

its label, had to do with the identity of the article. A tablet which contains 2.4 grains of thyroid and 1.6 grains of sugar, talcum, and acacia is not identical with a tablet which contains 2 grains of thyroid and 2 grains of the other substances. It is therefore not necessary to resort to an absolutely literal construction in order to cover the defendant's act. The more limited interpretation placed upon the statute by the Supreme Court will do it.

It remains to consider the argument of the defendant for a construction which would limit the application of the statute to cases in which the false representation is deceptive (in the fraudulent sense), detrimental to health, or otherwise injurious to the buying public.

We may accept, provisionally at least, this construction although it may be noted that the decisions cited for it (*Hall-Baker Grain Company vs. United States*, 198 Fed. 614; *French Silver Dragee Company vs. United States*, 179 Fed. 824) involved the misbranding of foods and not drugs.

Even so, I am of the opinion that the false statement that a tablet contains substantially less of a medicinal drug than it actually contains is prima facie injurious and potentially dangerous. That might not be so with a mixture of foods. It could certainly be argued with some reason that if the article contains nothing but a mixture of ordinary wholesome food substances as, for example, confectionery (see *French Silver Dragee vs. United States*), a false statement as to the relative proportions of sugar, chocolate, milk or butter contained in it would not be prima facie within the Act. Upon this point I express no opinion. I do, however, feel that with a drug which is sold to be prescribed by physicians, who should know with accuracy what size of doses they are giving, the rule is otherwise.

It may also be that there are some articles classified as drugs which are not intended to be so used and as to which an over or under statement would result in no possible harm. If thyroid were such a substance I have no doubt that evidence would have been produced by the defendant to show it. All that I hold here is that the prima facies are the other way.

Besides, I am by no means sure that there is not an element of commercial deception involved. I should think that physicians and others who buy drugs would feel that they were paying not only for purity of the ingredients but for an accurate and precise knowledge of their quantity. If a dealer, in order to save the expense of assaying his product, and at the same time escape liability for adulteration, includes an unascertained excess of it in the mixture he sells, the practice is not particularly commendable from a purely commercial standpoint.

For the reasons stated in this opinion I find a general verdict of Guilty.

Note: The case of *Breon Company vs. United States*, 74 Fed. (2d) 4, which has been much discussed at the trial and at the argument really has no bearing whatever upon the present case. The only point decided there was that the evidence was insufficient to establish beyond a reasonable doubt that there was an excess of thyroid in the tablets. In the present case the evidence is ample and persuasive beyond a reasonable doubt that there was such excess.

On February 1, 1937, the court imposed a fine of \$10.

HARRY L. BROWN, *Acting Secretary of Agriculture.*

26954. Alleged misbranding of Pulvis Alkantis. U. S. v. 99 Packages of Pulvis Alkantis. Tried to the court. Judgment for claimant. (F. & D. no. 33538. Sample no. 4175-B.)

The label of this article bore representations regarding its curative or therapeutic effects that were alleged to be false and fraudulent.

On September 22, 1934, the United States attorney for the Eastern District of Louisiana, acting upon a report by the Secretary of Agriculture, filed in the district court a libel praying seizure and condemnation of 99 packages of Pulvis Alkantis at New Orleans, La., alleging that it had been shipped in interstate commerce on or about June 1 and July 2, 1934, by Lafayette Pharmacal, Inc., from Lafayette, Ind., and that it was misbranded in violation of the Food and Drugs Act as amended.

Analysis of a sample of the article by this Department showed that it consisted essentially of magnesium carbonate and small proportions of bismuth subcarbonate, calcium carbonate, and cerium oxalate flavored with oil of peppermint.

The article was alleged to be misbranded in that the following statements regarding its curative or therapeutic effects, on the box labels were false and fraudulent: "A Symptomatic Treatment Gastric Ulcer—Acute Gastric Catarrh

Acute Enteritis * * * Reflex Vomiting Dosage Average dose: One teaspoonful in water, three times a day or more often if necessary. In acute attacks, dose may be doubled."

On December 14, 1936, the Lafayette Pharmacal Co., Inc., claimant, having filed an answer to the libel, and the cause having been tried to the court, a jury trial having been waived, judgment was entered against the United States. The court made the following findings of fact and conclusions of law:

FINDINGS OF FACT

(1) Lafayette Pharmacal Inc., of Lafayette, Indiana, on or about the 1st day of June and the 2nd day of July, 1934, shipped and caused to be transported in interstate commerce for sale, from Lafayette in the State of Indiana, to McKesson, Parker, Blake Corporation in the City of New Orleans, State of Louisiana, via parcel post, ninety-nine (99) packages, more or less, of a certain article of drug labeled in part "Pulvis Alkantis."

(2) Thereafter, on September 22nd, 1934, a libel for the condemnation of said packages of Pulvis Alkantis was filed by the United States Attorney with the Clerk of this Court and ninety-two (92) packages so shipped and in possession of McKesson, Parker, Blake Corporation, New Orleans, Louisiana, in the original and unbroken packages, were seized by the United States Marshal and are now in the custody of this Court.

(3) The libel filed alleged that the product was an article of drugs within the meaning and intent of the Act of Congress approved June 30, 1906, known as the Food and Drugs Act and amendments thereof; that an analysis of the product showed that it consisted essentially of cerium oxalate and carbonates of bismuth, calcium, and magnesium, flavored with menthol; that the product was misbranded in violation of Section 8 of the act as amended, and Paragraph Third, in that certain statements on the box label regarding the curative and therapeutic effects of the article were false and fraudulent.

(4) The label on the packages seized by the Government reads in part as follows: "Pulvis Alkantis. A symptomatic treatment Gastric Ulcer Acute Gastric Catarrh Acute Enteritis Hyperacidity Reflex Vomiting Dosage Average dose: One teaspoonful in water, three times a day or more often if necessary. In acute attacks, dose may be doubled." The Government charged that this portion of the label is false and fraudulent, omitting, however, any complaint with reference to the word "hyperacidity."

(5) The law under which the Government's libel is brought is known as the Sherley Amendment to the Food and Drugs Act, being contained in 21 U. S. C. 10, which reads in part as follows: "* * * an article shall be deemed to be misbranded; * * * Drugs. In the case of drugs: * * * False statement of curative or therapeutic effect. 3rd. 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 or fraudulent."

(6) Lafayette Pharmacal, Inc. appeared as claimant for the seized goods, admitting the shipment alleged by the United States that the article was a drug within the meaning and intent of the Food and Drugs Act and amendments thereof, and in general admitting the analysis proffered by the United States, but denying that the product was misbranded or that any of the statements on the box label were either false or fraudulent.

(7) The parties by a stipulation waived a jury and the case was tried before and submitted to this Court.

(8) The witnesses were in substantial accord regarding the analysis of the product Pulvis Alkantis, the drugs contained therein being bismuth subcarbonate, magnesium carbonate, precipitated calcium carbonate, and cerium oxalate, flavored with oil of peppermint.

(9) Cerium oxalate, a drug included in Pulvis Alkantis, is used by reputable members of the medical profession and recommended by writers of medical text books in the treatment of reflex vomiting; however, according to the preponderance of the testimony, the dosage required in order to have any curative or therapeutic effect in the treatment of reflex vomiting exceeds many times the amount of cerium oxalate in a dose of Pulvis Alkantis.

(10) Reflex vomiting is itself a symptom of certain diseases, therefore, it is false to say that Pulvis Alkantis is a symptomatic treatment for reflex vomiting.

(11) Some of the experts produced by plaintiff testified that they had prescribed Pulvis Alkantis.

(12) Lafayette Pharmacal, Inc. is a concern of high standing, with excellent commercial and professional connections; its President, who was present and testified at the trial, is an individual of high standing. The United States has no complaint to make except as to the specific language of the label as above set forth.

(13) The President of Lafayette Pharmacal, Inc., a graduate and registered pharmacist, recounted on the witness stand his conferences with various doctors in regard to the statements on the label, and his conclusion derived therefrom that no change in the wording of the label was required.

(14) The President of Lafayette Pharmacal, Inc. also described on the witness stand his company's policy of no exploitation to the laity, of no advertising of any character to the laity.

(15) The label complained of had been used by Lafayette Pharmacal, Inc. for twelve years. The United States, without lodging any complaint with Lafayette Pharmacal, Inc., and without any warning, had effected a prior seizure of Pulvis Alkantis and when Lafayette Pharmacal, Inc., discovered what was the complaint of the Food and Drug Administration, Lafayette Pharmacal, Inc. protesting that the label was in all respects correct, agreed to change it and accordingly the label was changed to one with respect to which the Food and Drug Administration declared it took no exception. The instant seizure was made after this had taken place. The President of Lafayette Pharmacal, Inc., explained the use of the old label on the seized shipment as the mistake of some employee at the factory of Lafayette Pharmacal, Inc., which explanation the Court accepts as correct.

CONCLUSIONS OF LAW

(1) In view of the foregoing Findings of Fact relative to reflex vomiting, the Court finds as a matter of law that the label is false. It is unnecessary for the Court to rule on the question of falsity. As to the other statements of the label, since the Court finds that where a label contains a list of ailments for which the drug is recommended, the charge of falsity is sustained by proof of the false character on any one of the claims.

(2) In a case of this kind it is not sufficient to establish merely the falsity of the claim; it must also appear that this false claim was made fraudulently; that is, either the defendant knew it was false, or without knowledge of its truth or falsity, made the claim recklessly and without a firm and honest belief in its truth. In the instant case, no knowledge of falsity, recklessness of statements, or lack of a firm and honest belief in the truth of the label statement can be attributed to Lafayette Pharmacal, Inc., or its President, and the label statement, therefore, cannot be regarded as fraudulent.

HARRY L. BROWN, *Acting Secretary of Agriculture.*

26955. Misbranding of Witter Water. U. S. v. Witter Water, Inc. Plea of guilty. Fine, \$100. (F. & D. no. 33808. Sample no. 33900-A.)

This case involved a mineral water the labeling of which bore false and fraudulent curative and therapeutic claims.

On March 29, 1935, the United States attorney for the Northern District of Illinois, acting upon a report by the Secretary of Agriculture, filed in the district court an information against Witter Water, Inc., Chicago, Ill., alleging shipment by said company in violation of the Food and Drugs Act as amended, on or about May 30, 1932, from the State of California into the State of Illinois of a quantity of Witter Water that was misbranded. The article was labeled in part: "Natural Medicinal Witter Water * * * Bottled and Sealed at Witter Water Medical Springs, California."

Analysis showed that the article was an alkaline water containing per quart 177 grains of dissolved mineral matter consisting essentially of sodium, magnesium, and calcium bicarbonate, borax, sodium chloride, and small proportions of other salts commonly present in ground waters.

The article was alleged to be misbranded in that certain statements, designs, and devices regarding its therapeutic and curative effects, appearing on the bottle label and cartons and in an accompanying circular, falsely and fraudulently represented that it was effective to neutralize the excess acid of the stomach; to relieve the pain and distress of most acid stomach disorders; to give remarkable results in improving general health, and to build up health and vitality; effective to bring relief to sufferers of excess acid stomach disorders and severe cases of acid stomach, and to assist greatly in building better health and vitality; effective to supply the system with elements vitally neces-