature of the material. Another testified, on cross-examination, that there might be a variance in the result of analysis performed by two men working under the same conditions, analyzing the same substance, but that it would be impossible for him to give a general idea as to what the amount of disagreement or discrepancy might be.

"As this is a criminal case, it was, of course, incumbent upon the Government to prove the charge by evidence that satisfies beyond a reasonable doubt that the defendant was guilty of the charge. *Lilienthal's Tobacco Co. v. United States* 97 U. S. 237; *Potter v. United States* 155 U. S. 438; *Davis v. United States* 160 U. S. 469; *Tinsley v. United States* (CCAS) 43 Fed. (2d) 890; *Read v. United States* (CCAS) 42 Fed. (2d) 636; *Salinger v. United States* (CCAS) 23 Fed. (2d) 48.

"The sufficiency of the evidence was challenged by proper motion for judgment of acquittal and demurrer to the evidence interposed at the close of the case. Unless, therefore, there was such substantial evidence in this case, it was the duty of the trial court, a jury being waived, to acquit the accused, and if all the substantial evidence is as consistent with innocence as with guilt, it is the duty of this court to reverse the judgment against the accused.

"It is contended by defendant that there was no evidence that the thyroid in these capsules, in combination with the other elements contained therein, was subject to accurate analysis and assay under the method prescribed in the pharmacopoeia. The pharmacopoeia formula or method appears to contemplate thyroid unmixed with other substances for its analysis. In the one analysis of the 1-grain capsule, made during the trial, the Government's chemist found 6.82 grains of thyroid per capsule, while in another he found 3.2 percent of 1 grain per capsule. This is a variation of about 22.000 percent in net result. The analysis showing 6.82 grains of thyroid is, of course, not only absurd but impossible, and this evidence places the stamp of uncertainty and unreliability for all practical purposes upon the method employed. The variations are so pronounced as to be startling.

"The court, in its decision and findings, among other things said, in referring to the third and fourth counts of the information: The chemists who have testified, both for the Government and for the defendant, undoubtedly are men of the finest character and ability in their profession, absolutely honest, but the testimony as to the Government on the one side, is diametrically opposed by the testimony on the other. That is, the original testimony offered by the Government and by the defendant was in direct opposition in that regard. If that testimony remained in that situation it would have been impossible to say that the Government had proved its case beyond a reasonable doubt. Upon the suggestion of the Government, however, at the close of the evidence, which suggestion the defendant accepted, an analysis was made by the chemists jointly of a part of the shipment referred to in counts 3 and 4. Well, that analysis showed that each of the capsules contained 6 grains of thyroid instead of 1 grain. It was an analysis which didn't help the Government any, and if it is certain that it is an impossible analysis, which is conceded, must be conceded,

it brings into some doubt the accuracy of the analysis testified to by the witnesses for the Government. * * * The other evidence which was offered by the defendant as to the manner of manufacture of these capsules, the care that is taken in the manufacture of the capsules to see that they went out just as represented and to see to it that there was no violation of any of the requirements of the law or of the regulations, that evidence convinces me that the defendant did not intentionally violate the law; on the contrary did everything that reasonably could be done apparently to comply with the requirements of the law. As the case stands, it seems to me I must find it has been proved beyond a reasonable doubt that the capsules which were in this shipment referred to in the second count of the information did contain a very slight excess of thyroid above the one-fourth grain which it was represented that they contained upon the label attached to and affixed to the bottle. The only argument that is advanced against that conclusion is that this method of analysis, the method of analysis which was used, is inaccurate, does not permit of an accurate result. Well, I don't know whether it permits of an accurate result or does not permit of an accurate result. * * * There is so little in this testimony to justify any punishment at all upon the defendant—nothing except a very technical violation of the law—that even if I were to consider this plea of *nolo contendere*, I don't think I would add anything to the punishment imposed.

"We are of the view that the lower court not only entertained but expressed a reasonable doubt of the guilt of the defendant, and we think the familiar rules applicable in criminal cases have not been satisfied in this case. The judgment appealed from is therefore reversed, and the cause remanded with directions to grant defendant a new trial."

M. L. WILSON, *Acting Secretary of Agriculture.*

24038. Misbranding of Beach's Gen-Sen Tonic. U. S. v. Frank E. Beach (Beach's Wonder Remedy Co.). Plea of guilty. Fine, \$100. (F. & D. no. 31453. Sample no. 39150-A.)

This case was based on an interstate shipment of Beach's Gen-Sen Tonic, the labeling of which contained unwarranted curative and therapeutic claims.

On May 25, 1934, the United States attorney for the Eastern District of South Carolina, acting upon a report by the Secretary of Agriculture, filed in the district aforesaid an information against Frank E. Beach, trading as Beach's Wonder Remedy Co., Columbia, S. C., alleging shipment by said defendant in violation of the Food and Drugs Act as amended, on or about June 6, 1933, from the State of South Carolina into the State of Georgia of a quantity of Beach's Gen-Sen Tonic which was misbranded.

Analysis showed that the article consisted of extracts of plant drugs including aloes and senna, magnesium sulphate, benzoic acid, glycerin, and water, flavored with oil of anise and methyl salicylate.

The article was alleged to be misbranded in that certain statements, designs, and devices regarding its curative and therapeutic effects, appearing on the bottle labels, cartons, and in a circular enclosed in the said cartons, falsely and fraudulently represented that it was effective as a tonic; effective to aid and benefit the blood, liver, kidneys and stomach; effective as a treatment for kidney and bladder trouble, rheumatism, impure blood, sluggish or torpid liver, loss of appetite, indigestion, female trouble or weakness, and worms in children; effective as a constructive tonic aid for enriching the blood, building the strength and improving the health in general; effective as a treatment, remedy, and cure for rheumatism, consumption, poison in the blood, and worms in children and adults; effective as a treatment, remedy, and cure for indigestion, irritation, pains in the belly, irritation or itching at the lower end of the bowels, alternation of diarrhoea and costiveness, great thirst and variable and often voracious appetite, fetid breath, pale, sallow and leaden complexion, occasional flushes, swelling of the upper lip, watery mouth, enlargement of the nostrils, livid circles around the eyes, dilation or contraction of the pupil, fixed unmeaning expression, enlargement of the belly, disturbed sleep, dry cough, headache, slow fever, spasmodic or convulsive affections, remittent fever, great drowsiness, morbid restlessness, pain in the bowels and pit of the stomach, gastric distress, affected head, stupor and delirium in children due to worms, temporary blindness, loss of memory, forgetfulness, falling vitality, lost manhood, fluttering action of the heart, palpitation of heart, shortness of breath, rolling or throbbing sensation in stomach, varying appetite, pain in small of back, bad stomach, irregular bowels,