5383. Pego Palo vine. (F. D. C. No. 40191. S. No. 48-358 M.)

QUANTITY: 1 ctn. containing 328 cellophane bags of vine at Floral Park, N.Y., in possession of Frank Miglio.

SHIPPED: 2-19-57, from Chicago, Ill., by A-1 Import Co.

LABEL IN PART: (Bag) "Pega Palo" or "Pega Palo Vine Chicago, Illinois."

ACCOMPANYING LABELING: Reprints entitled "Pega Palo The Vine That Makes You Virile."

RESULTS OF INVESTIGATION: The reprints were printed locally for the consignee.

LIBELED: 5-3-57, E. Dist. N. Y.

CHARGE: 505 (a)—the article, when shipped, was a new drug which may not be shipped in interstate commerce since an application filed pursuant to 505 (b) was not effective with respect to the drug; and 502 (f) (1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for use for the purpose for which it was intended, namely, as an aphrodisiac.

DISPOSITION: 6-4-57. Default—destruction.

5384. Pega Palo vine. (F. D. C. No. 40212. S. No. 63-854 M.)

QUANTITY: 2 pkgs., each containing 7 pieces of vine packed separately in pliofilm envelopes, at Albuquerque, N. Mex., in possession of Robert Garcia.

SHIPPED: 4-26-57, from Chicago, Ill., by Health Enterprises.

LABEL IN PART: (Envelope) "Pega Palo Vine * * * Packed by A-1 Import Company Chicago 51, Ill. Contents: 7 grams or over."

ACCOMPANYING LABELING: Reprints entitled "The Vine That Makes You Virile."

LIBELED: 5-20-57, Dist. N. Mex.

CHARGE: 505 (a)—the article, when shipped, was a new drug which may not be shipped in interstate commerce since an application filed pursuant to 505 (b) was not effective with respect to the drug; and 502 (f) (1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for use for the purpose for which it was intended, namely, as an aphrodisiac.

DISPOSITION: 6-21-57. Default—delivered to the Food and Drug Administration.

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

5385. Peppermint tea leaves, wheat germ oil, herb laxative, concentrated broth, whole wheat, wheat germ. (F. D. C. No. 33790. S. Nos. 14-497/8 L, 14-500 L, 14-502 L, 18-317/8 L, 18-322 L.)

INDICTMENT RETURNED: 8-2-54, against El Rancho Adolphus Products, Inc., Scientific Living, Inc., and Adolphus Hohensee, all of Scranton, Pa.

SHIPPED: Between 1-21-52 and 8-14-52, from Pennsylvania to Arizona and Colorado.

LABEL IN PART: (Can) "El Rancho Adolphus Brand Genuine-Select Imported Peppermint Tea Leaves * * * Net Weight 3 Ozs. [or "Herb Laxative (Minted) * * * Net Weight 3 Oz.," "Concentrated Broth In Dry Mechanically Pulverized Form * * * Net Weight 8 Oz.," or "Improved Wheat Germ

*See also Nos. 5381-5384, 5400.

Wheat-Hearts * * * Net Weight 12 Ozs."]"; (btl.) "Adolphus Contents: One Pint Wheat Germ Oil"; (bag) "El Rancho Brand Adolphus Whole Wheat 10 Lbs. Net Weight."

CHARGE: 502 (f) (1)—the labeling of the articles failed to bear adequate directions for use, in that such labeling failed to state the purposes, conditions, and diseases for which the articles were intended, namely—

Peppermint tea leaves—to assist in the removal of gallstones; for arthritis; to rebuild the whole body; to eliminate stagnant urine and thus prevent diseases which men and women have that result from toxins produced by decomposition of stagnant urine in collapsed bladders; to contract the bladder and so force urine to drain completely; for tuberculosis; to enable the blood to utilize vitamin C; to eliminate asthma, pinworms, tapeworms, and the symptoms of worms, namely, fits, convulsions, fainting spells, gritting of the teeth while asleep, dry cough, and restlessness at night; to use as an alkalizer; to give the user health; to act as a cleanser in toxemia; for headache and rheumatism; to effect diuresis; for reducing; for colitis; for cleansing; for high blood pressure; to improve eyesight and to enable one to discard eyeglasses; for treating the eyes, muscles, blood vessels, and kidneys; for the treatment of diabetes; and for helping to cure worms, fits, convulsions, and epilepsy;

Wheat germ oil—for change of life in men and women; to reduce the frequency of heat flashes; to activate the substance which aids coagulation of the blood; for difficulty with urination; for pelvic pains and cramps, prostate gland trouble, loss of sexual fluid, sterility, and absence of pep and life; to prevent atrophy of men's glands and loss of ambition; to affect in an essential way the muscles and the valves that control the various fluids; to exert an important effect on one's entire makeup; to enable the heart to maintain a normal rhythm and the brain to perform great feats; to prevent deterioration of women's glands, resulting in loss of charm, pep, broad smiles, and winning personality; to prevent senility, weakening of the memory, inactivation of thinking, imperfect coordination between brain and muscle, and death before anything worthwhile to be recorded in history had been accomplished; to preserve life with the plenitude of its physical and intellectual manifestations and to put off death to the very last limit; to cause one to be full of vigor, buoyant, and healthy; to promote general well-being, vigor of personality, glands, and mental and physical vigor; to prevent miscarriage; to fill an essential need of nerve and muscle tissue; to treat Lou Gehrig's disease; to reduce the period necessary to replace lost spermatozoa; to act as an antisterility guard; to effect maximum growth; for reducing; to treat diabetes; for multiple sclerosis; to dissolve incrustations that create arthritis; to supply a need of the pancreas; to rebuild the body; for the heart; to keep bladder muscles firm; to prevent prolapsing of the bladder which causes retention of urine which decomposes and throws into the blood stream toxins that produce the other diseases that men and women have; and for lumbago, soreness of muscles in the back, tuberculosis, impaired hearing, and paralysis;

Herb laxative—to rid one of gallstones; to eliminate pinworms and tapeworms; and for fits, convulsions, and fainting spells;

Concentrated broth—for cleansing the system; for eliminating worms; for curing epilepsy; for helping to cure fits, convulsions, and heart trouble; for preventing blindness; for helping to reduce excess weight; and for dissolving protruding veins;

Whole wheat—for preventing idiocy; for the treatment of cancers and ulcers; for helping to cure worms, fits, convulsions, and epilepsy; and for preventing mental instability, bad temper, heart disease, eye diseases, and sex crimes;

Wheat germ—for improving eyesight and enabling one to discard eyeglasses; for promoting willpower and mentality; for helping the "personality glands"; for treating multiple sclerosis; for aiding the endocrine glands; for lowering the blood pressure; and for preventing mental instability, bad temper, heart disease, eye diseases, and sex crimes.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 11–29–54; and, on 1–6–55, the trial was concluded with the return by the jury of a verdict of guilty. On 1–7–55, the defendants filed motions in arrest of judgment and for a new trial; and, on 4–19–56, the court handed down the following opinion (140 F. Supp. 645):

WATSON, *District Judge:* "The defendants found guilty by verdict of a jury on seven counts [1] of misbranding of drugs in interstate commerce, 21 U. S. C. A. 331 (b), move for arrest of judgment [2] or for a new trial.[3]

"The trial covered a period of seventeen days and presents a transcript of one thousand two hundred eighteen pages.

"The defendants contend that the indictment fails to state facts sufficient to constitute an offense against the United States. The indictment charges the defendants with causing the introduction or delivery for introduction into interstate commerce of a number of shipments of drugs which were misbranded, in the language of 21 U. S. C. A. 352 (f) (1),[4] by reason of the failure of their labeling to bear adequate directions for use. An indictment charging the elements of the offense is sufficient. United States v. Dobrow, 346 U. S. 374. The indictment further specifies that the directions for use were inadequate because they did not state the diseases, purposes, or conditions for which the drugs were intended to be used. In order that directions for use be adequate, a statement of the intended uses must be included. Alberty Food Products, et al. v. United States, 194 F. 2d 463. The reason for this requirement is clear. It enables a layman to attempt intelligently and safely self medication. It is not sufficient that the labeling contain a minimum of information and the use of the drug be induced by collateral representations either oral or written. Adequate labeling is best suited to obtain the beneficient purposes contemplated by the Federal Food, Drug and Cosmetic Act. viz: broad protection of the consumer from misbranded drugs, and as a practical matter places no onus on those motivated by an honest belief that the claims made for their drug will be accomplished by its use. Since the government in the indictment substantially states the elements of the crime charged, it has charged an offense against the United States.

"The defendants also contend that this Court is without jurisdiction of the offense charged. The offense was committed within the Middle District of Pennsylvania. The offense did not take place where the lectures were given or the literature was distributed by the defendant Hohensee, as defendants contend, but where the drugs were introduced in interstate commerce, which was within the Middle District of Pennsylvania. The tenor of the lectures and the excerpts from the literature were offered into evidence to show that the products in question were drugs and to show their intended uses. There was substantial evidence from which the jury could find beyond a reasonable doubt that the articles were intended to be used as drugs when they were introduced into interstate commerce. This Court did have jurisdiction.

"Defendants' motion in arrest of judgment must be denied.

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[1] The Government withdrew the charges contained in counts 8 and 9 of the indictment.
[2] Rule 34, Arrest of Judgment, 18 U. S. C. A.
[3] Rule 33, New Trial, 18 U. S. C. A.
[4] § 352. Misbranded Drugs . . .
A drug . . . shall be deemed to be misbranded— . . . (f) unless its labeling bears (1) adequate directions for use; . . .

"Defendants argue that the verdict was contrary to law and the weight of the evidence. In considering the sufficiency of the evidence to sustain the verdict of the jury, this Court must take that view of the evidence which is most favorable to the government and must give to the government the benefit of all the inferences which reasonably may be drawn from the evidence. United States v. Toner, 77 F. Supp. 908. The verdict of the jury must be sustained if there is substantial evidence to support it.

"A perusal of the record in the light of these principles satisfies the Court that the verdict of the jury must be upheld. It is not necessary to recount the evidence at this time. It is sufficient to say that there was ample substantial testimony supporting no other reasonable hypothesis but that of guilt of the defendants.

"Unless there was some error in the conduct of the trial the verdict of the jury must stand. The first error assigned by the defendants is that the Court failed to rule on and to grant defendants' motion for a bill of particulars. Defendants' motion for a bill of particulars was answered when Government's counsel supplied the requested particulars.[5] No objection was made at the time as to the sufficiency of the information given nor was any objection made at any later time until a motion for a new trial was filed.

"Moreover, the indictment in each count refers to specific shipments of the products on designated dates to designated destinations. Thus, the information contained in the indictment and the information given defendants in response to their request for a bill of particulars enabled them to prepare their defense, the traditional purpose for which a bill of particulars is allowed. Norris v. United States, 152 F. 2d 808.

"The next reason advanced by the defendants in support of their motion for a new trial is that the Court erred in granting the Government additional peremptory challenges even though counsel for the defendants stipulated that the government should have additional challenges. The defendants argue that this stipulation was entered into without the presence of the defendant, Hohensee.

"In spite of the cases cited by defendants to the broad effect that a defendant must be present at all proceedings after an indictment is returned, later cases hold that the right is not so sweeping. It is apparent that in every bench conference between Court and counsel, the defendant has no voice, and in effect is not present even though rulings may be made which vitally affect him. In the Third Circuit, perhaps the leading case on the subject is United States v. Johnson, 129 F. 2d 954 (C. A. 3, 1942), where the Court made an exhaustive analysis of precedent to determine the propriety of the exclusion of defendant for a portion of the proceedings, in that case during argument on a point of law.

"There are occasions during the proceedings after an indictment is returned when it is not necessary that the defendant be present. Johnson v. United States, 318 U. S. 189, and a conference at which the number of peremptory challenges is agreed upon by stipulation is one of those occasions. A defendant in a criminal case is bound by the stipulation of his counsel, and his specific assent is needed only as to waiver of his constitutional or other 'substantial' legal rights. Himmelfarb v. United States, 175 F. 2d 924 (C. A. 9, 1949). It has repeatedly been held that the peremptory challenges are governed by statute and not by the Constitution. United States v. Macke, 159 F. 2d 673 (C. A. 2, 1947).

"The defendants also contend that the Court erred in permitting counsel from the Food and Drug Administration to take part in the conduct of the case.

"Defendants argue that Mr. Risteau of the Department of Health, Education, and Welfare was improperly permitted to take part in the trial of the case, even though during the trial, documents were submitted showing his appointment as a special assistant to the United States Attorney. A similar factual situation was held not to constitute error, William v. United States, 218 F. 2d 276 (C. A. 4, 1954).

"The defendants also contend that the order of closing argument was improper.

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[5] See Transcript, pages 42–44, inclusive.

"Defendants cite a number of state cases to the effect that their counsel should have been entitled to present their closing argument after at least a portion of the argument of Government counsel. The practice in this District is for the complaining party to present its entire closing argument after argument of the defendant, unless the defendant presents no evidence, in which case the defendant argues last. Since defendants here presented evidence, they can make no complaint. In fact there was no complaint until the filing of their amended motion for new trial. It would seem apparent that, in the absence of any request for rebuttal at the trial, defendants have no standing to complain at this time. Furthermore, the order of argument is entirely within the Court's discretion. Hardie v. United States, 22 F. 2d 803, cert. denied 276 U. S. 636.

"The defendants also contend that the Court erred in submitting a copy of the indictment to the jury which copy did not include the portions relating to the prior conviction of the Defendant Hohensee.

"Defendants argue that the allegations of the previous conviction of the Defendant Hohensee in the indictment were improper, in that the prior conviction was a matter only to be considered by the Court in imposing sentence, and that it was error to submit the indictment to the jury without the portions relating to the prior conviction. At the trial counsel argued that cases under the Prohibition Act of the 1920's were not applicable in the present situation because of a specific provision in that law for the pleading and proof of prior convictions.

"The practice of alleging and proving prior convictions in order to permit the imposition of an increased penalty has been followed under a variety of statutes. The case most directly in point is United States v. Berkowitz, 45 F. Supp. 564 (W. D. Mo., 1942), a case under the Fair Labor Standards Act of 1938, where the court cited exhaustive authority for the proposition that a prior conviction must be both alleged and proved. In that case, as in the present one, the contention was made that the proper method of handling the problem was to permit the first conviction to be brought to the attention of the court in an informal manner, and it was this argument that the court rejected in its ruling.

"With respect to the omission of the allegations of prior conviction from the indictment sent to the jury, such allegations were alleged and proved until the Court of Appeals for the Second Circuit held in United States v. Modern Reed and Rattan Co., Inc., 159 F. 2d 656 (C. A. 2, 1947), cert. den. 331 U. S. 831), that it was error to bring to the attention of the jury a prior conviction. While there are no reported decisions on the point, it would seem that there could be no possible prejudice to a defendant in keeping from the jury the fact of the prior conviction until after the return of a verdict on the instant trial. See Rule 52 (a), Rules of Criminal Procedure.

"The defendants also argue that the Court made several errors in ruling on evidence.

"Defendants' objections to the evidence are based upon a number of general grounds.

"The first of these relates to the admissibility of the testimony of the witnesses Barnes, Eichenauer, and Megaarden as to their conversations with the Defendant Hohensee when making arrangements for the shipment of the El Rancho Adolphus products to the store of Barnes and Eichenauer. Since these conversations were for the very purpose of arranging for the goods to be shipped, they could not have taken place after the shipment as stated by defendants.

"Hohensee's conversations with these witnesses were relevant to show his connection with the shipment of the misbranded drugs from Scranton to Phoenix and Denver. Other evidence, including bank records, the stipulation as to Hohensee's Presidency of Scientific Living, Inc., and his common address with the corporations all show his relationship with those corporate defendants.

"Still other evidence, including the transportation records and labels on the containers of the drugs, were presented to tie in the corporations with the violative shipments. Cf. Strong, Cobb & Co., Inc. v. United States, 103 F. 2d 671 (C. A. 6, 1939). This evidence is all independent of any conversation which Hohensee may have had with any of the witnesses in question.

"The Government showed that the content of the lectures was proved to estab-

lish the uses for which the articles were intended from the time of shipment until they were disposed of to the public.

"Defendants also argue that the samples supplied by the witnesses Barnes and Eichenauer to food and drug inspectors were obtained in violation of Section 704 of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 374) which, when the samples were picked up in 1952, had not been amended to its present form.

"The former Section 704 conferred upon the inspectors of the Food and Drug Administration the power to enter, after obtaining permission of the owner, operator, or custodian of any 'establishment' where 'drugs' were 'held' after their introduction into interstate commerce, and to make inspections necessary for the enforcement of the Act. This right to make inspections has been held, in conjunction with Section 702 (b), 21 U. S. C. 372 (b), to include the right to obtain samples. United States v. 75 cases * * * Peanut Butter, 146 F. 2d 124 (C. A. 4, 1944) cert. den. 325 U. S. 856.

"In the present case it is undisputed that Barnes and Eichenauer willingly gave the inspectors permission to inspect and to take samples. Defendants argue, however, that a sample taken according to the above statutory procedure can only be used in evidence against the person in whose establishment it is found and who gave permission. They further contend that its use against any other person is in violation of the Fourth Amendment. It is well-established, however, that a person cannot complain under the Fourth Amendment when a third person consents to a search of property belonging to the defendant but in the possession of the third person. United States v. Walker, 197 F. 2d 287 (C. A. 2, 1954). In the present case, the property sampled by the inspectors did not even belong to defendants.

"It is apparent that if any other view were adopted, it would be virtually impossible to bring a criminal action under the Act. For Section 331 (a), 21 U. S. C., makes it a violation of the Act to introduce or deliver for introduction into interstate commerce a drug that is misbranded. Since the Government must prove the existence of the violative article by sampling, and since the article will never, after its introduction into interstate commerce, be in possession of the one who has introduced it, the shipper would never be on hand to give permission to sample an article. Section 704, even before amendment, was clear enough in authorizing sampling at destination with permission obtained from the person then in possession. Here the inspectors obtained permission from the owner, operator, or custodian of the premises where the samples were obtained. As pointed out above, their action was in no way improper.

"The defendants next contend that the Court erred in instructing the jury that intent is not an element of the offenses charged.

"It is well established that it is not necessary to allege or prove guilty knowledge or intent in cases brought under the Federal Food, Drug, and Cosmetic Act. In the leading cases on this point, United States v. Dotterweich, 320 U. S. 277, 285–286, the Supreme Court stated:

> * * * Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting. Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless. *United States* v. *Kaadt*, 171 F. 2d 600 (C. A. 7).

"Defendants now argue that because the offenses here charged to the defendant Hohensee are felonies, the present case is distinguishable from those cited above, which involved misdemeanors. This is not a valid distinction for in a number of cases the Supreme Court has held that other factors determine whether intent is an element of the offense. Thus, in Morisette v. United States, 342 U. S. 246, which contains an extensive discussion and analysis of intent in both 'common law' crimes and offenses which were unknown under the common law, the Court stated, at page 259:

> It was not until recently that the Court took occasion more explicitly to relate abandonment of the ingredient of intent, not merely with considerations of expediency in obtaining convictions, nor with the malum

> prohibitum classification of the crime, *but with the peculiar nature and quality of the offense.* We referred to ". . . a now familiar type of legislation whereby penalties serve as effective means of regulation," and continued, "such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger." But we warned: "Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting." *United States* v. *Dotterweich*, 320 U. S. 277, 280–281, 284. [Emphasis added.]

In other cases, including United States v. Balint, 258 U. S. 250, the United States v. Behrman, 258 U. S. 280, convictions of felonies were upheld even though no criminal intent was alleged or proved.

"Defendants next argue that they were deprived of a fair trial by Government counsel's summation, principally with reference to statements that the defendant Hohensee 'schemed' to violate the law. They further argue that there was no evidence to support such statements.

"This contention is not borne out by the record, which shows almost without contradiction that Hohensee represented his products for a variety of serious diseases and conditions in his lectures and booklets and that the labeling of the products did not say anything about these diseases and conditions. In referring to this method of merchandising as a 'scheme' to avoid the law, counsel was only paraphrasing the language of United States v. Alberty Food Products, 194 F. 2d 463 (C. A. 9, 1952) where the court stated with respect to the requirement that the labeling of a drug should state the purposes and conditions for which it was intended:

> Adequate labeling is best suited to obtaining the beneficient purposes contemplated by the Act, viz: broad protection of the consumer from adulterated or misbranded drugs, etc., *and as a practical matter places no burden on those motivated by an honest belief that the claims made for the drug will be accomplished by its use.* [Emphasis added.]

"Other evidence shows that Hohensee was indeed attempting to avoid the provisions of the law. Mrs. Barnes testified that Hohensee took the invoice and shipping records for his products from her because the Food and Drug Administration could not maintain any action against him without records of interstate shipment.

"It is also apparent from the record that Hohensee was being less than candid when he would state in one breath that he did not diagnose or prescribe for disease, and then in the very next proceed to diagnose a serious disease and recommend one of his 'diets' for its treatment. The testimony of Mr. Kimlel and Miss Streessner is full of instances of this type of evasive conduct, and defendants' evidence, in particular the testimony of Mrs. Anderson, corroborates that of the Government.

"These facts in themselves form a sufficient basis from which it could be inferred that the defendant Hohensee knew that he was violating the law and that he was taking whatever steps he could to forestall prosecution. Argument based upon the evidence and inferences from the evidence is always proper. Eastman v. United States, 153 F. 2d 80 (C. A. 8, 1946), cert. den. 328 U. S. 352.

"However, even if there was no evidence in the record to support the statement with respect to Hohensee's purpose to violate the law, the Court on two occasions, first in its general charge, and again when defendants first objected to Mr. Teller's remarks, instructed the jury to disregard all comments of counsel and to decide the case on the evidence. Czarnecki v. United States, 95 F. 2d 32 (C. A. 3, 1938); Chadwick v. United States, 117 F. 2d 902 (C. A. 5, 1951) cert. den. 313 U. S. 585. It is only rarely that the court should interrupt argument of counsel in the absence of objection, and, as pointed out above, the record provides ample basis for the arguments.

"Defendants' next argument is that the jury failed to consider all of the evidence, and was unduly influenced by allegedly improper argument of Gov-

ernment counsel. They also request the Court to grant permission to take testimony of jurors for the purpose of determining what effect these allegedly erroneous statements may have had upon them.

"Mattox v. United States, 146 U. S. 140, is cited by defendants for the proposition that jurors may be interrogated for the purpose of determining when an improper influence has been exerted on them. Actually the case holds that the jury may be questioned as to whether they saw a newspaper account published while they were deliberating, but the case specifically denies counsel the right to question jurors as to the effect which the newspaper account had on their minds.

"The rule in the *Mattox* case was recently and forcefully stated by Chief Judge Gourley of the Western District of Pennsylvania in United States v. Nystrom, 116 F. Supp, 771, 777 (1953):

> I am compelled to unequivocally disapprove the practice of interviewing a juror after a trial as to his state of mind during the trial. United States ex rel Daverse v. Hohn, 3 Cir., 198 F. 2d 934.

"The remaining reasons assigned by defendants in support of their motions are entirely without merit and require no discussion.

"It is the conclusion of this Court that the record shows no error in the trial that was prejudicial to the defendants. The verdicts were not contrary to the law. Defendants received a fair trial and the verdicts were supported by substantial evidence. Defendants' motion in arrest of judgment will be denied. Defendants have failed to advance any valid reason why a new trial should be granted and defendants' motion for a new trial will be denied.

"An appropriate order will be filed herewith."

Pursuant to the above opinion, the court, on 4–19–56, ordered that the defendants' motions in arrest of judgment and for a new trial be denied. On 5–25–56, the court fined El Rancho Adolphus Products, Inc., $700 and Scientific Living, Inc., $700 and sentenced Adolphus Hohensee to imprisonment for 1 year and 1 day. An appeal was taken to the United States Court of Appeals for the 3d Circuit; and, on 1–29–57, the following opinion was handed down by that court (243 F. 2d 367):

McLAUGHLIN, *Circuit Judge:* "Appellants were indicted on nine counts for causing the introduction and delivery for introduction into interstate commerce of misbranded drugs, contrary to the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. 321 et seq.[1] Counts VIII and IX were withdrawn by

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[1] 21 U. S. C. Chap. 9, Sub. Chap. II, Sec. 321 (g), (k), (m):
"For the purposes of this Chapter

* * * *

"(g) The term 'drug' means * * * (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

* * * *

"(k) The term 'label' means a display of written, printed, or graphic matter upon the immediate container of any article;

* * * *

"(m) The term '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."

21 U. S. C. Chap. 9, Sub. Chap. III, Sec. 331 (a):
"The following acts and the causing thereof are hereby prohibited:
"The introduction or delivery for introduction into interstate commerce of any * * * drug * * * that is * * * misbranded.

21 U. S. C. Chap. 9, Sub. Chap. III, Sec. 333 (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 or both such imprisonment and fine; but if the violation is committed after imprisonment for not more than one year, or a fine of not more than $1,000 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."

21 U. S. C. Chap. 9, Sub. Chap. V, Sec. 352 (f):
"A drug * * * shall be deemed to be misbranded—

* * * *

"Unless its labeling bears (1) adequate directions for use."

the government in the course of the trial and nolle prossed. All three appellants were convicted on the remaining seven counts.

"The government's theory and proof involved two parallel sets of incidents. The individual appellant is president of one of the corporate appellants, Scientific Living, Inc. and the moving spirit in both. Counts I, II and III of the indictment concern Hohensee going to a food store in Phoenix, Arizona, advising the proprietor that he intended lecturing on health subjects in Phoenix shortly and seeking his cooperation. Appellant gave the storekeeper leaflets and advertising copy to be distributed and used for arousing interest in the lectures.[2] He provided for stocking El Rancho Adolphus brand products in the health food store. Demand for these products was to be created by the forthcoming lecture series.

"Shipments of El Rancho Adolphus products began arriving at the Phoenix store in the latter part of January 1952 and were invoiced from one or the other of the corporate appellants at Scranton, Pennsylvania. The lectures were given by appellant at Phoenix from February 11 to March 6, 1952. At these lectures printed materials were distributed dealing with most chronic diseases and physical complaints, suggesting diets which included large quantities of El Rancho Adolphus products as remedies. According to the testimony, the oral representations of appellant at the lectures, regarding the subject matter of Count I, were astounding; peppermint tea, for example, was recommended for gall stones, colic, flatulence, headache, rheumatism, high blood pressure, arthritis, prostate trouble, lumbago, fits, convulsions, colitis, tuberculosis, asthma, pin worms and tape worms. The label on the El Rancho Adolphus brand peppermint tea leaves had only the following directions: 'Used as a delicious refreshing table beverage. Take one level teaspoon of Adolphus peppermint for each cup of water, steep for four minutes. Do not boil. Sweeten to taste.'

"Counts II and III arise out of other products of the Phoenix promotion, namely, wheat germ oil and herb laxative. There were similar fantastic representations of their curative qualities.

"Counts IV, V, VI and VII cover the campaign in Denver where Hohensee lectured during the months of July through September 1952. The preliminary arrangements for that city were made by one Miguarder, a government witness at the trial. The local retail outlet for the El Rancho Adolphus products was Leeds Health House, operated by Mrs. Ethel Barnes, who also testified for the government. El Rancho Adolphus brands of concentrated broth, whole wheat, peppermint tea leaves, and wheat germ called by the trade name, 'Wheat Hearts,' are the products alleged in those counts to have been misrepresented.

"Appellants attack the constitutionality of 21 U. S. C. Section 352 (f) (1) on the ground that the statutory language 'Bears adequate directions for use' with reference to misbranding is too vague, indefinite and uncertain if con-

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21 U. S. C. Chap. 9, Sub. Chap. VII, Sec. 371 (a):
"The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary."
Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act.
Sec. 1.106, 21 CFR 1.106:
"Drugs and Devices: directions for use—

"(a) Adequate directions for use. 'Adequate directions for use' means directions under which the layman can use a drug or device safely and for the purposes for which it is intended. Directions for use may be inadequate because (among other reasons) of omission, in whole or in part, or incorrect specification of:
"(1) Statements of all conditions, purposes, or uses for which such drug or device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising * * *."

[2] The leaflets described the lectures as including "* * * hope-awakening new light on scores of specific conditions which today are the scourge of mankind. What does science say about Cancer? Diabetes? Rheumatism? Liver disorders? Chronic constipation? Colitis? Stomach ulcers? Kidney stones? Kidney disease? Morning mouth? Tooth decay? Bleeding gums? Tuberculosis? Sinusitis? Asthma? Common Cold? Irritability? Vague pains? Scurvy? Rickets? Beri Beri? Glaucoma? Neuritis? Cataracts? Sexual Impotency? Frigidity in Women? Neurotic Symptoms? Heart disease? High blood pressure? Low blood pressure? Rebuilding of blood? Anemia? Arteriosclerosis? Hemorrhoids? Insomnia? Fatigue? Foot trouble? Better eyes without glasses? How to conquer premature old age? Better eyes without glasses! A startling revelation by a man who was actually blind! Today he enjoys perfect vision." The newspaper advertisements were similar in context.

strued to proscribe their activities. In Kordel v. United States, 335 U. S. 345 (1948) the Supreme Court upheld a conviction where the circumstances were very close to the case at bar. That decision definitely disposes of any question of constitutionality here.

"In Kordel promotional materials were shipped separately for the products intended for use as drugs.[3] The Supreme Court reaffirmed its position as outlined in United States v. Dotterweich, 320 U. S. 277 (1943) and United States v. Sullivan, 332 U. S. 689 (1948) that this legislation be given a liberal interpretation to effectuate its high purpose of protecting unwary consumers in vital matters of health. The intended uses of the products in the present issue as in Kordel 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. Alberty Food Products v. United States, 194 F. 2d 463 (9 Cir. 1952). The crime is that the labels on the containers were insufficient for the purposes for which the products were to be used. The statute prohibits the shipment of any products that are to be used as drugs, and are inadequately labeled for that purpose.

"Appellants challenge the sufficiency of the evidence to support the verdict. Their main thrust is against the time sequence of the various events in both Phoenix and Denver where the evidence of misbranding is primarily the oral representations and printed material distributed at the lectures. It is argued that since the lectures occurred some weeks after the products were introduced into interstate commerce, there was no proof of a medicinal or curative purpose or use of the products at the time of the shipments from Scranton to Phoenix and Denver. That problem was decided in Kordel, supra. There, the food products, including vitamins, minerals and herbs, were labeled innocuously as health foods. The advertising materials which proved the products were drugs for the amelioration of various ills were shipped separately both before and after the products.[4] The Supreme Court specifically held that:

> 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.

"Appellants further contend that false advertising is exclusively within the jurisdiction of the Federal Trade Commission. That argument was rejected in Kordel.

"Hohensee insists the principle that intent is not an element of the offenses charged[5] should not have been applied to him since as a second offender, if convicted, he would be subject to felony penalties. His guilt falls into the felony category not because of evil intent but because of the maximum sentence of three years for second offenders provided by Section 333 (a) of 21 U. S. C. The Act imposes criminal sanctions as a means of regulating activities so dangerous to the public welfare as not to permit of exception for good faith

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[3] United States v. Cruez, 144 F. Supp. 229 (D. C. E. D. Ill. 1956) involves a conviction based solely on evidence of oral representations. Weeks v. United States, 245 U. S. 618 (1918), affirmed a food misbranding conviction based on oral representations.

[4] The dissent points out "The evidence under one count was that the drugs were shipped July 10, 1942, while the booklets * * * were sent a year and a half later, January 18, 1944."

[5] See Morisette v. United States, 342 U. S. 246 (1952) for an exhaustive discussion of the principle.

or ignorance. A person acts at his peril in this field. United States v. Dotterweich, supra. The instant facts are well within the rule established by United States v. Balint, 258 U. S. 250 (1922) which sustained a maximum sentence of five years under another no intent statute, the Narcotic Act of 1914, 38 Stat. 785. And see United States v. Behrman, 258 U. S. 280 (1922).

"Hohensee had been convicted previously under the Federal Food, Drug and Cosmetic Act and that was pleaded in the indictment in order to call forth the second offender penalties under Section 303 (a) of 21 U. S. C. Knowledge of the prior conviction was meticulously kept from the jury and reference to it was blocked out of the copy of the indictment which went to the jury room. We find that no prejudice to the accused resulted from the procedure followed.

"Appellants suggest they were seriously harmed when, a week prior to the start of the trial, in the presence of the jury panel, Hohensee, explaining that his attorney was ill, was arguing pro se for a bill of particulars and the judge commented 'I don't think you need a lawyer.' The record does not reveal any prejudicial connotation. Presumably it was an offhand complimentary pleasantry coupled with an indication that the court would protect his interests. In any event the transcript shows three of the defense attorneys in court at the time with two of them seemingly discussing the information desired.

"Appellants also complain of a remark (lifted out of a sentence) the judge made at a sidebar conference during the trial. A Food and Drug inspector was on the witness stand. She testified she had attended three of Hohensee's Denver lectures. *Prior to any testimony of what Hohensee had said*, appellants, with the court's permission, objected to all such testimony as 'incompetent, irrelevant and immaterial to prove the allegations of the indictment, and, furthermore, oral statements cannot constitute misbranding of an article.' According to the transcript the court then stated at this sidebar colloquy with counsel, 'If I uphold your objection we would dismiss this jury, but I cannot do it with all the preparation in this case. Why this man must be a terrible person; I do not know, but anyway I am not going to form any opinion at all. It is none of my business, so you just go ahead and I will overrule you.'

"On occasion, stream of thought language, wrenched away from its setting, may not seem too clear later but that difficulty is not present in the above quoted statement. Manifestly the judge, feeling that the first part of his offhand observation did not properly express his state of mind, remedied it immediately and in the same sentence. No motion was made at the time or thereafter concerning it. The only purpose of counsel coming to the side of the bench was to prevent the jury overhearing the motion. There is no evidence that purpose failed.

"A third objection is voiced to the court's expressions with reference to the cost of the trial. In denying the motions for acquittal, the court did allude to the large trial expense but in its next sentence and the same paragraph stated 'If I determine that I am in error about this (the denial of the motions) at any time I shall gladly grant a new trial, or even enter a judgment of acquittal, if I think I should * * *.' Of the two other allusions to trial cost in appellants' appendix, one has to do with the court trying to narrow the trial scope. In the other, the court, at considerable length, rejected the government's plea not to postpone the trial at the defense request. The government urged it had expended large sums of money in preparation. The court concluded its decision to allow the continuance by saying:

> Now, this all means that the preservation of freedom is very expensive, just like everything else, more so every day, and it always has been. So I am not going to sustain the objections to the motion because of the expense, and I will grant the motion for a continuance, and I will fix November 29, 1954 at 2 o'clock in the afternoon for the trial of this case.

"Appellants assert the district attorney prevented a fair trial to them by asking leading questions. The one illustration of these in appellants' appendix shows their objection to the particular question was sustained without argument. As to several remarks of the district attorney, now protested, appellants have not bothered to set out the record of these in their appendix. Those that are shown do not evidence substantial harm, individually or collectively.

"Appellants before us assail the government summation but made no objection to it during its progress or after it had been concluded; examining it we do not find that it substantially exceeded fair inferences from the evidence. Its final note stressed that the government's concern was '* * * *with the misbranding of these drugs and we want them properly labeled.*' [Emphasis supplied.] As he finished his summation government counsel said to the jury, 'All I ask you is that you render a fair and proper verdict in this case * * *.' In the thorough and scrupulously fair charge, among many other things, the court said:

> In considering the evidence before you your attention is directed to the fact that not all matters coming to your attention in this trial can be considered by you as evidence. The indictment, the opening remarks of counsel, the arguments of counsel, the remarks of counsel, and the remarks of the Court during the trial of the case are not evidence and are not to be considered by you as such in determining the facts of the case.

"We have examined all other points of appellants. They do not raise substantial questions and need not be discussed at length."

"The judgments of the district court will be affirmed."

A petition for a rehearing was filed by the defendants with the court of appeals; and, on 3–1–57, the court denied the petition in the following opinion:

PER CURIAM: "The petition for rehearing contains nothing of merit which has not been heretofore presented to and considered by this court.

"There is a copy of an affidavit, executed February 11, 1957, annexed to the petition. It is submitted by appellants as an example of other affidavits which they state they are prepared to produce. It characterizes language, tone, range of voice and manner of the trial judge on two occasions; the first, during a pre trial motion and the second, during the course of the trial. Both those incidents were argued fully and disposed of specifically by our opinion in the case. The material offered was never before the trial court. It is entirely outside the record. In those circumstances the deliberate attempt to bring it before this court is inexcusable.

"The petition for rehearing will be denied."

A petition for a writ of certiorari was filed with the United States Supreme Court, and was denied on May 27, 1957.

5386. Appetum. (F. D. C. No. 40180. S. No. 59–375 M.)

QUANTITY: 6 ctns., 10,000 tablets each, at Philadelphia, Pa., in possession of Philadelphia Ampoule Laboratories.

SHIPPED: 5–29–56, from Brooklyn, N. Y., by Sweets Laboratories, Inc.

LABEL IN PART: (Ctn.) "Ford Gum & Machine Co., Akron, N. Y. Sweets Labs, Inc., Brooklyn, N. Y."

RESULTS OF INVESTIGATION: The dealer stated that it was his intention to repackage the material in bottles holding 28 tablets and relabel as follows: "28 Tablets appetum high potency Vitamin B_1 – B_{12} * * * Increases appetite and stimulates growth * * * speeds convalescence. Assists in the treatment of chronic diarrhea and celiac diseases * * * Ingredients Vitamin B_1 . . . 10 mg. * * * Vitamin B_{12} . . . 25 mcg."

Analysis showed that the article contained less than 5 mg. of vitamin B_1 per tablet.

LIBELED: 4–26–57, E. Dist. Pa.

CHARGE: 502 (f) (1)—the article, when shipped and while held for sale, failed to bear adequate directions for use for the purposes for which it was intended.

DISPOSITION: 5–27–57. Default—destruction.