lot) "Gall Bladder Herb Tea * * * It has restored health to thousands * * * The Way To Health * * * effectiveness in giving relief and in remedying ailments * * * They are of great benefit in the ailments for which they are recommended. They are reliable * * *"; (10-carton lot) "High Blood Pressure Herb Tea * * * It has restored health to thousands * * * The Way To Health * * * effectiveness in giving relief and in remedying ailments. * * * They are of great benefit in the ailments for which they are recommended. They are reliable * * *"; (6-carton lot) "Reducing Obestity Herbs * * * It has proven valuable to thousands. * * * This is a saline * * * very effective in correcting overweight. * * * The Way to Health * * *"; and (10-package lot) "The herbs used in this combination * * * have no habit forming effects. It has restored health to thousands. * * * used for chronic constipation of long standing conditions. * * * The Way To Health * * * effectiveness in giving relief and in remedying ailments * * *."

Further misbranding, Section 502 (f) (2), the labeling of the *Old Chief's Indian laxative herb tea* failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, or against unsafe duration of administration, in such manner and form, as are necessary for the protection of users, since it failed to bear a warning to the effect that the article should not be taken in case of acute abdominal pains, nausea, vomiting, or other symptoms of appendicitis, and that frequent or continued use of the article may result in dependence upon laxatives to move the bowels.

The articles were misbranded in the above respects while held for sale after shipment in interstate commerce.

Further misbranding, Section 502 (f) (1), the labeling of the articles other than the *Old Chief's Indian laxative herb tea* failed to bear adequate directions for use since it failed to state the purposes for which the articles were to be taken. These articles were misbranded in this respect when introduced into and while in interstate commerce.

DISPOSITION: June 5, 1952. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3785. Adulteration and misbranding of cortisone acetate tablets. U. S. v. Albert Feldman (Calvert Chemists). Plea of nolo contendere. Issue raised as to matters which the court could consider in imposing sentence. Court ruled willfullness or intentional wrongdoing not alleged in the information cannot be considered by court in imposing sentence on plea of nolo contendere. Defendant fined $500, given suspended sentence of one year in prison, and placed on probation for one year. (F. D. C. No. 31261. Sample Nos. 2962-L, 2963-L, 2966-L to 2968-L, incl., et al.)

INFORMATION FILED: December 27, 1951, District of Columbia, against Albert Feldman, trading as Calvert Chemists, Washington, D. C.

ALLEGED VIOLATION: On or about March 15, 17, 19, and 24, 1951, in response to prescriptions surrendered to the defendant for filling, calling for a number of compound tablets containing 25 milligrams of cortisone acetate, the defendant dispensed a number of tablets of a drug containing ascorbic acid, and by

*See also No. 3781.

such act caused the drug so dispensed to be adulterated and misbranded in interstate commerce.

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), a substance, namely, ascorbic acid had been substituted for cortisone acetate.

Misbranding, Section 502 (a), the label on the bottles in which the drug was dispensed contained statements which represented and suggested that the article contained in the bottles was cortisone acetate, which statements were false and misleading since the article contained in the bottles was ascorbic acid; and, Section 502 (i) (3), the article contained in the bottles was offered for sale under the name of another drug, namely, cortisone acetate.

DISPOSITION: On January 29, 1952, a plea of nolo contendere was entered by the defendant, after which the case was referred to the probation officer. Thereafter a dispute developed as to whether the defendant in filling the prescriptions referred to in the information, intentionally or mistakenly substituted another drug for the one prescribed. The matter was referred to the court, and on March 10, 1952, the following decision was handed down:

LAWS, *Chief Judge:* "On the recommendation of the District Attorney the Court accepted a plea of nolo contendere in the above-entitled case in which the defendant is charged with selling adulterated and misbranded drugs in violation of Title 21, Sections 331 (b) and 333 (a) United States Code. The information to which defendant pleaded charges a misdemeanor which does not require elements of willfulness or of any intentional wrongdoing. There is another section of the same statute under which the information against the defendant was filed which provides that if the acts charged against defendant were done with intent to defraud or mislead, the accused shall be guilty of a felony. No charge is brought against the defendant under this section. In submitting this case to the probation officer after accepting defendant's plea of nolo contendere to a charge not involving willfulness or intentional wrongdoing, the Government has taken the position that defendant has been guilty of willful acts. The defendant, on the other hand, has denied any such acts.

"The Court is definitely of the opinion that on a plea of nolo contendere to an offense which does not involve willfulness or intentional wrongdoing, it cannot take into consideration either willfulness or intentional wrongdoing. This would be true in any case, but is especially true where a part of the same statute provides a separate crime in the event of willfulness and intentional wrongdoing.

"Of course the Court will take into account the fact that the defendant has pleaded nolo contendere to repeated violations of the charge pending against him and to the extent this shows culpability, the Court will consider it. However, on the present state of the record, the Court is not in position to impose a sentence for willful and intentional wrongdoing.

"Counsel for defendant has made it plain that defendant does not wish to withdraw his plea of nolo contendere. The District Attorney has indicated that under certain conditions, depending upon the view of the Court as to its power to consider claims of willful and intentional wrongdoing, he might wish to have the plea withdrawn. Now that the Court has made clear its view as to the limitations on the evidence it may consider in imposing sentence, the District Attorney is requested to advise the Court definitely whether he wishes the plea to nolo contendere withdrawn and the case set down for trial."

Following the above decision, an indictment was returned against the defendant relating to the same acts alleged in the information, but charging intent to defraud and mislead. Subsequently, the Government and the defendant stipulated that the court might hear evidence as to whether or not the defendant acted willfully and intentionally. In accordance with such stipulation, the matter came on for hearing in open court on June 10, 1952, and at the conclusion of the hearing the matter was taken under advisement

by the court. On June 27, 1952, the court handed down the following memorandum:

MEMORANDUM ON IMPOSITION OF SENTENCE

LAWS, *Chief Judge:* "On December 27, 1951, an information was filed against defendant charging him with misdemeanors, consisting of misbranding and adulterating drugs on five different occasions between March 15 and March 24, 1951. On each instance it was claimed defendant substituted inexpensive ascorbic acid pills for cortisone pills, which were both rare and expensive. The charge made no reference to willful wrongdoing. On January 29, 1952, before the date set for trial of the case, defendant appeared before the Court with his counsel and an Assistant United States Attorney. The latter informed the Court that the defendant wished to enter a plea of *nolo contendere* and that this disposition was satisfactory to the prosecution. Relying upon this statement, the Court accepted the plea. Such a plea is regarded as of less significance than a plea of guilty and is properly used only in offenses implying little or no moral dereliction. A widely accepted definition of the plea refers to it as 'An implied confession * * * where, in a case not capital, a defendant does not directly own himself to be guilty, but tacitly admits it by throwing himself on the King's mercy, and desiring to submit to a small fine, which the court may either accept or decline, as they think proper.' *1 Chitty, Criminal Law, 1819 ed., c. 10, p. 430.*

"During pre-sentence investigation by the Court's Probation Officer, it became known for the first time that the prosecution claimed guilt of willful wrongdoing. When informed of this, the Court called the prosecutor and counsel for defendant to a conference in chambers. It was then made clear that the Court would not impose sentence for willful acts upon an information not charging willfulness, especially in a case such as this in which the statute provided a separate and far more serious offense for willful and intentional wrongdoing. On March 10, 1952, the Court, in a written memorandum, confirmed its position in this regard, and stated that if the District Attorney wished to have the plea of *nolo contendere* withdrawn, he should so advise the Court. No request to have the plea withdrawn was made. But on April 28, 1952, the Grand Jury filed an indictment against the defendant covering the same transactions as the information, but charging intent to defraud and to mislead.

"Notwithstanding the Court's unequivocal statement that in sentencing defendant on his plea of *nolo contendere* to the information, it would not consider willful or intentional acts charged in the indictment, as to which no guilt had been established, the prosecution and defendant stipulated that the Court might hear evidence as to whether or not the defendant acted willfully and intentionally. Pursuant to this stipulation, both parties adduced such evidence in open court. While hearing this evidence, the Court asked whether the parties had stipulated, or were willing to stipulate, that it might make a decision as to defendant's guilt or innocence of intentional wrongdoing. While the Assistant District Attorney expressed his willingness to so stipulate, counsel for defendant announced he did not so stipulate and did not wish to do so. Thus the Court was called on to hear, at some length, evidence as to guilt or innocence on an untried indictment, without any right to deal with that evidence.

"The Court knows of no precedent for the unusual procedure followed in this case. It is one which should not be sanctioned. If the prosecution relies on willful misconduct, which defendant denies, it should charge it and prove it at a regular trial in accordance with established procedures. Here it is suggested that the Court consider alleged willful acts, when guilt of those acts has neither been admitted nor proved and when the Court has no legal right to determine guilt or innocence.

"The Court has considered the cases cited by the Government in support of the procedure followed in this case. At most, they hold that the Court in imposing sentence, may consider a wide area of collateral factors, such as environmental background, past record, and aggravating or mitigating circumstances incidental to the offense for which sentence is to be imposed. It does not follow the Court may impose sentence upon the basis of evidence tending to show that the offense for which defendant is to be sentenced was

merely an incident of a much greater offense as to which there has been neither a plea of guilty nor a trial.

"Defendant has had a good reputation. Leading citizens have testified to this. But it is apparent he was culpable in respect of his filling of at least five prescriptions for an important and rare drug. There is obligation on a druggist to exercise extreme care in filling prescriptions. Cortisone was scarce and expensive. It was supplied from small bottles. The substituted drug, while similar in appearance to cortisone, was inexpensive and supplied from large bottles. In this case the drug furnished was not harmful, and, as stated, the Court cannot consider claims that the substitution was willful. However, lack of a needed prescription may prove disastrous, and culpable acts may be quite as injurious as intentional acts. Defendant's acts on the different occasions (he has no explanation other than conjecture as to how it happened) cannot be treated lightly. Since the Court on the present record may and does not find intentional wrongdoing or any moral turpitude on defendant's part but is dealing only with an uncontested charge of culpability, it will not require defendant to serve a term of imprisonment."

Immediately thereafter, on June 27, 1952, the court fined the defendant $500, imposed a suspended sentence of 1 year in prison, and placed him on probation for 1 year. On July 2, 1952, the indictment against the defendant was dismissed on motion of the Government.

3786. Adulteration and misbranding of phenobarbital and atropine sulfate tablets, pentobarbital sodium capsules, phenobarbital tablets, thyroid tablets, and phenacetin tablets. U. S. v. Cowley Pharmaceuticals, Inc., and Ben C. Cowley. Pleas of guilty. Fine of $500 against corporation and fine of $100 against individual. (F. D. C. No. 32741. Sample Nos. 4810–L, 4815–L, 5355–L, 22833–L, 22836–L.)

INFORMATION FILED: May 8, 1952, District of Massachusetts, against Cowley Pharmaceuticals, Inc., Worcester, Mass., and Ben C. Cowley, president and treasurer of the corporation.

ALLEGED SHIPMENT: Between the approximate dates of November 24, 1950, and April 24, 1951, from the State of Massachusetts into the States of Vermont, New Hampshire, and New York.

NATURE OF CHARGE: *Phenobarbital and atropine sulfate tablets.* Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess in that it was represented to contain ¼ grain phenobarbital per tablet, whereas it contained less than ¼ grain of phenobarbital per tablet. Misbranding, Section 502 (a), the label statement "Each tablet contains: Phenobarbital USP ¼ gr." was false and misleading.

Pentobarbital sodium capsules. Adulteration, Section 501 (b), the article was represented as "Pentobarbital Sodium Capsules," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard in that it contained less than 90 percent of the labeled amount of sodium pentobarbital, the minimum permitted by the standard. Misbranding, Section 502 (a), the label statement "Capsules Sodium Pentobarbital * * * 100 mgs. (1½ gr.)" was false and misleading since each capsule of the article contained less than 100 mg. (1½ grs.) of pentobarbital sodium.

Phenobarbital tablets. Adulteration, Section 501 (b), the article was represented as *phenobarbital tablets*, a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard since it contained less than 94 percent of the labeled amount of phenobarbital, the minimum permitted by the standard. Mis-