DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

5306. First aid kits. (F. D. C. No. 39284. S. No. 46–619 M.)

QUANTITY: 43 *first aid kits* at Philadelphia, Pa.

SHIPPED: 5–11–56, from Bellbluff, Va., by Goldberg Army & Navy Goods.

ACCOMPANYING LABELING: Leaflet entitled "First Aid Instructions Vest, Emergency, Sustenance Type C–1."

RESULTS OF INVESTIGATION: Examination showed the product to be a 4" x 3" plastic case containing the following: 4 adhesive bandages, 1 vial of mild iodine, 2 compress bandages, 1 small cake of soap, 1 plastic vial of amphetamine sulfate tablets, 1 plastic vial of sulfadiazine tablets, 1 plastic vial of atabrine tablets, 1 plastic vial of halazone tablets, and 1 plastic vial of salt tablets.

LIBELED: 6–19–56, E. Dist. Pa.

CHARGE: 503 (b) (4)—the article contained amphetamine sulfate tablets, sulfadiazine tablets, and atabrine tablets, which were drugs subject to 503 (b) (1), and the label of the article failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 8–1–56. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

5307. Dexedrine Sulfate tablets, secobarbital sodium capsules, and capsules containing a mixture of secobarbital sodium and amobarbital sodium. (F. D. C. No. 39831. S. Nos. 46–264/5 M, 46–272/5 M.)

INDICTMENT RETURNED: 5–9–57, E. Dist. Pa., against Bernard Friedman, t/a Barclay Pharmacy, Philadelphia, Pa.

SHIPPED: Between 4–3–56 and 4–26–56, from Pennsylvania to New Jersey.

CHARGE: 502 (f) (1)—when shipped, the labeling of the articles failed to bear adequate directions for use.

PLEA: Nolo contendere.

DISPOSITION: 7–8–57 and 9–4–57. The defendant was fined $6,000, given a jail sentence of 6 months, which was suspended, and placed on probation for 1½ years.

5308. Vit-Ra-Tox No. 21 and No. 16. (F. D. C. No. 35574. S. Nos. 55–951/4 L, 62–612 L.)

INFORMATION FILED: 12–9–54, Dist. Mass., against V. E. Irons, Inc., Boston, Mass., and V. Earl Irons, president and treasurer.

SHIPPED: Between 12–3–52 and 7–28–53, from Massachusetts to Missouri and New York.

LABEL IN PART: (Ctn.) "Vit-Ra-Tox No. 21 A Natural Food with green life In three bottles Two of No. 21A and one of 21B"; (btl.) "V. E. VIT-RA-TOX Irons Inc. No. 21A . . . . . Part of No. 21 A Natural Food with green life Raw Veal Bone and Defatted Wheat Germ VIT-RA-TOX No. 21A with green life (2-⅛ oz.) Green Life is a concentrate of the juices of 2 or more young, tender green cereal (grain) shoots (oats, corn, barley, rye or wheat); raised in one of the richest soils known to man on the world's largest Organic Com-

*See also Nos. 5302–5304.

post Farm near Kansas City, Mo.; extracted in a manner as to retain Nature's vitamins, living enzymes, synergistes, and activating minerals (except Vitamin D); a rich natural source of Carotene (provitamin A) and the complete natural complexes of Vitamins B, C, E, F, and K with the P fractions of the C complex and the WULZEN factor of the F complex, plus the living enzymes, synergists and mineral activators. It contains organic iron, calcium, phosphorus, iodine and a host of other minerals in trace amounts with Live Chlorophyll in its natural, untreated, and edible state. * * * Contents 4-⅛ ozs. in tablet form 180 tablets of 10 grs. each"; (btl.) "No. 21B V. E. VIT-RA-TOX Irons Inc. Part of No. 21 A Natural Food This part containing: Garlic Derivative Wheat Germ and Lecithin as Emulsifiers Contents 60 capsules VIT-RA-TOX No. 21B Two green capsules contain the following: Garlic Derivative 4 mgs. Formulated in the following Organic Base (good natural sources of nutritional elements.) Wheat Germ Oil 129.6 Mgs. and Lecithin from soy beans 666.4 mgs. are used as emulsifiers"; (ctn.) "V. E. Vit-Ra-Tox Irons Inc. Products VIT-RA-TOX No. 21 A Dietary Supplement in tablet form containing a mixture of dried extracted juices of Cereal Grasses green life Plus Bone Meal Brewer's Yeast Fish Liver Oils Alfalfa Kelp (or Dulse)"; (btl.) "V. E. VIT-RA-TOX Irons '16' An Adsorbent Aid in Systemic Detoxification and An Intestinal Purificant National Distributors Irons & Moore Division of V. E. Irons, Inc., Boston, Mass. Contents One Quart Mechanically active adsorbent ingredient: Colloidal Bentonite (U. S. P. Grade) Distilled water as vehicle with certified flavor and color."

ACCOMPANYING LABELING: *Vit-Ra-Tox No. 21.* Leaflet headed "No. 21 A Natural Food * * * with green life the basis of all basic sources of Natural Vitamins"; leaflet entitled "What Price Refinement"; sales kit containing (a) looseleaf booklet known as "Civilization—Benefactor or Bandit," the first page of which begins "The National Malnutrition—D. T. Quigley"; (b) booklet entitled "Your Future with Irons and Moore"; (c) pamphlet entitled "Vitamins What Are They?" (d) pamphlet entitled "No. 21—A Natural Food Concentrate with green life," and pamphlet entitled "Ask for your Money Back Now"; and various issues of a newsletter.

Vit-Ra-Tox No. 16. Letter beginning with the words "Dear Friend"; pamphlet entitled "Ask For Your Money Back Now"; and certain portions of a sales kit, namely, (a) two pages of a looseleaf booklet known as "Civilization—Benefactor or Bandit," the first page beginning "Civilization? Primitives Can Teach Us Much" and the second page beginning "Civilization vs. Primitives Toxemia Eliminated the Primitive Way"; and (b) pages 14–18 of a booklet entitled "Your Future with Irons and Moore."

CHARGE: *Vit-Ra-Tox No. 21, No. 21A,* and *No. 21B.* 502 (a)—the labeling of the articles, when viewed in its entirety as well as through specific claims, contained false and misleading representations that nearly everyone in this country is suffering from malnutrition or in danger of such suffering because of the demineralization and depletion of soils and the refining and processing of foods; that practically all illnesses and diseases of mankind are due to improper nutrition; that the best way to treat, cure, and prevent all the diseases of mankind would be by using the articles; that the articles possessed nutritive properties superior to any other vitamin and mineral supplement; that the articles would be effective in the cure, treatment, and prevention of the ills and diseases of mankind, including heart trouble, diabetes, indigestion, anemia, nervousness, varicose veins, asthma, hay fever, tuberculosis, cancer, arthritis, polio, mental

disease, dental decay, high blood pressure, kidney disease and diseases of the digestive system, respiratory system, glands, bones, skin, and muscles; that the article designated No. 21B, by reason of its garlic content, possessed marvelous healing power and would be effective in the cure, treatment, and prevention of high blood pressure, low blood pressure, intestinal infections, polio, tuberculosis, arterial disease, flatulence, infections of the respiratory system, worms, lice and nits, skin disease and ulcers, symptoms of aging, and would make the dread symptoms of diphtheria present in the throat disappear; and that the action of the portion of the articles designated as No. 21B was, by reason of its garlic content, comparable to that of penicillin.

Vit-Ra-Tox No. 16. 502 (a)—the labeling of the article, when viewed in its entirety as well as through specific claims, contained false and misleading representations that the article was an adequate and effective treatment for rheumatic and pulmonary affections, disorders of the scrofulous and eczematous types, abscesses, cleansing of sores and wounds, serious disturbances of the digestive tract, and bacterial infections of the gut; and that the article was effective as a systemic detoxificant.

All articles. 502 (f) (1)—the labeling of the articles failed to bear adequate directions for use for the diseases and conditions for which they were intended.

The information alleged also that a quantity of *Vit-Ra-Tox No. 21* consisting of *No. 21A* and *No. 21B* was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 9–18–56 and was concluded on 10–2–56, with the return by the jury of a verdict of guilty. On 10–22–56, the court imposed a fine of $6,000 against the corporation and sentenced the individual to 1 year in jail.

The case was appealed to the United States Court of Appeals for the First Circuit; and on 4–24–57, after consideration of the briefs and arguments of counsel, the court handed down the following opinion (244 F 2d 34):

MAGRUDER, *Chief Judge:* "V. E. Irons, Inc., and V. Earl Irons in his individual capacity stand convicted, after a three-weeks trial, on a six-count information for causing the introduction into interstate commerce of misbranded food and drugs in violation of the Federal Food, Drug, and Cosmetic Act,[1] 52 Stat. 1040, as amended, 21 U. S. C. § 301 *et seq.*

"Count I of the information charged that the defendants (appellants herein) caused to be introduced into interstate commerce articles of food, known as Vit-Ra-Tox 21A (raw veal bone, defatted wheat germ, and the concentrate of juices of young, green cereal shoots) and Vit-Ra-Tox 21B (garlic derivative, wheat germ, and lecithin as emulsifiers), which were misbranded under 21 U. S. C. § 343 (j)[2] in that they 'purported to be and [were] represented as a food for special dietary uses by man by reason of [their] vitamin and mineral content and [their] label[s] failed to bear such information concerning [their] vitamin and mineral properties as had been determined to be and by regulations[3] prescribed as necessary in order fully to inform purchasers as to [their] value for such uses'.

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[1] Evidence introduced at the trial seems conclusively to establish that the defendants did introduce their products into interstate commerce. No issue as to this has been seriously pressed on appeal.

[2] § 343. Misbranded food.

A food shall be deemed to be misbranded—. . .

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Administrator determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

[3] The pertinent regulations are as follows:

§ 125.2 *General label statements.* (a) If a food (including food to which any one or more of §§ 125.3 to 125.8, inclusive, is applicable) purports to be or is represented

(Footnote continued on p. 226)

"Count II charged that the appellants caused to be introduced into interstate commerce articles of drug known as Vit-Ra-Tox 21A and Vit-Ra-Tox 21B (the same products referred to in Count I) which were (a) misbranded under 21 U. S. C. § 352 (a)[4] in that their accompanying labeling—consisting of certain leaflets and various issues of a newsletter—falsely represented 'when viewed in [their] entirety as well as through specific claims . . . that nearly everyone in this country is suffering from malnutrition or in danger of such suffering because of demineralization and depletion of soils and the refining and processing of foods, that particularly all illnesses and diseases of mankind are due to improper nutrition, that said article[s] possessed nutritive properties superior to any other vitamin and mineral supplement, that said article[s] would be effective in the cure, treatment, and prevention of the ills and diseases of mankind,' including certain specific diseases; and which were (b) misbranded under 21 U. S. C. § 352 (f) (1)[5] in that their labeling failed to bear adequate directions for the use for which they were intended, namely, for treatment of the specific diseases which appellants represented that the drugs could cure or prevent.

"Counts III and V named two products similar to the vitamin and mineral products specified in Counts I and II, and alleged that the said articles (being also articles of 'drug' within the meaning of the statutory definition) were

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for any special dietary use by man, its label shall bear a statement of the dietary properties upon which such use is based in whole or in part. Such statement shall show the presence or absence of any substance, any alteration of the quantity or character of any constituent, and any other dietary property of such food upon which such use is so based.

(b) If a food (including food to which any one or more of §§ 125.3 to 125.8, inclusive, is applicable) purports to be or is represented for special dietary use by reason of its use for treating any disease resulting from a dietary deficiency in man, its label shall bear, in addition to the information required under paragraph (a) of this section, adequate directions for such use.

§ 125.3 *Label statements relating to vitamins.* (a) (1) If a food purports to be or is represented for special dietary use by man by reason of its vitamin property in respect of:

Vitamin A or its precursors,
Vitamin B_1 (thiamine),
Vitamin C (ascorbic acid),
Vitamin D, or
Riboflavin (vitamin B_2, vitamin G).

the label . . . shall bear a statement of the proportion of the minimum daily requirement for such vitamin supplied by such food when consumed in a specified quantity during a period of one day. . . .

(2) If a food purports to be or is represented for special dietary use by man by reason of its vitamin property in respect of any vitamin not listed in subparagraph (1) of this paragraph, the label shall bear a statement of the quantity of such vitamin in a specified quantity of such food. The quantity of food specified as required by this section, shall be the quantity customarily or usually consumed during a period of one day or a quantity reasonably suitable for and practicable of consumption within such period. If the need in human nutrition for such vitamin has not been established, the label shall also bear the statement 'The need for _____ in human nutrition has not been established,' the blank to be filled in with the name of such vitamin. . . .

§ 125.4 *Label statements relating to minerals.* (a) (1) If a food purports to be or is represented for special dietary use by man by reason of its mineral property in respect of:

Calcium,
Phosphorus,
Iron, or
Iodine,

the label . . . shall bear a statement of the proportion of the minimum daily requirement for such element supplied by such food when consumed in a specific quantity during a period of one day. . . .

(2) If a food purports to be or is represented for special dietary use by man by reason of its mineral property in respect of any element not listed in subparagraph (1) of this paragraph, the label shall bear a statement of the quantity of such element in a specified quantity of such food. Except in the case of foods subject to § 125.9, the quantity of food specified as required in this section shall be the quantity customarily or usually consumed during a period of one day, or a quantity reasonably suitable for and practicable of consumption within such period. If the need in human nutrition for such element has not been established, the label shall also bear the statement 'The need for _____ in human nutrition has not been established,' the blank to be filled in with the name of such element. . . . (21 C. F. R. 247–49 (1955))

[4] § 352. Misbranded drugs and devices.
A drug or device shall be deemed to be misbranded—
(a) If its labeling is false or misleading in any particular.

[5] § 352. Misbranded drugs and devices.
A drug or device shall be deemed to be misbranded— . . .
(f) Unless its labeling bears (1) adequate directions for use . . .

introduced into interstate commerce on or about July 28, 1953, and July 14, 1953, respectively, consigned to the Delvita Company, Wilmington, Delaware, and to one Joseph T. Stoeckl, of Buffalo, New York, respectively, and were (a) misbranded under 21 U. S. C. § 352 (a) in that their labeling, when viewed in its entirety, falsely represented and suggested that 'nearly everyone in this country is suffering from malnutrition or is in danger of such suffering because of the demineralization and depletion of soils and the refining and processing of foods, that practically all human ailments and diseases are traceable to improper nutrition, that the best way to treat, cure, and prevent all the diseases of mankind would be by using said article[s] of drug, that said article[s] [possess] nutritive properties superior to any other vitamin or mineral supplement, that said article[s] constituted an adequate and effective cure, preventive and treatment' for various specific diseases; and were (b) misbranded under 21 U. S. C. § 352 (f) (1) in that their labeling failed to bear adequate directions for use.

"Counts IV and VI involved a different product, known as Vit-Ra-Tox '16,' whose label described it as 'An Adsorbent Aid in Systematic Detoxification and An Intestinal Purificant,' and alleges that said article of drug was introduced into interstate commerce on or about July 28, 1953, and December 3, 1952, respectively, and consigned to the Delvita Company, Wilmington, Delaware, and to one Joseph T. Stoeckl, of Buffalo, New York, respectively, and was (a) misbranded under 21 U. S. C. § 352 (a) in that its labeling falsely represented that the article was an adequate and effective treatment for certain specific disorders and disturbances; and was (b) misbranded under 21 U. S. C. § 352 (f) (1) in that its labeling failed to bear adequate directions for use.

"At the trial it was shown that appellants were engaged in the manufacture and distribution of certain 'natural' vitamin products (distinguished from sythetic vitamins in that they are produced from natural food sources), and that sales of the products were made to consumers by distributors who received from appellants both the product to be sold and supporting literature. The evidence indicated that appellants recruited salespeople from among their customers and acquaintances, as well as through advertisements in newspapers. Selling techniques were explained to these people at meetings and by printed material comprising the sales kit, which contained certain leaflets in addition to supplemental newsletters written at frequent intervals by appellants and sent to such distributors. The printed promotional material was shown to be an integral part of the selling process, and constitutes the major source of the government's proof of the charges contained in the information.

"The written, printed, and graphic material used was all identified and introduced into evidence by a food and drug inspector of the Department of Health, Education, and Welfare, who had posed as a salesman in order to obtain the material from appellants. The inspector made application and became an accepted distributor; he obtained a complete sales kit, purchased products, attended a lecture by Irons, and received a series of newsletters.

"At the conclusion of the trial the jury returned a verdict of guilty against both defendants on all six counts. The court sentenced V. Earl Irons to one year of imprisonment on each of the six counts, the sentences to run concurrently; and imposed upon the defendant corporation a fine of $1,000 on each count. Appeals were duly taken by both defendants.

"The brief for appellants lists twelve major points as grounds for reversal, as well as a large number of subpoints. But after a complete reading of the voluminous record, we are satisfied that no error was committed by the district court.

"Since appellants make no serious argument with respect to Count I, it may be dealt with summarily. The label on the carton introduced into evidence by the government states that Vit-Ra-Tox No. 21A retains 'Natures' vitamins, living enzymes, synergists, and activating materials (except Vitamin D); a rich natural source of Carotene (provitamin A) and the complete natural complexes of Vitamins B, C, E, F, and K with the P fractions of the C complex and the Wulzen factor of the F complex, plus the living enzymes, synergists and mineral activators. It contains organic iron, calcium, phosphorus, iodine and a host of other minerals in trace amounts . . . .' The label thus represents that the product has special dietary uses for man, by reason of its vitamin and mineral properties, within the scope of the Administrator's regulations con-

tained in note 3, *supra;* and because there is no claim that the label satisfied the requirements of the regulations, it is quite clear that there was a violation of the Act, so far as Count I is concerned.

"Before proceeding further, it is to be noted that the Act makes a distinction between the terms 'label' and 'labeling'. Under 21 U. S. C. § 321 (k), 'label' is defined to mean 'a display of written, printed or graphic matter upon the immediate container of any article . . . .' But by 21 U. S. C. § 321 (m), 'labeling' means 'all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.' It is clear that the term 'labeling' must be given a broad meaning to include all literature used in the sale of food and drugs, whether or not it is shipped into interstate commerce along with the article. 'One article or thing is accompanied by another when it supplements or explains it, in the manner that a committee report of the Congress accompanies a bill. No physical attachment one to the other is necessary. It is the textual relationship that is significant.' *Kordel* v. *United States*, 335 U. S. 345, 350 (1948). There is no doubt that the printed circulars, pamphlets, brochures and newsletters distributed by appellants in the present case constituted 'labeling' within the statutory definition, and thus may properly be received in evidence as proof of false or misleading statements.

"In determining whether such labeling contained 'false or misleading' statements, we must be careful not to read the literature with the eyes either of experts in nutrition or of overly skeptical buyers. What is pertinent is the effect the claims would have on those to whom they are addressed, namely, prospective purchasers and actual customers of appellants, who cannot be presumed to have special expertness or to be unduly cautious, but who are more likely than not to be persons who are pathetically eager to find some simple cure-all for the diseases with which they are afflicted or who are susceptible to luridly painted scare literature as to the prospect of being disease-ridden unless they consistently partake of the vaunted drug product. This approach has been authoritatively approved. In *Federal Trade Commission* v. *Standard Education Society*, 302 U. S. 112, 116 (1937), it is stated: 'The fact that a false statement may be obviously false to those who are trained and experienced does not change its character, nor take away its power to deceive others less experienced. There is no duty resting upon a citizen to suspect the honesty of those with whom he transacts business. Laws are made to protect the trusting as well as the suspicious. The best element of business has long since decided that honesty should govern competitive enterprises, and that the rule of *caveat emptor* should not be relied upon to reward fraud and deception.' See also *Donaldson* v. *Read Magazine, Inc.*, 333 U. S. 178, 188 (1948).

"When appellants' labeling is examined in this light and in its entirety, it readily appears that the government introduced at least sufficient evidence to warrant submission to the jury of the issues whether appellants made the representations charged against them, and whether these representations were false or misleading.

"The literature contains considerable material that is either obviously harmless or irrelevant to this case, such as lists of food with their vitamin content, instructions to salesmen, and shipping details for the various products. But, beyond that, many representations are made that, fairly interpreted, provide adequate support for the government's charges. There are, first of all, numerous assertions that 'all human ailments' can be traced to nutritive deficiencies and that various specific ills are caused thereby. For example, there is the statement:

> The evidence is overwhelming! That we Are what we Eat. That practically All Human ailments are traceable to our food. From the time we are conceived until we reach 150 lbs;
>
> It's The Material Out of Which we are built that determines the structure. If that material is faulty the structure Breaks Down. If it is Not faulty, it does Not Break Down . . . It's our Food, that makes us sick or well.

Similarly, in one of appellants' pamphlets it is stated: "We believe that practically all the ailments that beset our civilized world are caused by deficient foods which can lower one's resistance."

"With respect to specific diseases, the literature quotes from the writings of one Dr. Sutherland [6] that:

> At the present time many conditions are considered as essentially deficiency diseases and are associated in one's thought with the classical Beri-Beri, Pellagra, Rickets and Scurvy. Such conditions are Infantile Scorbutus, Marasmus, Dentition Difficulties and Imperfect Teeth in Children and Adults, Dyspepsias, Indigestions, Diarrhoeas and Constipation, Obesity, Inability to Nurse Children, Diabetes, Neuroses, Infantile Paralysis, Certain Myalgias or "Rheumatism," Dementia Praecox, and even Tuberculosis and Cancer. The list can be extended but it is already a formidable one.

"Furthermore, there are numerous examples in the record of statements attributing extraordinary powers to appellants' products:

> Our customers are indeed fortunate that Vit-Ra-Tox was chosen by Green Life Products Co. of Kansas City, as the First and Only organization of its Kind to offer to the public Green Life, the richest, most potent and easily assimilated Natural Food, known to man.
>
> We believe that Green Life, because of its high concentration of Nature's unknown mysteries, is at present the only hope for overcoming the deficiencies of civilized, processed foods. Green Life alone should be able to help lessen current deficiencies in an average reasonable daily diet if the right amount for each individual can be determined through experience.

"At another point appellants modestly state in an unqualified way that 'It [Vit-Ra-Tox No. 21] is the One Hope for suffering humanity.' And again, that ' "This Product" *alone* of all products now on the market has *all* the vitamins, minerals, enzymes, co-enzymes, mineral activators and synergists (co-workers or helpers) needed by the human body (except Vitamin D).'

"Apart from these general representations about the value of their product, the record discloses that appellants claimed the power to cure or ameliorate specific diseases. These claims are to be found both with respect to the products which were the subject of Counts II, III and V, and also with respect to those which were the subject of Counts IV and VI. Regarding the products mentioned in Counts II, III and V, it is said: 'Hence Dr. Lee believes that arthritis cannot possibly reside permanently in a *body* which has a sufficient daily intake of this product.' And, again quoting Dr. Lee,[7] 'No one could continue to have arthritis and use this product daily.'

"With respect to Vit-Ra-Tox 16 (the Bentonite product) referred to in Counts IV and VI, a book of appellants' which was provided to all distributors quoted, somewhat out of context, from U. S. Government Bureau of Mines Booklet No. 609: 'Moistened with water or glycerin, it ["Alkali Bentonites"] also has been used, apparently with some success, for rheumatic and pulmonary affections, disorders of the scrofulous and eczeatous type, abscesses, and the cleansing of sores and wounds.'

"Laying aside these specific claims, it is true that most of the representations in the literature relating to diseases are more indirect; virtues of appellants' products are juxtaposed with descriptions of the symptoms or cures for various diseases, although no statement is made overtly correlating the products with the diseases. For example, the first few pages of one of the pamphlets are devoted to very general statements about nutritive deficiencies in the United States; it then goes on to say:

> No one can listen to the radio or television day after day without being reminded of the enormity of this health problem. Constantly we hear

[6] The literature employs quotations from the writings of others. It is obvious that so long as these writings are quoted with approval, they become the representations of appellants and can be used by the government to sustain its charges.

[7] The newsletter containing the second statement attributed to Dr. Lee said: "The above is what Dr. Lee thinks of the base of our new product and we consider him tops, the best authority on vitamins and minerals in the country today." Dr. Lee testified at the trial. It appeared that he was a licensed dentist (1924) not presently practicing dentistry but whose "principal business" was the Lee Engineering Company which manufactured custom-made electrical equipment.

There was evidence that these representations were effective to induce purchases of "Green Life". One witness testified that he was told, when handed the literature, that the product would cure arthritis and that he bought it for that purpose.

appeals for donations to the Heart Fund on the grounds that over 50% of all the deaths in 1951 were due to Heart trouble of some kind. Yet in 1890 only 5% of the deaths were from Heart Disease. This indicates a 1,000% increase in 60 years. Can anyone doubt that this is a major problem?

In their recent plea, the Cancer Fund announced that one-fifth of those now living will die of Cancer (⅕ of 150,000,000 is 30,000,000). Since 1890 the percent of Deaths from Cancer has increased 650%. In the drive for a better understanding of Diabetes it was broadcast and advertised that 1,000,000 people in the country have Diabetes that don't know they have it. Dr. Joslin, the greatest living authority on Diabetes states that at the rate we are going, almost everyone in America will have Diabetes within 50 years.

"Later on in the same pamphlet appellants proceed to discuss the virtues of their products: 'To the best of our knowledge there is absolutely nothing on the market today with which Vit-Ra-Tox #16 can be compared. It seems to have the faculty of assisting the body in removing toxins and poisons.' Another example of the juxtaposition of a discussion of appellants' products with a discussion of specific diseases is contained in one of the newsletters in which, under the heading 'The Garlic Cure for Tuberculosis', there is a long exposition of certain alleged cures of tuberculosis by garlic and garlic products. The latter part of the newsletter contains information for salesmen as to how to speed up their orders for the Vit-Ra-Tox products which contain a garlic derivative. The record discloses many other illustrations of references to specific diseases cleverly coupled with boosts for or information concerning Vit-Ra-Tox. On the basis of this record it is not at all surprising that a lay jury reading the literature came to the conclusion that special curative or at least preventive powers for the diseases mentioned were claimed by appellants for their Vit-Ra-Tox line.[8] And if such was the impression made upon the jury, it seems more than likely that a prospective purchaser, hoping finally to obtain relief from a long-endured disease, would not read appellants' literature with any skeptical literalness. Bearing in mind the broadly remedial purposes of the Act in preventing deception, the Congress must be taken to have meant to strike not only at palpably false claims but also at clever indirection and ambiguity in the creation of misleading impressions. See *United States* v. *One Device, Intended for Use as a Colonic Irrigator*, 160 F. 2d 194, 200 (C. A. 10th, 1947).

"In order to show that many of the representations contained in the literature, or labeling, were 'false or misleading', the government put on the stand five expert medical witnesses, authorities in the field of nutrition or internal medicine.

"These experts testified, first of all, that not all human illnesses are traceable to nutritive deficiencies, as appellants claimed, pointing out that some diseases are caused by congenital defects, others by specific viruses or bacteria, and that numerous degenerative diseases of old age have nothing to do with nutrition. Moreover, they stated that, after experiments with appellants' products, these were found to lack the powers attributed to them, either as general aids to health or in connection with the specific diseases mentioned in the literature. One doctor said: 'In the directions recommended, it would have absolutely no effect in any of the ten leading causes of death in the United States, or in any other way you would like to take it.' There is no need to recite the evidence in detail, for the record is replete with medical testimony

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[8] On its cartons and in one or two of appellants' newsletters or pamphlets, one may find disclaimers such as the following:

"Important—We do not diagnose or prescribe

"Neither we nor our Vit-Ra-Tox Distributors are doctors. We do not attempt to diagnose or prescribe. We do not approach our customer's health problem from the standpoint of specific ailments. We are however, interested in teaching them how, to the extent possible through nutritional influences, we can help them. . . .

"Our sales talk and theory of body building through nutritional elements are not to be interpreted as entering the field of medicine or as violating a doctor's prerogative. Since, therefore, we try only to improve the nutritional vitality of our customers, if any dangerous acute conditions exist or are suspected, a physician should be consulted."

Such disclaimers occur only rarely. And even when they appear in conjunction with some of the literature found to be false or misleading, they should not be regarded as conferring any immunity on appellants, so long as the literature in its entirety is reasonably understood by readers to make the curative claims alleged by the government.

contradicting the various claims; and there is no doubt that the jury was provided with a sufficient foundation for its findings.

"Appellants introduced their own expert witnesses at the trial, but it does not take one well versed in the field of nutrition to appreciate why the jury might have accorded their testimony diminished weight. One of them was a soils expert who was not shown to be qualified to discuss human nutrition or the claim that soil deficiency resulted either in national malnutrition or in diseases of man. Several practising physicians also testified, but none seemed to possess extensive qualifications in nutrition. One of these, who had not practised medicine for over thirty years, testified to laboratory tests he made for high blood pressure using garlic on cats and on humans, but he admitted on cross-examination that, to supply a daily dose comparable to the dose of garlic administered in his tests, he would have to give a patient 855 tablets of Vit-Ra-Tox 21B per day. Appellants also presented two dentists, neither of whom disclosed any additional training to equip them as an expert in nutrition, and one of whose writings—those of Dr. Lee—had been employed as part of appellants' sales literature. See note 7, *supra*. Incidentally, this is the Dr. Lee whom one of the government's experts caustically referred to as 'known as one of the biggest charlatans in the food quackery business.' The jury, after hearing these expert witnesses for both sides, was in a position to compare their respective qualifications, and we are not prepared to set aside its determination as to where the truth lay.

"Concerning the accuracy of therapeutic claims, it was held in an earlier mail fraud case that fraud could not be found to exist so long as bona fide differences of medical opinion existed. *American School of Magnetic Healing* v. *McAnnulty*, 187 U. S. 94 (1902). But the terms of the Federal Food, Drug, and Cosmetic Act of 1938, outlawing 'false or misleading' labeling, and the regulations issued under the Act, proceed upon a different basis. One may be guilty of the misdemeanor described in 21 U. S. C. § 333 (a) without having any intent to defraud or mislead. In contrast with this is the provision of § 333 (b), which imposes more severe penalties in case of a violation of any of the provisions of § 331, 'with intent to defraud or mislead'. In the applicable regulations it is provided: 'The existence of a difference of opinion, among experts qualified by scientific training and experience, as to the truth of a representation made or suggested in the labeling is a fact (among other facts) the failure to reveal which may render the labeling misleading, if there is a material weight of opinion contrary to such representation.' 21 C. F. R. § 1.3. The cases decided under the Act indicate that the jury will be allowed to determine the truth of a therapeutic claim as it would that of any other fact. *United States* v. *Kaadt*, 171 F. 2d 600, 603 (C. A. 7th, 1949). The danger has been pointed out, in 67 Harv. L. Rev. 632 at 654, 'that juries, if always allowed to determine the validity of a claim after hearing contradictory medical testimony, will brand false new, temporarily unpopular, but possibly correct scientific theories.' On the other hand, the potentiality of harm to gullible consumers, from acceptance of false or misleading representations, may be just as real even though the maker of the representations has a bona fide belief in their truth. Which of these more or less competing considerations is to be accorded priority is, of course, a matter of policy for the Congress to decide. See *United States* v. *Dotterweich*, 320 U. S. 277, 284–85 (1943).

"It must be remembered that a representation may be 'misleading' from the very fact of overemphasis and exaggeration, even though the product in question may be helpful, and in some circumstances useful, though not really indispensable to good health. This is no doubt what one of the government's expert witnesses had in mind when he testified:

> Well, obviously food is important, and we have to develop our bodies from building materials and blocks we get from food; but in order to utilize our food properly we have to have a liver that is functioning, and a pancreas that is functioning, and various other of our body organs, in order to utilize food properly. So we may very well get the best of food, and yet if we have faulty processes of digestion, or liver functioning, which is mentioned specifically, we can't get the most out of our food. On the other hand, if we have a good liver and a good pancreas and a good insides, you might say, working properly and we get poor food, we aren't going to do

a good job either, so the answer to the last part is Yes or No, food is important but other things are also important.

"The same expert testified subsequently, on cross-examination:

> If anybody eats nothing but sugar, that is, this white sugar you mentioned nothing but white bread, you would need some type of vitamin and mineral supplement. If you put in a little milk, if you put in a little meat, if you put in a little egg, vegetable, fruits, you don't need Mr. Irons or anybody else, if you are in good health.

"Turning now to the second charge contained in each of Counts II–VI of the information, that is, that the articles of drug were misbranded in that their labeling failed to bear 'adequate directions for use' for the various diseases and conditions for which they were intended, it may be pointed out that we are free to look to all relevant sources in order to ascertain what is the 'intended use' of a drug, and are not merely confined to the labels on the drug or the 'labeling'. The legislative history of the 1938 Act makes this clear. See Dunn, Federal Food, Drug, and Cosmetic Act 111–12, 240 (1938). Such also has been the undeviating opinion of the courts which have had occasion to deal with the issue. For example, in a recent decision the Third Circuit said:

> The intended uses of the products in the present issue as in *Kordel* [*Kordel* v. *United States*, *supra*, 335 U. S. 345] were to cure, ameliorate or prevent diseases. The evidence to prove their uses included both graphic materials distributed and testimony of oral representations to users and prospective users. The latter are no less relevant on the question than the former. Both show that the products shipped were to be used as drugs. "*United States* v. *El Rancho Adolphus Products et al.*, F. 2d (C. A. 3d Jan. 29, 1957). See also *United States* v. *3 Cartons, More or Less, No. 26 Formula GM etc.*," 132 F. Supp. 569, 574 (S. D. Cal. 1952).

"In the present case, therefore, we are entitled to utilize all of appellants' literature as well as the oral representations made by V. Earl Irons at his lectures or by authorized sales distributors.[9]

"As a matter of fact, appellants introduced no label which provided adequate directions if the use of the products is to be taken to effect the cure or prevention of the various diseases mentioned in the literature. Indeed, appellants do not maintain that they ever issued any such label, but content themselves in saying that the government's case must fall because there was no showing that the voluminous literature admitted in evidence constituted *all* of the labeling of the products; in other words, it is argued that other items of labeling which might exist might have contained adequate directions for use. But once the government has introduced into evidence a substantial

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[9] The following testimony of the food and drug inspector about a speech made by appellant V. Earl Irons was thus admissible in order to show the intended use of the products.

"Q. In what way? What did he say about conditions?

A. Well, he mentioned there are four different types of cancer, he mentioned female troubles, and he also mentioned sexual impotence, sexual perversion. With regard to female troubles, he said, he mentioned a case of a woman who had not menstruated for a long time and after starting on Vit-Ra-Tox had no more trouble in that regard.

Mr. Foley: If your Honor please, I just want to make sure I have a running objection to all of this.

The Court: Oh, yes, yes. Perfectly admissible.

Q. Will you go on mentioning the others?

The Court: Go ahead.

A. Certainly.

Q. Give to the best of your memory the substance of this lecture given by Mr. Irons. A. When he began to talk about cancer, he made the statement: 'Ladies and gentlemen, I would rather have cancer than a bad case of asthma because cancer can be cured in three to ten weeks.' "

One consumer testified without objection that he had bought some Vit-Ra-Tox No. 21 upon an oral representation by the salesman that it would cure arthritis (see note 7, *supra*). The court charged the jury, in terms that were not objected to at the conclusion of the charge (see Rule 30 F. R. Cr. P.), that they might consider oral statements of Irons or a distributor of the corporation in determining whether the product was offered for treatment of specific diseases.

number of documents constituting 'labeling' of the various drug products, none of which provided 'adequate directions for use', it seems perfectly reasonable to require that the defendants have the burden of going forward with the production of other labeling which does satisfy the demands of the statute. It would be quite unthinkable to impose upon the government the further necessity of proving that there are no other, secreted, labelings in existence, especially since all such literature used by appellants can be assumed to be in their possession. Therefore we find no error in the conclusion that the labeling of appellants' products did not provide adequate directions for use.

"Appellants present a variety of other defenses, some of which are clearly untenable. For example, it is a bit late in the day to sustain the assertion that the Federal Food, Drug and Cosmetic Act is unconstitutionally vague. Nor, after a review of the entire record, are we able to agree that the court below committed prejudicial procedural errors in its conduct of the trial.

"However, the propriety of the sentences imposed merits a brief comment. It is argued that Counts I and II of the information and Counts III and IV each charged but a single offense and therefore that it was an error to sentence appellants separately on each of these four counts. (The individual defendant is hardly in a position to raise this point, since the sentences imposed upon him were to run concurrently. However, separate fines were imposed upon the corporate defendant as to each count.) The rule is now well settled that a conviction with sentence upon one indictment or information does not bar conviction with sentence upon another 'if the evidence required to support the one would not have been sufficient to warrant the conviction upon the other without proof of an additional fact . . . .' *Eberling* v. *Morgan*, 237 U. S. 625, 631 (1915); *Ekberg* v. *United States*, 167 F. 2d 380, 384 (C. A. 1st, 1948). In the present case this test is satisfactorily met. The violation in Count I is based upon the charge that the article was represented as a food for special dietary uses by reason of its vitamin and mineral content, and that the label did not bear certain information required under the authorized regulations issued by the Secretary of Health, Education, and Welfare. In contrast, Count II alleges the same product to be a misbranded drug on the basis of false and misleading statements which appear on the 'labeling' literature disseminated by appellants; and to obtain a conviction under this count the government had to prove the additional fact that the statements contained in such literature were false or misleading.

"The arguments based on Counts III and IV are even more flimsy, for these counts involve entirely different drugs. The drug named in Count III is a tablet known as Vit-Ra-Tox No. 21, which is said on its label to contain 'a mixture of dried extracted juices of cereal grasses green life, plus bone meal, brewer's yeast, fish liver oils, alfalfa kelp (or dulse).' The drug which is the subject of Count IV is a liquid known as Vit-Ra-Tox No. 16, described in the label thus: 'Colloidal Bentonite (U. S. P. Grade). Distilled water as vehicle with certified flavor and color'. Obviously they are different drugs. As the statute forbids the introduction into interstate commerce of *any* drug that is adulterated or misbranded (21 U. S. C. § 331 (a)), Counts III and IV do not charge the commission of a single offense but rather two separate and distinct offenses, and the sentence imposed upon the corporate defendant by the trial court was therefore entirely proper."

A petition for a writ of certiorari was filed with the United States Supreme Court on 5–23–57, and on 6–17–57 the petition was denied.

5309. Nutrilite food supplement. (F. D. C. No. 39368. S. Nos. 20–490 M, 20–495 M.)

INFORMATION FILED: 2–7–57, Dist. Columbia, against Berneice Small, Washington, D. C.

ALLEGED VIOLATION: On 1–18–56 and 1–27–56, the defendant sold and delivered quantities of the article which had been orally recommended by the defendant for the diseases, symptoms, and conditions set forth below, which acts resulted in the article being misbranded while held for sale.