20162. Misbranding of Dr. Williams' No. 101 Tonic. U.S. v. Interstate Drug Co. Plea of guilty. Fine, $25. (F. & D. No. 26560. I.S. Nos. 02389, 030378, 030461, 14469.)

The drug product Dr. Williams' No. 101 tonic was recommended as a treatment and cure for certain ailments for which quinine sulphate and other cinchona derivatives are customarily prescribed. Examination showed that the article did not contain quinine sulphate or other cinchona derivatives in sufficient amount to cure such ailments, when administered according to directions. The labeling of the article bore further unwarranted curative and therapeutic claims. It was also claimed for the article that it contained no injurious drugs and could be given to children with perfect safety, whereas it contained quinine or other cinchona derivatives which might be harmful.

On September 24, 1931, the United States attorney for the Middle District of Georgia, acting upon a report by the Secretary of Agriculture, filed in the District Court of the United States for the district aforesaid an information against the Interstate Drug Co., a corporation, Quitman, Ga., alleging shipment by said company in violation of the Food and Drugs Act in various consignments, on or about January 24, November 9, November 15, and December 6, 1929, and October 16, 1930, from the State of Georgia into the State of Florida, of quantities of Dr. Williams' No. 101 tonic which was misbranded. The article was labeled in part: (Bottle) "Dr. Williams' No. 101 Tonic A Ready Prepared Prescription for Malaria, Chills, Chills and Fever"; (circular) "No. 101 contains no alcohol, arsenic or other injurious Drugs. You give it to your children with perfect safety."

Analyses of samples of the article by this Department showed that it consisted essentially of cinchona alkaloid sulphates not more than 6 grains per fluid ounce, ferric chloride, magnesium sulphate, glycerin, and water.

It was alleged in the information that the article was misbranded in that the statements appearing in the circular, "No. 101 contains no * * * injurious drugs. You give it to children with perfect safety," were false and misleading, since the article contained injurious drugs, quinine sulphate or cinchona alkaloid sulphates, and it could not be given to children with perfect safety. Misbranding was alleged for the further reason that certain statements, designs, and devices appearing on the bottle labels, regarding the curative and therapeutic effects of the article, falsely and fraudulently represented that it was effective as a specific, remedy, treatment, and cure for malaria, chills, chills and fever, la grippe, bilious fever, intermittent and remittent fever, and effective to give appetite, and as a specific, remedy, treatment, and cure for dengue fever, constipation, rundown systems, and effective as a sure and safe preventive for colds, pneumonia, malarial chills and fever, and as a wonderful body-building, strength-giving tonic, and in the case of certain of the shipments of the article that it was effective as a specific, remedy, treatment, and cure for influenza. The information further alleged that certain statements, designs, or devices appearing on the carton, enclosing a portion of the article, falsely and fraudulently represented that it was effective as a specific, remedy, treatment, and cure for continued fever, and effective to restore vitality, renew health, kill the malaria germ, to give strength to the patient, and to act upon the liver.

On September 19, 1932, a plea of guilty to the information was entered on behalf of the defendant company, and the court imposed a fine of $25.

R. G. TUGWELL, *Acting Secretary of Agriculture.*

20163. National Remedy Co. (F. E. Rollins Co.) v. Arthur M. Hyde, et al. Appeal from decree of the Supreme Court of the District of Columbia dismissing bill of complaint. Judgment of Lower Court reversed and cause remanded.

The National Remedy Co., at the time of the entry of final judgment in this case known as the F. E. Rollins Co., of Boston, Mass., filed a bill of complaint in the Supreme Court of the District of Columbia against William M. Jardine, Secretary of Agriculture, Walter G. Campbell, Director of Regulatory Work, and J. J. Durrett, Chief of Drug Control of the Food and Drug Administration, as the result of libels filed in various United States District Courts charging complainant's product, B. & M. external remedy, with violation of the Federal Food and Drugs Act as amended. Subsequent to the filing of the bill Arthur M. Hyde, who had succeeded William M. Jardine as Secretary of Agriculture, was substituted as party defendant. The bill prayed that the defendants be restrained from prosecuting the said libels, with the exception of one test case, and from causing to be instituted further libels against complainant's product.

On August 19, 1929, the bill came on for hearing in the Supreme Court of the District of Columbia and was dismissed as reported in notice of judgment No. 16780. The complainant thereupon took an appeal to the Court of Appeals of the District of Columbia.

On April 14, 1931, the appeal was argued, and on June 1, 1931, the following decision was handed down reversing the lower court (50 F. (2d), 1066): Robb (*A. J.*).

"Appeal from a decree in the Supreme Court of the District sustaining a motion to dismiss appellant's bill to enjoin appellees from causing to be made so-called 'multiple seizures' of appellant's 'B. & M. External Remedy' until such time as the disputed questions of law and fact can be judicially determined in some one of the several libels already filed against the remedy.

"The averments of the complaint, stated in narrative form, are substantially as follows: Appellant, the National Remedy Company, is a Massachusetts corporation, with its principal place of business in Boston, in that State. In 1913 it commenced and has since continued to manufacture and sell the above proprietary remedy. This enterprise has prospered to such an extent that the business and good-will now 'amount to about the sum of $100,000.'

"The remedy is not a nostrum, but is of value in the treatment of diseases of the human body, as has been demonstrated by practical experience and also by scientific, laboratory, and clinical research, experimentation, and study. It is intended, as its name signifies, solely and only as an external remedy. 'The statements contained in and upon the labels, pamphlets, booklets, circulars and other printed matter have been prepared with care, under scientific direction, and in the utmost of good faith.' No representations have been made which appellant and its officers and agents did not believe, and have reason to believe, were and are true, and the medicine never has been, and is not now, adulterated.

"The medicine is manufactured in the State of Massachusetts and distributed, not only in that State, but also in interstate commerce to practically all the other States of the Union, to the District of Columbia, and also to foreign countries.

"During the year 1919, at the instance of officials of the Department of Agriculture of the United States, a hearing was had in that Department, at which appellant appeared and presented evidence in support of the claims made in the labels, circulars, pamphlets, and booklets advertising the remedy. The representations made at that time in the labels, books, pamphlets, etc., were substantially the same as those contained in the present literature accompanying the remedy. Appellant being unable at that time to satisfy the Department as to this advertising matter, the Department caused seizures of the remedy to be made under libels filed by the United States in various jurisdictions, and among other places, in the city of Concord, N.H., in October, 1922. Trial was had before a jury in the District Court of the United States for the District of New Hampshire, at which it was contended by the Government that the statements in the advertising matter of appellant, regarding the curative and therapeutic effects of its remedy, were false and fraudulent. A verdict was rendered for the claimant, appellant here. Judgment was entered on this verdict.

"For a period of six consecutive years following the judgment in the New Hampshire District Court appellant continuously sold and distributed its remedy in interstate commerce and in the State of Massachusetts without molestation or criticism. The remedy is now carried in stock and sold by many thousand drug dealers in practically all of the States of the Union and the District of Columbia.

"In December, 1928, and January, 1929, the Department of Agriculture caused libels to be brought against appellant's remedy, and seizures thereof to be made in the following cities: New York, N.Y.; Pittsburgh, Pa.; Philadelphia, Pa.; Baltimore, Md.; Oakland, Calif.; Portland, Me.; Miami, Fla.; and elsewhere.

"Appellant avers, upon information and belief, that the Secretary of Agriculture, acting through subordinates, is purposing and intending to cause to be instituted and prosecuted libels in numerous other places in the United States, all arising out of and based upon the same general allegations and statements so contained in the circulars, pamphlets, booklets, and cartons of appellant. The several libels already instituted contain identical statements and allege the adulteration and misbranding of appellant's remedy. So far as appellant is advised, the specifications and details of the charges made against appellant's remedy in the several States where the libels have been filed are

identical. If the appellees proceed with other seizures in other places, as they have threatened to do, the entire output of appellant's factory and workshop could be seized and held for an indefinite period of time.

"The prosecution of libels in various courts in widely separated parts of the United States is unnecessarily oppressive and causing appellant great and unnecessary expense, and is ruining, and will ruin and destroy, its business and good will.

"Appellant does not seek to restrain appellees from obtaining, 'by the due and proper method provided by law, a decision upon the disputed questions of law and fact involved, but merely wants to prevent irreparable injury to itself arising out of the multiplicity of such libels in widely separated jurisdictions.' Appellant has no plain, adequate, and complete remedy at law, and its property, business, and goodwill will be ruined and destroyed, unless relief is granted herein.

"The motion to dismiss admits all material facts averred in the bill. American School of Magnetic Healing *v.* McAnnulty, 187 U.S. 94, 103, 23 S.Ct. 33, 47 L.Ed. 90.

"Under the Pure Food Law (act of June 30, 1906, 34 Stat. 768 (21 USCA §§ 1-5, 7-15), as amended by the act of August 23, 1912, 37 Stat. 416 (21 USCA §§ 9, 10)) it is the duty of the Department of Agriculture (section 4 (section 11)) to make examination of specimens of certain foods and drugs for the purpose of determining whether such articles are adulterated or misbranded within the meaning of the act, and, if it shall appear from such examination that any of such specimens is adulterated or misbranded to 'certify the facts to the proper United States district attorney,' who (under section 5 (section 12)), without delay, must institute 'appropriate proceedings,' by indictment or libel for condemnation, or both, as the facts may warrant. *United States* v. *Morgan*, 222 U.S. 274, 280, 32 S.Ct. 81, 56 L.Ed. 198.

"It is conceded by appellees that the determination of the question whether a given product is adulterated or misbranded is for the court, and that 'the function and duty of appellees under section 4 of the food and drugs act is one of investigation. Their findings and conclusions in respect to adulteration and misbranding are merely tentative, and have no binding or obligatory force in themselves. They are not a regulation or an order but are merely the assertion of an opinion that the law has been violated and that proceedings in the name of the United States as directed by statute should be instituted for this alleged violation.' Indeed, such was the conclusion of the court in the Morgan case. Due process of law required this. *Ohio Valley Water Co.* v. *Ben Avon Borough*, 253 U.S. 287, 40 S.Ct., 527, 64 L.Ed. 908.

"Inasmuch as every district attorney to whom the Department makes certification must institute appropriate proceedings, by indictment or libel for condemnation, or both, it is evident that, even though the findings of the Department are merely administrative, nevertheless, if such certification should be made to the district attorney in every district where a product might be found, the manufacturer would be crippled or ruined long before the final adjudication in the court could be had. Such a result, we think, was not contemplated by Congress, except possibly in unusual cases where drastic action would be necessary for the immediate protection of the public. Is this a case of that character? We think not.

"Appellant's remedy is for external use only. Its business was started in 1913. In 1919 the Department caused seizures to be made in various jurisdictions, and at the trial in the United States District Court for the District of New Hampshire the issue whether the advertising matter constituted misbranding was submitted to the jury, and resulted in a verdict and judgment for the defendant (appellant here). We must assume, therefore, that the Department at that time was mistaken, and that the remedy was not misbranded within the meaning of the law. The remedy was the same and the advertising was substantially the same as it is now. The contention then was that the remedy was misbranded. It is now contended that it is not only misbranded but adulterated. If it is adulterated now, it must have been then, yet the analysis at that time failed to disclose adulteration. We may assume, therefore, that the adulteration (if any) is not of such character as to endanger the public. This assumption is justified, not only because of the failure to detect adulteration in the analysis of 1919, but because for a period of six years after the judgment in the District Court for New Hampshire appellant was unmolested in the conduct of its business.

"In Ex parte Young, 209 U.S. 123, 28 S.Ct. 441, 52 L.Ed. 714, 13 L.R.A. (N.S.) 932, 14 Ann. Cas. 764, it was held that, while there is no rule permitting a person to disobey a statute with impunity at least once for the purpose of testing its validity, when such validity can only be determined by judicial determination and construction, a provision in the statute which imposes such severe penalties for disobedience of its provisions as to intimidate the parties affected thereby from resorting to the courts to test its validity practically prohibits those parties from seeking such judicial construction and denies them the equal protection of the law. In the present case, the action and proposed action of the Department would, under the averments of the bill, in effect deprive appellant of its property through the destruction of its business before the issues involved could be determined by the court. The result, therefore, would be little different than as though no provision had been made for judicial review. Such a course of conduct on the part of the Department amounts to arbitrary exercise of power, and is a deprivation of due process of law. It is not, therefore, a suit against the United States. *Philadelphia Co.* v. *Stimson*, 223 U.S. 605, 620, 32 S.Ct. 340, 56 L.Ed. 570; *Heath & Milligan Co.* v. *Worst*, 207 U.S. 338, 28 S.Ct. 114, 52 L.Ed. 236.

"A court of equity has jurisdiction to restrain by injunction the institution of a multiplicity of suits under such circumstances as are here present. In *Third Ave. R.R. Co.* v. *Mayor, etc., of N.Y.*, 54 N.Y. 159 (cited with approval in *Cave* v. *Rudolph*, 53 App.D.C. 12, 15, 287 F. 989), the municipal authorities had commenced 27 actions against the railroad company to recover penalties prescribed and imposed by city ordinances for running cars without a license. The railroad company brought an action to restrain the prosecution of more than one until that one could be finally heard and determined. The Court of Appeals ruled that, as the prosecution of all the suits would be unnecessarily oppressive, the interference of a court of equity was properly invoked and exercised. But it is contended that, 'If appellees should be enjoined in this case no practical relief would be afforded appellant, since under section 5 of the act the United States Attorney could proceed against various shipments of the product throughout the country when any health, food, or drug officer or agent of any State, Territory, or the District of Columbia should present satisfactory evidence of such violations.' This contention is without merit. The relief prayed for is against appellees to prevent them from causing seizures of practically all of appellant's product, and to this relief, under the admitted facts, appellant is entitled.

"The decree will be reversed and the cause remanded for further proceedings not inconsistent with this opinion.

"Reversed and remanded."

No further action was taken in the case, all seizure proceedings in litigation at the time of the institution of the injunction suit having been terminated prior to the said decision of June 1, 1931, by the entry of judgments ordering destruction of the product, as reported in notice of judgment No. 18176.

R. G. TUGWELL, *Acting Secretary of Agriculture.*

20164. Misbranding of Sinapole ointment. U.S. v. 25 Large Jars, et al., of Sinapole Ointment. Default decree of condemnation, forfeiture, and destruction. (F. & D. No. 28650. Sample No. 2395-A.)

Examination of the drug product involved in this case disclosed that the article contained no ingredient or combination of ingredients capable of producing certain curative or therapeutic effects claimed in the labeling.

On August 15, 1932, the United States attorney for the District of New Mexico, acting upon a report by the Secretary of Agriculture, filed in the District Court of the United States for the district aforesaid a libel praying seizure and condemnation of 25 large jars and 25 small jars of Sinapole ointment, remaining in the original packages at Santa Fe., N.Mex., alleging that the article had been shipped in interstate commerce on or about September 15, 1925, by the Sinapole Co., from Los Angeles, Calif., to Santa Fe, New Mex., and charging misbranding in violation of the Food and Drugs Act as amended.

Analysis of a sample of the article by this Department showed that it consisted of an ointment with a petrolatum base containing volatile oils including mustard oil, 12.5 milliliters per 100 grams.

It was alleged in the libel that the article was misbranded in that the following statements appearing in the labeling, regarding its curative or therapeutic effects, were false and fraudulent: (Jar label) "Uses Pleurisy * * * Rheumatism, * * * Lumbago, Croup, * * * Sore Throat, Neuritis,