2920. Adulteration and misbranding of prophylactics. U. S. v. 78 Gross * * *. (F. D. C. No. 27429. Sample No. 44931–K.)

LIBEL FILED: June 21, 1949, District of Minnesota.

ALLEGED SHIPMENT: On or about May 25, 1949, by Hughes Products, Inc., from Memphis, Tenn.

PRODUCT: 78 gross of *prophylactics* at Minneapolis, Minn. Examination of samples showed that 10.38 percent were defective in that they contained holes.

LABEL, IN PART: "Texide Prophylactic Manufactured by L. E. Shunk Latex Prod., Inc., Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactic" and "For Your Protection" were false and misleading as applied to an article containing holes.

DISPOSITION: October 21, 1949. Default decree of destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2921. Misbranding of Nue-Ovo. U. S. v. 600 Units, etc. (and 3 other seizure actions). Trial by jury. Verdict for Government. Decree of condemnation and destruction. Judgment affirmed on appeal to court of appeals. Certiorari denied by United States Supreme Court. (F. D. C. Nos. 14342, 16711, 20239, 20768. Sample Nos. 3830–F, 80924–F, 27846–H, 45063–H, 45068–H, 58379–H.)

LIBELS FILED: On or about November 8, 1944, August 6, 1945, and June 18 and August 29, 1946, Western District of Missouri, Western District of Washington, and Southern District of California.

ALLEGED SHIPMENT: The product was shipped by Research Laboratories, Inc., from Portland, Oreg., between the approximate dates of June 27, 1944, and August 24, 1946, and quantities of printed matter were shipped by the above firm, from Portland, Oreg., on or about April 16, 1945, and February 1 and June 1946. Quantities of printed matter also were shipped by Nue-Ovo, Inc., from Chicago, Ill., on or about July 19, 1943, and April 7 and August 8, 1944.

PRODUCT: 600 units, each containing 3 bottles; 71 packages, each containing 3 bottles; and 160 cases, each containing 18 bottles, of *Nue-Ovo* at Kansas City, Mo., Seattle, Wash., and Los Angeles, Calif., together with copies of circulars entitled "Information on Nue-Ovo and its Value in Arthritic and other Rheumatoid Symptoms" and "Read and see what Nue-Ovo has done for this man," copies of a circular letter headed "California Division Research Laboratories, Inc." and beginning "We thank you for your inquiry regarding Nue-Ovo in the treatment of Arthritic and Rheumatic symptoms, which was used successfully by Mrs. Emma Ives," and a number of placards reading, in part, "Are you suffering from arthritis or rheumatism?" Analysis disclosed that the product contained water, sugars, sodium benzoate, and extracts of plant materials, including a caffeine-bearing drug, such as kola nut, and licorice and cinnamon, and a laxative drug, such as cascara sagrada, and that certain portions of the product also contained sodium salicylate and a minute amount of vitamin B_1.

*See also Nos. 2913–2916, 2918–2920.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars, circular letter, and placards were false and misleading. The nature of the false and misleading statements is set forth in the opinion of the circuit court of appeals, supra.

DISPOSITION: Research Laboratories, Inc., having appeared as claimant and filed a motion for the removal of the libel proceedings in the Western District of Missouri, an order was entered on March 1, 1945, by the court for that district, directing that the proceedings be removed for trial to the District of Oregon. Thereafter, a motion to vacate such order was filed on behalf of the Government, on the grounds that the court was without authority to transfer the case to the district in which the claimant had its home office.

On March 23, 1945, after consideration of the briefs of the parties, the following opinion was handed down:

REEVES, *District Judge:* "On the first day of March 1945 this court entered an order removing and transferring the above entitled cause to the district court of the United States sitting at Portland, Oregon, for trial. This is the place intervenor's business is located. The order was made pursuant to motion filed by the intervenor for removal and transfer of the libel proceeding pursuant to provisions of Section 334 (a), Title 21 U. S. C. A. The language of the motion conforms to the statutory requirements, as follows:

> In any case where the number of libel for condemnation proceedings is limited * * * the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

"At the time the order was made the United States Attorney appeared with counsel for the intervenor or claimant and then insisted that the only order that could be properly made was one transferring and removing the case to the Western District of Washington, being a district of reasonable proximity to the claimant's principal place of business. The court was then of the opinion that the statute contemplated a place for holding court as near to the principal place of business of the claimant as practicable. Such a place of holding court was at Portland, Oregon. A hurried interpretation of the statute seemed to warrant the court in removing the case for trial to that point. The District Attorney did not agree to the order and, as indicated, has subsequently filed a motion to vacate the order of removal. The parties have favored the court with briefs and suggestions in support of their respective contentions. Congressional records showing the history of the legislation indicate that the Senate attempted to provide that a case of this kind might be removed and transferred to the district court in which claimant's principal place of business was located, while, on the other hand, the House of Representatives attempted to provide that the removal could be made only to a district court of a state contiguous to the state of claimant's principal place of business. Both the Senate and House receded from their several extreme positions. The Senate no longer contended that the transfer should be made to a state contiguous to that of the claimant's domicile. The compromise involved the use of the words 'a district of reasonable proximity to the claimant's principal place of business.' In order to give a proper meaning to the statute, in view of the concessions made by the two legislative bodies, a district of reasonable proximity would mean a district other than that of the domicile of the claimant, whether in the same state or a contiguous state. Oregon has but one district, whereas the State of Washington has two districts. The Western District of Washington, Southern Division, is a district of 'reasonable proximity to the claimant's principal place of business.'

"1. A statement of the facts and the law, as above, suggests a proper interpretation of the statute and what order should be made in the case. This is not a case of first impression.

"In the case of United States v. 6 dozen bottles, etc., 55 Fed. Supp. 458, Judge Duffy of the District Court of the Eastern District of Wisconsin, was presiding in a similar case. That case, however, had been transferred to his district from one of the district courts in the State of Washington. The claimant in that case had originally applied to one of the district judges in one of the districts of Washington to transfer the case to the Northern District of Illinois for the reason that the claimant's principal place of business was in Chicago. The District Judge declined to transfer the case to the Northern District of Illinois but did order its removal or transfer to the Eastern District of Wisconsin, being a district of reasonable proximity to the claimant's place of business. After the transfer to that district of reasonable proximity the claimant renewed its motion for a transfer to the Northern District of Illinois. While District Judge Duffy ruled that the claimant had exhausted his right of removal as having been accorded by statute but one removal, nevertheless he took occasion to say:

> Manifestly, claimant's application for removal to the district court in Illinois was not granted by the district court in Washington, *because the same would not have been and is not authorized.* In the absence of stipulation between the parties, *the power of removal of the court of original jurisdiction is limited and restricted.* Such court is required to order removal to "a district of reasonable proximity to the claimant's principal place of business." Accordingly, it would have been beyond the power of the district court in Washington to have removed this proceeding to the designated district court in Illinois.

"2. Moreover, in this case, the claimant apparently so interpreted the statute for the reason that, in its motion to transfer it said:

> Intervenor further states that the United States District Court next closest to Intervenor's place of business is the District Court of the United States for the District of Washington, Western District, Southern Division, sitting at Tacoma, Washington, which said district court is approximately 150 miles from Portland, Oregon.
>
> Wherefore, Intervenor prays that said cause be transferred and removed from this Court to a district of reasonable proximity to Intervenor's principal place of business.

It will be observed that the intervenor does not ask that the case be transferred to the district in which the claimant's principal place of business is located.

"In view of the above, the order of removal transferring the case for trial to the District Court of Oregon, sitting at Portland should be amended so that the order of removal will be to the Western District of Washington, Southern Division, at Tacoma, Washington, and it will be so ordered."

In accordance with the above opinion, an order was entered on March 23, 1945, providing that the order of March 1, 1945, be vacated and that the libel proceedings in the Western District of Missouri be removed to the Southern Division of the Western District of Washington.

On April 23, 1945, the claimant filed in the United States District Court for the Western District of Washington, Southern Division, exceptions to the libel proceedings so removed, based on the grounds (1) that the libel failed to state facts sufficient to constitute a cause of action and (2) that the printed matter did not accompany the product or constitute labeling of the product.

On March 25, 1946, after consideration of the arguments of counsel, an order was entered overruling and denying the exceptions to the libel. Thereafter, on stipulations of the parties, an order was entered directing the consolidation for trial, in the Western District of Washington, of the case removed from the Western District of Missouri, with the two libel proceedings originally instituted in the Western District of Washington and the libel proceeding originally instituted in the Southern District of California.

An answer was filed by the claimant, denying the pertinent allegations of the libel; and on October 22, 1946, the case came on for trial before the court and jury. On November 1, 1946, the trial was concluded with the return of a verdict in favor of the Government. On November 22, 1946, judgments of condemnation were entered and it was ordered that the circulars be destroyed and that the product be subsequently disposed of as ordered by the court.

The case was appealed to the Court of Appeals for the Ninth Circuit; and

on April 2, 1948, the following opinion was handed down by that court, affirming the judgment of the district court:

GARRECHT, *Circuit Judge:* "In four cases consolidated for trial, judgments and decrees were entered condemning and ordering destroyed quantities of a proprietary drug known as 'Nue-Ovo' and certain written material alleged to constitute the labeling thereof. The action of the court below was taken pursuant to libels alleging misbranding, under 21 USCA § 352 (a). From the judgments and orders referred to, the present appeals have been taken by the intervenor below, as claimant of the property seized.

"The appellant, an Oregon corporation, has engaged in the manufacture, sale, and distribution of proprietary drug products known as 'Nue-Ovo,' 'Sal Trag,' and 'Burvidin' continuously since 1925. The formulas of the products have been changed from time to time, and the merchandise now under seizure differs from products of the same name involved in previous litigation.

"Nue-Ovo is sold direct to consumers. In concentrated form, called 'Sal-Trag,' it is sold to licensed physicians. The products are manufactured at Portland, Oregon, and shipped to purchasers and distributors in most of the states west of the Mississippi River. The appellant's direct sales program involves extensive use of advertisements in daily and weekly newspapers and similar publications. In general, these advertisements solicit mail inquiries regarding the effectiveness of Nue-Ovo in the treatment of arthritis, neuritis, rheumatism, sciatica, and lumbago, to which inquiries the appellant replies by mail. The advertisements referred to are not, of course, part of the labeling.

"In November, 1944, a libel was filed in the United States District Court for the Western District of Missouri, Western Division, pursuant to which there were seized by the United States Marshal about 600 units of Nue-Ovo, each unit containing three bottles. Some of the unit cartons are labeled in part:

Active Ingredients: An aqueous extraction of Plume Thistle, Burdock, Quassia, Sage, Cinnamon, Horehound, Dandelion, Kola Nut, Ginseng, Althea, Cascara and Licorice.
This is the regular Nue-Ovo Formula to which have been added laxatives.
Less than one-half of one per cent Sodium Benzoate added as a preservative.

Other unit cartons are labeled in part:

This is the regular Nue-Ovo formula to which have been added Cascara, Licorice and Sodium Salicylate. Less than one half of one per cent Sodium Benzoate added as a preservative. Vitamin B1 added.

"The libel alleges that 600 units were shipped by the Appellant on or about June 27, 1944, and August 2, 1944, from Portland to Crown Drug Company, Kansas City, Missouri.

"Pursuant to the same libel there were also seized at the same time stocks of circulars entitled 'information on Nue-Ovo and its value in Arthritic and other Rheumatoid symptoms.' The circulars were alleged to have been shipped in interstate commerce on or about April 7 and August 8, 1944, from Chicago, Illinois, by Nue-Ovo, Inc.—not the appellant herein—to the Crown Drug Company at Kansas City.

"The libel alleges that:

The article is misbranded within the meaning of 21 U. S. C., 352 (a) in that the statements in the attached Exhibits "A" and "B" which appear in the labeling of the article . . . are false and misleading in this, that such statements represent and suggest and create in the mind of the reader thereof, the impression that the article of drug, Nue-Ovo, is effective in the treatment of arthritis, rheumatism, neuritis, sciatica, and lumbago, whereas, the article is not effective in the treatment of such conditions.

"Other seizures were made later pursuant to libels following the same general pattern as the foregoing.

"The proceedings were all removed to the court below, where they were consolidated for trial in accordance with the provisions of 21 USCA § 334 (b).

"The court below entered a pre-trial order which specified as an agreed fact that 'the labeling alleged in the several libels constituted the labeling of the product seized.'

"The agreed issues were stated in the pre-trial order as follows:

1. Whether or not the Nue-Ovo under seizure is ineffective in the treatment of arthritis, rheumatism, neuritis, sciatica, or lumbago.
2. Whether or not the labeling under seizure suggests to the user that the Nue-Ovo is effective in the treatment of arthritis, rheumatism, neuritis, sciatica, or lumbago.

3. Whether or not the product is misbranded by reason of the labeling.

"The appellant admitted that the labeling represented the product to be effective. Thus the misbranding and the ineffectiveness of the product were the issues to be litigated.

"Summarized, the appellant's attacks upon the judgment below are as follows:

1. The court below erred in submitting issues to the jury, since every statement in the labeling as to the effectiveness of the product is a statement of opinion, and at the conclusion of the case the record showed nothing more than a difference of opinion among qualified medical experts as to the effectiveness of the product.
2. The court erred in receiving testimony intended to show a misleading of the witnesses by material that was not part of the labeling seized.
3. The court erred in instructing the jury as to the elements to be taken into account in determining whether the labeling is misleading, under 21 USCA 321 (n), infra.
4. If it should be held that the court did not err in giving an instruction based upon 21 USCA 321 (n), infra, the court's denial of the appellant's motion for the release of the product under bond was an abuse of discretion.
5. As applied by the court the statute is unconstitutional.

"If the first four objections urged by the appellant are found to be untenable, the fifth must fall of its own weight and need not be discussed.

1. *The Rule in the McAnnulty Case*

"The appellant bases its first contention upon a line of decisions commencing with American School of Magnetic Healing v. McAnnulty, 187 U. S. 94, 105–106. There the court said:

> As the effectiveness of almost any particular method of treatment of disease is, to a more or less extent, a fruitful source of difference of opinion, even though the great majority may be of one way of thinking, the efficacy of any special method is certainly not a matter for the decision of the Postmaster General within these statutes relative to fraud. Unless the question may be reduced to one of fact as disinguished from mere opinion, we think these statutes cannot be invoked for the purpose of stopping the delivery of mail matter.

"Although the McAnnulty case was decided four years before the passage of the original Food and Drugs Act of June 30, 1906, c. 3915, 34 Stat. 768, the doctrine there announced was applied to the misbranding of drugs in United States v. Johnson, 221 U. S. 488, 498–499 (1911), and in Seven Cases of Eckman's Alterative v. United States, 239 U. S. 510, 517 (1916).

2. *Three Limitations to the McAnnulty Rule*

"It should be borne in mind, however, that the McAnnulty case, supra, was heard on a demurrer and involved the Postmaster General's power to decide what was in reality a medical question, as to which he would presumably have no professional training.

"It cannot be assumed that the Supreme Court intended to reach out a dead hand over the power of Congress to pass legislation in the future setting up a well-equipped Federal agency capable of arriving at a professional conclusion as to the adulteration or misbranding of drugs 'when introduced into or while in interstate commerce.' 21 USCA § 334 (a). In the McAnnulty case the court not only pointed out that 'as the case arises on demurrer, all material facts in the bill are of course admitted,' but throughout the opinion doubt was expressed as to the qualifications of a *postmaster general* to pass on medical questions.

"In the excerpt which we have already quoted, the Supreme Court expressed the view that 'the efficacy of any special method [of treatment of disease] is certainly not a matter for the decision of the Postmaster General within these statutes relative to fraud.' Again, on page 105 of the opinion, referring to the place of electricity in therapeutics, the court pointedly asks: 'Was this kind of question intended to be submitted for decision to a Postmaster General, . . .?'

"On the following page, the court thus summarized its holding as to the Postmaster General's power under the mail fraud statutes:

> Other instances might be adduced to illustrate the proposition that these statutes were not intended to cover any case of what the Postmaster General might think to be false opinions, but only cases of actual fraud in fact, in regard to which opinion formed no basis.

"Even in that case, however, the court conceded that the Postmaster General might make a showing that fraud was being committed:

> In overruling the demurrer we do not mean to preclude the defendant from showing on the trial, if he can, that the business of complainants as in fact conducted amounts to a violation of the statutes as herein construed. [Cf. Leach 1. Carlile, 258 U. S. 139, 139, 140.]

"And in Seven Cases of Eckman's Alterative v. United States, supra, 239 U. S. at page 518, Mr. Justice Hughes said:

> It cannot be said, for example, that one who should put inert matter or a worthless composition in the channels of trade, labeled or described in an accompanying circular as a cure for disease when he knows it is not, is beyond the reach of the law-making power. Congress recognized that there was a wide field in which assertions as to curative effect are in no sense honest expressions of opinion but constitute absolute falsehoods and in the nature of the case can be deemed to have been made only with fraudulent purpose.

"In contrast to the meager technical facilities for the determination of medical questions possessed by the Postmaster General—at least at the time that the McAnnulty case was decided—we find that the Federal Security Agency has at its disposal almost unlimited professional resources with which to carry out its investigations in the enforcement of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040, 21 USCA § 301 et seq. Typical of this elaborate set-up are the provisions of 21 USCA § 372 (a):

> The Administrator is authorized to conduct examinations and investigations for the purposes of this chapter through officers and employees of the Agency *or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof,* duly commissioned by the Administrator as an officer of the Agency. [Emphasis supplied.]

"As we shall disclose in our discussion of the evidence hereinafter, this extensive professional implementation authorized by the statute under consideration was fully utilized in the case at bar.

"In view of the foregoing, it could well have been reasoned *a priori* that the impact of the McAnnulty case would be carefully limited in later decisions. And that is precisely what has occurred.

"As was said in United States v. 7 Jugs, etc., of Dr. Salsbury's Rakos (DC Minn.), 53 F. Supp. 746, 759, heavily relied upon by the appellant itself:

> Moreover, it must be obvious that tremendous advancements in scientific knowledge and certainty have been made since the rule in the McAnnulty case was first announced. Questions which previously were subjects only of opinion have now been answered with certainty by the application of scientifically known facts. In the consideration of the McAnnulty rule, courts should give recognition to this advancement.

(a) *Jury May Consider Testimony as to Actual Experiments*

"Much of the appellee's evidence in the instant case consisted of 'controlled clinical studies' conducted by eminently qualified physicians and surgeons.

"Dr. Frances Baker, Director of the Department of Physical Medicine at the University of California, whose professional qualifications appear to be highly impressive testified at great length regarding a clinical study that she made in 1944 with Nue-Ovo that contained cascara and licorice, but not B-1 and salicylate. The study was made on patients in the orthopedic clinic at the University of California Hospital. At the end of two months, five of the patients 'were no better at all' and 'one felt better.' As the result of her studies, Dr. Baker testified that she thought that Nue-Ovo 'offers us nothing that is of value in the treatment of arthritis.' She expressed similar opinions as to Nue-Ovo's effectiveness in cases of lumbago, sciatica, neuritis, and rheumatism, and stated that the addition of sodium salicylate and Vitamin B-1 in quantities found in one type of Nue-Ovo would not 'give us any value whatever.'

"Dr. John H. Wheeler is a practicing physician in Kansas City, Missouri, and is on the teaching staff of the University of Kansas, in Kansas City, Kansas. In 1944, at the request of the Food and Drug Administration in Kansas City,

he made a study of Nue-Ovo in the Out-Patient Department of the University of Kansas. The type of Nue-Ovo that he used was that containing cascara and licorice, without the B-1 and salicylates. Six patients were asked to continue the medicine for six weeks. Dr. Wheeler testified that the medicine had 'no effect whatsoever' on three patients, and two patients stated that they 'were of the opinion . . . that they were no worse.' On the day of his return, the sixth patient 'felt that he had definitely improved while taking his Nue-Ovo,' but 'was complaining of some new pains involving both knees.' This sixth patient, however, made that report ten months after starting the medication with Nue-Ovo, and still had some of the six weeks' supply of the medicine left.

"In 1940, Dr. Wheeler 'had experience' with Nue-Ovo with no added cascara or licorice with twenty-three patients, nine of whom took the preparation for as long as three months. Some took it for as short a period as two weeks, in one case because the discomfort was so great that the patient desired some other type of medication. Of the twenty-three cases, there were eighteen upon whom Nue-Ovo had no 'effect whatsoever,' three were 'questionable, in that perhaps their symptoms had improved slightly over the . . . previous period of nine months,' and 'two were definitely of the opinion that they felt better.' Based upon his total experience with the product in 1944 and the product in 1940, Dr. Wheeler's opinion was that, with or without cascara, licorice, or sodium salicylate or thiamine in the amount stipulated, Nue-Ovo's 'effectiveness is nil' in the treatment of arthritis, rheumatism, lumbago, neuritis, and sciatica.

"Testimony of experts that is based upon tests or experiments made by them does not come within the ambit of the McAnnulty rule. In Elliott Works v. Frisk (DC Iowa), 58 F. 2d 820, 825, the problem was fully and lucidly discussed:

> Complainants are mistaken in their claim that the only evidence introduced as against them was mere opinions of witnesses and that the opinion of the expert for the government should not be considered as substantive evidence. In this contention complainants reply upon the case of American School of Magnetic Healing v. McAnnulty, 187 U. S. 94, 23 S. Ct. 33, 47 L. Ed. 90. The facts here are entirely different from what they are in that case, which arose on a demurrer wherein all the material facts averred in the bill were admitted for the purpose of the hearing. It may be conceded that the court there held that mere matters of opinon on which witnesses might vary in their conclusions would not substantiate a fraud order such as is here under consideration; but the finding of the solicitor in this case is not based on opinions, but upon a scientific investigation, findings, and tests made by the United States Bureau of Standards. Opinions of experts when founded upon known scientific facts are not to be considered the same as opinions of laymen, but are considered by the courts as substantive evidence. (Cases cited.) However, the evidence upon which the facts here were found was not alone based upon such scientific opinions, but upon tests made and facts actually disclosed by independent research of experts in an outstanding scientific bureau of the national government. [See also Kar-Ru Chemical Co. v. United States (CCA 9), 264 F. 921, 928; United States v. Lesser (CCA 2), 66 F. 2nd 612, 616; United States v. 7 Jugs, etc., of Dr. Salsbury's Rakos, supra, 53 F. Supp. at pages 758–759.]

(b) *Testimony of Experts as to Consensus of Scientific Opinion Is Also Relevant*

"Dr. James M. Dille, professor of pharmacology and assistant dean of the School of Medicine of the University of Washington, while on the witness stand went down the list of ingredients of Nue-Ovo and categorically reported that scientific 'investigation' by 'doctors or pharmacologists' has shown that many of the ingredients have no 'action' as drugs. For example concerning plume thistle, the first ingredient listed in the statement of 'agreed facts', Dr. Dille said:

> It has no action that doctors or pharmacologists can find, at all.

"Again, as to ginseng, another Nue-Ovo ingredient, Dr. Dille said:

> . . . as modern pharmacology developed and they made all sorts of investigations on ginseng, they found that it is absolutely without any potent principal (principle?) of any value to medicine.

"It is generally agreed that testimony as to the consensus of medical opinion may be considered in drug-misbranding cases. In United States v. Dr. David Roberts Veterinary Co. (CCA 7), 104 F. 2d 785, 788, the court said:

> In support of this count the testimony disclosed that the product does not contain ingredients which would be effective as a treatment for shoeboils or poll evil; that it has no value in the treatment of enlarged glands; and that no drug or mixture of drugs is known to the profession generally, or agreed upon by the consensus of veterinary opinion, that can do all of the things claimed by this label.
>
> The record also discloses that the professional witnesses for the government testified that the opinions expressed by them were in accord with the consensus of medical opinion. * * *

In the instant case, the question was reduced to one of fact, as distinguished from mere opinion, [cases cited], and, as defendants' testimony made for conflicting evidence, a question of weighing the evidence was presented. To weigh the evidence is not within the power of this court. [*See also* 28 C. J. S. Druggists § 12 k (2), page 531.]

(c) *Even Opinion Testimony as to Therapeutic Value is Admissible*

"In this circuit and elsewhere, it has been held that expert testimony even in its broadest sense—i. e., where the witness has neither tested the product nor purports to report the consensus of medical opinion—is admissible on the question of therapeutic value.

"In John J. Fulton Co. v. Federal Trade Commission (CCA 9), 130 F. 2d 85, 86, certiorari denied, 317 U. S. 679, we said:

The findings have support in the testimony of expert witnesses called by the Commission. But the petitioner argues that since none of the experts had prescribed Uvursin or observed its effects in concrete cases their testimony was incompetent and inadmissible. We think otherwise. The witnesses were shown to possess wide knowledge in the field under inquiry. There is no reason to suppose them incompetent to express an opinion as to the lack of therapeutic value of petititioner's preparation merely because they had had no personal experience with it in the treatment of the disease. Their general medical and pharmacological knowledge qualified them to testify. [Cases cited.] [1]

"The same doctrine has been followed in misbranding cases tried before juries. In Goodwin v. United States (CCA 6), 2 F. 2d 200, 201, cited by us with approval in the Fulton case, supra, it was said:

Upon the trial of the issue of fact joined by the libel charging the misbranding of mineral water and the answer of the intervener, expert evidence may be properly admitted. If it appears from the testimony of a witness upon preliminary examination that he is learned in the science of chemistry or has been regularly and legally admitted to the practice of medicine, and that he has knowledge of the drug elements contained in the article transported in . . . interstate commerce and their efficacy or lack of efficacy as curative agents, used either separately or in combination in the treatment of the diseases specified on the label, his opinion on that subject is competent evidence regardless of whether he has had actual experience or observation of the effect of the use of such drugs in the exact form in which they are transported in interstate commerce. *The weight of his evidence is a question for the jury.* [Emphasis supplied.] [2]

The evidence in this case included the three types that we have discussed hereinabove: Testimony by experts based on (a) tests made of the product itself; (b) the consensus of medical opinion as to the various ingredients used in Nue-Ovo; and (c) the expert witnesses' personal opinions regarding the effectiveness of such ingredients. Altogether, there was ample evidence to support the verdict of the jury.

3. *Much of the Factual Evidence of the Appellee Consisted of Other Than Medical Testimony*

"It will be remembered that in the Eckman's Alterative case, supra, Mr. Justice Hughes has pointed out that Congress has 'recognized that there was a wide field in which assertions as to curative effect are in no sense honest expressions of opinion but constitute absolute falsehoods.' In the instant case, the appellee presented factual evidence of definite untruths and half-truths contained in the labeling of Nue-Ovo. This evidence did not come from medical experts but from documents and from lay witnesses.

"The labeling purports to quote from a letter written by Mrs. Fred Anderson, of Albany, Oregon, in part as follows:

I wish to say that after taking Nue-Ovo I feel like a new person, inasmuch as my nerves are 100% better—no trace of Neuritis left and a general built-up condition.

"This letter is one of a group that appears on the labeling, with the following notation: 'Original letters on file in office. Copies may be obtained on request.'

"In a 'motion to produce documents,' the appellee demanded that the originals of a number of these letters be produced by the appellant, including the letter attributed to Mrs. Anderson.

"Mrs. Eleanor M. Feldman, president of the appellant, was unable to produce the originals of at least four of the letters, including that of Mrs. Anderson. Instead, 'copies' were offered. Mrs. Feldman explained that in moving from

[1] *See also* Irwin v. Fed. Trade Comm. (CCA 8), 143 F. 2d 316, 324; Charles of the Ritz Distributors Corp. v. Fed. Trade Comm. (CCA 2), 143 F. 2d, 676, 678–679.
[2] *See also* 28 C. J. S. id.

one location to another, some of the appellant's documents were lost, an entire steel file having disappeared from her office.

"Mrs. Anderson gave a deposition in which she stated that after taking the first three or four bottles of Nue-Ovo she thought that her 'time had come'; that she didn't think it had done her any good; that she did not have neuritis, but arthritis; that she did not write the letter, and could not account for it; 'How on earth they got my name is more than I know.' A former employee of the appellant asked Mrs. Anderson to give him a testimonial, but she refused, according to her deposition.

"Another part of the Nue-Ovo labeling contains two 'before-and-after' photographs of H. J. Shermer of Leaburg, Oregon, flanking the facsimile of a notarized letter by him extolling the merits of that nostrum. The photograph taken 'before' Nue-Ovo shows Mr. Shermer in an emaciated condition, his weight being given as 110 pounds. The post-Nue-Ovo photograph shows Mr. Shermer as he appeared eighteen months later, weighing 165 pounds.

"In his letter, Mr. Shermer stated that he was first afflicted with arthritis fifteen years prior to the date of writing, October 8, 1934. After taking Nue-Ovo for 18 months, Mr. Shermer wrote, he was able to attend to his business, pursue his hobbies of hunting and fishing, 'and enjoy life generally.'

"C. W. Frazier, of Newburg, Oregon, who had been for sixteen years the sheriff of Harney County, Oregon, himself a sufferer from arthritis or rheumatism, or possibly both, saw the photographs and the facsimile letter of Mr. Shermer. With the traditional skepticism of a peace officer, the former sheriff decided to investigate. He called upon Mr. Shermer and found him sitting by a trailer, with his feet on a padded stool and a pair of crutches at his side.

"Mr. Frazier wrote to the appellant about his 'disappointing visit' to Mr. Shermer. In reply, Mrs. Feldman 'explained' that the 'back-set' was due to the complete extraction of Mr. Shermer's teeth at one time and to overwork. Mrs. Feldman further wrote that Nue-Ovo was helping Mr. Shermer 'for the third time,' and she felt certain 'that now that he is free of responsibility and that he and Mrs. Shermer can have a little more leisure time, he will make his third recovery.'

"Still not satisfied with the outcome of the Shermer investigation, Mr. Frazier called upon Mrs. Feldman in person. Mr. Frazier testified:

> Well, the conversation got a little exciting a time or two. Mrs. Feldman sort of accused me of trying to make her out one damn liar, so she said. Why I told her, I said "Mrs. Feldman, I wouldn't think of putting it that way," but I said "Your advertising I still question quite a little."

"Finally, the Nue-Ovo labeling contains an 'analysis of ingredients,' with the prefatory explanation that it is based chiefly on the United States Dispensatory, the Pharmacopoeia, and various textbooks on pharmacology.

"It is here that half-truths enter the picture. While the label's 'analysis' followed part of the language of the above-named authorities somewhat closely and sometimes verbatim, there were significant omissions in the excerpts. Here are a few of the deleted portions:

> (Ginseng) The extraordinary medicinal virtues formerly described as [ascribed to] Ginseng had no other existence than in the imagination of the Chinese.
> (Horehound) It has, however, been almost completely abandoned by physicians.
> (Salvia or sage) For what reason this condiment was admitted into the N. F. is not obvious. While the ancients say it is highly esteemed, there is no evidence that it possesses therapeutic virtues, and it is practically never prescribed by physicians.
> (Lappa or Burdock) There is not sufficient reason, however, to believe it has any medicinal virtues.

"The apocryphal or misleading testimonials and the scientific half-truths in the labeling alone make out a case of actionable misbranding. As was said by the Supreme Court in Donaldson v. Read Magazine, Slip Opinion, page 10, decided on March 8, 1948:

> Advertisements as a whole may be completely misleading although every sentence separately considered is literally true. This may be because things are omitted that should be said, . . .

As we shall see hereafter, this doctrine is specifically incorporated in the statute now under consideration. *See* 21 USCA § 321 (n), infra.

4. *There Was No Error in the Admission of Evidence of Misleading Material Not part of the Labeling*

"The appellant complains that the appellee sought to show that its 'lay witnesses' had been misled by material that was not part of the labeling seized.

Particular criticism is directed against the questioning of 'witness after witness' regarding a newspaper advertisement in which Anna Pautz invited persons suffering from arthritis, neuritis, rheumatism, sciatica and lumbago to communicate with her; and also regarding a letter in her handwriting and with her signature, stating that she had been benefited by using Nue-Ovo. The appellant concedes that the testimony showed that the letter in each instance that it was sent out had not been written personally by Mrs. Pautz, but was the reproduction of a letter originally written and signed by her.

"To say that the appellant did not deal frankly with the public in connection with the Pautz letter would be a distinct understatement. Further details are necessary to bring out the complete shadiness of this publicity project, which in the oral argument counsel for the appellant declined to defend.

"Mrs. Pautz, who was 76 years old at the time she testified, became a stockholder in the appellant about 1924, before using Nue-Ovo for arthritis. She testified that it cured her. She has never taken Nue-Ovo since 1923 or 1924.

"Beginning in 1945, there appeared in Portland newspapers, and later in other publications in the United States the following advertisement:

Rheumatism and Arthritis

I suffered for years and am so thankful that I am free from pain and able to do my work that I will gladly answer any one writing me for information. Mrs. Anna Pautz, P. O. Box 825, Vancouver, Wash.

Pd. Adv. Nue-Ovo Laboratories, 403 N. W. 9th Ave., Portland 9, Ore.

"At first, Mrs. Pautz financed the running of the advertisement and the rental of the post office box out of her own funds. Later, however, according to Mrs. Feldman's testimony, the appellant apparently took over the advertising costs, through a block advertising agency:

Mrs. Pautz is quite an old lady, and a very sweet old soul. When I found she was running it, I certainly wouldn't permit her to pay for it.

"A month or two after the advertisement first appeared, in a Portland newspaper, Mrs. Pautz composed and wrote out the letter in question, no one helping her with it. Her motive for doing so was just because she 'wanted to help somebody.'

"The letter contained the salutation 'Dear Friend,' and advised sufferers from arthritis and rheumatism to visit or write to the appellant's headquarters. In the letter Mrs. Pautz gave the Vancouver post office box as her mail address.

"Mrs. Pautz testified that at the time she wrote the letter, she did not own any stock in the appellant, having sold her shares to one of her sisters.

"Mrs. Pautz actually lives in Portland, which has been her home for fifty-eight years. The evidence adduced by the appellant as to why Mrs. Pautz gave the Vancouver address is contradictory. Mrs. Pautz herself testified that she never used the Vancouver box for her personal mail and that Vancouver was selected—

Because there is a girl working in the laboratories at Vancouver, Washington, and she could pick up the mail and bring it to the laboratories.

"Mrs. Feldman gave a different explanation of the Vancouver arrangements. She testified that the appellant has a contract with a *transfer company* to pick up the mail from the Vancouver box and take it to Portland, where, as we have seen, both Mrs. Pautz and the appellant have their domiciles. The replies to the letters thus received are then carted back to Vancouver and mailed there, by 'that same man that brings the letters.'

"When she was asked why this roundabout way of handling Mrs. Pautz' mail is employed, Mrs. Feldman repeatedly gave this cryptic reply:

Because it is convenient.

"The handwritten letter of Mrs. Pautz was mimeographed and sent out directly from the appellant's laboratories without any notation or other disclosure to the addressee that it is being sent from the appellant's headquarters, or that the appellant has had it mimeographed. The envelopes in which the Pautz letters are sent out are addressed in handwriting, although all the other correspondence of the appellant goes out in typed envelopes.

"The evidence on this point makes it quite clear that it was the appellant's intention to have the recipients of the Pautz letters believe that Mrs. Pautz herself had written each individual letter and had mailed it at Vancouver.

"After Mrs. Pautz's letter was sent out, the office of the appellant customarily mailed to those answering her advertisement a letter in which it was stated

that Mr. and Mrs. Pautz usually have some Nue-Ovo 'on hand and take it for a time every Spring as more or less of general tonic.' This statement is in direct contradiction to Mrs. Pautz's testimony that she had not used Nue-Ovo since 1923 or 1924.

"Both sides agree that 'the question of good faith and the question of intent is not involved' in this case; that 'the Government does not have to show a fraudulent intent on the part of the shipper or manufacturer'; and that, 'conversely, if it is shown that the product proceeded against is adulterated or misbranded, then good faith or a lawful intent will not constitute a defense.'

"Prior to 1938, when the present Food, Drug, and Cosmetic law was enacted, the statute *did* provide that an untrue statement in the labeling of a drug product had to be 'false and fraudulent' in order to render the product subject to condemnation for misbranding. Section 10 of the 1927 edition of 21 USCA read in part as follows:

§ 10 *Misbranded articles.* For the purpose of sections 1 to 15, inclusive, of this title, an article shall be deemed to be misbranded;

Drugs. In case of drugs.

* * * * * * *

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.* [Emphasis supplied.]

"The present law requires only that the labeling be 'false or misleading in any particular' in order to bring the drug within the definition of 'misbranded.' 21 USCA 352 (a).

"This does not mean, however, that under the present law the appellee, in presenting to the jury a fair and complete picture of the claimant's activities, must sedulously avoid adducing any evidence of fraud. As the appellee points out—

In the instant case, the jury had the right to know that whatever propensity the purchasers of Nue-Ovo might have had to analyze had been reduced to a minimum by the groundwork laid by Appellant. In determining whether the labeling suggests to the user that Nue-Ovo is effective in the treatment of arthritis, rheumatism, neuritis, sciatica, and lumbago, we submit that it was proper for the jury to consider the labeling representations in the light of the setting in which the manufacturer intended the user to read them.

"It is well settled that the 1938 act was intended to make the provisions against misbranding stricter and not more lenient than they had been in pre-existing laws. The new statute was not designed to provide the misbrander of drugs with additional technical loopholes for escape, but to batten down those already existing.

"The evidence of the Congressional intent, as construed by the Supreme Court of the United States, is impressive. In United States v. Dotterweich, 320 U. S. 277, 280–282, the court said:

The Food and Drugs Act of 1906 was an exertion by Congress of its power to keep impure and adulterated food and drugs out of the channels of commerce. By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words. [Cases cited] The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger. [Case cited] And so it is clear that shipments like those now in issue are "punished by the statute if the article is misbranded [or adulterated], and that the article may be misbranded [or adulterated] without any conscious fraud at all. It was natural enough to throw this risk on shippers with regard to the identity of their wares. . . ." *United States* v. *Johnson,* 221 U. S. 488, 497–98.

* * * * * * *

* * * Nothing is clearer than that the later legislation was designed to enlarge and stiffen the penal net and not to narrow and loosen it. This purpose was unequivocally avowed by the two committees which reported the bills to the Congress. The House Committee reported that the Act "seeks to set up effective provisions against abuses of consumer welfare growing out of inadequacies in the Food and Drugs Act of June 30, 1906." (H. Rep. No. 2139, 75th Cong., 3d Sess., p. 1.) And the Senate Committee explicitly pointed out that the new legislation "must not weaken the existing laws," but on the contrary "it must strengthen and extend that law's protection of the consumer." (S. Rep. No. 152, 75th Cong., 1st Sess., p. 1)

"Furthermore, the Act is remedial, and should be liberally construed so as to carry out its beneficent purposes. In United States v. 95 Barrels of Vinegar, 265 U. S. 438, 442–443, the court said:

> The statute is plain and direct. Its comprehensive terms condemn every statement, design and device which may mislead or deceive. *Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity,* as well as from statements which are false. It is not difficult to choose statements, designs and devices which will not deceive. *Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the Act.* [Emphasis supplied.] [3]

"We do not think that we would be construing the statute in accordance with the Congressional purposes if we were to hold that it was reversible error for the appellee to be allowed to introduce evidence regarding the 'indirection' employed by the appellant in connection with the shuttling of the Pautz mail back and forth between Vancouver and Portland, Oregon. One would have to be quite naive not to discern in this subterfuge, the thinly disguised purpose of causing the public to believe that there was no connection between the appellant and Mrs. Pautz.

"It is true that the letter was not part of the labeling. It was, however, part and parcel of the appellant's questionable promotional methods, some of which *were* reflected in the labels, as was amply disclosed by the evidence to which we have referred in the preceding section. It was not error for the court below to permit the appellee to lay before the jury the entire picture.

5. *There Was No Error in the Instruction Regarding the Test to Be Applied in Determining Whether the Labeling Is Misleading*

"The appellant complains that the 'error' in the admission in evidence of the Pautz letter and advertisement, supra, was 'compounded' when the court instructed the jury on 21 USCA § 321 (n). That subsection reads as follows:

> (n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

"The objection is not that the instruction as to this subsection was erroneous per se, but that the error lay in giving *any* instruction as to that provision of the statute. The appellant contends that 'the instant libels make no general charge of misbranding under which the appellee is entitled to rely upon Section 201 (n) of the Act, [21 USCA § 321 (n)] supra,' but that the present charge is 'merely that the product *is not effective.*' 'Certainly,' it is argued, 'no reference to Section 201 (n) appears in any of the pleadings or the pretrial order,' etc.

"In making this attack upon the court's instruction as to the subsection in question, the appellant seems to forget the half-truths *in the labeling* to which we have referred in a preceding section herein. It will be remembered that, though the appellant announced in its label that its 'analysis of Ingredients' was based chiefly on the United States Dispensatory, the Pharmacopoeia, and various textbooks, and although it did indeed quote verbatim from some of these authorities, it unfairly omitted unfavorable comments regarding some of Nue-Ovo's ingredients.

"It was to cover precisely such tricky omissions and suppressions that Section 321 (n) was designed.

"Furthermore, in *any* case where 'an article is alleged to be misbranded because the labeling is misleading' in *any* respect, it is made mandatory by § 321 (n) itself that the jury 'shall' take into account such omissions or suppressions. In the instant case, the third agreed issue in the pretrial order was 'Whether or not the product is misbranded by reason of the labeling.' In the libels themselves, it is set forth that the article 'was misbranded . . . in that the statements . . . which appear in the labeling . . . are false and misleading in this,' etc.

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[3] See also U. S. v. Dotterweich, supra, 320 U. S. at page 282; U. S. v. Antikamnia Co., 231 U. S. 654, 667; U. S. v. John J. Fulton Co. (CCA 9), 33 F. 2d 506, 507; U. S. v. 62 packages, more or less, of Marmola Prescription Tablets (DC Wis.), 48 F. Supp. 878, 887, affirmed, 142 F. 2d 107, certiorari denied, 323 U. S. 731–732; 50 Am. Jur., Statutes, § 395, page 420.

"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