

3868. (Supplement to Notice of Judgment 1056.) Alleged misbranding of antikamnia tablets. United States of America, plaintiff in error and appellant, v. The Antikamnia Chemical Co. Decree of the lower court, sustaining the exceptions to the libel, reversed. (F. & D. No. 1640. S. No. 575.)

On November 21, 1910, the Supreme Court of the District of Columbia sustained the exceptions and objections to the libel that had been filed by the United States attorney on July 7, 1910, in said court for the seizure and condemnation of certain packages of antikamnia tablets, antikamnia and codein tablets, and antikamnia and quinin tablets found in the possession of the Wholesale Drug Exchange, Washington, D. C., and ordered and decreed that said libel be dismissed.

On the same date an appeal from this decree to the Court of Appeals of the District of Columbia was prayed and granted by the court. On May 29, 1911, the Court of Appeals of the District of Columbia affirmed the decision of the lower court, and thereafter a writ of error was brought and an appeal was taken from the decision of the said Court of Appeals on behalf of the United States to the Supreme Court of the United States, and on October 3, 1911, said appeal and writ of error was allowed, and on the same date assignments of error were filed.

On January 6, 1912, the Antikamnia Chemical Co., which, upon its petition filed in the lower court, had been made a party defendant, filed by its counsel in the Supreme Court of the United States motions (1) to dismiss the writ of error and appeal, and (2) to affirm the judgment or decree of the lower court, and on January 29, 1912, the motions to dismiss or affirm were submitted to the court. On February 19, 1912, the case came on for hearing on said motions and on that date the motions were denied by the court, the final disposition of said motions being postponed until the hearing of the case on the merits.

On January 5, 1914, the case having come on for final hearing on the merits, after the submission of briefs and arguments by counsel, the decree of the lower court was reversed and the case was remanded with directions to reverse the decree of the Supreme Court of the District of Columbia and remand the cause with directions to overrule the exceptions to the libel, as will more fully appear from the following opinion by the Supreme Court of the United States (Mr. Justice McKenna):

Libel for the seizure and condemnation of certain drugs under the provisions of the act of Congress of June 30, 1906, commonly known as the Food and Drugs Act (34 Stat., 768).

The libel alleges that the drugs are in the possession and custody of The Wholesale Drug Exchange, a body corporate, at a numbered place in the city of Washington.

The drugs, it is alleged, are intended to be used for the cure and mitigation and prevention of diseases of man. They are described as follows:

"Twenty packages, more or less, of said drug, labelled and branded as follows: 'Antikamnia Tablets, Contain 305 grains of acetphenetidin, U. S. P. per ounce, Guaranteed by the Antikamnia Chemical Company, under the Food and Drugs Act, June 30, 1906, U. S. Serial Number 10. The Antikamnia tablets in this original ounce package contain no acetanilid, antifebrin, antipyrin, morphine, opium, codein, heroin, cocaine, alpha, or beta eucaine, arsenic, strychnine, chloroform, cannabis indica, or chloral hydrate, Antikamnia tablets five grains. One ounce Antikamnia Tablets. Manufactured in the United States of America by the Antikamnia Chemical Co., St. Louis, U. S. A.'

"Also seventy other packages, more or less, of said drug, labelled and branded as follows: 'Antikamnia and Codein Tablets. Contain 296 grains acetphenetidin, U. S. P. per ounce. Contain 18 grains sulph. codein per ounce. Guaranteed by the Antikamnia Chemical Company, under the Food and Drugs Act, June 30, 1906. U. S. Serial Number 10. The Antikamnia and Codein tablets in this original ounce package contain no acetanilid, antifebrin, antipyrin, morphine, opium, heroin, cocaine, alpha, or beta eucaine, arsenic, strychnine, chloroform, cannabis indica, or chloral hydrate. One ounce Antikamnia and Codein Tablets. Manufactured in the United States of America by the Antikamnia Chemical Co., St. Louis, U. S. A.'

"Also ten other packages, more or less, of said drug, labelled and branded as follows: 'Antikamnia and Quinine Tablets. Contain 165 grains acetphenetidin, U. S. P. per ounce. Guaranteed by the Antikamnia Chemical Company under the Food and Drugs

Act, June 30, 1906, U. S. Serial Number 10. The Antikamnia and Quinine Tablets in this original ounce package contain no acetanilid, antifebrin, antipyrin, morphine, opium, codein, heroin, cocaine, alpha, or beta eucaine, arsenic, strychnine, chloroform, cannabis indica, or chloral hydrate. One ounce Antikamnia and Quinine Tablets. Manufactured in the United States of America by the Antikamnia Chemical Co., St. Louis, U. S. A.'"

The ground of confiscation and condemnation alleged is that all of the packages of the drugs contain a large quantity and proportion of acetphenetidin, which, it is alleged, is a derivative of acetanilid, and that under the provisions of the act of Congress and of the regulations lawfully made thereunder it is provided and required that the label on each of the packages shall bear a statement that the acetphenetidin contained therein is a derivative of acetanilid; and yet, it is alleged that each and all of the packages fail to comply with such provisions.

It is also alleged that the packages are further misbranded, in that the labels thereon are false and misleading, for the reason that each and all of them bear the statement that no acetanilid is contained therein, and that the statement imports and signifies that there is no quantity of any derivative of acetanilid contained in the drug.

A warrant of arrest was issued upon which the marshal duly made return that he had arrested 20 packages of antikamnia tablets, 10 packages of antikamnia quinine tablets, and 63 packages labeled "Antikamnia and Codein Tablets," and otherwise duly executed the warrant.

The Antikamnia Chemical Co., appellee and defendant in error, alleging itself to be the owner of the drugs, petitioned to be made a defendant in the libel. The petition was granted, and the company thereupon filed the exceptions to the libel. The exceptions negative in detail the charges of the libel and assert conformity in the labeling of the packages to the act of Congress of June 30, 1906, quoting its eighth section as follows: "* * * or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha, or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilid, or any derivative or preparation of any such substances contained therein." And it is averred that the act does not provide that there should be added to any derivative of any of the substances contained therein the name of the parent substance, and the act can not be added to or enlarged by requiring the company to add to the name of a known article the fact that the article is a derivative of any of the substances mentioned in the act. It is averred, therefore, that the packages are not misbranded and that the statement on the labels that no acetanilid is contained therein is in no way false or misleading because the libel does not allege that there is acetanilid in the packages, and, therefore, the statement instead of being false and misleading is, according to the allegations of the libel, true.

The exceptions were sustained and the libel dismissed.

It was stipulated that Food Inspection Decision No. 112, issued January 27, 1910, by the United States Department of Agriculture was considered by the court upon the hearing of the cause and should be included in and be considered part of the record on appeal.

The decision quotes section 8 of the act, states that the Attorney General, in an opinion rendered January 15, 1909, held that a derivative is a substance so related to one of the specified substances "that it would be rightly regarded by recognized authorities in chemistry as obtained from the latter 'by actual or theoretical substitution,' and it is not indispensable that it should be actually produced therefrom as a matter of fact"; further that the labeling of derivatives, as prescribed by section 8, is a proper subject conferred upon the department by section 3, and that a rule or regulation requiring the name of the specified substance to follow that of the derivative would be in harmony with the general purpose of the act, and an appropriate method by which to give effect to its provisions.

In conformity to this opinion, regulation 28 of the Rules and Regulations for the enforcement of the Food and Drugs Act was amended as follows: "* * * Acetanilid (antifebrine, phenylacetamid) Derivatives—Acetphenetidin. * * * (g) In declaring the quantity or proportion of any of the specified substances the names by which they are designated in the act shall be used, and in declaring the quantity or proportion of the derivatives of any of the specified substances, in addition to the trade names of the derivative, the name of the specified substance shall also be stated, so as to indicate clearly that the product is a derivative of the particular specified substance."

The decree of the Supreme Court of the District dismissing the libel was affirmed by the Court of Appeals.

The case is not in very broad compass, though the arguments of counsel are somewhat elaborate. The libel is prosecuted for the condemnation of 100 packages of Antikamnia tablets as being misbranded in violation of the Food and Drugs Act of

June 30, 1906. (34 Stat., 768.) The tablets contain acetphenetidin and the labels so state, and the proportion of the substance. It is a derivative of acetanilid, but the labels do not so state but do state that the tablets contain no acetanilid. And these omissions, it is contended by the Government, constitute a violation of the statute and of regulation No. 28 as amended. The chemical company contends that the first statement is not required by the law and that the second statement is true, and therefore can not be false or misleading.

Preceding the discussion of these contentions a question of jurisdiction is presented by the chemical company and a motion to dismiss is made on the ground that only the construction of the statute is involved in the decision of the court below. The company also moves for an affirmation of the judgment on the ground that the appeal is frivolous. *Contra* the Government contends that the Court of Appeals held invalid the regulation requiring the name of the primary substance as well as that of the derivative to be stated on the label; and that there is not only drawn in question, but so far denied, an authority exercised under the United States. We concur in this view. The validity of the regulation was and is denied. Its validity may, indeed, rest on the statute, but so did the validity of the rule of the Patent Office passed on in *Steinmetz v. Allen* (192 U. S., 543). We there said of a rule of practice established by the Commissioner of Patents under a section of the Revised Statutes, "It thereby became a rule of procedure and constituted, in part, the powers of the primary examiner and Commissioner. In other words, it became an authority of those officers, and, necessarily, an authority 'under the United States.' Its validity was and is assailed by plaintiff in error. We think, therefore, we have jurisdiction, and the motion to dismiss is denied." *United States ex rel. Taylor v. Taft, Secretary of War* (203 U. S., 461) is not in antagonism to this ruling. In that case the relator was dismissed from the public service by an order of the Secretary of War as representative of the President. She sought restoration by mandamus. It was denied and she brought the case to this court on the ground that the validity of an authority exercised under the United States was drawn in question. Dismissing the case, this court said that as she did not question the authority of the President or his representative to dismiss her but contended only that certain rules and regulations of the civil service had not been observed, the validity of an authority exercised under the United States was not drawn in question but only the construction and application of regulation of the exercise of such authority. *Steinmetz v. Allen* was said not to be contrary, "for there the validity of a rule constituting the authority of certain officers in the Patent Office was drawn in question.

Motion to dismiss is denied.

Joined with the motion to dismiss, we have seen, was a motion to affirm on the ground that the question of the authority of the Secretaries to make the regulation is frivolous in view of the decisions in *United States v. Grimaud* (220 U. S., 506), *Williamson v. United States* (207 U. S., 425), and other cases. How far this contention is tenable will be developed as we proceed with the consideration of the act and the power of the secretaries under it.

The purpose of the act is to secure the purity of food and drugs and to inform purchasers of what they are buying. Its provisions are directed to that purpose and must be construed to effect it.

Section 3 gives the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce and Labor power to "make uniform rules and regulations for carrying out the provisions" of the act and the power to collect specimens of foods and drugs offered in interstate and foreign commerce. It adopts the definitions of the United States Pharmacopoeia or National Formulary and provides (section 8) that the term "misbranded" as used in the act "shall apply to all drugs * * * the package or label of which shall bear any statement, design or device regarding such article, or the ingredients or substances contained therein, which shall be false or misleading in any particular." And, further, in case of drugs, an article shall be deemed to be misbranded "if the package fail to bear a statement on the label of the quantity or proportion" of certain enumerated substances "or acetanilid, or any derivative or preparation of any such substances contained therein."

These are the applicatory provisions. How are they to be construed?

First, as to the power of the secretaries. It is undoubtedly one of regulation only—an administrative power only—not a power to alter or add to the act. The extent of the power, however, must be determined by the purpose of the act and the difficulties its execution might encounter. The fact that a council of three secretaries of governmental departments was given power to make the rules and regulations for the execution of the law shows how complex the matters dealt with were considered to be, and the care that was necessary to be taken to guard against their defeat or perversion. The composition of drugs is a matter of technical skill, their denomination often by words of scholastic origin, conveying no meaning to the uninformed, their

uses and abuses learned only by experience, beneficial or evil. It was this experience that the law sought to avail itself of and to avail itself against the ever increasing powers of the laboratory or the disguises of a technical nomenclature. Hence the provision of the law that the term "drug" as used in the act shall include all medicines and preparations recognized in the United States Pharmacopœia or National Formulary for internal or external use, and hence also the provision that a drug or food product is misbranded in case it fails to bear a statement on the label of the quantity or proportion of certain enumerated substances, including acetanilid, "or any derivative or preparation of any such substance contained therein." Experience had demonstrated the quality of those substances, their effects had become common knowledge; their names, therefore, were all the warning it was necessary for the law to give. But derivatives of them might, probably would, be of their quality, so derivatives of them were to be guarded against, and the law hence further provided that the labels on them should state the "quantity or proportion" of "any derivative or preparation" of them. This much is clear—there is no obscurity in the words and purpose of the law. The query then occurs, such being the words and purpose, if the quantity or proportion of the substances or any derivative or preparation of them must be stated, is it administrative of the law or additive to it to require by regulation that not only the name of the derivative or preparation be stated but from what substance derived or of what it is a preparation? It certainly can not be said that the purpose of the law is not exactly fulfilled by the regulation. If it fulfills the purpose of the law it can not be said to be an addition to the law, unless, indeed, it can be contended that the law provided a means for its defeat by the easy device of mysterious names. There is illustration in the present case. What information does the use of the word "acetphenetidin" convey to anybody of its good or evil origin? If it be said that the like question may be asked of any of the primary substances, we reply that they are the precautions of the law and adopted as such because they had demonstrated themselves, the value of their use, the detriment of their abuse, and it was believed that their names would carry no deception.

But let us turn from the power of the secretaries to the law itself and inquire if it needs the assistance of a regulation. It is the contention of the Government that it does not, that its requirement that the primary substances should be labelled and that their derivatives should be labelled means, necessarily, that it should be stated of what they are the derivatives to make the warning of the labels complete. A great deal of what we have said in discussing the power of the secretaries applies to this contention and supports it. The purpose of the law is the ever insistent consideration in its interpretation. The purpose is to prevent the surreptitious sale of certain noxious drugs or their derivatives, the latter supposedly partaking of the quality of parent article and as effective of evil consequences. This being the purpose, did the law leave it unexecuted? We can not attribute to it such defect, and a serious defect it might be. Nor can we consider as a case of omission that which involves so definitely the mischief which was intended to be redressed and which is fairly within the language of the law. And we say this without regard to the various illustrations contained in the Government's brief of the deceptions which can be practiced by using the name of the derivative alone, for the chemical company insists that we may not, in the absence of allegations and proof, look for knowledge in the encyclopedias, or medical lexicons or to trade practices for trade disguises, actual or possible. It is not necessary to enter upon the challenged ground. The law furnishes its own tests of what the labels should reveal, and we may grant, for the argument's sake, as contended, that it has penal character; but this does not mean that it should not be given its reasonable intentment. There is no hardship in this either to the manufacturer or the seller of drugs. They surely know what they make or vend—know whether it is primary or of what a derivative—and the law requires only that they put their knowledge on the labels for the information of purchasers. No serious burden is thereby imposed on honest business. Indeed, it makes the label on the packages an assurance as well as a warning and benefits all concerned, manufacturer, seller, and purchaser. And this in the interest of the public health.

Decree reversed and cause remanded with direction to reverse the decree of the supreme court and remand the cause with direction to overrule the exceptions to the libel.

On April 8, 1914, in pursuance of the mandate of the Supreme Court of the United States, it was ordered by the Court of Appeals of the District of Columbia that the decree entered in the case on May 29, 1911, be vacated and that the decree of the Supreme Court of the District of Columbia be reversed, and that the case be remanded to said Supreme Court with directions to overrule the exceptions to the libel.

On May 4, 1914, upon presentation of the mandate of the Court of Appeals of the District of Columbia, it was ordered by the Supreme Court of the District of Columbia that the decree entered in the case on November 21, 1910, be vacated and set aside, and that the exceptions and objections to the libel be overruled.

The case is now pending in the Supreme Court of the District of Columbia upon the libel and answer filed by the claimant company on June 4, 1914.

CARL VROOMAN, *Acting Secretary of Agriculture.*

WASHINGTON, D. C., *May 11, 1915.*