for the relief of persons suffering from stomach ailments caused by improper diet, irregular eating habits, consuming too many acid-producing foods, or overeating. The article would not be efficacious for such conditions.

The article was alleged to be misbranded further (1) in that the statement of active ingredients, "contain: Bismuth Subcarbonate; Magnesium Oxide; Sodium Bicarbonate; Saccharine; Rochelle Salt," appearing on the box label of the article, was not prominently placed thereon with such conspicuousness as to render it likely to be read under customary conditions of purchase and use; (2) in that its labeling failed to bear adequate directions for use since the directions did not provide a limitation as to duration of use; and (3) in that its labeling did not bear a warning that the article should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, and that frequent or continued use might result in dependence on laxatives.

On April 4, 1945, Udga, Inc., claimant, having admitted the facts in the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1359. Adulteration and misbranding of Pso-Ridisal. U. S. v. 38 Packages and 83 Gross of Pso-Ridisal. Consent decrees of condemnation. Product ordered released under bond. (F. D. C. Nos. 6679, 11683. Sample Nos. 86401–E, 66407–F, 66408–F, 66443–F.)

On or about January 17 and 28, 1944, the United States attorneys for the Northern District of Illinois and the Western District of Missouri filed libels against 38 packages of Pso-Ridisal at Chicago, Ill., and 83 gross of the same product at Kansas City, Mo., alleging that the article had been shipped from Royal Oak, Mich., by the Nu-Basic Products Co., between the approximate dates of November 19, 1941, and December 15, 1943. The libels against the Missouri and Illinois lots were amended on or about February 14 and 23, 1944, respectively.

Analysis of samples disclosed that the article consisted essentially of sulfanilamide, mineral oil, glycerin, small proportions of carbolic acid, and soap and water.

The article was alleged to be misbranded in that certain statements appearing in the labeling of each lot regarding the efficacy of the article in the treatment of psoriasis, and certain additional statements in the labeling of the Missouri lot regarding the efficacy of the article in the treatment of skin diseases, including athlete's foot, dandruff, eczema, acne, diaper rash, and industrial dermatitis, were false and misleading since the article would not be efficacious in the treatment of the conditions mentioned.

The article was alleged to be misbranded further in that its labeling failed to bear adequate warnings, since the article contained sulfanilamide and its labeling failed to warn that its use should be discontinued if a new skin rash appeared or if the skin condition under treatment became worse.

The article in the Illinois lot was alleged to be adulterated in that its strength differed from that which it was represented to possess since its labeling represented that each fluid ounce contained ⅜ grain of sulfanilamide, whereas each fluid ounce contained 6.7 grains of sulfanilamide.

On June 30, 1942, the Nu-Basic Products Co. having appeared as claimant for the Illinois lot and having requested that the case be removed for trial to the United States District Court for the Eastern District of Michigan on the ground that that district was in reasonable proximity to the claimant's principal place of business, the court, after due consideration, entered an order denying the claimant's request for a change of venue. Thereafter, the Nu-Basic Products Co. appeared as claimant in the case of the Missouri lot and, pursuant to a motion filed by the claimant, an order was entered on April 11, 1944, providing for the removal of the case to the Northern District of Illinois. On April 12 and 26, 1944, the claimant having admitted the facts of the libels, judgments of condemnation were entered in each case and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1360. Misbranding of Sulfa-Seb and Sulfa-Ped. U. S. v. 50¾ Dozen Bottles of Sulfa-Seb and 17¾ Dozen Bottles of Sulfa-Ped. Tried to the court. Judgment for the Government. Decree ordering the condemnation and destruction of the labeling and the release of the product to the claimant. (F. D. C. No. 11075. Sample Nos. 3933–F, 3934–F.)

On or about November 10, 1943, the United States attorney for the Western District of Missouri filed a libel against 50¾ dozen bottles of Sulfa-Seb and 17¾ dozen bottles of Sulfa-Ped at Kansas City, Mo. On February 14, 1944, an amended libel was filed. It was alleged that the articles had been shipped on

or about October 19, 1943, from Royal Oak, Mich., by the Nu-Basic Products Co.; and charged that they were misbranded. The misbranding charges appear in the opinion infra.

Examination of samples disclosed that each of the articles contained approximately ½ gram of sulfanilamide per fluid ounce, approximately 0.75 gram of phenol (carbolic acid) per 100 cc., oil, including a large proportion of mineral oil, and water.

On March 27, 1944, the Nu-Basic Products Co., claimant, having filed an answer denying that the products were misbranded as alleged in the libel, the case came on for trial before the court without a jury. The trial was concluded on March 29, 1944, and on April 3, 1944, the court handed down the following memorandum opinion and findings of fact and conclusion of law:

OTIS, *District Judge:* "The amended information in libel in this proceeding was filed February 14, 1944. It makes reference to two preparations, one known as 'Sulfa-Seb,' the other as 'Sulfa-Ped.' The charge is that these preparations are misbranded within the meaning of Title 21, U. S. C., Section 352. That section provides *inter alia* that a drug 'shall be deemed to be misbranded (a) if its labeling is false or misleading in any particular' and that it 'shall be deemed to be misbranded (f) unless its labeling bears . . . such adequate warnings . . . against unsafe dosage or methods . . . of administration or application, in such manner and form, as are necessary for the protection of users; . . .'

"The information charges that the labeling of the preparation known as 'Sulfa-Seb,' which reads, in part, 'For hair and scalp . . . Designed as a fungicide to relieve itching, and treat and control the condition resulting from infection round the follicles of the hair,' is false and misleading in the following respects: that the article (1) is not an adequate treatment for disease conditions of the hair and scalp; (2) that it is not fungicidal; and (3) that it will not control conditions resulting from infection around the follicles of the hair.

"The information charges that the labeling of the preparation known as 'Sulfa-Ped,' which reads, in part, 'A new treatment for Athletes Foot . . . Designed as a fungicide to relieve discomfort and treat and control the conditions identified with fungus and bacterial conditions of the feet . . . ,' is false and misleading in that the preparation is (1) not a treatment for athlete's foot; (2) is not a fungicide; and (3) will not relieve discomfort and treat and control conditions identified with fungus and bacterial conditions of the feet.

"The information alleges that both preparations are misbranded for that the labels contain no such adequate warnings 'as are necessary for the protection of users since the articles contain sulfanilamide' and no warnings that 'their use [i. e. of the preparations] should be discontinued if a new skin rash appears or if the skin condition under treatment becomes worse.'

"We begin this memorandum by first discussing the first charge in the information, that the preparation known as 'Sulfa-Seb' is false and misleading in the respects indicated in the information.

"1. There has been no real controversy in the case between counsel for plaintiff and counsel for claimant touching the applicable law. The language of the statute is clear enough. If the labeling 'is false and misleading in any particular' the preparation bearing the label has been misbranded. Obviously it is necessary first of all to determine *what* representation is made by the label and to determine whether *that* representation is false and misleading in any particular. It would seem to be obvious, moreover, that in determining whether the representation on a label is false and misleading in any particular *all* the language of the label must be considered. None would contend that single words or phrases should be lifted out and that if those words or phrases separately considered can be found to be untrue, then the preparation should be condemned as misbranded. Single words or phrases might be so explained by other language as that there is no misrepresentation whatever. Fairness requires that the whole legend upon the label of 'Sulfa-Seb' should be set out so that the label may be considered as a whole. Accordingly, we do set out the label by inserting at this point one of the labels:

A SULFA-DRUG COMPOUND SULFA-SEB A Nu-Basic [design] Product FOR HAIR AND SCALP A proprietary compound of mineral and vegetable oils which acts as a carrying agent for Sulfanilamide, the active medicant. Designed as a fungicide to relieve itching, and treat and control the condition resulting from infection round the follicles of the hair. ACTIVE MEDICANT SULFANILAMIDE ⅜ GRAM TO EA. FL. OZ. Distributed by SULFA PRODUCTS CO. 1125 Grand Ave. Kansas City, Mo. SHAKE WELL BEFORE APPLYING ALSO CONTAINS Phenol (less than 1% by volume) and other inert ingredients in varying amounts. GUARANTEE Return for refund must be made within 2 weeks of purchase. EXTERNAL USE ONLY SHAKE WELL BEFORE APPLYING Directions for Use Massage

thoroughly into scalp. Comb out loosened scale using fine tooth comb. Use often as necessary to keep scalp moist with preparation. If hair is left too oily from treatment, remove excess oil by brushing. Set and groom with wetted comb. Wash hair no oftener than once a week. Content 4 Fluid Ounces $2.50. EXTERNAL USE ONLY MFG. BY—SULFA PRODUCTS COMPANY OF AMERICA—DIV. NU-BASIC PROD. CO., ROYAL OAK, MICH.

"Any one who inspects this label will at once discern that it contains much language which is not charged as being false or misleading and which obviously is not false or misleading. Some of the language is devoted to precise directions as to how the preparation is to be used. Some of it is a guarantee of return of money. A part of it is a warning that the preparation is 'for external use only.' Some of it describes accurately all of the ingredients in the preparation. Much of that part of the legend which is the object of the government's complaint is in type so small that it would almost certainly escape being read by any ordinary purchaser. The most prominent part of the label is *the name* of the preparation, *'Sulfa-Seb,'* a name which certainly means nothing and conveys no significance. In somewhat smaller type, and yet in legible type as distinguished from the minute wording of the rest of the label, are the words 'FOR HAIR AND SCALP.' Here is the real representation which is made to the purchasing public. Nine out of ten of the purchasers of this preparation in all probability would read no other part of the label than the words in conspicuous letters 'FOR HAIR AND SCALP.' (What advertising, what circular, what verbal recommendations may have influenced purchasers we do not know but very reasonably we may conclude that an intention to purchase was formed *before* the label was read). Let us then first consider whether the 'FOR HAIR AND SCALP' is false and misleading.

"We agree at once with the contention of the Government in this case that there is an implication in the words 'FOR HAIR AND SCALP' which constitutes a part of the meaning to the ordinary observer and purchaser. By the use of these words it is represented that the preparation, when applied externally and in the manner prescribed by the directions on the label, is *beneficial* to the hair and scalp, that the use of the preparation will promote the health of hair and scalp. To say, however, that the words 'FOR HAIR AND SCALP' alone (as was said in the argument by learned counsel for the Government) would mean to an ordinary observer that the preparation was a *panacea* for every possible disease that might attack the hair or scalp seems to us grossly to distort the meaning which the reader would derive from the language employed. The reasonable interpretation of the words, considered alone, is that the use of the preparation in the manner directed will benefit the hair and scalp when affected by such commonly known maladies as those causing, for example, dandruff, falling hair, threatening baldness.

"When we descend from the words in large type, 'FOR HAIR AND SCALP,' into the legend minutely printed beneath them, we are given the more specific information that the preparation is 'Designed as a fungicide to relieve itching' and that is it 'Designed as a fungicide to treat and control the condition resulting from infection round the follicles of the hair.' Here the words that would mean anything to the ordinary reader and observer (the word 'fungicide' would mean nothing except to the rare individual) are the words to 'relieve itching' and the words 'to treat and control the condition resulting from infection around the follicles of the hair.'

"The impression then created by this label on the ordinary purchaser and observer, if he reads only the conspicuous words, is that here is a preparation that will be helpful in dealing with such common maladies as dandruff, falling hair, etc., and, if he descends into the minute type, that here is a preparation that will relieve itching in the scalp and that will beneficially affect a condition resulting from infection in the scalp.

"With such an interpretation placed upon the label, and we believe it is a fair interpretation, not a far fetched and distorted one, the question is, is this preparation one which will benefit the hair and the scalp with respect to the common maladies referred to and is it a preparation which will relieve itching in the scalp and will benefit conditions resulting from infection in the hair. If the preparation will do these things it certainly cannot justly be condemned as falsely labeled.

"2. The evidence in the case was of two general classes, the testimony of experts and the testimony of laymen. The testimony of the laymen called by the Government (there were only a half dozen of these) chiefly related to the charge of misbranding for failure to warn of dangers. It did not particularly bear upon the charge which we now are especially considering, namely, was the label of 'Sulfa-Seb' false and misleading. The testimony of the laymen who testified for the claimants (there were fifteen of these) did directly bear upon this charge, either as against 'Sulfa-Seb' or 'Sulfa-Ped.' But the testimony of a few

laymen, however honest that testimony may be (and we regard the testimony of each of the laymen appearing in this case as entirely honest) is of slight value upon the issue under present discussion. There were many thousands of users of these preparations. The evidence indicated that there were hundreds of users even in Kansas City. That a small number experienced unsatisfactory results, which they ascribed to some deficiency or injurious element in the preparation, and that a small number experienced satisfactory results which they ascribed to the preparation, is of small significance. The nature of the simplest disease is so obscure to a layman that his conclusions touching what will benefit it and what will not benefit it mean little. We would not say, of course, that if we were dealing with and had the results of tens of thousands of cases, we would not have something significant. A few dozen instances are of such trifling value as that they can almost entirely be disregarded.

"The scientific testimony in a case of this character is the testimony that counts. Scientific testimony is available to support any meritorious cause, even, as we know, when the leading physician in a community or the American Medical Association itself is under attack. Of course, scientific testimony is available to the Government in support of any meritorious cause presented by the Government. The Government has its official staff of scientists of outstanding ability and the government is able to obtain the services of other scientists of outstanding ability. But private individuals also are able to obtain the testimony of outstanding men of science *provided there is real merit in their cause.* Claimants in this case had the financial ability to obtain testimony. But they put only one so-called expert (we use the word 'so-called' advisedly) on the stand. They brought him from San Antonio, Texas, to Kansas City and paid him, according to his testimony, at the rate of $100 a day and, we suppose, his expenses also. (We judge that was the zenith of his professional earnings to the present date.)

"The testimony of the young M. D. brought by claimants from Texas was pitifully weak. His qualifications were unsatisfactory, his experience in the practice of medicine was brief and limited, his knowledge of the science of the subject under inquiry was obviously slight. He could say 'Yes' to leading questions, but if he had been asked to discuss the sciences involved he would have floundered hopelessly. He was spared, if not by merciful counsel (who also were floundering) at least by a merciful court.

"There was a reason for the complete failure of the claimants to support their contentions by outstanding expert testimony. That testimony just was not procurable. The failure of the claimants in this respect impressed us as almost the equivalent of a confession of the general accuracy of the testimony of the Govermnment's experts. The general effect of that testimony was that while the preparation 'Sulfa-Seb' might have some slight temporary value in some instances by way of relieving an itching scalp or by way of temporarily removing dandruff, it had no real value with respect to any malady of the scalp, whether generally and commonly known or obscure in character and difficult to diagnose. The general effect of the testimony of the experts for the Government, whose qualifications were outstanding, was certainly to the effect that the preparation known as 'Sulfa-Seb' constituted no kind of a treatment or control for infection in the scalp and round the follicles of the hair. We are bound to say that the effect of the scientific testimony offered by the Government was overwhelming *as against the complete emptiness of the scientific testimony offered by the claimant.*

"3. Much of what we have said concerning the preparation known as 'Sulfa-Seb' is equally applicable to the preparation known as 'Sulfa-Ped.' We set out here the exact label of 'Sulfa-Ped' which the Government has attacked. There cannot be any objection to much of this label. Most of it is entirely true and accurate. But we have reached the conclusion that there is some exaggeration in the label in that part of the legend in which it is represented that the preparation is a beneficial treatment and a control for 'the conditions identified with fungus and bacterial conditions of the feet.'

A SULFA DRUG COMPOUND SULFA-PED A NEW TREATMENT FOR ATHLETE'S FOOT S P A nu-Basic Product. A proprietary compound of mineral and vegetable oils which acts as a carrying agent for Sulfanilamide, the active medicant. Designed as a fungicide to relieve discomfort and treat and control the conditions identified with fungus and bacterial conditions of the feet. ACTIVE MEDICANT SULFANILAMIDE ½ Gram To EA. FL. OZ. SHAKE WELL BEFORE APPLYING Also Contains Phenol (less then 1% by volume) and other inert ingredients in varying amounts. GUARANTEE Return for refund must be made within 2 weeks of purchase. EXTERNAL USE ONLY SHAKE WELL BEFORE APPLYING Directions for use. Chronic Cases: Massage well into affected parts. morning and night. Take daily foot bath in warm water before applying night application. Use only mild soap. Acute Cases: Puncture blebs and permit fluid to drain out. Bathe in warm water using mild soap. Dry thoroughly. Apply and cover

with white cotton hose. Use new footwear. CONTENTS: 4 FL. OZS. $2.50 EXTERNAL USE ONLY Distributed by SULFA PRODUCTS CO. 1125 GRAND AVE. KANSAS CITY, MO. MFG. BY—SULFA PRODUCTS COMPANY OF AMERICA—DIV. NU-BASIC PROD. CO. ROYAL OAK, MICH.

CERTAIN MATTERS OF EVIDENCE

"4. During the trial of the case there was offered in evidence by claimants a large number of letters (responses received from purportedly satisfied customers to questionnaires mailed out by claimants). We refused to receive these letters in evidence for reasons which were stated at the time of the ruling. Such letters are so obviously hearsay that the matter of the propriety of the ruling does not seem to us to be at all debatable. No question of the good faith of the manufacturers or of the claimants is involved in this proceeding. The proceeding is not brought against individuals. The proceeding is against inanimate preparations. The preparations, not individuals, are attacked. There is no reason to question the good faith of any one in this proceeding. We believe the claimants did act in good faith. The only question in the case is, are the labels on the bottles false and misleading in the sense that the information conveyed by them to ordinary readers is erroneous.

"Another matter of evidence, which was taken under submission, is made up of a number of exhibits, being claimants' Exhibits 14 to 21, inclusive. Objection was made by the Government to the reception of these exhibits. The exhibits were scientific treatises, each of which discusses the particular preparation involved in this proceeding. It seems clear to us that these exhibits were not competent in evidence. The reasons for that conclusion are elementary. Undoubtedly in the cross examination of an expert witness he may be asked whether he agrees or does not agree with certain statements contained in reputable treatises. There is no convincing authority, however, for the view advanced by learned counsel for the claimants in this case, to-wit, that *as affirmative proof* treatises may be offered in evidence. If the testimony of Dr. *X*, for example, is desired by a party, he can call him as a witness so that he can be cross examined in court. If he is beyond the jurisdiction of the court, undoubtedly the party can take his deposition, when again he may be cross examined. But it is unthinkable that a party may have some witness (in this instance it was a layman) say that Dr. *X* is an authority in a certain field and then to offer in evidence some book or treatise which may have been written by Dr. *X*.

"Notwithstanding our views of the law in this regard are very clear, we have read all of the exhibits referred to which were offered in evidence by the claimants. *For the purpose of this case we overrule the objection to these exhibits.* Nothing contained in the exhibits affects the findings of fact which we shall hereafter make. Findings of fact are made as of the time when the information in libel was filed. What may have been the view of scientific men on dates earlier than that date, of course, is not controlling. The knowledge of scientists, especially in a field so new as that which deals with the sulfa-drugs, is a growing knowledge. The science is in the process of evolution. The best views of the ablest scientists two or three years ago may not be especially valuable now.

MATTER OF WARNINGS

"The charge of inadequate warnings upon the labels was an afterthought. The original information in libel did not contain that charge. We are satisfied that the evidence does not warrant condemnation of the preparations on account of failure to include warnings.

FINDINGS OF FACT

"1. The label 'Sulfa-Seb' is false and misleading in that it represents that the preparation labeled is a remedy effective as a treatment for the commonly known maladies affecting the scalp and hair, whereas its only value is in relieving an itching scalp and in temporarily, in some instances, removing dandruff, and it is false and misleading in that it represents that the preparation labeled is a treatment or control for infections in the scalp and round the follicles of the hair.

"2. The label 'Sulfa-Ped' is false and misleading in that it represents that the preparation labeled is a treatment of and will control the conditions identified with fungus and bacterial conditions of the feet.

"3. Neither the labels of 'Sulfa-Seb' or 'Sulfa-Ped' is misbranded in that it does not contain an appropriate warning of dangers incident to the use of the preparations.

CONCLUSION OF LAW

"The prayer of the amended information in libel should be granted. The labels on the preparation known as 'Sulfa-Seb' and 'Sulfa-Ped' seized by the marshal should be condemned. The false and misleading labels on such preparations should be destroyed."

On the same date, judgment was entered condemning and ordering the destruction of the labels of the products. It was further ordered that when the labels had been destroyed the products should be returned to the claimant for use in compliance with the law.

1361. Misbranding of citrate of magnesia. U. S. v. 200 Cases of Citrate of Magnesia. Default decree of condemnation and destruction. (F. D. C. No. 11648. Sample No. 23693–F.)

On or about January 20, 1944, the United States attorney for the District of New Jersey filed a libel against 200 cases, each containing 24 bottles, of citrate of magnesia at Atlantic City, N. J., alleging that the article had been shipped on or about November 5, 1943, from Brooklyn, N. Y., by the National Magnesia Co.; and charging that it was misbranded. The labeling consisted of the words "Citrate of Magnesia" blown into the glass of the bottles, and the words "Citrate of Magnesia U. S. P." on the bottle cap.

The article was alleged to be misbranded (1) in that it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor and an accurate statement of the quantity of the contents; (2) in that its labeling failed to bear adequate directions for use; and (3) in that its labeling failed to warn that the article should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, and that frequent or continued use of the preparation might result in dependence on laxatives.

On October 27, 1944, no claimant having appeared, judgment of condemnation was entered and it was ordered that the contents of the bottles be destroyed and that the empty bottles be released to the consignee from whom the product was seized.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

1362. Adulteration of sterile distilled water and dextrose solution. U. S. v. Winthrop Chemical Co., Inc. Plea of guilty. Fine, $18,000. (F. D. C. No. 11420. Sample Nos. 6962–F, 6963–F, 20251–F, 20568–F, 20569–F, 23819–F, 39113–F, 45035–F, 51318–F, 52893–F, 53059–F.)

On May 25, 1944, the United States attorney for the Southern District of New York filed an information against the Winthrop Chemical Co., Inc., New York, N. Y., alleging shipment of quantities of the above-named products between the approximate dates of May 3 and August 6, 1943, from the State of New York into the States of Missouri, Connecticut, Rhode Island, Massachusetts, Virginia, Pennsylvania, and Illinois.

Examination disclosed that all shipments of the sterile distilled water contained pyrogens; that certain shipments of the article contained undissolved material; and that one shipment was contaminated with living micro-organisms. The United States Pharmacopoeia requires that water for injection, which the article purported to be, shall be sterile, free from pyrogens, and free from any turbidity or undissolved material.

Examination of the dextrose solution disclosed that it contained pyrogens and undissolved material, and that a portion also was contaminated with viable mold. The United States Pharmacopoeia requires that dextrose injection or dextrose ampuls, which the article purported to be, shall be sterile and free from pyrogens and undissolved material.

The articles were alleged to be adulterated in that the sterile distilled water purported to be water for injection and the dextrose solution purported to be dextrose injection or dextrose ampuls, drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, but the quality and purity of the articles fell below the standard set forth in that compendium; and the differences in quality and purity of the articles from the official standards were not plainly stated, or stated at all, on their labels. The articles were alleged to be adulterated further in that pyrogens and undissolved material had been mixed or packed with all lots of the articles, and mold had been mixed or packed with a portion of the dextrose solution, so as to reduce the quality of the articles.