beautiful; that it would minerally balance the blood stream; that it would enable one to attain good eyesight without glasses; that it would prevent children's diseases; that it would correct farsightedness, middle-age sight, nearsightedness, astigmatism, and inflamed eyes; and that it would insure healthy sinuses and vigorous lungs.

That the *Pure Soy Bean Lecithin and Vitamin D Capsules* would be of value as a brain food; that it possessed special virtues for the treatment of rickets, dyspepsia, diabetes, anemia, and tuberculosis; that it was especially required by the stomach, kidneys, liver, lungs, and pancreas; that it would be efficacious in the correction in an undernourished person of despondency, early discouragement, and lack of will-power and enthusiasm; that it would provide proper reasoning power; that it would restore loss of memory; that it would correct lack of power to concentrate and lack of coordination between the brain and muscles; that it would be efficacious in the correction of an inferiority complex; that it would increase mental efficiency; and that it would produce healthy physical and mental developments and glandular functioning in children.

That the *Wheat Germ Oil Capsules* would be of benefit to women during the menopause; that it would supply proper nourishment to all important glands including the sex glands; that it would be efficacious in the correction of nervous irritability, flashes before the eyes, fever, chills, and heat spells; that it would be efficacious in the correction in men of difficult urination, pelvic pains, cramps, prostate gland trouble, and loss of the sexual fluid; that it would supply pep and life; that it would benefit every fiber of the muscles in his body as well as the valves that control the various fluids; that it would be efficacious in the prevention of gland atrophy; that it would lengthen life; that it would permit living a life free from suffering and disease; that it would promote general well-being, vigor of personality, glands, and mental and physical vigor; and that it was essential to nerve and muscle tissue, for maximum growth and nutrition, and for pregnant women.

The information charged further that, with the exception of the *Garlic Parsley Capsules*, the above products and a shipment of *Concentrated Broth* were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: A plea of not guilty having been entered, the case came on for trial before a jury on February 17, 1948. The trial ended on February 20, 1948, with the return by the jury of a verdict of not guilty on the count which related to the *Concentrated Broth* and a verdict of guilty on all other counts of the information. The court imposed a fine of $1,800 on March 8, 1948. On the same day, the court denied the defendant's motion for a new trial and arrest of judgment.

2580. Misbranding of Gotu Kola tablets, Minerals Plus tablets, sarsaparilla root, Cetabs tablets, Fenugreek tea, Fero-B-Plex tablets, Bolax tablets, Ormotabs tablets, Ribotabs tablets, Kordel tablets, Everm wheat germ oil capsules, Kordel-A capsules, Garlic Plus tablets, Niamin tablets, and sarsaparilla tea. Three Informations: U. S. v. Laura Kordel (Gotu Kola Distributors) and Lelord Kordel, U. S. v. Lelord Kordel (Lelord Kordel Products), and U. S. v. Lelord Kordel (Lelord Kordel Products and Nutrition Enterprises). Pleas of not guilty. Tried to the court. Verdict of guilty against Lelord Kordel; verdict of not guilty

against Laura Kordel. Fine of $4,000 against Lelord Kordel. Judgment affirmed upon appeal to U. S. Court of Appeals for the Seventh Circuit and upon appeal to U. S. Supreme Court. (F. D. C. Nos. 14307, 14308, 17777. Sample Nos. 49028–F, 70727–F, 70767–F to 70771–F, incl., 28363–H to 28371–H, incl., 28373–H, 28375–H, 28376–H, 29408–H.)

INFORMATIONS FILED: On July 11 and 13, 1945, and January 21, 1946, in the Northern District of Illinois, against Laura Kordel, trading as Gotu Kola Distributors, at Chicago, Ill., and Lelord Kordel, and against Lelord Kordel, trading as Lelord Kordel Products and Nutrition Enterprises, at Chicago, Ill.

ALLEGED SHIPMENT: Between the approximate dates of July 10, 1942, and February 28, 1945, from the State of Illinois into the States of Ohio, Washington, and California. It was alleged that the *Gotu Kola tablets* were shipped by Laura and Lelord Kordel and that the other products were shipped by Lelord Kordel.

PRODUCT: Analyses disclosed that the *Gotu Kola tablets* consisted of white sugar- and lime carbonate-coated tablets containing, chiefly, pennywort, iron sulfate, calcium sulfate, and talc; that the *Ferro-B-Plex tablets* consisted of calcium carbonate-coated tablets containing vitamins B_1 and B_2 and niacin, and 273 milligrams of calcium per 3 tablets, 66 milligrams of iron per 3 tablets, and 158 milligrams of phosphorus per 3 tablets; that the *Minerals Plus tablets* consisted of gray compressed tablets containing per 6 tablets approximately 687 milligrams of calcium, 579 milligrams of phosphorus, and 81.6 milligrams of iron, together with a small amount of iodine, vitamin D, and chlorophyll; that the *sarsaparilla root* consisted of a coarsely cut plant mixture consisting principally of sarsaparilla root with a small amount of sassafras bark; that the *Cetabs tablets* consisted of coated tablets containing 31 milligrams of ascorbic acid per tablet; that the *fenugreek tea* consisted essentially of whole fenugreek seeds with some whole barley seeds and other whole unidentified seeds; that the *Bolax tablets* were brown compressed tablets consisting essentially of powdered plant material, including the emodin bearing drugs, senna and buckthorn; that the *Ormotabs tablets* were sugar-coated tablets consisting essentially of plant material, including sassafras, chlorophyll, and an iodine bearing substance; that the *Ribotabs tablets* were compressed tablets containing riboflavin; that the *Kordel tablets* consisted essentially of sodium citrate, plant material, and oil of wintergreen; that the *Everm wheat germ oil capsules* were gelatin capsules containing an oil-like wheat germ oil; that the *Kordel-A capsules* were gelatin capsules containing a vitamin-A-bearing oil; that the *Garlic-Plus tablets* consisted essentially of dried plant material, including garlic; that the *Niamin tablets* were coated tablets containing 10 milligrams of niacinamide and a small amount of yeast; and that the *sarsaparilla tea* consisted essentially of a mixture of sarsaparilla root and sassafras bark.

NATURE OF CHARGE: *Gotu Kola tablets.* Misbranding, Section 502 (a), certain statements in a circular accompanying the article were false and misleading. These statements represented and suggested that *Hydrocotyle asiatica*, the common or usual name of which is Indian Pennywort, is a rich, natural, seemingly secret source of dynamic energy; that the article would be effective in producing marvelous physique and full, vibrant physical existence; that it would be effective in prolonging life, perpetuating and restoring youth, and increasing vitality; that it would have an energizing effect on the cells of the brain and would preserve it indefinitely; that it would be effective in strengthening and revitalizing worn-out bodies and brains, prevent brainfag and nervous

breakdowns, keep old age away, and prolong the existence of the brain; that it would be effective in producing energy, a perfect physical life, more abundant power, more perfect living, and a fuller, richer physical existence; that it would generally enhance physical life and manifest a brighter, keener, mental activity, a restimulated ambition, and a renewed optimistic outlook; that it would be effective in the treatment of those below par physically and mentally; that it would be effective in producing erect posture, sharp eyes, velvety skin, limbs of splendid proportion, deep chests, firm bodies, gracefully curved hips, flat abdomens, rhythm of motion, gracefulness and poise, stately bearing, intelligence of eyes, pleasing laughter, and extraordinary physique; and that the article would be effective in the treatment of rheumatism, neuritis, and nervous breakdown. The drug *Hydrocotyle asiatica* is not a rich, natural, seemingly secret source of dynamic energy, and the article would not be effective for the purposes represented.

Cetabs tablets, Ormotabs tablets, Ribotabs tablets, Fero-B-Plex tablets, Minerals Plus tablets, Bolax tablets, Kordel tablets, Everm wheat germ oil capsules, Kordel-A capsules, fenugreek tea, Garlic Plus tablets, and Niamin tablets. Misbranding, Section 502 (a), certain statements and designs in the bulletins and booklets and on the placard accompanying these articles were false and misleading. The statements and designs represented and suggested:

That the *Cetabs tablets* would be effective to insure strong teeth, healthy gums, good digestion, clear complexion, and vigorous health; and that it would be effective to prevent and correct premature old age, liver troubles, stiff joints, hormone deficiency and malfunction, diabetes, poor complexion, fatigue, heart trouble, colds, high blood pressure, pyorrhea, loss of weight, tooth decay retarded growth, and poor appetite.

That the *Ormotabs tablets* would be effective in the treatment of anemias, internal infections, peritonitis, brain ulcer, osteomyelitis, ulcerated varicose veins, respiratory infections, arteriosclerosis, cardiac hypertension or other heart ailments, nervous fatigue, tubercular infections, and undernourishment in children; that it would be effective to promote hormone production; and that it would provide substances possessing hormone activity.

That the *Ribotabs tablets* would be effective in the treatment and prevention of blindness, high blood pressure, ulcer, loss of weight, oily skin, falling hair, digestive disturbances, and poor complexion.

That the *Fero-B-Plex tablets* would be effective to correct lack of vitality, poor appetite, indigestion, constipation, nervousness, and irritability.

That the *Minerals Plus tablets* would be effective in the treatment and prevention of poor memory, ulceration, bad teeth, general weakness, impaired respiration, fatigue, obesity, liver disorders, stiff joints, nervous breakdown, tonsillitis, rheumatic conditions, impaired glandular function, constipation, and abnormal body cell growth.

That the *Bolax tablets* would be effective in the treatment of acidosis, colds, lack of appetite, and constipation.

That the *Kordel tablets* would be effective in the treatment of arthritis, rheumatism, sciatica, neuralgia, lumbago, and aching joints and muscles.

That the *Everm wheat germ oil capsules* would be effective in the treatment and prevention of heart failure, paralysis, muscular diseases, mental disorders, impotency, reproductive disorders, and infertility.

That the *Kordel-A capsules* would be effective in the cure, mitigation, treatment, and prevention of failing eyesight, red and swollen eyelids, squinting of eyes, color blindness, and acne and other skin disorders.

That the *fenugreek tea* would be effective in the treatment and prevention of stomach upsets, sour taste in the mouth, gas pains, heartburn, hyperacidity, belching, bloating, liver disorders, rheumatic and neuritic pains, debility, ulcers, colitis, internal inflammations, and acidosis.

That the *Garlic Plus tablets* would be effective in the treatment of high blood pressure, headaches, dizziness, shortness of breath, heart pains, sleeplessness, and inability to concentrate.

That the *Niamin tablets* would be effective in the treatment of heart ailments, angina pectoris, cerebral thrombosis, headaches, dizziness, ringing in the ears, deafness, allergies, high blood pressure, nervousness, poor appetite, irritability, kidney disorders, and fatigue.

Further misbranding, Section 502 (a), certain statements in the booklet accompanying the *sarsaparilla root*, *Minerals Plus tablets*, *Fero-B-Plex tablets*, *Bolax tablets*, *fenugreek tea*, *Cetabs tablets*, and *sarsaparilla tea* were false and misleading. These statements represented and suggested that the articles, when taken alone or in combination with each other or with the diets recommended in the booklet, would be effective in the cure, mitigation, treatment, and prevention of arthritis. The articles, when taken alone or in combination with each other or with the recommended diets, would not be effective for such purposes.

Further misbranding, Section 502 (a), certain statements on the label of the *Ormotabs tablets* were false and misleading. These statements represented and suggested that sarsaparilla root, sassafras bark, papain, and chlorophyll are nutritional factors and are of dietary importance. Such substances are not nutritional factors, nor are they of dietary importance.

Further misbranding, Section 502 (a), certain statements on the label of the *Minerals Plus tablets* were misleading. These statements represented and suggested that the tablets were of nutritional significance by reason of the presence of the minerals, magnesium, cobalt, sodium, sulfur, potassium, chlorine, manganese, zinc, nickel, lithium, boron, strontium, silicon, and bismuth. The tablets were of no nutritional significance by reason of the presence of those minerals.

Further misbranding, Section 502 (a), certain statements on the label of the *Kordel tablets* were false and misleading. These statements represented and suggested that the tablets were a food adjunct and would provide ingredients of nutritional significance. The tablets were not a food adjunct and would provide no ingredients of nutritional significance.

Further misbranding, Section 502 (a), certain statements on the label of the *Everm wheat germ oil capsules* were misleading. These statements represented and suggested that there were definite disease conditions in man recognized as due to a vitamin E deficiency in which the capsules would be an effective treatment.

Further misbranding, Section 502 (a), certain statement in the bulletin accompanying the *Kordel-A capsules* were false and misleading. These statements represented and suggested that defective eyes in infants are frequently due to inadequate intake of vitamin A by the mothers. Defective eyes in infants are not frequently due to the condition represented.

DISPOSITION: Pleas of not guilty having been entered, the cases were consolidated for trial before the court. The trial commenced on March 18, 1946, and at its conclusion the court accorded the parties the opportunity to submit briefs. After consideration of all the evidence and the briefs of the parties, the court on June 26, 1946, handed down the following opinion:

LA BUY, *District Judge:* "There are three informations, comprising twenty counts, brought against Laura Kordel and Lelord Kordel for violation of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. § 301 et seq., by misbranding. A stipulation between Lelord Kordel trading as Gotu Kola Distributors and as Lelord Kordel Products, and as Lelord Kordel Products and Nutrition Enterprises, has been filed wherein the facts contained in the three informations are agreed. This stipulation is not made by Laura Kordel and is not to be construed as admissions by her.

"With the stipulation of facts as stated in the informations, the only question tried by the court was whether the violation has been proved by the evidence.

"The main contention of defendants' counsel is that since the booklets did not, in a number of counts, physically accompany the drugs they did not therefor 'accompany' the drug within the meaning of Section 321 (m) of the Act. Defendants' counsel urges a strict construction of the word 'accompany' since this is a criminal action and that the penal provisions of the Federal Food, Drug and Cosmetic Act be strictly construed.

"[1–2] It is necessary first to determine the nature of the statute before us. The United States Supreme Court in the case of United States v. Dotterweich, 1943 320 U. S. 277, 64 S. Ct. 134, 136, 88 L. Ed. 48, said: '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.' Also in United States v. Antikamnia Co., 1914, 231 U. S. 654, 34 S. Ct. 222, 58 L. Ed. 419, and United States v. Schider, 1917, 246 U. S. 519, 38 S. Ct. 369, 370, 62 L. Ed. 863: 'The purpose of the act is to secure the purity of food and drugs and to inform purchasers of what they are buying. Its provisions are directed to that purpose and must be construed to effect it.'

"It is apparent, therefore, that the purpose of the law is the ever-insistent consideration in its interpretation. Congress by enacting it intended to promote honesty and fair dealing in trade and secure to the public pure and wholesome food and drugs and there must be a reasonable construction to carry out the intention of Congress. This being 'remedial legislation,' the rule of liberal construction is to be followed irrespective of its penal provisions.

"Mr. Justice Story in Taylor et al. v. United States, 1845, 3 How. 197, 11 L. Ed. 559, stated this principle as follows: 'In one sense, every law imposing a penalty or forfeiture may be deemed a penal law; in another sense, such laws are often deemed, and truly deserve to be called remedial.' The judge was, therefore, strictly accurate, when he stated that 'It must not be understood that every law which imposes a penalty is, therefore, legally speaking, a penal law, that is, a law which is to be construed with great strictness in favor of the defendant. Laws enacted for the prevention of fraud, for the suppression of a public wrong, or to effect a public good, are not, in the strict sense, penal acts, although they may inflict a penalty for violating them.' And he added, 'It is in this light I view the revenue laws, and I would construe them so as most effectually to accomplish the intention of the legislature in passing them.' The same distinction will be found recognized in the elementary writers, as, for example, in Blackstone's Commentaries

* * * and Bacon's Abridgement * * * and Comyns' Digest * * * and it is also abundantly supported by the authorities.

"[3] The word 'accompany' has been defined in a number of cases. See United States v. Lee, 7 Cir., 1942, 131 F. 2d 464, 143 A. L. R. 1451; United States v. Research Laboratories, Inc., 9 Cir., 1942, 126 F. 2d 42, certiorari denied 317 U. S. 656, 63 S. Ct. 54, 87 L. Ed. 528; United States v. 7 Jugs, etc., Dr. Salsbury's Rakos, D. C. Minn., 1944, 53 F. Supp. 746, 755. An excellent analysis was made by District Judge Joyce in the Rakos case supra. He said:

The word "accompany," as used in Section 201 (m) (2) was said in United States v. Lee, 7 Cir., 1942, 131 F. 2d 464, 466, 143 A. L. R. 1451, to mean: "The word 'accompany' is not defined in the Act, but we observe that among the meanings attributed to the word are 'to go along with,' 'to go with or attend as a companion or associate,' and 'to occur in association with,' Webster's New International Dictionary, 2d Ed." Naturally, the meanings of accompany will vary in connection with subject matter. "Accompany" as used in this Act is used to describe a relationship between an article of drug and its labeling. Since there "can be no question that among the usual characteristics of labeling is that of informing a purchaser of the uses of an article to which the labeling relates" (United States v. Lee, 131 F. 2d at page 466), the booklets here involved should be scrutinized from this viewpoint. * * *

The stipulation clearly shows that the printed matter and the drugs had a common origin. They had a common destination in that both were intended to come together in the stores of dealers in Achilles' territory. They were interlocking units of a distributional scheme the objective of which was ultimate association and distribution together. There was actual, physical association together in the stores of dealers and actual distribution together in connection with purchases by farmers. It is fair to conclude that these booklets were prepared, shipped and distributed to dealers with the ultimate expectation and intention on the part of the Laboratories that they would serve the purpose of labeling for the three articles of merchandise here involved. Without the booklets, the products themselves lacked labeling, at least in so far as informing purchasers of the purposes and uses of the remedies. The mere fact that the products were shipped at different times, over a different route and were received at a different time from the booklets should not be permitted to confuse or obscure the substance of the matter. * * *

What is vital are such factors as interdependence of the drug and the booklets, common origin, common destination, display, distribution and use together. These determine whether there has been that degree of accompaniment which provides the necessary "misbranded" status under Section 304 (a) [21 U. S. C. A. § 334 (a)]. The mere fortuitous circumstance of an absence of physical association between the booklets and drugs during the interstate journey of the drugs does not in my opinion control.

"[4, 5] It is contended by defendant that the above cited cases were brought under libels of information for the condemnation of the articles involved; that these were civil proceedings; that the present case involves the criminal aspects of the statute and the definition should therefore be differently construed. To adhere to defendant's construction would result in a strange situation wherein under the same statute and the same section, a single word would have a different meaning dependent only on the nature of the action brought. This interpretation would defeat the enforcement of the statute and the court cannot subscribe to such a proposition. Furthermore, the element of forfeiture in a statute is as much a penal provision as is the one imposing a penalty.

"[6] These booklets were shipped by the defendant. The drugs and booklets were sent to the same consignee. They were 'displayed' and were intended to be distributed in relation to the drug. The booklets, pamphlets, or circulars were false and misleading.

"From the evidence and proof in the trial of this case, the court finds the defendant Lelord Kordel guilty of violating the misbranding provisions of the Act. As to the defendant, Laura Kordel, the court is of the opinion the evidence is insufficient to support a conviction and she is therefore discharged."

On the same date, the court fined Lelord Kordel $200 on each count in the informations, a total fine of $4,000, plus costs. An appeal was thereupon taken by Lelord Kordel to the United States Court of Appeals for the Seventh Circuit, and on November 6, 1947, the following opinion was handed down by that court:

SPARKS, *Circuit Judge:* "Appellant was charged by three criminal informations with violation of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. sections 301, *et seq.* He waived jury trial and, upon trial by the court, was found guilty and fined $200 on each of the twenty counts contained in the three informations. The appeal is from those judgments.

"The facts as to the shipping of the drugs and the literature alleged to constitute the misbranding charged in the informations were entirely stipulated. Error is asserted in the court's finding that that literature 'accompanied' the drugs in interstate commerce in the purview of the Act prohibiting the introduction or delivery for introduction of any drug that is misbranded. Other contested issues relate to the degree of proof necessary in a criminal proceeding under the Act, whether the Act should be strictly construed, and whether prosecution should have been by indictment rather than by information.

"Appellant is a self-styled authority on nutrition and vitamins. He testified that he had written many papers on the subject of vitamins, herbs, minerals and nutritional diet subjects in general, securing the material for preparation of his papers from books. Operating under various trade names, he had been producing and marketing his own products since January 1941, largely through 'health food' stores. The products appear to be, for the most part, compounded of various vitamins, minerals, and herbs. No charge of falsehood is made as to the principal labels printed on the packages in which each is contained. These labels give the name of the article and distributor, content, recommended dosage, and, in some cases, the alleged daily minimum requirement of the vitamins or minerals therein. Otherwise they give no indication as to their intended uses.[1] The misbranding charged is contained in a number of printed pamphlets and circulars, and one display placard. The modes of distribution of this literature differed as charged in the various counts of the informations. In some cases it was contained in the carton in which the articles were shipped. More often, it was separately shipped to the same consignees, and, in at least one case, a period of a year and a half intervened between the shipment of the product and the literature, respectively.

"Section 301 of the Food and Drugs Act as amended in 1938, 21 U. S. C. A. sec. 331, prohibits the introduction or delivery for introduction into interstate commerce of any drug that is misbranded; section 502, 21 U. S. C. A. sec. 352, provides that a drug shall be deemed to be misbranded if its labeling is false or misleading in any particular; and section 201 (m), 21 U. S. C. A. sec. 321 (m), defines the term 'labeling' to include 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.'

[1] The articles involved in the three informations are named "Gotu Kola," "Minerals plus Chlorophyll and Vitamin D," "Cetabs," "Fenugreek Tea," "Fero-B-Plex," "Bolax," "Ormotabs," "Ribotabs," "Kordel Tablets," "Everm," "Kordel A," "Garlic Plus," "Niamin," and "Sarsaparilla Tea."

"It is now generally held that in order to support a misbranding charge under the Act as amended and revised in 1938, it is not necessary that the matter alleged to accompany the product be shipped in the same container (*United States* v. *Research Laboratories*, 126 F. 2d 42), nor even that it be shipped simultaneously (*United States* v. *Lee*, 131 F. 2d 464; *United States* v. 7 *Jugs* ** *Rakos*, 53 Fed. Supp. 746; *United States* v. *Paddock*, 67 Fed. Supp. 819).

"Appellant contends that the cases referred to are not applicable for the reason that all involved civil proceedings rather than criminal, and further, that the literature here involved was not only not shipped in the same carton with the products in all cases, but neither was it intended by him that product and literature should be placed together by the dealer to whom they were sent. His theory apparently is that the matter was not intended for labeling, but for advertising. He points to the fact that all of the printed matter was intended either to be mailed out or to be sold, as indicated by the fact that with the exception of the one display placard, each piece either contained a price mark or a mailing permit with space for address. This, he contends, supports his theory that product and literature were not to be distributed together, hence cannot be said to accompany each other.

"We find two answers to this contention. In the first place, labeling and advertising are not mutually exclusive, and the same matter may serve both purposes. As the Court of Appeals for the Ninth Circuit states in *United States* v. *Research Laboratories*, 126 F. 2d 42, 'Most, if not all, labeling is advertising. The term "labeling" is defined in the Act as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising.' See also *United States* v. *Paddock*, 67 Fed. Supp. 819. In the second place, the placing of the mailing permit or the price tag on the literature cannot insulate appellant from liability for introducing the drugs and their related descriptive matter into interstate commerce together by consignment to the same consignee for distribution by him. The evidence is clear that the booklets were actually displayed on racks close to the counter where the products were sold and that they were necessary to inform the purchasing public of the uses to which these products were to be put.

"We agree with appellee that 'the correct concept of "accompaniment" is one of a commercial or business association.' As stated in the *Rakos* case *supra*, 'misbranding has true significance only in terms of the consumer. * * * "Accompany" as used in this Act is used to describe a relationship between an article of drug and its labeling. Since there "can be no question that among the usual characteristics of labeling is that of informing a purchaser of the uses of an article to which the labeling relates" (citing the decision of this court in *United States* v. *Lee*, *supra*) the booklets here involved should be scrutinized from this viewpoint. In the sense just stated, if the booklets are not labeling, then the products * * * have none.'

"We, too, are convinced that the test is not of physical contiguity but of textual relationship. Viewed thus, the products and literature here involved were interdependent because without the latter, the former lacked the labeling necessary to inform the purchasing public of their uses and purposes—it is significant that the labels printed on the immediate containers did not indicate the purposes for which the articles were to be used. Hence, the literature was intended and essential to explain the alleged uses of the products. They constituted a supplement to the label physically attached to the product container. One of the health food dealers in whose store the

Kordel products were sold admitted that if he were buying one of the products he would have to go to 'reliable sources' to know to what use to put the product. Presumably those reliable sources were the booklets displayed in racks close by the counter where the drugs were dispensed or lying on the counters where they were available to the public and could be picked up and examined. Some also were wrapped with merchandise or handed to customers.

"We agree with the District Court that, because the literature was shipped by appellant or at his order, to the same consignees as the products, related to those products, and was intended to be distributed in relation to them, it did accompany the products into interstate commerce within the definition of the Act. To hold otherwise would be to permit evasion of the Act by the very easy subterfuge of printing a purchase price or a mailing permit on advertising matter otherwise unquestionably accompanying products into interstate commerce.

"With respect to the misrepresentations contained in the accompanying literature we think there can be no serious question. The two booklets, 'Nutrition Guide,' and 'What you can do about relieving the agonies of Arthritis,' were written by appellant who, in the latter, is described as 'America's leading vitamin and diet expert.' 'Health Today, Spring 1945,' is edited by the same 'famous nutrition and vitamin authority.' While all purport to be scientific publications of general interest apart from the articles produced and marketed by appellant, written by an expert in the field, in fact, all are replete with references to the Kordel products and their uses to prevent, ameliorate or cure a vast and diverse variety of ailments, and each conveniently closes with a price list of the various Kordel products recommended for use therein. All are concerned primarily with promoting the sale of the various products by explaining the need for each, along with extravagant claims as to the usefulness of each. A study of the three pamphlets reveals that the products therein described are recommended for relieving stomach agonies, general weakness, anemia, premature old age, high blood pressure, liver troubles, failing eyesight, sore feet; maintaining blood energy, muscular activity, sound teeth and gums, healthy skin, hair and eyes, normal functioning of the pituitary and thyroid glands, stomach, intestines, colon, liver and kidneys; and preventing arthritis and stiff joints, excess weight, catarrh, nervous breakdown, sterility, and paralysis.

"Thus the scheme devised by appellant for the distribution of his products and related literature contemplates an elaborate system of self-diagnosis and medication. The danger inherent in this system lies not in any positive unwholesomeness of the articles themselves. As to them as such there is no charge and it may be that they are quite harmless in and of themselves. The danger however, lies in the fact that ignorant and gullible persons are likely to rely upon them instead of seeking professional advice for conditions they are represented to relieve or prevent. The Government introduced the evidence of many very eminent men in the medical profession to prove the dangerously misleading character of the literature in that the drugs were useless to combat the conditions they were represented to relieve, while delay in correct diagnosis and treatment for those conditions might render the treatment useless. As one of them stated, the literature encouraged people to experiment with themselves and that meant they were gambling with their health and life. He branded as scientifically ridiculous and nonsensical various of the claims and, when asked whether he would say that the products in themselves were

harmful, replied, 'They are definitely harmful in that they encourage a patient with a serious disease to experiment with himself when he should seek medical advice and precise diagnosis and therapy.'

"All were agreed that while the claims were absurd and fantastic, they were dangerous in that they tended to lull people into a false sense of security in reliance on the drugs when they might need professional diagnosis and treatment for conditions which might respond to treatment if correctly diagnosed early enough, but which might become much more serious if not taken care of early. Since the literature which we have already held accompanied the products embodies such misleading representations, it constitutes misbranding within the meaning of the Act.

"Appellant contends that, since the current proceedings are criminal, he is entitled to a strict construction of the Act, with proof of the violation, if any, beyond a reasonable doubt. Courts for a long time have been committed to the doctrine of giving statutes intended to protect the public health a very liberal construction. As stated in Sutherland on Statutory Construction (Vol. III, sec. 7202), 'The public and social purposes served by such legislation greatly exceed the inconvenience and hardship imposed upon the individual, and therefore the former is given greater emphasis in the problems of interpretation. Therefore the courts are inclined to give health statutes a liberal interpretation despite the fact that such statutes are primarily penal in nature and frequently impose criminal penalties.' To the same effect is the ruling in *United States* v. *Dotterweich*, 321 U. S. 277, where the Court said, '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.'

"We think there can be no doubt of the sufficiency of the evidence to sustain the charge beyond a reasonable doubt.

"Appellant strongly relies upon *Alberty* v. *United States*, 159 F. 2d 278, to sustain his proposition that booklets and the like, not shipped at the time of the articles, do not 'accompany' the article when they are introduced or offered for introduction into interstate commerce, and consequently cannot 'then and there' misbrand them. The Circuit Court of Appeals for the Ninth Circuit there reversed an order overruling a demurrer to an information and remanded the cause with directions to dismiss the information. It distinguished three of the cases to which we have referred (*United States* v. *Research Laboratories, United States* v. *7 Jugs* * * * *Rakos*, and *United States* v. *Lee*) on the ground that all involved civil proceedings and construed the Act liberally. We have already indicated that under the authorities cited, we do not consider the distinction applicable to the construction of the statute here involved. To the extent that the court limits the definition of the word 'accompany' to mean only physical association and contiguity, we do not agree with its reasoning and are convinced that it is not in harmony with those authorities.

"We find no merit in appellant's contention that he should have been prosecuted by indictment rather than by information. Section 303 (a) upon which the informations were based (21 U. S. C. A. sec. 333 (a)) provides that any person violating any of the provisions of section 201 shall be guilty of a misdemeanor, and subject to imprisonment for not more than one year or a fine of $1,000 or both, unless he has already been convicted of a prior offense under the same section. The charges were brought under this section. That being

the case, there was no necessity for prosecution by indictment. See *United States* v. *Wells Co.*, 186 Fed. 248 (holding violation of the 1906 Food and Drugs Act not an infamous crime). See also *Falconi* v. *United States* 280 Fed. 766, and cases there cited. *Judgments affirmed.*"

The above opinion was followed by the filing of a petition for rehearing, which was denied on January 22, 1948. A petition for a writ of certiorari was thereupon filed in the United States Supreme Court and was subsequently granted. On November 22, 1948, the following decision was handed down by that court:

MR. JUSTICE DOUGLAS: "This case and *United States* v. *Urbuteit*, decided this day, are here on certiorari to resolve a conflict among the circuits in the construction of the Federal Food, Drug, and Cosmetic Act of June 25, 1938. 52 Stat. 1040, 21 U. S. C. § 301 *et seq.*

"Kordel is charged by informations containing twenty counts of introducing or delivering for introduction into interstate commerce misbranded drugs. He was tried without a jury, found guilty, and fined two hundred dollars on each count. This judgment was affirmed on appeal. 164 F. 2d 913. Kordel writes and lectures on health foods from information derived from studies in public and private libraries. Since 1941 he has been marketing his own health food products; which appear to be compounds of various vitamins, minerals and herbs. The alleged misbranding consists of statements in circulars or pamphlets distributed to consumers by the vendors of the products, relating to their efficacy. The petitioner supplies these pamphlets as well as the products to the vendors. Some of the literature was displayed in stores in which the petitioner's products were on sale. Some of it was given away with the sale of products; some sold independently of the drugs; and some mailed to customers by the vendors.

"It is undisputed that petitioner shipped or caused to be shipped in interstate commerce both the drugs and the literature. Seven of the counts charged that the drugs and literature were shipped in the same cartons. The literature involved in the other counts was shipped separately from the drugs and at different times—both before and after the shipments of the drugs with which they were associated. The question whether the separate shipment of the literature saved the drugs from being misbranded within the meaning of the Act presents the main issue in the case.

"Section 301 (a) of the Act prohibits the introduction into interstate commerce of any drug that is adulterated or misbranded.[1] It is misbranded according to § 502 (a) if its 'labeling is false or misleading in any particular,' unless the labeling bears 'adequate directions for use.' § 502 (f). The term

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[1] Section 301 in relevant part reads as follows:

"The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

* * * * * * *

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded."

labeling is defined in § 201 (m) to mean 'all labels[2] and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.' Section 303 makes the violation of any of the provisions of § 301 a crime.[3]

"In this case the drugs and the literature had a common origin and a common destination. The literature was used in the sale of the drugs. It explained their uses. Nowhere else was the purchaser advised how to use them. It constituted an essential supplement to the label attached to the package. Thus the products and the literature were interdependent, as the Court of Appeals observed.

"It would take an extremely narrow reading of the Act to hold that these drugs were not misbranded. A criminal law is not to be read expansively to include what is not plainly embraced within the language of the statute (*United States* v. *Resnick*, 299 U. S. 207; *Kraus & Kraus* v. *United States*, 327 U. S. 614, 621–622), since the purpose fairly to apprise men of the boundaries of the prohibited action would then be defeated. *United States* v. *Sullivan*, 332 U. S. 689, 693; *Winters* v. *New York*, 333 U. S. 507. But there is no canon against using common sense in reading a criminal law, so that strained and technical constructions do not defeat its purpose by creating exceptions from or loopholes in it. See *Roschen* v. *Ward*, 279 U. S. 337, 339.

"It would, indeed, create an obviously wide loophole to hold that these drugs would be misbranded if the literature had been shipped in the same container but not misbranded if the literature left in the next or in the preceding mail. The high purpose of the Act to protect consumers who under present conditions are largely unable to protect themselves in this field[4] would then be easily defeated. The administrative agency charged with its enforcement[5] has not given the Act any such restricted construction.[6] The textual structure of the Act is not agreeable to it. Accordingly, we conclude that the phrase 'accompanying such article' is not restricted to labels that are on or in the article or package that is transported.

"The first clause of § 201 (m)—all labels 'upon any article or any of its containers or wrappers'—clearly embraces advertising or descriptive matter that goes with the package in which the articles are transported. The second clause—'accompanying such article' has no specific reference to packages, containers or their contents as did a predecessor statute. See *Seven Cases* v.

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[2] The term label is defined as "a display of written, printed, or graphic matter upon the immediate container of any article." § 201 (k).

[3] "SEC. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

"(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 301, with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine."

The informations, in charging violations of § 301 (a), did not allege that the acts committed were done "with intent to defraud." Hence the maximum penalty was that provided in § 303 (a), *viz*, imprisonment for not more than a year, or a fine of not more than $1,000, or both. Prosecution by information was therefore authorized by the statute (see *Duke* v. *United States*, 301 U. S. 492) and by § 7 (a) of the Rules of Criminal Procedure.

[4] See *United States* v. *Dotterweich*, 320 U. S. 277, 280; *United States* v. *Sullivan*, *supra*, p. 696.

[5] See § 701 and § 201 (c), 1940 Reorg. Plan No. IV, § 12, 54 Stat. 231, 5 U. S. C. § 133 (u).

[6] The Federal Security Agency by regulation (21 C. F. R. Cum. Supp. § 2.2) has ruled: "Labeling includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce."

United States, 239 U. S. 510, 513, 515. It plainly includes what is contained within the package whether or not it is 'upon' the article or its wrapper or container. But the second clause does not say 'accompanying such article in the package or container,' and we see no reason for reading the additional words into the text.

"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. The analogy to the present case is obvious. We need not labor the point.

"The false and misleading literature in the present case was designed for use in the distribution and sale of the drug, and it was so used. The fact that it went in a different mail was wholly irrelevant whether we judge the transaction by purpose or result. And to say that the prior or subsequent shipment of the literature disproves that it 'is' misbranded when introduced into commerce within the meaning of § 301 (a), is to overlook the integrated nature of the transactions established in this case.

"Moreover, the fact that some of the booklets carried a selling price is immaterial on the facts shown here. As stated by the Court of Appeals, the booklets and drugs were nonetheless interdependent; they were parts of an integrated distribution program. The Act cannot be circumvented by the easy device of a 'sale' of the advertising matter where the advertising performs the function of labeling.

"Petitioner points out that in the evolution of the Act the ban on false advertising was eliminated, the control over it being transferred to the Federal Trade Commission. 52 Stat. 114, 15 U. S. C. § 55 (a). We have searched the legislative history in vain, however, to find any indication that Congress had the purpose to eliminate from the Act advertising which performs the function of labeling. Every labeling is in a sense an advertisement. The advertising which we have here performs the same function as it would if it were on the article or on the containers or wrappers. As we have said, physical attachment or contiguity is unnecessary under § 201 (m) (2).

"There is a suggestion that the offense in this case falls under § 301 (k) of the Act which includes misbranding of a drug while it is held for sale after shipment in interstate commerce.[7] Since the informations contain no such charge, it is therefore claimed that the judgment must be reversed. We do not agree. Section 301 (k) has a broad sweep, not restricted to those who introduce or deliver for introduction drugs in interstate commerce.[8] See *United States* v. *Sullivan, supra.* Nor is it confined to adulteration or misbranding as is § 301 (a). *Id.* It is, however, restricted to cases where the article is held for sale after shipment in interstate commerce; and, unlike § 301 (a) it does not reach situations where the manufacturer sells directly to the consumer. Cf. *United States* v. *Urbuteit, supra.* Hence we conclude that we do not disturb the statutory scheme when we refuse to take from § 301 (a) what is fairly included in it in order to leave the matter wholly to the service of § 301 (k). The reach of § 301 (a) is in this respect longer. Such a transfer to § 301 (k) would create a new hiatus in the Act and thus disturb the pattern which we discern in it.

[7] See note 1, *supra.*

[8] The purpose of § 301 (k) was described in H. Rep. No. 2139, 75th Cong., 3d Sess. 3 (1938), as follows:

"In order to extend the protection of consumers contemplated by the law to the full extent constitutionally possible, paragraph (k) has been inserted prohibiting the changing of labels so as to misbrand articles held for sale after interstate shipment."

"We have considered the other objections tendered by petitioner and find them without merit. *Affirmed.*"

MR. JUSTICE BLACK, *with whom* MR. JUSTICE FRANKFURTER, MR. JUSTICE MURPHY, *and* MR. JUSTICE JACKSON *concur, dissenting:* "I agree with the court's interpretation of § 502 (a) and § 201 (m) of the Pure Food and Drug Act. These sections considered together provide a definition for the 'misbranding' of drugs. I agree that a drug is misbranded within the meaning of the statute if false and misleading written, printed, or graphic matter is either placed upon the drug, its container or wrappers, or used in the sale of the drug as a supplement to the package label to advise consumers how to use the drug. I agree that false labels may, within the meaning of the statute, 'accompany,' that is go along with, a drug on its interstate journey even though not in the same carton, on the same train, in the same mail, or delivered for shipment the same day. But these agreements do not settle all the problems in this case.

"The Pure Food and Drug Act does not purport to make all misbranding of drugs within the foregoing definition a federal offense. Congressional power to pass the Act is based upon the commerce clause. Consequently misbranding is only an offense if the misbranded drugs bear the statutorily defined relationships to interstate commerce. For illustration, if a person misbranded a drug which had not been and was not thereafter introduced into interstate commerce, there would be no violation of the federal Act, whatever violation there might be of state law.

"As we pointed out in *United States* v. *Sullivan*, 332 U. S. 689, the Pure Food and Drug Act creates several offenses each of which separately depends upon the relationship the misbranded drug then bears to interstate commerce. Section 301 (a) forbids the 'introduction or delivery for introduction into interstate commerce' of misbranded drugs; § 301 (b) forbids misbranding while the drugs are 'in interstate commerce'; § 301 (c) prohibits the 'receipt' of such drugs in interstate commerce; and § 301 (k) forbids misbranding while drugs are 'held for sale after shipment in interstate commerce.'

"The twenty counts of the information upon which this petitioner's conviction rests, charge that he had introduced drugs into interstate commerce, and that 'when' he so introduced the drugs, they were 'misbranded . . . in that . . . statements appearing in . . . bulletins and booklets *accompanying*' the drugs 'were false and misleading.' [Emphasis supplied.] The undisputed evidence as to thirteen of these counts showed that when the drugs were 'introduced' into interstate commerce for shipment, they were not within any fair meaning of the word 'accompanied' by the printed matter relied on as 'labeling.' The evidence under one count was that the drugs were shipped July 10, 1942, while the booklets said to be 'labels' were sent a year and a half later, January 18, 1944. Thus, each of these counts charged a violation of the separate and distinct offense of introducing misbranded drugs into interstate commerce, prohibited by § 301 (a). The evidence proves the offense, if any, of violation of § 301 (k), which prohibits the misbranding of drugs while held for sale after an interstate shipment.

"The court's interpretation of § 301 (a) seems to me to create a new offense to make it a crime to introduce drugs into interstate commerce if they should subsequently be misbranded, even so long as eighteen months later while held for sale. This judicial action is justified in part on the ground that the offense Congress created in § 301 (k) for holding misbranded drugs for sale after interstate shipment might not reach all situations covered by the congressionally created offense defined by § 301 (a). If as the Court believes, Congress in

§ 301 (k) has limited the situations for which it will direct punishment for holding misbranded articles for sale, I cannot agree that we should rewrite § 301 (a) so as to broaden its coverage. If Congress left a hiatus, Congress should fill it if it so desires. While I do not doubt the wisdom of separating these offenses as Congress has here done, we must remember that there are dangers in splitting up one and the same transaction into many offenses. See *Blockberger* v. *United States*, 284 U. S. 299, 304–305.

"These are serious offenses. While petitioner was fined only $200 on each count, or a total of $4,000, the maximum allowable punishment was $1,000 per count and imprisonment for one year, or for three years under other circumstances. § 303 (a). The approach of Congress in this field of penal regulation has been cautious. The language used by Congress in the present law in defining new offenses has been marked by precision. I think we should exercise a similar caution before reading into the 'introduction to interstate commerce' offense, conduct which patently fits into the 'held for sale' offense.

"I would reverse the judgment here insofar as it rests on the thirteen counts in which the Government charged offenses under § 301 (a) and failed to prove them."

2581. Misbranding of Gotu Kola tablets, fenugreek tea, Bolax tablets, Garlic Plus tablets, Ribotabs tablets, Minerals Plus tablets, sarsaparilla tea, Everm wheat germ oil capsules, Kordel tablets, Ormotabs tablets, Cetabs tablets, Fero-B-Plex tablets, Kordel-A capsules, Niamin tablets, Papaya Plus tablets, and Matto tablets. U. S. v. 134 Packages, etc. (and 3 other seizure actions). (F. D. C. Nos. 11810, 15807, 15916, 15926. Sample Nos. 49028–F, 28330–H, 28332–H, 28335–H, 28336–H, 28338–H, 28340–H, 28363–H to 28371–H, incl., 28373–H to 28376–H, incl., 28390–H, 28392–H, 28394–H to 28396–H, incl., 28398–H, 29402–H to 29412–H, incl.)

LIBELS FILED: February 22, 1944, and April 16 and May 3 and 4, 1945, Northern District of California, Southern District of Ohio, and Western District of Washington.

ALLEGED SHIPMENT: Between the approximate dates of December 6, 1943, and March 21, 1945, by Lelord Kordel Products and Nutrition Enterprises, from Chicago, Ill.

PRODUCT: 134 packages of *Gotu Kola tablets*, 1,794 packages of *fenugreek tea*, 153 cartons of *Bolax tablets*, 104 cartons of *Garlic Plus tablets*, 239 cartons of *Papaya Plus tablets*, 184 cartons of *Ribotabs tablets*, 404 cartons of *Minerals Plus tablets*, 76 boxes of *sarsaparilla tea*, 209 cartons of *Everm wheat germ oil capsules*, 19 cartons of *Kordel tablets*, 242 cartons of *Ormotabs tablets*, 80 cartons of *Matto tablets*, 61 packages of *Cetabs tablets*, 411 packages of *Fero-B-Plex tablets*, 64 packages of *Kordel-A capsules*, and 41 packages of *Niamin tablets* at San Francisco, Calif., Cincinnati, Ohio, and Seattle, Wash.

Analyses disclosed that the *Papaya Plus tablets* consisted essentially of plant material containing oil of wintergreen and vitamin B_1, and that the *Matto tablets* consisted of powdered plant material. The results of analyses of the other products were essentially the same as the results of analyses reported in the preceding notice of judgment, No. 2580, with respect to the products of the same names involved therein.

NATURE OF CHARGE: *Gotu Kola tablets, fenugreek tea, Bolax tablets, Garlic Plus tablets, Ribotabs tablets, Minerals Plus tablets, sarsaparilla tea, Everm wheat germ oil capsules, Kordel tablets, Ormotabs tablets, Cetabs tablets, Fero-B-Plex tablets, Kordel-A capsules,* and *Niamin tablets.* Misbranding,