United States Supreme Court. The Sherley Amendment to the Pure Food and Drugs Act Is Constitutional. A Misbranded "Patent Medicine" Condemned. Seven Cases Eckman's Alterative v. United States,. U. S.. (Jan. 10, 1916)

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SANITARY LEGISLATION.

COURT DECISIONS.

UNITED STATES SUPREME COURT.

The Sherley Amendment to the Pure Food and Drugs Act is Constitutional—A Misbranded "Patent Medicine" Condemned.

SEVEN CASES ECKMAN'S ALTERATIVE v. UNITED STATES, —— U. S. —— (Jan. 10, 1916.)

Congress has power to condemn the interstate transportation of swindling preparations designed to cheat credulous sufferers, and to make such preparations, accompanied by false and fraudulent statements, illicit with respect to interstate commerce.

Persons who make or deal in substances or compositions alleged to be curative are in a position to have superior knowledge regarding the curative properties of the substances, and such persons may be held to good faith in their statements.

The word "package" or its equivalent expression, as used in sections 7 and 8 of the Federal pure food and drugs act, refers to the immediate container of the article which is intended for consumption by the public.

The amendment of 1912 to the pure food and drugs act (the Sherley amendment) is broad enough to include false and fraudulent statements in circulars contained in the package in which drugs are inclosed.

The phrase "false and fraudulent" as used in the Sherley amendment to the Federal pure food and drugs act must be taken with its accepted legal meaning, and thus it must be found that the statement regarding the curative or therapeutic effect of the article was made with actual intent to deceive—an intent which may be derived from facts and circumstances, but which must be established.

Several cases of a proprietary remedy were shipped in interstate commerce. In every package containing one of the bottles was a circular with this statement: "Effective as a preventative for pneumonia." "We know it has cured and that it has and will cure tuberculosis." The goods were seized and condemned on the ground that the statement was false and fraudulent. The defense challenged the constitutionality of the Sherley amendment, under which the goods were seized, but the court held that it was valid.

Mr. Justice HUGHES delivered the opinion of the Court.

Libels were filed by the United States, in December, 1912, to condemn certain articles of drugs (known as "Eckman's Alterative") as misbranded in violation of section 8 of the food and drugs act. The articles had been shipped in interstate commerce, from Chicago to Omaha, and remained at the latter place unsold and in the unbroken original packages. The two cases present the same questions, the libels being identical save with respect to quantities and the persons in possession. In each case demurrers were filed by the shipper, the Eckman Manufacturing Co., which challenged both the sufficiency of the libels under the applicable provision of the statute and the constitutionality of that provision. The demurrers were overruled and, the Eckman company having elected to stand on the demurrers, judgments of condemnation were entered.

Section 8 of the food and drugs act, as amended by the act of August 23, 1912, c. 352, 37 Stat. 416, provides, with respect to the misbranding of drugs, as follows:

"SEC. 8. That the term 'misbranded,' as used herein, shall apply to all drugs or articles of food or articles which enter into the composition of food, 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 to any food or drug product which is falsely branded as to the State, Territory, or country in which it is manufactured or produced.

"That for the purposes of this act an article shall also be deemed to be misbranded. In case of drugs:

* * * * * * *

"Third. If its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein which is false and fraudulent."

The amendment of 1912 consisted in the addition of paragraph "Third," which is the provision here involved.

It is alleged in each libel that every one of the cases of drugs sought to be condemned contained 12 bottles, each of which was labeled as follows:

"Eckman's Alterative,—contains twelve per cent. of alcohol by weight, or fourteen per cent. by volume—used as a solvent. For all throat and lung diseases including Bronchitis, Bronchial Catarrh, Asthma, Hay Fever, Coughs and Colds, and Catarrh of the Stomach and Bowels, and Tuberculosis (Consumption) * * * Two dollars a bottle. Prepared only by Eckman Mfg. Co. Laboratory Philadelphia, Penna., U. S. A."

And in every package containing one of the bottles there was contained a circular with this statement:

"Effective as a preventative for pneumonia." "We know it has cured and that it has and will cure tuberculosis."

The libel charges that the statement "effective as a preventative for pneumonia" is "false, fraudulent, and misleading in this, to wit, that it conveys the impression to purchasers that said article of drugs can be used as an effective preventative for pneumonia, whereas, in truth and in fact said article of drugs could not be so used;" and that the statement, "we know it has cured" and that it "will cure tuberculosis" is "false, fraudulent, and misleading in this, to wit, that it conveys the impression to purchasers that said article of drugs will cure tuberculosis, or consumption, whereas, in truth and in fact said article of drugs would not cure tuberculosis, or consumption, there being no medicinal substance nor mixture of substances known at present which can be relied upon for the effective treatment or cure of tuberculosis, or consumption."

The principal question presented on this writ of error is with respect to the validity of the amendment of 1912.

So far it is objected that this measure, though relating to articles transported in interstate commerce, is an encroachment upon the reserved powers of the States, the objection is not to be distinguished in substance from that which was overruled in sustaining the white slave act (36 Stat., 825). Hoke *v.* United States, 227 U. S., 308. There, after stating that "if the facility of interstate transportation" can be denied in the case of lotteries, obscene literature, diseased cattle and persons, and impure food and drugs, the like facility could be taken away from "the systematic enticement of and the enslavement in prostitution and debauchery of women," the court concluded with the reassertion of the simple principle that Congress is not to be denied the exercise of its constitutional authority over interstate commerce, and its power to adopt not only means necessary but convenient to its exercise, because these means may have the quality of police regulations. (Id. pp. 322, 323. See Gloucester Ferry Co. *v.* Pennsylvania, 114 U. S., 196, 215; Hipolite Egg Co. *v.* United States, 220 U. S., 45, 57; Lottery Case, 188 U. S., 321).

It is urged that the amendment of 1912 does not embrace circulars contained in the package, but only applies to those statements which appear on the package or on the bottles themselves; that is, it is said that the word "contain" in the amendment must have the same meaning in the case of both "package" and "label." Reference is made to the original provision in the first sentence of section 8 with respect to the statements, etc., which the package or label shall "bear." And it is insisted that if the amendment of 1912 covers statements in circulars which are contained in the package it is unconstitutional. Such statements, it is said, are not so related to the

commodity as to form part of the commerce which is within the regulating power of Congress.

But it appears from the legislative history of the act that the word "contain" was inserted in the amendment to hit precisely the case of circulars or printed matter placed inside the package, and we think that is the fair import of the provision. (Cong. Rec., 62d Cong., 2d sess., vol. 48, pt. 11, p. 11322.) And the power of Congress manifestly does not depend upon the mere location of the statement accompanying the article; that is, upon the question whether the statement is *on* or *in* the package which is transported in interstate commerce. The further contention that Congress may not deal with the package thus transported in the sense of the immediate container of the article as it is intended for consumption is met by McDermott *v.* Wisconsin (228 U. S., 115). There the court said: "That the word 'package' or its equivalent expression, as used by Congress in sections 7 and 8 in defining what shall constitute adulteration and what shall constitute misbranding within the meaning of the act," (Food and Drugs Act) "clearly refers to the immediate container of the article which is intended for consumption by the public, there can be no question. * * * Limiting the requirements of the act as to adulteration and misbranding simply to the outside wrapping or box containing the packages intended to be purchased by the consumer, so that the importer, by removing and destroying such covering, could prevent the operation of the law on the imported article yet unsold, would render the act nugatory and its provisions wholly inadequate to accomplish the purposes for which it was passed." And, after stating that the requirements of the act thus construed were clearly within the power of Congress over the facilities of interstate commerce, the court added that the doctrine of original packages set forth in repeated decisions, which protected the importer in the right to sell the imported goods, was not "intended to limit the right of Congress, now asserted, to keep the channels of interstate commerce free from the carriage of injurious or fraudulently branded articles and to choose appropriate means to that end." (Id., pp. 130, 131, 137.)

Referring to the nature of the statements which are within the purview of the amendment, it is said that a distinction should be taken between articles that are illicit, immoral, or harmful and those which are legitimate, and that the amendment goes beyond statements dealing with identity or ingredients. But the question remains as to what may be regarded as "illicit," and we find no ground for saying that Congress may not condemn the interstate transportation of swindling preparations designed to cheat credulous sufferers and make such preparations, accompanied by false and fraudulent statements, illicit with respect to interstate commerce, as well as, for example, lottery tickets. The fact that the amendment is not limited, as was the original statute, to statements regarding identity or composition (United States *v.* Johnson, 221 U. S., 488) does not mark a constitutional distinction. The false and fraudulent statement, which the amendment describes, accompanies the article in the package, and thus gives to the article its character in interstate commerce.

Finally, the statute is attacked upon the ground that it enters the domain of speculation (American School of Magnetic Healing *v.* McAnnulty, 187 U. S., 94) and by virtue of consequent uncertainty operates as a deprivation of liberty and property without due process of law in violation of the fifth amendment of the Constitution and does not permit of the laying of a definite charge as required by the sixth amendment. We think that this objection proceeds upon a misconstruction of the provision. Congress deliberately excluded the field where there are honest differences of opinion between schools and practitioners. (Cong. Rec., 62d Cong., 2d sess., vol. 48, pt. 12, App., p. 675.) It was, plainly, to leave no doubt upon this point that the words "false *and fraudulent*" were used. This phrase must be taken with its accepted legal meaning, and thus it must be found that the statement contained in the package was put there to accompany the goods with actual intent to deceive—an intent which

may be derived from the facts and circumstances, but which must be established. (Id., 676.) That false and fraudulent representations may be made with respect to the curative effect of substances is obvious. It is said that the owner has the right to give his views regarding the effect of his drugs. But state of mind is itself a fact, and may be a material fact, and false and fraudulent representations may be made about it; and persons who make or deal in substances or compositions alleged to be curative are in a position to have superior knowledge and may be held to good faith in their statements. (Russell *v.* Clark's Executors, 7 Cranch, 69, 92; Durland *v.* United States, 161 U. S., 306, 313; Stebbins *v.* Eddy, 4 Mason, 414, 423; Kohler Mfg. Co. *v.* Beeshore, 59 Fed., 572, 574; Missouri Drug Co. *v.* Wyman, 129 Fed., 623, 628; McDonald *v.* Smith, 139 Mich., 211; Hedin *v.* Minneapolis Medical Institute, 62 Minn., 146, 149; Hickey *v.* Morrell, 102 N. Y., 454, 463; Regina *v.* Giles, 10 Cox, C. C., 44; Smith *v.* Land & House Corporation, L. R., 28 Ch. Div., 7, 15.) It can not be said, for example, that one who should put inert matter or a worthless composition in the channels of trade labeled or described in an accompanying circular as a cure for disease, when he knows it is not, is beyond the reach of the law-making power. Congress recognized that there was a wide field in which assertions as to curative effect are in no sense honest expressions of opinion, but constitute absolute falsehoods and, in the nature of the case, can be deemed to have been made only with fraudulent purpose. The amendment of 1912 applies to this field, and we have no doubt of its validity.

With respect to the sufficiency of the averments of the libels, it is enough to say that these averments should receive a sensible construction. There must be a definite charge of the statutory offense, but we are not at liberty to indulge in hypercriticism in order to escape the plain import of the words used. There is no question as to the adequacy of the description of the article or of the shipments or of the packages. It is said that there was no proper statement of the contents of the circular. But the libels give the words of the circular, and we think that the allegations were sufficient to show the manner in which they were used. The objection that it was not alleged that the statements in question appeared on the original packages or on the bottles themselves, as already pointed out, is based on a misconstruction of the statutory provision. The remaining and most important criticism is that the libels did not sufficiently show that the statements were false and fraudulent. But it was alleged that they were false and fraudulent, and, with respect to tuberculosis, it was averred that the statement was that the article "has cured" and "will cure," whereas, "in truth and in fact," it would "not cure," and that there was no "medicinal substance nor mixture of substances known at present" which could be relied upon to effect a cure. We think that this was enough to apprise those interested in the goods of the charge which they must meet. It was, in substance, a charge that, contrary to the statute, the article had been made the subject of interstate transportation with a statement contained in the package that the article had cured and would cure tuberculosis, and that this statement was contrary to the fact and was made with actual intent to deceive.

Judgments affirmed.

Mr. Justice McReynolds took no part in the consideration or decision of these cases.