

The article was alleged to be adulterated in that its strength differed from and its quality fell below that shown on the label, 625 units [of vitamin D] per tablet.

It was alleged to be misbranded in that statements on the label pertaining to vitamin D content, "Active Ingredients Only—Per Tablet Vitamin D (Viosterol) 625 Units Each Tablet Contains The Equivalent of Two Teaspoonfuls Cod Liver Oil Minimum USP Strength in Vitamin Potency," were false when applied to an article that contained not more than 470 U. S. P. units of vitamin D per tablet.

The article was also charged to be adulterated and misbranded in violation of the provisions of the law applicable to food, as reported in F. N. J. No. 3643.

On May 5, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING STATEMENTS IN THE LABELING²

725. Action to enjoin and restrain distribution in interstate commerce of Diaplex under false and misleading labeling. U. S. v. Henry Wayne Pierce (Horace Wayne Pierce) and Alice Pierce. Permanent injunction granted. (Inj. No. 18.)

On October 14, 1941, the United States attorney for the District of Colorado filed a complaint against Henry Wayne Pierce, also known as Horace Wayne Pierce, and Alice Pierce, Larimer, Colo., alleging that the defendants were engaged in the business of selling, distributing, and shipping in interstate commerce, and on numerous occasions had shipped or caused to be shipped to various persons throughout the United States a food, drug, or weed commonly known as Diaplex, which bore certain false and misleading statements in the labeling as quoted hereinafter.

The complaint alleged further that the defendant on divers occasions had been informed that the statements on the labels hereinafter quoted were false and misleading and that said product was misbranded; that the defendants had been warned that further shipments in interstate commerce of Diaplex with false and misleading statements on the labels must cease; that the defendants had continued to ship and cause to be shipped in interstate commerce large quantities of Diaplex with directions and false and misleading statements printed on the labels; that they had announced their present and future intentions to continue making shipments of Diaplex in interstate commerce with the said false and misleading statements in the labeling until restrained and enjoined by law from doing so; and prayed that a temporary injunction issue restraining the defendants and those acting on their behalf from shipping such product or causing it to be shipped in interstate commerce and that the temporary injunction be made permanent on final hearing of the case.

On October 29, 1941, the court orally instructed the defendants that neither they nor their agents were to conduct any further business in the manufacture and interstate shipment of the article, pending the hearing of medical testimony on November 22, 1941.

On October 31, 1941, the defendants filed an answer denying the making of any dogmatic claims of cure for the product and also denying that the labeling was false and misleading. On December 1, 1941, the case having come on for trial and the plaintiffs having appeared by counsel and the defendants appearing for themselves and without counsel, the court made the following findings of fact and conclusions of law:

I

SYMES, D. J. "That at all times hereinafter mentioned, and for a long time prior thereto, the defendants, Henry Wayne Pierce, also known as Horace Wayne Pierce, and Alice Pierce, were engaged in the business of selling, distributing, and shipping in interstate commerce, a product more commonly known as 'Diaplex' for the treatment and benefit of persons suffering from diabetes.

II

"That on or about July 3, 1941, the defendants did ship and cause to be shipped in interstate commerce, namely, from the town of Wellington, Colo., a shipment of a product more commonly known as 'Diaplex' and billed as 'dried

² See also Nos. 701-706, 708, 710, 711, 714-717, 720.

herbs ground,' to Henry Legler at Boise, Idaho; that said shipment consisted of 5 boxes, each box containing 50 cartons of the product known as Diaplex; that each carton had then and there affixed the following label: 'Diaplex—Directions as a Beverage: Place two heaping tablespoons of Diaplex in a porcelain or earthen percolator (never use aluminum) and pour one quart of hot water over it, percolate same for ten minutes and serve hot. Directions to Doctors: For those whose blood-sugar count tests 125 Mgs. per 100 C.C. or over, use four heaping tablespoons of Diaplex to the quart of water and percolate ten to fifteen minutes. Always serve Diaplex hot, never ice cold or lukewarm. (Never use aluminum.) An adult should use two quarts of Diaplex tea daily and a child, one, for a period of nine to eighteen months. Diaplex is a food, not a drug. It should never lower the blood-sugar below normal. Therefore, a great amount is effective. Small doses are worthless for the diabetic. Diaplex contains no opiates and is non-injurious. Notice! . . . Warning! Persons using Diaplex with insulin should make the urine test daily, and as the pancreas increases its normal function, reduce the amount of insulin sufficiently to avoid insulin reaction. Only use enough insulin to take care of the surplus sugar reducing the amount of insulin from time to time sufficiently to avoid insulin reaction; but continue the use of Diaplex until you are well and strong. If you are using Protamine Zinc insulin write for further instructions; Diaplex, Wellington, Colorado Diaplex—Trademark reg. U. S. Pat Office—by H. W. Pierce. Net Weight 12 ounces avoirdupois when packed.'

III

"That the defendants were on this and previous occasions informed by proper notice, through the proper officials and representatives of the plaintiff, that the statements printed on said label in conjunction with the name 'Diaplex' were false and misleading when the product was presented either as a food or as a drug.

IV

"That the defendants did on September 22, 1941, notify the plaintiff, through its proper officials and representatives that they produced Diaplex and would continue to sell it in interstate commerce.

V

"That said product more commonly known as 'Diaplex' has never been recognized as a food for human consumption, nor is it a plant containing ingredients of medicinal value, but on the contrary, is a common weed, saltbush, which is scientifically known as *Atriplex canescens*.

Conclusions of Law

I

"That the product commonly known as 'Diaplex,' as heretofore described in the complaint and as so labeled, is misbranded in violation of the Federal Food, Drug, and Cosmetic Act, a statute 'to prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices and cosmetics, and for other purposes,' by reason of the false and misleading statements directly and impliedly indicating that the product was and is of therapeutic value in the treatment of diabetes.

II

"That the plaintiff is entitled to a permanent injunction enjoining said defendants, their agents, servants, employees, attorneys, representatives, and assigns, and all persons acting or claiming to act in their behalf in the same regard and the same effect from shipping or causing to be shipped in interstate commerce, or from receiving in interstate commerce, shipments of the weed, saltbush (*Atriplex canescens*) for subsequent sale under the name 'Diaplex,' or other language directly and impliedly offering or claiming the product of therapeutic value in the treatment of diabetes."

On December 5, 1941, a decree was entered granting a permanent injunction in accordance with the prayer of the complaint.