

"Accordingly, it was not only not erroneous for the court to instruct the jury on § 321 (n), but, under the facts of this case and under the terms of the subsection itself, it was the court's duty to do so.

6. The Court Did Not Abuse Its Discretion in Refusing to Release the Product under Bond

"Finally, the appellant asserts that, even if this court should hold 'that the verdict may be construed as finding merely mislabeling consisting of the failure to disclose the difference of opinion among the experts,' etc, then 'fairness to appellant requires the release of the product under bond to permit amendment of the labeling and the [lower] court's denial of appellant's motion for that relief is an abuse of discretion,' etc.

"As we have tried to show, however, the appellee's evidence was not confined to 'opinion among the experts,' but was definitely *factual*.

"In denying the application for the release of Nue-Ovo under bond, the court below said:

... [Nue-Ovo] hasn't any intrinsic value for food or for uses other than a medicinal use. The jury has determined that it hasn't any value for that purpose, so it would be inconsistent, it seems to me, for me to hold that it should be preserved and released to the claimant.

"It is well settled that the trial court, in a case of this kind, shall exercise its sound discretion as to whether the article shall be released under bond. *United States v. Two Cans of Oil of Sweet Birch, etc.* (DC N. Y.), 268 F. 866, 867; *United States v. 143 Packages, etc., of Nue-Ovo* (DC Wash.), 51 F. Supp. 1, 2; *United States v. 1322 Cans More or Less, of Black Raspberry Puree* (DC Ohio), 68 F Supp. 881, 882.

"After careful consideration of the 1100-page record in this case, we are convinced that the court below exercised its discretion soundly and judiciously. We believe that the interests of the public will be better subserved by having this product kept off of the market altogether.

"The judgments are affirmed."

A petition for certiorari was filed on July 1, 1948, in the United States Supreme Court on behalf of the claimant, but was denied on October 18, 1948. On February 14, 1949, an order was entered directing that the product and the printed matter be destroyed.

2922. Misbranding of Colusa Natural Oil and Colusa Natural Oil Capsules. U. S. v. 9 Bottles, etc. (and 5 other seizure actions). Tried to the court; judgment for the Government. Decree of condemnation and destruction. Judgment affirmed upon appeal. Petition for writ of certiorari denied by U. S. Supreme Court. (F. D. C. Nos: 23160, 23197, 23200, 23493, 23512, 23548. Sample Nos. 39279-H, 39280-H, 39289-H, 39290-H, 79506-H, 79507-H, 86499-H, 86500-H, 86909-H, 86910-H, 87072-H, 87073-H.)

LIBELS FILED: Between June 2 and August 4, 1947, Northern District of Iowa, District of Colorado, and Eastern District of Wisconsin.

ALLEGED SHIPMENT: Between the approximate dates of April 1 and July 9, 1947, by the Colusa Remedy Co., from Chicago, Ill., and Los Angeles and Hollywood, Calif.

PRODUCT: 129 2-ounce bottles and 38 4-ounce bottles of *Colusa Natural Oil* and 135 100-capsule bottles and 39 200-capsule bottles of *Colusa Natural Oil Capsules* at Waterloo and Fort Dodge, Iowa; Colorado Springs, Colo.; and Green Bay, Racine, and Appleton, Wis. Examination disclosed that the products consisted of crude petroleum oil.

LABEL, IN PART: "Colusa Natural Oil."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle labels were false and misleading. These statements represented and suggested that the articles, when taken individually or in combination, were

effective in the treatment of psoriasis, eczema, leg ulcers, athlete's foot, and open sores, whereas the articles when taken as directed were not effective for such purposes.

DISPOSITION: The cases were consolidated for trial in the Northern District of Iowa, and answers were filed by the Colusa Remedy Co., claimant, denying that the products were misbranded.

The trial commenced on November 13, 1947, and was concluded on November 18, 1947. On November 26, 1947, the court handed down its findings of fact and conclusions of law and, in accordance therewith, entered a decree providing for the condemnation and destruction of the products.

The matter was appealed to the United States Court of Appeals for the Eighth Circuit, and on July 28, 1949, after consideration of the briefs and arguments of counsel, the following opinion was handed down, affirming the judgment of the district court:

THOMAS, Circuit Judge: "This is an appeal by the claimant from decrees entered under Section 304 of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. Section 334, condemning shipments in interstate commerce of certain drugs on the ground that they were misbranded within the meaning of Section 502 (a) of the Act, 21 U. S. C. Section 352 (a).

"Six libel proceedings were commenced by the government in three different jurisdictions to condemn six shipments in interstate commerce of Colusa Natural Oil and Colusa Natural Oil Capsules alleged to have been misbranded, and the proceedings were consolidated for trial in the Northern District of Iowa under the provisions of 21 U. S. C. Section 334 (b).

"The shipments involved were made in interstate commerce by the Colusa Remedy Company, a Nevada corporation, from Los Angeles, California, to the places and to the consignees named in each of the libels filed in each of the consolidated proceedings. The drug was bottled in two forms, capsule and liquid, it being stipulated that the contents in each case were identical, both containing 'natural unrefined petroleum oil.' It was further stipulated that the labels attached to the bottles in every case read:

[Colusa Natural Oil] A natural unrefined petroleum oil intended for use in treatment of Psoriasis, Eczema, Athlete's foot and Leg Ulcers. Directions: Apply to affected parts and rub it in thoroughly morning and night. For open sores saturate cotton pad with oil and bind on by gauze. Change to fresh dressing morning and night. For tender skin oil can be diluted 50% with olive oil. Continue treatment until skin is smooth and comfortable. We suggest in treatment of Psoriasis, Eczema and Leg Ulcers using Colusa Natural Oil externally as above directed and Colusa Natural Oil capsules internally as directed on bottle containing Colusa Natural Oil capsules.

[Colusa Natural Oil Capsules] A natural unrefined petroleum oil in capsules intended for internal use in treatment of Psoriasis, Eczema, Leg Ulcers. Directions: For adults start with one capsule at bedtime then after 3 days change to one capsule after each meal until skin is smooth and comfortable. For children under ten—one capsule or its contents squeezed into milk or water at bedtime until skin is smooth and comfortable. We suggest use of capsules as above directed in conjunction with liquid Colusa Natural Oil applied externally to affected parts as directed on bottle containing Colusa Natural Oil in liquid form.

"In each libel it was charged that such labels 'are false and misleading in that such statements represent and suggest that the articles when taken individually or in combination are effective in the treatment of psoriasis, eczema, leg ulcers, athlete's foot, and open sores, whereas, the articles when taken as directed are not effective for such purposes.'

"In each of the consolidated cases the appellant appeared as claimant and filed an answer, admitting the interstate shipments, the accuracy of the quoted labels, and denying that the articles were misbranded in interstate commerce within the meaning of the statute, or that the wording of the labels is false and misleading in the respects alleged, or that they were liable to seizure and condemnation pursuant to the provisions of the Act, and praying for the return of the articles and for such other relief as the case may require.

"The Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, 21 U. S. C. Section 301, et seq., provides:

[Section 201 (g), 21 U. S. C. 321 (g)] The term "drug" means . . . (2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals.

"Section 304 (a), 21 U. S. C. Section 334, provides that any drug that is misbranded when introduced into or while in interstate commerce, shall be liable to be proceeded against on libel of information in any district court within the jurisdiction of which the article is found.

(b) The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty.

When proceedings involving the same claimant and the same issues of misbranding are pending in two or more jurisdictions they may upon application of the claimant be consolidated for trial in any district selected by the claimant where one of the proceedings is pending.

[Section 502, 21 U. S. C. Section 352] A drug . . . shall be deemed to be misbranded—(a) if its labeling is false or misleading in any particular.

"The consolidated cases were tried to the court without a jury and thereafter the court made findings of fact, conclusions of law, and entered the decrees in each of the consolidated cases condemning the articles involved, from which decrees the claimant appeals. *United States v. 9 Bottles, More or Less, etc., Colusa Natural Oil, et al.*, 78 F. Supp. 721. And see *United States v. Colgrove, et al.*, S. D. Cal., 83 F. Supp. 880.

"Under the issues the burden was upon the government to establish that the labeling upon the bottles was false or misleading in some particular. That means in this case that the proof must warrant findings by the court (1) that Colusa Natural Oil and Colusa Natural Oil capsules are represented in the labeling to be effective or efficacious in the treatment of the skin diseases named in the labels and (2) that they are neither effective nor efficacious in the treatment of those diseases.

"Upon the trial the appellant contented that the labeling upon the articles involved is not 'false or misleading in any particular' within the meaning of 21 U. S. C. Section 352 (a). Its position was and is here that it does not claim in the labels or otherwise that Colusa Natural Oil will cure any of the diseases named in such labels. Its claim is that the labels represent only that the remedies will assist or relieve in the treatment of the diseases referred to in the labels.

"We think the law is settled both as to the issues and as to the review on appeal.

"A proceeding to forfeit and condemn property for violation of a federal statute but which does not involve the personal conviction of the wrong-doer for the offense charged is one of a civil nature and not criminal. *Dobbin's Distillery v. United States*, 96 U. S. 395, 399; *United States v. 935 Cases More or Less, Etc.*, 6 Cir., 136 F. 2d 523, 526.

"The provision of Section 304 (b) of the Federal Food, Drug, and Cosmetic Act, supra, that the procedure to seize misbranded drugs by libel should conform as nearly as may be to the procedure in admiralty was not intended 'to liken the proceedings to those in admiralty beyond the seizure of the property by process in rem, then giving the case the character of a law action. . . .' *445 Cases of Frozen Egg Product v. United States*, 226 U. S. 162, 183.

"The Federal Rules of Civil Procedure govern proceedings on appeals in actions for forfeiture of property for violation of a statute of the United States. Rule 81 (a) (2), 28 U. S. C. A. following Section 723c; *United States v. Cataldo*, 1 Cir., 157 F. 2d 803; *C. C. Co. v. United States*, 5 Cir., 147 F. 2d 820; *Reynal v. United States*, 5 Cir., 153 F. 2d 929; *United States v. 5 Cases, Etc.*, 9 F. R. D. 81.

"Since this is an action for the forfeiture of property for violation of a statute of the United States it is governed on appeal by Rule 52 (a) of the Rules of Civil Procedure, which provides that 'Findings of fact shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses.' In the notes to the rules prepared under the direction of the Advisory Committee on rules appointed by the Supreme Court it is said the foregoing rule 'accords with the decisions on the scope of the review in modern equity practice'; and 'It is applicable to all classes of findings in cases tried without a jury whether the finding is of a fact concerning which there was conflict of testimony, or of a fact deduced or inferred from uncontradicted testimony.' For a clear statement of the meaning of the rule the notes cite *Silver King Coalition Mines Co. v. Silver King Consolidated Mining Co.*, 8 Cir., 204 Fed. 166, 177, in which Judge Walter Sanborn, writing the opinion for the court, said: '. . . where a court has considered conflicting evidence, and made a finding or

decree, it is presumptively correct, and unless some obvious error of law has intervened, or some serious mistake of fact has been made, the findings or decree must be permitted to stand.' The rule has been repeated by the courts in cases too numerous to be cited. But see *Johnson v. Cooper*, 8 Cir., 172 F. 2d 937, and *Hudspeth v. Esso Standard Oil Co.*, 8 Cir., 170 F. 2d 418. The Supreme Court recently said in *United States v. U. S. Gypsum Co.*, 333 U. S. 364, 395, that a finding of fact is clearly erroneous when 'although there is evidence to support it, the reviewing court, on the entire evidence, is left with the definite and firm conviction that a mistake has been committed.'

"Upon the trial the government introduced the testimony of ten witnesses. The first three were agents and employees of the Federal Food and Drug Administration. They testified that they procured samples of Colusa Natural Oil and of the Colusa Natural Oil capsules and forwarded portions thereof to Dr. Hatch, Dr. Rosenberg, Dr. Carney, Dr. Trunnel, and Dr. Brewer. These doctors testified for the government; and it was agreed that the samples used by them in their tests and analyses were true samples of the drugs seized and condemned.

"Dr. Lewis F. Hatch of Austin, Texas, testified that he is Associate Professor of Chemistry at the University of Texas, and Research Chemist for the Defense Research Laboratory at the University of Texas. He had received degrees of Bachelor of Science in Chemistry, Master of Science in Chemistry and Doctor of Philosophy, specializing in chemistry. His work had been done on petroleum and its derivatives. He had published some 15 papers and pamphlets relating to the chemistry of petroleum and its derivatives. He had made several physical and chemical analyses of the samples furnished him of Colusa Natural Oil and of Colusa Natural Oil capsules and found them to be the same and apparently from the same source. He found that the material was essentially insoluble in water, was not radioactive, contained 0.2 of 1 per cent of nitrogen, 0.2 of 1 per cent of sulphur; its specific gravity was 0.924 at 24 degrees centigrade. It did not contain iodine, turpentine, camphor or ichthyol. He found no evidence of phenol, creosol or similar compounds. The material he found to be a natural petroleum oil. Ichthyol, he explained, is a manufactured product made from shale oil originating in Austria. He did not make a complete breakdown of all the elements of the samples. Such an examination would require many months.

"Dr. Irwin G. Gross, Ph. D., M. D., head of the Department of Pharmacology at the University of Iowa, testified that pharmacology is the study of drugs as to their chemistry, source, physical properties, preparation and physiological effects on living tissue, whether they be used in therapeutic amounts or otherwise, their absorption, their fats, their excretion and therapeutic indications for their use. In his opinion crude oil applied to the skin would act as an emollient; it would soften the skin, and act as an irritant to a slight extent. It would tend to block the hair follicles of the sebaceous glands and probably produce an infection of the plugged glands. In his opinion there is no pharmacological basis for the use of crude oil as beneficial action.

"Dr. Adolph Rostenberg, Jr., of Chicago, Illinois, is Associate Professor of Dermatology and Assistant Director of the Allergy unit of the University of Illinois, College of Medicine. He has been connected with other medical colleges and has had experience on the staffs of various hospitals. He is a member of the American Medical Association, of the Society for Investigative Dermatology, of the American Academy of Dermatology and Syphilology, and of the American Academy of Allergy. He testified that eczema is a response by the skin to a variety of stimulations; that the causes are various, such as poison ivy; and that in some instances crude petroleum oils are primary irritants. The treatments for eczema are various, depending upon the cause and the symptoms. In acute eczema oils should not be used because in some cases they are an irritant, and they should be used in no case because they tend to dam up the accretions of the skin and provide a good medium on which bacteria can flourish. Based upon his knowledge, training and experience in the field of dermatology crude petroleum oil applied either externally or internally is not an appropriate or effective treatment for all types of eczema, and that Colusa Natural Oil when used as directed on the label is neither an effective nor an appropriate treatment for all types of eczema. He had treated five patients, including himself, with Colusa Natural Oil and it effected no improvement in their cases. He expressed the same opinion as to the effectiveness of Colusa Natural Oil for the treatment of psoriasis, athlete's foot, and leg ulcers. It was his opinion that Colusa Natural Oil has no merit for the treatment of

any of those diseases. He observed that psoriasis is a recurring disease. It may get better for a short or indefinite period and then relapse again.

"Dr. Charles M. Brewer, Ph. D., a bacteriologist for the Food and Drug Administration, tested Colusa Natural Oil to determine whether it had any bactericidal or antifungicidal action, and found that it had none.

"Dr. Thomas L. Trunnell graduated from a four-year college course, after which he completed the course in medicine at the University of Iowa, followed by three years as an intern with training in dermatology. He practices dermatology at Waterloo, Iowa. Seven of his patients he treated with Colusa Natural Oil, two suffering from psoriasis. They became progressively worse and the treatment was stopped. Three were treated for eczema without results, and two for athlete's foot with no improvement. He expressed the opinion that Colusa Natural Oil has no merit for the treatment of any of those diseases.

"Dr. Robert G. Carney, Assistant Professor of Dermatology at the Iowa University Medical School at Iowa City, Iowa, spends 8 hours a day teaching students, treating patients, and carrying out research in dermatology. He is a member of several medical societies. In 1947 he treated patients in the University hospital with Colusa Natural Oil for eczema, stasis ulcer, psoriasis, and leg ulcers. He concluded that Colusa Natural Oil is neither an appropriate nor an effective treatment for any such diseases.

"The appellant's evidence consisted of the testimony of 30 witnesses: 14 lay-users of Colusa; 14 medical doctors by deposition; 1 medical doctor appeared in person; and a chemist referred to as Dr. Radovich.

"The lay witnesses testified that they had suffered from skin diseases (without naming them), describing the symptoms, their suffering; their treatment in most cases by doctors without practical results; and when at length they tried Colusa they received relief in every case; and in some cases they believed their ailment was cured.

"The medical doctors were general practitioners who treated skin diseases as well as ailments generally. Their testimony was that they had found Colusa Natural Oil and Colusa Natural Oil capsules both efficacious in the treatment of the four skin diseases named in the quoted labels; that it had in many cases effected permanent cures and had resulted in great relief in all cases.

"Dr. William T. Vincent of Houston, Texas, appeared at the trial and testified. He is 83 years of age and has practiced medicine since 1889. He studied at the Allopathic Medical College at Columbus, Ohio, and is a graduate of the University of Cincinnati. He testified that he had used Colusa Natural Oil in his practice for eight years; that he had treated hundreds of cases of skin diseases, including psoriasis, with good results; that he considers it an efficacious remedy, 'but not a cure all.'

"(Dr.) Frank O. Radovich of North Hollywood, California, is a chemist with a degree of Bachelor of Science and Applied Chemistry from the California Institute of Technology. His experience has been in the petroleum field entirely. He has been chemist for various petroleum refineries and has had charge of various testing laboratories; and he has done research work. He has produced a black viscous tarry material having the appearance of ichthyol from oils in the United States in and about California. He produced some of this material from Colusa Natural Oil in 1947. It was of the sulphur type. It does not, however, fulfill the specifications of the National Formulary. It would be possible, in his opinion, to manufacture ichthyol from Colusa crude oil.

"The first question for determination is whether the findings of the court that the labeling on each of the bottles containing Colusa Natural Oil in the liquid state or in capsules, when considered in its entirety, would be understood by a person of average intelligence who was suffering from one of the diseases referred to therein, and who was seeking a remedy for such disease as representing that if he would use Colusa Natural Oil as directed, that such oil would cure or alleviate such diseases of all types and kinds and at all stages thereof are 'clearly erroneous' within the meaning of those words as used in Rule 52 (a) of the Federal Rules of Civil Procedure, supra. After careful consideration of the entire record we think this finding of the court is not erroneous.

"In argument to the trial court counsel for appellant observed that 'The law with respect to the interpretation of such a label is this. The Court has the right to presume that purchasers are of average intelligence.' The court approved and applied this standard. Counsel for appellant continued, saying that 'The most that can be contended is that . . . there is an implied representation this (Colusa Natural Oil) would be of assistance, that it would be effica-

cious,' defining efficacy to mean to assist in the treatment of disease. We can find nothing in the label suggesting that Colusa Natural Oil is recommended as an auxiliary to some other remedy or that the purchaser should use it as an 'assistant' only in the cure or alleviation of any of the diseases named. The label reads:

A natural unrefined petroleum oil for use in treatment of [the named skin diseases] . . . Directions: Apply to affected parts . . . Continue treatment *until skin is smooth and comfortable* . . . [Italics supplied.]

Certainly the first quoted clause implies that the use of the oil as directed will be useful in some way and in some measure in the treatment of the named skin diseases. It could hardly be said to be a useful treatment if it will neither cure nor alleviate such diseases.

"The meaning and implications of the second quoted direction, 'Continue treatment until skin is smooth and comfortable,' are not explained by counsel. Certainly it implies that the 'smooth and comfortable' condition of the skin will be the result of the treatment, and that the Colusa Oil when used as directed is an effective agent which will produce such a result. It is true the words 'cure' or 'cured' are not used, but neither is the word 'assist.' If appellant had intended that persons afflicted with the named diseases would by the use of Colusa Oil as directed receive assistance only to endure their suffering it would have been easy to say so and thus avoid any ambiguity in the labeling. We think the interpretation of the labels by the trial court is reasonable and neither 'absurd' nor based upon 'a wholly distorted reasoning,' as suggested by appellant.

"Second, is the representation in the labeling that Colusa Natural Oil when used as directed 'will cure or alleviate' the named diseases 'false or misleading in any particular'?

"The evidence on this issue is conflicting. Based upon such evidence the court found that the labeling of the bottles seized in all the cases consolidated for trial is false and misleading in that there is no credible or adequate scientific or medical foundation for any claim or representation that Colusa Natural Oil when used externally or internally will cure or will alleviate the named skin diseases, or will give relief from such diseases or will assist in the treatment of them. The court heard all of the government's witnesses, all of appellant's lay witnesses and one of its doctors. Appellant's other evidence was in the form of depositions. So, giving due regard 'to the opportunity for the trial court to judge of the credibility of the witnesses' (Rule 52 (a)), we cannot say that this finding is clearly erroneous.

"But says the appellant in its printed brief the findings of the court are unsound and indefensible; that the great weight of the evidence is contrary to the findings. We did not see and hear the witnesses testify, of course, and we cannot be guided by the opinions of counsel. We may consider only their reasoning supported by applicable authorities to determine whether the court's findings are clearly erroneous.

"In its written brief counsel for appellant asserts that 'There is no allegation (in the libels) that the labels in question were on the Colusa bottles when they were shipped in interstate commerce.' This point was not suggested in the trial court. On the other hand it admitted in its answer the allegations of paragraphs 2 and 3 of the libel of information wherein the government alleged:

2. . . . that Colusa Remedy Company *shipped in interstate commerce* from Los Angeles, California, to Waterloo, Iowa, . . . 9 bottles . . . each containing 4 fluid ounces of an article *labeled in part* 'Colusa Natural Oil', and 13 bottles . . . each containing 100 capsules and 7 bottles . . . each containing 200 capsules of an article labeled in part 'Colusa Natural Oil . . . in capsules intended for internal use.' 3. *That the aforesaid articles were misbranded in interstate commerce . . . in that the following statements which appear in the labeling of the articles, namely, [quoting the entire labels] . . . are false and misleading. . . . [Italics supplied.]*

These allegations cannot be reasonably or fairly construed to mean anything other than that the labels were on the bottles in which the 'article,' liquid oil, was contained at the time they were in interstate commerce.

"In discussing the weight of the evidence appellant in its brief contends that the Act does not apply to the situation presented here because its testimony demonstrated the merit and efficacy of Colusa Natural Oil, leaving nothing in dispute except the 'medical opinion' of the doctors; that putting aside the factual proof of appellant nothing more 'is involved than mere difference of opinion between schools of practitioners,' citing *United States v. 7 Jugs, Etc.*, D. C. Minn., 53 F. Supp. 746, and that 'the evidence is such that it appears that