

be processed so as to comply with the law, under the supervision of the Food and Drug Administration.

1039. Adulteration and misbranding of silk sutures. U. S. v. 7,200 Packages and 7,200 Packages of Silk Sutures. Decrees of condemnation. Portion of product ordered released under bond for reprocessing and relabeling, and remainder ordered destroyed. (F. D. C. Nos. 9255, 9396. Sample Nos. 6509-F, 32823-F.)

Each package of these sutures contained 3 smaller packages labeled in part: "Size 00," "Size 1," or "Size 2." The "Size 2" sutures were contaminated with living micro-organisms.

On January 27 and February 19, 1943, the United States attorneys for the Eastern District of Missouri and the Northern District of New York filed libels against 7,200 packages of silk sutures at St. Louis, Mo., and 7,200 packages at Binghamton, N. Y., alleging that the article had been shipped in interstate commerce on or about December 17 and 28, 1942, by the Gudebrod Brothers Silk Co., Inc., from Pottstown, Pa.; and charging that it was adulterated and misbranded. The article was labeled in part: "Sizes 00-1-2 Two 18" Strands of Each Sterile * * * Braided Silk Sutures."

The "Size 2" sutures were alleged to be adulterated in that they purported to be and were represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but their quality and purity fell below the standard set forth therein since the sutures did not meet the test for sterility of solids as required by that compendium.

They were alleged to be misbranded in that the statement on the label, "Sterile," was false and misleading.

On April 13, 1943, the Gudebrod Brothers Co., Inc., having appeared as claimant for the lot at St. Louis, and having consented to the entry of a decree, judgment of condemnation was entered and that lot was ordered released under bond for reprocessing and relabeling under the supervision of the Food and Drug Administration. On May 4, 1943, no claimant having appeared for the lot at Binghamton, judgment of condemnation was entered and the lot was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS FOR HUMAN USE

1040. Misbranding of Colusa Natural Oil, Colusa Natural Oil Capsules, and Colusa Natural Oil Hemorrhoid Ointment. U. S. v. Empire Oil & Gas Corporation and Chester Walker Colgrove (Colusa Products Co.) Pleas of not guilty. Tried to a jury. Verdict of guilty. Fine of \$500 and 6 months in jail imposed against individual defendant on each of the 3 counts, the jail sentences to run concurrently and terminate upon payment of fine. Corporate defendant fined \$3. Fines deposited in escrow and appeal noted. Judgment reversed by appellate court and case remanded for retrial. Pleas of nolo contendere thereafter entered. Defendants given same sentences as those originally imposed. (F. D. C. No. 6408. Sample Nos. 65381-E to 65383-E, incl.)

On March 24, 1942, the United States attorney for the Northern District of California filed an information against the Empire Oil & Gas Corporation, trading as the Colusa Products Co. at Berkeley, Calif., and against Chester Walker Colgrove, president and treasurer of the corporation, alleging shipment on or about January 31, 1941, from the State of California into the State of New Mexico of quantities of the above-named products which were misbranded.

Analyses of the Colusa Natural Oil and the Colusa Natural Oil Capsules showed that they consisted of crude petroleum oil containing 0.75 percent of sulfur, and that they did not contain camphor, turpentine, and iodine or iodine compounds, or possess any radio activity.

These articles were alleged to be misbranded in that the statements in their labeling which represented and suggested that, when used alone or in conjunction with each other, they would be efficacious in the treatment of eczema, psoriasis, acne, ringworm, athlete's foot, burns, cuts, poison ivy, and varicose ulcers; that they would act on surface skin irritations as a stimulant and would increase circulation and aid in healing; that they would be efficacious to relieve discomfort and pain; that they would be efficacious to inhibit the spreading of skin irritations and to restore the normal skin surface; and that they would be efficacious to kill or check disease germs were false and misleading since the articles were not efficacious for such purposes.

*See also Nos. 1001-1020, 1023, 1025-1039.

Analysis of the Colusa Natural Oil Hemorrhoid Ointment showed that it consisted essentially of zinc oxide, crude petroleum oil, and small proportions of camphor, menthol, and benzocaine incorporated in a base of lanolin and beeswax.

The article was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that it would be efficacious in the treatment of hemorrhoids and piles were false and misleading since it would not be efficacious for such purposes. It was alleged to be misbranded further in that it was in package form and its label did not bear an accurate statement of the quantity of the contents in terms of weight or measure since it didn't bear a statement of the quantity of the contents.

On June 23, 1942, the defendants having entered pleas of not guilty, the case came on for trial before a jury. On June 30, 1942, the trial was concluded and the jury returned a verdict of guilty as to each defendant. On July 8, 1942, the court imposed against the corporate defendant a fine of \$1 upon each of 3 counts, a total of \$3; and against the individual defendant a fine of \$500 upon each of 3 counts, a total of \$1,500, together with a sentence of 6 months in jail on each count, the jail sentences to run concurrently and terminate upon payment of his fine. The fines were deposited in escrow and an appeal was noted.

On June 28, 1943, the circuit court of appeals for the Ninth Circuit reversed the judgment of the district court, handing down the following opinion:

STEPHENS, *Circuit Judge*:

"Empire Oil and Gas Corporation, (a corporation) and Chester Walker Colgrove, trading as Colusa Products Company, were informed against in three separate counts charging the violation of the Act of Congress (June 25, 1938), known as the Federal Food, Drug, and Cosmetic Act [52 Statutes at Large, 1040, 21 USCA, §§ 331 (a), 352 (a)]. The corporation and Colgrove were tried by judge and jury and were convicted upon all three counts. Judgments and sentence followed and both the corporation and Colgrove appeal therefrom.

"It is charged in all three counts that packages containing drugs which were sent into interstate commerce were misbranded in that the branding falsely claimed the drugs were efficacious in the treatment of various named diseases.

"In counts I and II the following skin diseases are specifically named: eczema, psoriasis, acne, ringworm, Athlete's Foot, burns, cuts, poison ivy and varicose ulcers. In count III the disease named is hemorrhoids or piles.

"As to count III, an additional charge of misbranding is made that the labels on jars of ointment did not bear an accurate statement of the quantity of the contents in terms of weight and measure.

"The evidence establishes without conflict that the Empire Oil and Gas Corporation, with Chester Walker Colgrove as its president and active manager in immediate charge of the business, was conducting the business of producing and marketing products, the base of which came from a California oil well. As alleged in the information, appellants placed some of such products in the course of interstate commerce. The oil produced from the well is called Colusa Oil and is claimed by the producers and marketers to have remarkable remedial qualities. It is offered for sale as a liquid and as an ointment. The immediate containers of the products are labeled and packed in cartons or boxes which contain advertising matter related to the efficacy of the product as a remedy for a number of skin diseases and for hemorrhoids.

"In their opening brief on appeal, appellants treat their assignments of error under six major points, and we shall treat them in their order of presentation therein.

"It is claimed that the evidence is insufficient. There is no question but that there is great conflict upon the issue of misbranding as to the efficacy of the remedies. As will hereinafter appear, there was error committed which greatly affected the evidence upon this issue. As to count III, there is substantial evidence that the remedy containers went into interstate commerce without the required quantity of contents being printed upon the label [21 USCA, §§ 331 (a), 352 (a), 352 (b) (2)]. No error can be predicated upon this point.

"Appellants claim highly prejudicial error by reason of the trial court's rulings as to the testimony of Dr. C. E. Von Hoover.

"Dr. Von Hoover was presented as an expert witness for the defense, and his qualifying testimony revealed the following: Between 1922 and 1924 he attended New York Chemical College, now City College. There he spent eighteen months in the study of biochemistry and was awarded the Smedley D. Butler scholarship. (For convenience we quote definitions from Webster's New International Dictionary, Second Edition, of certain technical terms.)

Biochemistry: 'The chemistry plant and animal life; biological, or physiological chemistry.'

From 1924 to 1926 he attended Kings College in London, receiving therefrom the degree of Master of Science. While there he studied pharmacology and general science, including microbiology.

Pharmacology: '1. The science of drugs, including materia medica and therapeutics: 2. The materials of this science: the properties and phenomena of drugs especially with relation to their therapeutic value.'

Materia medica: 'a. Material or substance of remedies. b. That branch of medical science which treats of the nature and properties of all the substances employed for the cure of diseases.'

Therapeutics: 'That part of medical science which treats of the application of remedies for diseases; therapy.'

Therapy: 'Treatment of disease.'

Microbiology: 'The science or study of microbes.'

He attended the University of Vienna two years under the Smedley D. Butler scholarship, receiving the degree of Doctor of Science. There he studied microbiology, laboratory pharmacology and general science and materia medica, with the use of the American pharmacopoeia. These subjects are the same as lead to a degree of M. D. The degree of M. D. also requires practice on patients. He is a professional dermatologist.

Dermatology: 'The science which treats of the skin, its structure, functions and diseases.'

He was with Goodman Research Laboratory, New York, for a year on the clinical staff, testing pharmaceuticals and ointments and practicing general pharmaceutical chemistry. In collaboration with Medical Doctors and Doctors of Science he there tested the therapeutic value of and dangers of medicinal preparations to human patients. In 1930 he established a clinical testing agency under his name at San Antonio, Texas, receiving business in that line of endeavor from high grade manufacturing chemists and especially from well-known firms manufacturing skin disease preparations. He has been so employed by Vitamin Research Company who manufacture synthetic vitamins. In his clinic a Medical Doctor diagnoses and prescribes. An assistant in the clinic is Dr. Beal, for some time United States Public Health Officer and surgeon. Another Medical Doctor assistant is a former Health Officer of San Antonio and past Trustee of the American Medical Society. Another assistant is Major Burby, retired Trustee of the American Veterinary Association, who acts as veterinary consultant in the handling of small animal practice and experimentation.

"While Dr. Von Hoover was on the witness stand as a witness for the defendants, he was shown a report designated as Exhibit 'L' for identification relating to the effect of Colusa Oil on dogs suffering from mange. He testified: 'It is my report. I prepared it; that is my report of the results of the application of Colusa Natural Oil to the skin of animals; associated with me was Dr. Burby, a veterinarian.—I am not a veterinarian.'

"Mr. Zirpoli, the assistant district attorney: 'And this is a veterinarian's report?'

"A. 'You see my name on the other side as the laboratory man, * * * the man that made the findings in the presence of the veterinarian. He couldn't make those tests because he is not qualified in bacteriology. * * *'

"Q. 'This report is predicated upon the experiments conducted upon the animal?' A. 'That is correct.'

"Q. 'Made by Dr. Burby?' A. 'And myself.'

"Q. 'And Dr. Burby did the actual administration?'

"A. 'No. I administered to some dogs the application of oil in his presence.'

"Q. 'This purports to be his conclusion as a veterinarian too does it not?'

"A. 'Canine dermatology is the practice of the veterinarian, and naturally, he would sign as the veterinarian, and I as the scientist, the micrologist.'

* * *

"Mr. Gleason, the attorney for defendants-appellants: Q. 'I am going to ask you to refer to Defendants' Exhibit L for identification and ask you if that document refreshes your recollection as to facts observed by you in these clinical tests on animals as to the therapeutic value and power of the Colusa Natural Oil?'

"A. 'Yes.'

"Q. 'Please state briefly the facts observed by you in these clinical tests on this animal therapy as to the results of the use of Colusa Natural Oil and skin diseases of animals. And, Doctor, confine yourself to the facts that you know of your own knowledge and do not read any of the opinions if they are opinions of Dr. Burby.'

"Mr. Zirpoli, the assistant district attorney: 'I want to make this objection, your Honor. He is asked to testify as to the effect of the application of this oil, which calls for his opinion and conclusion as a veterinarian.'

"The Court: 'Objection sustained.'

"(Exception noted.)

"Mr. Gleason: Q. 'Doctor, in the practice of your profession as a pharmacologist and your work for these firms that you mentioned yesterday, including the Goodman Laboratories and the rest of them, as their consultant, do you in the practice of your profession resort to animal therapy to test the efficacy of drugs and preparations?'

"A. 'Yes.'

"Q. 'Is that a part of the ordinary practice of the ordinary pharmacologist?'

"A. 'That is the practice.'

"Q. 'I will ask you to state, Doctor, the facts that you observed, in your clinical examinations; that is to say, this animal therapy, from the use of Colusa Natural Oil upon the skin diseases of dogs and cats used in this animal therapy.'

"Mr. Zirpoli, the assistant district attorney: 'May it please the Court, I submit that the question is identical in different terms and objection is made exactly as it was made to the last question.'

"Mr. Doyle, attorney for defendant-appellant: 'This question asks for the knowledge of the witness.'

"The Court: 'The objection will be sustained.'

"It is apparent that the trial judge unduly limited the examination of the witness Dr. Von Hoover to the very great prejudice of the accused. The qualifications of Dr. Von Hoover were far more extensive than the average medical doctor or veterinarian possesses, and his familiarity with the materia medica, bacteriology, therapeutics, pharmacology and dermatology well qualified him to answer all of the questions which were put to him.

"In regard to the report which he had prepared, it does not appear that he was asked to do otherwise than use it to refresh his recollection as to his own acts in the testing of appellants' remedies. It is quite probable that the report contained matter as to which he could not testify, but this fact could not prevent its use in the limited manner suggested by appellants' counsel by their questions. There were other reports, some of them referring to experiments upon humans, which were similar in nature to the one above detailed, and their use by Dr. Von Hoover was prevented in like manner. This was error.

"It is claimed that 'The trial court committed prejudicial error in refusing to admit in evidence the testimonials offered by the defense.' It appears in count I of the information, and is incorporated in the second count by reference (we do not here consider the legal effect of the practice), that advertising matter within the package contained the following recitation: 'Colusa Natural Oil is credited by others with producing relatively as remarkable results as above pictured in relieving irritation of external Acne—Eczema—Psoriasis—Athlete's Foot or Ring Worm—Poison Ivy— * * * Varicose Ulcers—Burns and Cuts.'

"It is claimed that defendants had a right to introduce written testimonials of many people to prove the truthfulness of this statement. It does not appear from defendants' recitation of the testimony that the government offered any proof upon this subject. This being true, there was no occasion for the truth to be established by the evidence. Aside from this, the introduction of letters received through the mail could not be received. The whole subject matter is immaterial.

"Under a single subhead appellants treat a number of assignments which we shall treat briefly.

"Appellants think they were prejudiced by the court's refusal to permit proof going to the truth of a certain statement contained in the advertising matter regarding the action of radium. The government had introduced testimony along this line—probably to show that the preparations do not contain radium. Appellants admit, however, that they have never claimed and do not claim that the preparations contain radium. In this circumstance any testimony relative to radium would be immaterial.

"Appellants complain that Dr. Tainter, an expert witness for the government, was permitted to testify as to the effect of Colusa Oil in poison oak cases and that Colusa Oil is an ordinary crude oil. This claim is without merit.

"Appellants complain that the attitude of the court was prejudicial. The court evidenced some lack of patience, as we read the record, against both sides. No objections were interposed. We think the impatience exhibited was not of a degree sufficient to constitute reversible error.

"They also complain of the cross-examination on immaterial matters. This amounts to nothing.

"In their brief under the subheading 'The court erred in refusing to permit appellants to prove various facts to show their good faith,' we have examined the claim and the argument and find no error.

"Appellants complain that the testimony of a Mr. Everett and of a Mr. Baumgartner was unduly limited upon objections that the questions call for the witnesses' conclusions. We agree but think the error inconsequential in the circumstances. It appears that counsel for defendants voluntarily abandoned the subject.

"Appellants sought to show they were wrongfully prevented from showing that the public was not misled by their advertisements. There is nothing to the point.

"Appellants claim that the third count is bad as being duplicitous. Upon authority of *Weeks v. United States*, 445 US 618, and *United States v. Swift*, 188 Fed. 92, we hold that the third count of the information is not duplicitous. In the latter cited case it is said, 'Duplicity in an indictment means the charging of more than one offense, not the charging of a single offense committed in more than one way. Duplicity may be applied only to the result charged, and not to the method of its attainment.'

"The government insists that there is substantial, even conclusive, evidence to support the conclusion that each package of drugs referred to in count III did not bear an accurate statement of the quantity of the contents in terms of weight or measure and that the verdict must stand as to this count upon that evidence alone. But the issue of guilt or innocence upon each separate count was submitted to the jury upon all of the material evidence relevant to each count. We have seen that reversible error was committed in the admission of evidence relative and material to count III and a verdict of guilty was returned. In these circumstances we cannot speculate as to whether the guilt was premised upon one or the other or upon all of the allegations contained in this count. Evidence was offered by appellants to show that any failure upon their parts to properly designate the amount of contents on labels used as charged in count III was accidental or by mistake of another. Upon objection that the evidence was immaterial, the court denied its reception.

"The instructions to the jury are in accord with the government's contention that no intent is necessary to a conviction upon the applicable statute and that no explanation of accident or mistake in any way affects the guilt or innocence of the accused. This subject is inadequately treated in the briefs, and since the judgments must be reversed upon the errors occurring during the examination of Dr. Von Hoover, we do not pass upon it.

"Reversed."

On October 7, 1943, the case was remanded for retrial and on December 10, 1943, the defendants entered pleas of *nolo contendere*. On December 23, 1943, the court imposed the same sentence upon the defendants that it had originally imposed.

1041. Misbranding of Vitaminerals VM No. 1, VM No. 150, VM 100, VM 120, and VM No. 204 Pneumatic Dilator. U. S. v. John Francis Gorman (Vitaminerals Co.). Plea of *nolo contendere*. Fine, \$1,000 on 2 counts, and probation for 1 year on 3 counts. (F. D. C. No. 8791. Sample Nos. 81451-E, 81453-E to 81455-E, incl.)

On April 30, 1943, the United States attorney for the Southern District of California filed an information against John Francis Gorman, trading as the Vitaminerals Co., Los Angeles, Calif., alleging shipment on or about May 5, 1942, from the State of California into the State of Colorado of a quantity of the above-named products which were misbranded.

Examination of Vitaminerals VM No. 1 disclosed that this article was in the form of orange-colored tablets containing a large proportion of rhubarb root tissues together with Irish moss tissues (*Chondrus*), okra tissues, cranberry fruit tissues, parsley leaf tissues, and acid-insoluble material. It was alleged to be misbranded in that the statements in its labeling which created in the mind of the reader the impression that the article was a supplement in the dietary treatment of constipation; that the ingredient rhubarb root was a food; and that the article derived its physiological activity principally from concentrates and extracts from common vegetables used for food purposes, and from vitamins, were misleading since the article was not a supplement in the dietary treatment