

**DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED
ACCORDING TO DIRECTIONS**

3201. Misbranding of procaine hydrochloride 2% and adulteration and misbranding of Salicyline No. 2 tablets. U. S. v. C. B. Kendall Co., Inc., Claude B. Kendall, and Ralph E. Monteith. Pleas of nolo contendere. Fines of \$1,800 against corporation, \$1,800 against defendant Monteith, and \$900 against defendant Kendall. (F. D. C. No. 28097. Sample Nos. 23084-K, 23086-K, 23441-K, 23774-K, 23776-K, 23778-K, 23973-K, 43464-K, 43465-K.)

INDICTMENT RETURNED: On or about March 13, 1950, Southern District of Indiana, against C. B. Kendall Co., Inc., Indianapolis, Ind., Claude B. Kendall, president of the corporation, and Ralph E. Monteith, chief chemist for the corporation.

ALLEGED SHIPMENT: Between the approximate dates of February 23, 1948, and January 20, 1949, from the State of Indiana into the States of Louisiana, Texas, and Illinois.

LABEL, IN PART: "Procaine Hydrochloride 2%, Kendall" and "Tablets Salicyline No. 2 * * * Kendall."

NATURE OF CHARGE: *Procaine hydrochloride 2%.* Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency prescribed, recommended, and suggested in its labeling, namely, "Average Dose: As required, inject subcutaneous or intradermal" and "Average Dose: As required, subcutaneous or intradermal," since such use of the article in such dosage and frequency may result in destruction of body tissue because of the acidity of the article.

Salicyline No. 2 tablets. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since each tablet was represented to contain 5,000 units of vitamin D, whereas each tablet contained less than 5,000 units of vitamin D. Misbranding, Section 502 (a), the label statement "Each tablet contains: * * * Vitamin D 5,000 units" was false and misleading.

DISPOSITION: On May 26, 1950, pleas of nolo contendere were entered on behalf of each of the defendants, and on July 14, 1950, after consideration of the written statements and oral comments of counsel, the court found the defendants guilty as charged and imposed the fines hereinbefore reported. In sentencing the defendants, the court made the following statement:

STECKLER, District Judge: "This case has certainly given the Court a great deal of concern, not by reason of the particular facts in this case, but in addition to that, this seems to be the home of some of the largest pharmaceutical manufacturers in the world. It is my understanding that this city is beginning to be known somewhat as a pharmaceutical city, along with Philadelphia and a few other large cities.

"I fully realize that the company, without penalty of the Court, will be seriously injured by reason of the civil actions which no doubt will be brought, claims that will be made. On the other hand, the Court can't lose sight of the fact that any company that is engaged in the drug business is under the strictest duty to maintain the integrity of that industry. The public has no way at all of protecting itself against the use of harmful drugs, if they are harmful, particularly when they are given under the prescription of the doctor, or injected by a doctor. Usually, I would say, the doctor in those circumstances would be innocent, too, if something was wrong with the drug.

"The penalty in a case like this, as far as punishing the corporation, would be, primarily, to serve as a reminder ever in the future to exercise the strictest policies in respect to the work of the personnel in reference to their particular

duties, such as the measuring, the weighing, the checking and double checking.

"I understand that the company has made extensive additions in the way of equipment since this alleged crime was committed. The Court is taking that into consideration.

"I might also say that there are cases like this all over the United States that happen all the time with a drug company. I have had placed before me a number of judgments that have been rendered by other courts, not only by your counsel but by the counsel for the government. Fines are assessed from \$20 up to as high as a thousand dollars on a number of counts. Some of the cases impose as high as \$15,000 penalty on these companies.

"As far as punishing the individuals, I think there is a growing trend on the part of the courts to begin to punish the individuals, those that actually have charge of the company, and the technicians in charge, by sentences. I think that is not the majority rule, however. Of course, most of the courts seem to take the other view and punish the defendants with monetary assessments against them. It has been very difficult for the Court to try to ascertain what would be a correct amount of penalty to impose in this case. The Court is taking into consideration the size of the company, the net income of the company, the fact that the company has made additions to its equipment.

"As I understand this case, it appears to me that it was somewhat of a case of negligence on the part of someone in the company in not checking the apparatus that measured the amount of hydrochloric acid. . . .

"The man that is president of the company must not only bear the penalties that go with operating the company, but he is also given the right to enjoy the benefits of being the head of the company. I think the one calls for the other. You have a right to enjoy the profits and the growth of the company as the president. Perhaps the owner of the company must also stand the penalties that come with it. It is hard to decide whether the president of the company, though he may not be actually involved in doing the thing, — making up the capsules, or measuring the chemicals and shipping them himself, — wrapping the packages, etc., — it is hard to decide whether or not he should be indicted.

"I am inclined to think that the intent of the law is to keep the same company from doing the same thing over, more so than to deter others from doing it, because in a scientific industry like this, they are constantly making new developments, and I think the reason that the penalty is imposed is to make that particular company ever mindful of the fact that they must check and double check. I understand that some of the drug firms make three different types of checks whenever they have a complaint, and that prior to this offense, this company did not do that, did not make the different types of analyses, and that now, however, you are making the various types of analyses.

"All those things indicate progress as far as the drug industry is concerned, the pharmaceutical profession. I know some of the largest in the country have had penalties against them. I have gone back and looked in the record. I have found practically all of them have had penalties assessed at one time or another."

"Mr. Cox. But not the President. I haven't seen any where the President has."

"The COURT. There have been a number where the officials have . . .

"Even in the food industry I found a case where the Roma Macaroni Company had ten thousand dollars assessed against the President, a similar fine assessed against one of the other officials, or against the corporation. One of the technicians was released.

"I realize that under the law, intent is not an element in this case. That may be unfortunate from the standpoint of the defendant, but from the standpoint of the public it is a safeguard, and the mere fact that the drug reaches the status of being in interstate commerce, then and there you are guilty of having committed a pure food and drug law violation if the transaction comes within the scope of the act.

"Well, this is a case involving ten counts against each of these defendants, and if one were to sit down and figure up the maximum that could be imposed, the Court could virtually put the company out of business, but the Court, under the circumstances, has no such intention.

"It is a matter in which the Court feels, however, that the company should pay a penalty sufficient that the public will fully realize they are being

protected by the courts. It is a case, by the same token, where the company will have a reminder in the future to guard against the occurrence of the same thing.

"I don't believe that these men are criminals. They don't look like it; they don't appear to be criminals; I don't think there is anything criminal about them. It is a matter where they are engaged in a business that has a lot of hazards and we are all free to choose the type of business we would like to go into.

"So, it is the judgment of the Court, based upon the findings of the Court in this case, there having been a plea of nolo contendere made in the case, that the defendant, the C. B. Kendall Company, Inc., is guilty as charged in the indictment, and that the defendant corporation be fined in the sum of \$100 on the first eight counts of the indictment, and that the defendant corporation be fined in the sum of \$500 each on each of the last two indictments.

"I might explain that under the law the penalty could be twice the sum provided in the Act. The Act provides \$1,000. I am merely explaining that to show you that as far as the Court is concerned, you are not being given the absolute maximum penalty. I am making no apologies. It is a matter that the Court feels they should pay this additional penalty as a corporation.

"It is the judgment of the Court, based upon the plea of Defendant Ralph E. Monteith, his plea being that of nolo contendere, and the finding of the Court in this case, that the defendant Ralph Monteith is guilty as charged in the indictment and that he be sentenced to pay a fine in the amount of \$100 on each of the first eight counts and that he be sentenced to pay a fine of \$500 on each of the last two counts, Counts 9 and 10.

"It is the judgment of the Court, based upon the plea of the Defendant Claude B. Kendall, and based upon the findings of the Court that the Defendant Claude B. Kendall is guilty as charged in the indictment, that he be sentenced to pay a fine of \$50 on each of the first eight counts, and that he be sentenced to pay a fine of \$250 on each of the last two counts.

"Do you understand the fines?"

"The DEFENDANTS. Yes, sir."

"The COURT. That is almost a \$5,000 fine. I feel it is reasonable. I don't think it is too low; I don't think it is too high for a company of this size. I do believe this company will gain by this experience in the future."

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

3202. Alleged misbranding of Benadryl capsules, Benzedrine Sulfate tablets, Dexedrine Sulfate tablets, and phenobarbital tablets. U. S. v. Earl S. Fitzgerald (Fitzgerald Drug Store). Plea of nolo contendere. Case dismissed by court. (F. D. C. No. 26731. Sample Nos. 46195-K, 46196-K, 46229-K, 46230-K, 46438-K, 46439-K.)

INFORMATION FILED: September 23, 1949, Eastern District of Arkansas, against Earl S. Fitzgerald, trading as the Fitzgerald Drug Store, Corning, Ark.

INTERSTATE SHIPMENT: Between the approximate dates of May 10 and November 9, 1948, from St. Louis, Mo., and Cairo, Ill., into the State of Arkansas.

ALLEGED VIOLATION: On or about January 21 and 22 and February 1, 1949, and while the drugs were being held for sale after shipment in interstate commerce, the defendant caused quantities of the drugs to be repackaged and sold to various persons without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Alleged misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use since the directions for use, "As Directed" on the labeling of the *Benadryl capsules*, "One 9 A. M. and 3 P. M."