

N. J., F. D. 19651-19652

Issued January, 1933

**United States Department of Agriculture****FOOD AND DRUG ADMINISTRATION****NOTICES OF JUDGMENT UNDER THE FOOD AND DRUGS ACT**

[Given pursuant to section 4 of the food and drugs act]

**19651-19652**

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**19651. Misbranding and alleged adulteration of B. & M. U. S. v. 17 Large Bottles, et al., of B. & M. Hearing on exceptions to libel. Court sustains claimant's exceptions to charges that article was adulterated, sustains further exceptions to libel on contention that statements, alleged to be false and misleading, concerning strength of article appearing in booklet contained within the package, does not constitute misbranding, but overruled claimant's exception to the remaining charge. Tried to a jury on misbranding charge based on false and fraudulent curative and therapeutic claims. Verdict for the Government. Decree of condemnation, forfeiture, and destruction. (F. & D. Nos. 26900, 26905. I. S. Nos. 28871, 28872, 28875, 28876. S. Nos. 5067, 5095.)**

These cases involved shipments of a drug preparation labeled "B. & M. Formerly Called B. & M. External Remedy." The cartons, the bottle labels, and a booklet shipped with the article bore extensive curative and therapeutic claims. Investigation by this department showed that the article contained no ingredient or combination of ingredients capable of producing the curative and therapeutic effects claimed. On the cover and first page of the booklet the article was described as an "Antiseptic." The booklet also contained statements supported by tables and plates purporting to prove its penetrating and germ-destroying properties. Tests showed that it would not destroy germs in the tissues and organs when used externally or by inhalation in accordance with instructions contained in the booklet.

On August 22, 1931, the United States attorney for the District of Maryland, acting upon reports by the Secretary of Agriculture, filed in the District Court of the United States for the district aforesaid two libels praying seizure and condemnation of a total of 43 large bottles and 95 small bottles of the said B. & M., remaining in the original unbroken packages at Baltimore, Md. The libels charged that the article had been shipped from Boston, Mass., by the F. E. Rollins Co. to Baltimore, Md., a portion having been shipped on or about August 1, 1931, and the remainder on or about August 6, 1931, and that it was adulterated and misbranded in violation of the food and drugs act as amended.

Chemical analyses of samples of the article by this department showed that it consisted essentially of approximately 42 per cent of turpentine oil, approximately 5 per cent of ammonia, small proportions of ammonium salicylate, hexamethylenamine, thiosinamine, and a phenolic substance such as cresol, albuminous and phosphorus-containing material such as egg, and water. Bacteriological examination showed that it failed to kill a resistant strain of *Staphylococcus aureus* at body temperature within 30 minutes.

Adulteration of the article was alleged in the libel for the reason that it was sold under its own standard of strength, to wit, (booklet cover) "For External Applications, Inhalations, Antiseptic," (booklet, p. 1) "An Antiseptic \* \* \* Application, For Antiseptic Applications," and the strength of the article fell below such professed standard, in that it was not antiseptic when used as directed in the labeling.

Misbranding was alleged for the reason that certain statements appearing in the booklet were false and misleading, since the article fell below the professed standard of strength set forth in said statements. These alleged false and misleading statements were annexed to the libels as Exhibit A and made a part thereof and are appended hereto. Misbranding was alleged for the further reason that certain statements borne on the cartons and bottle labels and appearing in the booklet, regarding the curative and therapeutic effects of the article, were false and fraudulent, since it contained no ingredient or combination of ingredients capable of producing the effects claimed. These statements also were annexed to the libels as Exhibit B and made a part thereof and are appended hereto.

On September 12, 1931, the F. E. Rollins Co., Boston, Mass., entered an appearance as claimant and filed a motion to consolidate the cases, which motion was allowed, and on the same date claimant filed exceptions to the adulteration and misbranding charges contained in the libels. On January 5, 1932, claimant's bill of exceptions having been heard on briefs and oral argument submitted on behalf of the Government and claimant, the court handed down the following opinion sustaining claimant's exceptions to paragraphs 2 and 3, the adulteration and misbranding charges based on the claims as to the strength of the article, and overruling the exceptions to paragraph 4, based on the false and fraudulent therapeutic claims. Chestnut (*D. J.*):

"In these consolidated cases the Government seeks to condemn under the act of Congress known as the food and drugs act of June 30, 1906, as amended in 1912 (United States Code, title 21, sections 1 to 15), certain cartons containing bottles of a proprietary drug arbitrarily called "B. & M." It is alleged in the libels that this drug is (1) adulterated and (2) misbranded, within the meaning of the act. The act is operative, so far as the States are concerned, only to interstate commerce, and it is alleged in the libels that the offending packages were shipped from Massachusetts to Baltimore.

"Section 14 of title 21 of the United States Code provides that the procedure in such cases shall begin by a process of libel for condemnation, and that the procedure shall conform as near as may be to proceedings in admiralty, except that either party may demand trial by a jury of any issue of fact. In accordance with this procedure the manufacturer of the drugs, the F. E. Rollins Co., a corporation of the State of Massachusetts with principal office in Boston, has appeared as claimant of the seized articles and has filed exceptions to the legal sufficiency of the libels. It is admitted by the claimant that its preparation is a drug subject to the provisions of the act. It is sold to the consumer in paper cartons containing bottles. The outside of the cartons contain certain printed matter descriptive of the drug and the uses for which it is recommended. The bottles also contain labels with similar information and directions for use. Inside the cartons, but not physically annexed thereto or to the bottles, is a printed booklet of 32 pages containing much more extensive information and description of the drug and its properties and its claimed effects. It is stated to be 'for external use' and 'for application and inhalation in the treatment of tuberculosis, influenza, pleurisy, bronchitis and other respiratory diseases' and 'for application and relief of inflamed muscles, rheumatism, neuralgia, neuritis, sciatica, lumbago,' and other diseases and injuries.

"Three questions of law are presented as follows: (1) Is the drug 'adulterated' within the meaning of the act; (2) is it 'misbranded' within the meaning of the act in that certain of the statements in the booklet referred to are false and misleading; (3) is it misbranded because certain other statements in the booklet are false and fraudulent within the meaning of the act?

"These questions will be discussed in the order stated.

"Adulteration. It is, of course, clear enough that in the construction of language upon the cartons or bottle labels or in the booklet the meaning given to the language is that ordinarily conveyed by it to purchasers. *Libby v. United States* (C. C. A. 4th), 210 Fed. 148; *Hall v. United States*, 267 Fed. 795, (C. C. A. 5th); *United States v. 150 Cases*, 211 Fed. 350, (D. C. Mass.); *Chichester Chemical Co. v. United States*, 49 Fed. (2) 516, (D. C. App.). But the term 'adulterated' is given a special definition by the act, title 21, section 8. In the case of drugs the term as thus defined means (1) when it is sold under a name recognized by the United States Pharmacopoeia or National Formulary, that it differs from the standard of strength, quality, or purity as determined by those publications and (2) where not sold under such a standard name, 'if its strength or purity fall below the professed standard or quality under which it is sold.'

"Paragraph 2 of the libels alleges that this drug is adulterated 'in this, that said article is sold under its own standard of strength,' to wit, 'for external application, inhalations, antiseptic' and 'an antiseptic \* \* \* application,' 'for antiseptic applications,' while in truth and fact the strength of said article falls below such professed standard in that the article is not antiseptic when used as directed in the labeling thereof.

"This statement appears on the cover and on the inside of the 'booklet' which, as stated above, is inclosed in the carton but not physically annexed thereto, or to the label on the bottle. The label on the bottle, however, contains the following reference to the booklet: 'For full directions and information please read the booklet which accompanies this bottle.' It is objected by the claimant that the contents of the booklet are to be disregarded because they do not appear on the outside of the package. The same point is made and hereafter more fully discussed in connection with the charge of misbranding. It is sufficient to say that this point is, in my opinion, not sound with respect to the charge of adulteration because the statements in the booklet are, I think, quite clearly within the mischief aimed at, and are not excluded by the language of the act as to adulteration. It is also to be noted that the wording of the first paragraph defining 'adulteration' is 'difference from recognized standards; explanatory statement on the container.'

"There is, however, another objection made by the claimant in answer to this charge of adulteration which is more meritorious, and, in my opinion, sound. This objection is that the statement or claim that the drug is 'antiseptic,' although in fact not antiseptic, is not within the definition of adulteration as contained in the act. The drug is not sold under a name recognized in the United States Pharmacopœia or National Formulary and therefore the charge of adulteration, if it can be sustained at all, must fall within the second paragraph of the definition which reads as follows:

Below Professed Standard 2. If its strength or purity fall below the professed standard or quality under which it is sold.

"The argument on behalf of the Government is that the statement by the manufacturer that the article is 'antiseptic,' professes a standard of strength for the article to which it does not conform. But I am unable to accept the view that the use of the word 'antiseptic' is a profession of standard of strength within the meaning of the definition. The word 'antiseptic' does not of itself convey the idea of any particular strength or degree. The primary meaning of 'antiseptic' is 'tending to prevent putrefaction or decay.' It is said that the word was in common use long before the bacteriological discoveries of Pasteur and Koch. The word is not equivalent in meaning to the word 'germicide;' that is to say, an antiseptic substance is not necessarily one that kills germs. It is probably true that the most common use of the word 'antiseptic' is in relation to antiseptic surgery, but the term is in its dictionary meaning, and I understand also in its scientific meaning, much broader than its special application to antiseptic surgery. And, as I understand it, the word does not import or imply or 'profess' any particular standard of strength or quality with respect to germs or bacteria. Different antiseptic substances vary in the degree of their strength or effectiveness in killing or tending to prevent the formation of bacteria, and probably vary also with the conditions and duration of application. Therefore, to say that a substance is 'antiseptic' is merely to affirm that it has a tendency to prevent putrefaction, decay, or the development or increase of bacteria; and not to affirm any particular potency in connection therewith.

"Then again it is to be noted that, to be within the definition, there must be not only a professed standard asserted or implied but the 'strength or purity' of the article must fall below the professed standard. The construction contended for by the Government, would, I think, introduce forbidden elements of vagueness and uncertainty into the definition. *Small v. American Sugar Refining Co.* (267 U. S. 237); *Cline v. Frink Dairy Co.* (274 U. S. 445, 453, 454).

"Even if the claim that the article is antiseptic, when in fact it is not, could be brought literally within the wording of the definition, yet, in my opinion, it is clearly not within the intent of the act when we look to the context of the whole definition of the word 'adulterated' and also to the structure of the whole food and drugs act. The obvious purpose of Congress in defining the word 'adulterated' was to cover cases where a drug recognized in the United States Pharmacopœia or National Formulary is sold

under its established name but does not conform to the standard of strength, quality, or purity as determined in that official publication; and when not sold under such an established name, the second paragraph of the definition applies where the manufacturer professes a particular standard of 'strength or purity' to which the article does not conform. In one case the drug fails to conform to its official recognized standard; in the other to its particular professed standard. If the drug does not profess a particular standard of strength or purity, it is not 'adulterated' by reason of a falsely asserted quality, which would be a 'misbranding' under the act.

"The claim that the drug is 'antiseptic' is a profession of quality rather than of strength or purity. It would at least be inapt to say that the 'strength or purity' of a drug 'falls below the professed quality' of the drug because 'strength' and 'purity' are ideas that can not readily be stated in comparison with or in proportion to 'quality'; and it is to be noted that while the first paragraph of the definition of 'adulterated' condemns a drug which falls below the standard of 'strength, quality, or purity,' yet the second paragraph (with which we are concerned) comprehends a case where only the 'strength or purity' falls below a professed standard. A simple illustration of the application of this second paragraph of the definition, with respect to purity, is afforded by the well-known instance of an article that is widely advertised as "99 44/100 per cent Pure." If, on analysis, such an article proves to be only 90 per cent pure it would obviously fall below a professed standard of purity. And so with respect to 'strength.' If a manufacturer represents that a drug contains 50 per cent formaldehyde when in fact it contains only 5 per cent, it falls below the professed standard of strength.

"Apart from this merely verbal analysis of the definition, I have the conviction that the sense of the definition as a whole excludes its application to the case under consideration. A sentence from the opinion of Justice Holmes, speaking for the Supreme Court of the United States in the case of *United States v. Johnson* (221 U. S. 488, 496), construing a clause of the same act, aptly expresses my view. He there said:

It seems to us that the words used convey to the ear trained to the usage of English speech a different aim; and although the meaning of a sentence is to be felt rather than proved, generally and here, the impression may be strengthened by argument.

"Counsel for the Government are not able to point to any precedent for similar application of the act although it has now been in force for 25 years, and it would seem highly probable that instances must have heretofore arisen in which a similar application could and should have been made if justified. The absence of such prior application seems to me to be not without significance in interpreting the true intent of the act.

"The claimant's exceptions to the second paragraph of the libel will therefore be sustained.

"Misbranding. The libels allege that the booklet in the carton contains some statements which are (a) false and misleading, and other statements which are (b) false and fraudulent, and that they both constitute 'misbranding' within the definition contained in the act (Code, title 21, sections 9 and 10). By section 9 'misbranding' covers, as to drugs, cases where 'the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substance contained therein which shall be false or misleading in any particular' and in section 10, there is included three additional classes of misbranding, the third of which reads as follows:

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.

It is apparent from this that statements which are false or misleading are hit by the act only when the package or label bears the statement; but if the statement is both false and fraudulent, it is covered by the act if the package or label bears or contains the statement. In this case all the alleged offending statements are contained in the booklet which, as has already been stated, is inclosed within the enveloping carton but is not physically attached thereto and is not a part of the printed matter on the label on the bottle, although referred to thereon. It is clear enough and is indeed conceded by the claimant, that the word 'contain' aptly covers the statements in the booklet, and that therefore statements therein which are false and fraudulent are reached by the

act, but claimant also contends that the narrower language of section 9 with respect to statements which are only 'false or misleading' exclude the consideration of statements in the booklet because the word 'bear' is limited to statements which appear on the outside of the package as sold to the customer. If this were a case of first instance, bearing in mind the obvious and indeed oft stated beneficent purpose of the act, and the mischief it was designed to prevent, I should be inclined to hold that the construction was perhaps unnecessarily narrow, although it must be conceded that the word 'bear' is more aptly used with reference to descriptive matter on the package or label than with reference to a nonattached booklet of advertising matter regarding the drug contained within the package. It is, I think, true that false and misleading statements in the booklet are quite as much within the mischief aimed at by the act as statements on the outside of the carton or on the label on the bottle. It is a matter of common knowledge that many proprietary medicines are sold in carton form with booklets or paper wrappers within the carton which give much fuller information regarding the article than is possible in the limited space provided by the outside of the carton or the label on the bottle. A careful user of articles will read the fuller statements in the booklet and probably rely upon them as much if not more, than the more condensed reading matter on the outside of the carton or label. Emphasis is placed by counsel for the claimant on the proposition that the article is bought by the purchaser principally on the strength of the statements appearing on the outside cover of the package, and that it must be supposed that Congress, acting only on the power to regulate interstate commerce, must have intended to limit its regulations to conditions applicable to the sale in the original package and not to have intended to extend its regulatory power beyond this to the opening of the original package by the purchaser. But certainly this is too narrow a view of the power of Congress. *Seven Cases v. United States* (239 U. S. 510).

"However this may be, I find that the claimant's contention with respect to the construction of the act relating to statements which are merely false or misleading, including the unattached booklet, is supported by authority. The original act became effective June 30, 1906. In 1911, the District Court for the Eastern District of New York held in the case of *United States v. American Druggists' Syndicate*, 186 Fed. 387, 389, 391, that this section of the act under consideration did not cover false or misleading statements in a separate circular inclosed with the article in the enveloping package. And a similar holding was made very briefly in the Southern District of Ohio, in *United States v. Newton Tea & Spice Co.*, in 1920, 275 Fed. 384, affirmed on other grounds in 288 Fed. 475. In 1911, in the case of *United States v. Johnson*, 221 U. S. 488 (above cited), the Supreme Court held that this section of the act was aimed at false statements as to the identity of the article, possibly including strength, quality, and purity, and not at statements as to curative effects. Promptly thereafter, pursuant to recommendation by President Taft, Congress, in 1912, amended what is now section 10 of title 21 of the act by adding the paragraph to cover false and fraudulent statements regarding the curative or therapeutic effect of the article. And the legislative history of the act tends to indicate that the word 'contain' in the amendment was inserted by reason at least of existing doubts as to whether a circular or booklet within the carton would otherwise be covered. But still more importantly the Supreme Court in the case of *Seven Cases v. United States* (239 U. S. 510), speaking by Mr. Justice Hughes (who had written the dissenting opinion in the *Johnson* case above cited) at least impliedly approves the limited effect of the word 'bear' in the earlier section of the law. At page 515 in contrasting the significance of the words 'bear' and 'contain,' he said:

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 that this is the fair import of the provision. Cong. Rec. 62d Cong., 2d Sess., vol. 48, part 11, p. 11, 322. 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, 130).

"The claimant's contention is that no merely false or misleading statements can be construed as covered by the act unless they appear on the outside of the package. And the contention so expressed would seem to exclude even statements on the label on the bottle contained within the package. It is true

that this contention finds support in the dictum rather than in the decision in 186 Fed. 386, 391. But the broad language there used was not necessary to the decision either in that case or in this and finds no support in the Supreme Court cases above referred to. In that case the expressed view that the statements are limited to the outside of the package is based largely on the consideration of the wording of other sections of the law, which, in my opinion, are not controlling or even persuasive on the particular point because they relate to different conditions. The sounder rule of construction is to limit the consideration to the language of the particular section and when so limited, we find that statements on the label of the bottle are expressly included.

"I reach the conclusion that in dealing with false or misleading statements the booklet is to be excluded, on the authority of the judicial and legislative history of the act. But before finishing the discussion on this point I think some attention may possibly at some later stage of this case be given to the effect, if any, of the legend on the label of the bottle reading as follows: 'For full directions and information please read the booklet which accompanies this bottle.' The significance, if any, of this notation on the bottle has not been set up in the pleadings or referred to in the written or printed arguments of counsel. As the subject is not covered by the libels as now drawn it is not before me for consideration at the present time and I, therefore, express no opinion upon it.

"This particular point as to false and misleading statements is set up in paragraph 3 of the libel and refers to certain statements appearing in the printed booklet as false and misleading 'in that the article falls below the standard of strength set forth in said statement.' The claimant also excepts to the sufficiency of this averment on the ground that statements which are only false or misleading are not condemned by the act unless they relate to the identity of the article; and that the statements referred to in the libel do not relate to the identity of the article or its constituents but at most only to its quality. In this connection it is to be noted that the Supreme Court in the Johnson case, speaking by Mr. Justice Holmes, said: 'But we are of the opinion that the phrase is aimed not at all possible false statements, but only at such as determine the identity of the article, possibly including its strength, quality, or purity.' Justices Hughes, Harlan, and Day dissented on the ground that the section also covered false statements of fact as to the curative properties of the article. In the opinion by Mr. Justice Hughes, page 506, he says:

I take it to be conceded that misbranding may cover statements as to strength, quality, and purity.

In the later case of *Seven Cases v. United States* (239 U. S. 510), Mr. Justice Hughes, writing the opinion for the court, said at page 517:

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.

As a result of these judicial expressions it is at least doubtful whether statements merely false or misleading are prohibited by the act if they relate to matters other than identity or composition. But it is unnecessary to decide this point in this case in view of the conclusion above reached which excludes consideration of the booklet with respect to merely false or misleading statements. The exceptions to the third paragraph of the libels must also be sustained.

"False and fraudulent claims. The fourth paragraph alleges that certain statements on the cartons and labels of the bottles and also in the booklet regarding the curative and therapeutic effect of the drug are:

False and fraudulent, in this, that the article contains no ingredients or combination of ingredients capable of producing the effects claimed, and that the same were applied to said article knowingly or in reckless and wanton disregard of their truth or falsity; so as to represent falsely and fraudulently that the article was in whole or in part composed of or contained medicinal ingredients effective for the diseases and conditions named therein.

"The exception to this paragraph is based on the contention that the term 'fraudulent' as contained in section 10 of the Code, title 27 (above quoted), means 'actual intent to deceive;' and although the libel alleges the statements are both 'false and fraudulent,' yet it nevertheless narrows the statutory phrase by the expression 'or in reckless and wanton disregard of their truth or falsity' and that as so narrowed they are not within the act which, as construed by the Supreme Court, requires 'an actual intent to deceive,' and therefore it is argued

that this paragraph of the libel is legally insufficient. On this point the court in the case referred to, *Seven Cases v. United States* (239 U. S. 510, 517), said:

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.

"The point here presented is, I think, a nicety in pleading rather than one of substantial trial importance. The jury in this case would, of course, be instructed that the false and fraudulent statements relied on by the Government must be of such character that the jury could infer from them an actual intent to deceive. It is to be noted that the libels do expressly allege that the statements were false and fraudulent (in the language of the statute), and also allege that the false and fraudulent statements made in reckless and wanton disregard of their truth or falsity, were effective to represent falsely and fraudulently that the article was 'in whole or in part composed of or contained ingredients or medicinal agents effective for the diseases and conditions named therein.' The narrow question of pleading thus presented is whether false and fraudulent statements made 'in reckless and wanton disregard of their truth or falsity,' and with the effect of false and fraudulent representation in fact, are within the act. As said by the Supreme Court, 'the phrase "false and fraudulent" must be taken with its accepted legal meaning.' The accepted legal meaning of the term 'fraudulent' includes false statements made in reckless and wanton disregard of their truth or falsity. *Cooper v. Schlesinger* (111 U. S. 148); *Lehigh Zinc & Iron Co. v. Banford* (150 U. S. 665); 26 C. J. Title 'Fraud,' section 40 bb., page 1112. Under this act libels or informations or indictments similarly worded have been held sufficient. *Eleven Gross Packages v. United States*, 233 Fed. 71 (C. C. A. 3d); *Simpson v. United States*, 241 Fed. 841, 843 (C. C. A. 6th); *United States v. 23½ Dozen Bottles*, 44 Fed. (2d) 831 (D. C. Conn.), except that the libels in those cases alleged that the false and fraudulent claims were made 'knowingly "and" (instead of "or") in reckless and wanton disregard of their truth or falsity. But the approved charge in 233 Fed. page 74, was 'if you believe from the evidence that any one of the therapeutic claims \* \* \* was false and was made by the claimant with a reckless and wanton disregard as to whether it was true or false, you may find a verdict for the Government.' The use of the word 'or' instead of 'and' in the libels in this case is emphasized as a defect by the claimant. As a matter of pleading I think it would have been preferable in this case to use 'and' instead of 'or,' in which event the proof would have been sufficient if it had shown the statements were made knowingly and recklessly, etc., or knowingly or recklessly, etc. Clearly, if false and fraudulent statements were made knowingly, which I interpret to mean with knowledge of their false and fraudulent character, there could be no question of the sufficiency of the proof. And likewise, the accepted legal meaning of 'fraudulent' includes statements not based on knowledge and made with reckless and wanton disregard of their truth or falsity, for statements so made necessarily exclude the idea of good faith, or honest belief in the truth of the statements, or any reasonable ground for believing them to be true. See also *Erwin v. Jackson* (C. C. A. 4th) 22 Fed. (2d) 56, 57; *Knickerbocker Merchandising Co. v. United States* (C. C. A. 2d) 13 Fed. (2d) 544, 546; *Fidelity & Deposit Co. v. Drovers State Bank* (C. C. C. 8th) 15 Fed. (2d) 306, 308.

"For these reasons the exceptions to the fourth paragraph of the libel are hereby overruled."

On March 29, 1932, claimant filed a motion to strike certain portions of the labeling contained in the Government's Exhibit B annexed to the libels, which motion was overruled without opinion. On June 28, 1932, the case went to trial. At the commencement of the trial the claimant offered in bar, the record and judgment in a case involving a libel filed October 14, 1919, in the United States District Court for the District of New Hampshire, against a quantity of B. & M. external remedy, in which the claimant in this action, at that time known as the National Remedy Co., appeared as claimant, and which was tried to a jury, and verdict and judgment entered for claimant (F. & D. No. 11492, Docket No. 95 Adm., N. J. No. 11671). The court permitted the introduction of the record and judgment, not as a bar to the action, but as evidence bearing on the question of good faith. At the conclusion of the testimony the court



delivered the following instructions to the jury, which contain a summary of the evidence introduced on behalf of the Government and claimant. Chesnut, (D. J.):

"Mr. Foreman, and Gentlemen of the Jury: I congratulate you that you have now reached the final stages of this long litigation. You have been listening, I have noted, very attentively to the testimony in this case for the past three weeks. You may have found some compensation for your arduous public service in the interest of the subject matter covered by the testimony and in the consciousness that you are dealing with a case which involves very important issues. The direct effect of your verdict will relate only to the condemnation or release of the particular bottles of the proprietary medicine labeled 'B. & M.' which the Government is seeking to condemn in this proceeding. But, according to the contentions of both parties respectively, although for widely different reasons, your verdict will probably indirectly affect the health and possibly even the lives of many persons. Therefore, the verdict that you render in this case is one of considerable importance and is worthy of your very best consideration in order that you reach a right conclusion.

"In order to be of what assistance I can to you in reaching your verdict, it now becomes my duty to instruct you as to the law of the case and to make some summation of the testimony submitted by the adversary parties in support of their respective contentions. At the outset, let me make it plain to you what are the respective duties and responsibilities of the judge and the jury in the case. It is my responsibility to state to you the governing and controlling law of the case. It is your duty and responsibility to determine the facts of the case. What I say to you as to the law should be accepted by you as controlling, as that is my responsibility only. On the other hand, the determination of the facts is solely your responsibility and anything that I may say in this charge with respect to the facts is to be regarded by you as purely advisory and not in any way controlling of your own determination of what are the facts of the case. In other words, but more briefly, the court determines the law for you, and you determine the facts for yourselves. The summation of any reference to the testimony by me are merely as an aid or assistance to you in a review of the case. If I express any view as to the facts or as to any part of the testimony or seem to do so, you are entirely at liberty to reject that view and substitute your own determination of the facts. But when you have determined for yourselves what are the controlling facts in the case, your verdict is properly arrived at by applying the law which I determine, to the facts which you determine. This is the usual and obligatory practice of this court in all cases, including this one.

"Now first let me explain to you the nature of this proceeding. It is brought under the statute passed by Congress originally in 1906, based on the power of Congress given by the Constitution of the United States, to regulate commerce between the States. The law is known as the Federal food and drugs law and is to be found in title 21 of the United States Code. This act was passed by Congress after many years of public discussion and the underlying purpose was to make unlawful interstate transactions in impure foods and drugs and incidentally the scope of the law included a prohibition of the facilities of interstate commerce to food and drugs which were 'misbranded' and thereby tended to mislead or deceive the public. The section of the statute with regard to misbranding as originally included in the act of 1906, as construed by the Supreme Court of the United States in the case of *United States v. Johnson* (221 U. S. 588), was aimed only at false statements as to the identity of the article, possibly including its strength, quality, and purity, and not at statements as to its curative effect. In consequence of this decision it was felt that the law was not sufficiently broad to protect the public and therefore on June 21, 1911, President Taft (afterwards Chief Justice of the Supreme Court) sent a message to Congress advising an addition to the law in which he said in part:

In my opinion the sale of dangerously adulterated drugs, or the sale of drugs under knowingly false claims as to their effect in diseases, constitutes such an evil and warrants me in calling the matter to the attention of Congress. Fraudulent misrepresentations of the curative value of nostrums not only operate to defraud purchasers, but are a distinct menace to public health. There are none so credulous as sufferers from disease. The need is urgent for legislation which will prevent the raising of false hopes of speedy cures of serious ailments by misstatement of facts as to worthless mixtures on which the sick will rely while their disease progresses unchecked.



"I take this quotation from the charge of Judge Morris in the New Hampshire case.

"As a result of this message Congress passed an amendment to the original Food and Drugs Act known as the Sherley Amendment, so that the law (U. S. C. A., title 21, section 10) in this respect now reads as follows:

An article shall be deemed to be misbranded \* \* \* in case of drugs \* \* \* if its package or label 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.

"Other provisions of the act authorize proceedings by the Government to seize and condemn misbranded drugs which have been shipped in interstate commerce. The proceeding is called a libel for condemnation of the offending article.

"In these particular cases which you are now trying the Government seized certain bottles of an article of drugs, labeled in part 'B. & M.,' here in Baltimore and on August 21, 1931, filed in this court its libel to condemn the articles, in which it is alleged in paragraph 4:

That certain statements borne on the labels of said cartons and borne on the labels of said bottles and certain further statements appearing in said printed booklet regarding the curative and therapeutic effect of said article are false and fraudulent, in this, that the article contains no ingredients or combination of ingredients capable of producing the effects claimed, and that the same were applied to said article knowingly or in reckless and wanton disregard of their truth or falsity so as to represent fraudulently and falsely that the article was in whole or in part composed of or contained ingredients or medicinal agents effective in the diseases named therein.

"The particular statements complained of are set out in an exhibit marked 'B' filed with the libel and consisting of labels on the bottles and the cartons containing them, and also for the most part, of the statements in the booklet which was inclosed in the carton around the bottle.

"When you retire to consider your verdict you will receive from the clerk and take with you to your jury room the libel papers filed by the Government in the two consolidated cases which are now on trial. I call to your attention that paragraphs 2 and 3 of the libel set out additional grounds for the claim of condemnation of the drugs, based on other alleged violations of the act but you should give no consideration to these paragraphs 2 and 3 of the libels because after argument of counsel I have determined as a matter of law that the grounds alleged in paragraphs 2 and 3 are insufficient in this case and therefore, these particular grounds of condemnation are out of the case and are not submitted in any way for your consideration. You are to limit your consideration to the ground of condemnation set up in paragraph 4 of the libels which I have already read to you.

"After the bottles of 'B. & M.' involved in these cases were seized by the Government, the manufacturer, the F. E. Rollins Co., a corporation of the State of Massachusetts, intervened in the case as claimant and filed an answer in opposition to the condemnation in which it stated that it was the manufacturer, the shipper, and the owner of the bottles of 'B. & M.' and of the containers thereof, that it denied that the drug is misbranded and denies that the statements on the labels of the cartons and on the bottles and in the booklets are false and fraudulent. The answer admits that the articles were transported in interstate commerce.

"The nature of this proceeding is not exactly like the ordinary case, either civil or criminal, which juries are called upon to try. The ordinary civil case tried by a jury is one where the plaintiff is seeking to recover a sum of money or other property from the defendant. The ordinary criminal case is one where the Government proceeds by indictment or information against the defendant and where, in the event of a conviction, there is a penalty by way of fine or imprisonment imposed. But the proceeding in this 'B. & M.' case differs from the ordinary civil or criminal case tried by a jury in that it is not a proceeding to impose any monetary damages as in a civil case or any fine or imprisonment as in a criminal case, but only a proceeding to condemn and forfeit the particular articles seized. The manufacturer of these articles, in accordance with the established practice, is permitted to, and in this case has, come into court and claimed the articles and denied that they are subject to forfeiture or condemnation. It results, therefore, that in this particular case the two parties to the case are not called plaintiff and defendant but one party is the Government of the United States seeking to condemn the articles,

and the other party is called the claimant who is opposing the condemnation. The nature of the case, therefore, is a civil case between these two adversary parties. If you should find for the Government, your verdict would so state and the direct effect is the condemnation of the articles and their destruction or other disposition in accordance with the provisions of the statute. And if your verdict should be in condemnation of the articles, they might, upon order of court and the payment of costs of these proceedings and the execution and delivery of a good and sufficient bond to the effect that the articles shall not be sold or otherwise disposed of contrary to the provisions of the food and drugs act, or the laws of any State or Territory, be delivered to the owner thereof. You will see, therefore, that the main purpose of this proceeding on the part of the Government is not primarily to acquire any property but to prevent the sale of the bottles of 'B. & M.' contrary to law. The essential nature of the case, therefore, is that this is something in the nature of a test case in which the Government is seeking to condemn the practice on the part of the manufacturer of selling this drug in interstate commerce under the alleged misbranding. But from the standpoint of the claimant the case is also indirectly of much greater importance to it than the mere condemnation of the particular bottles of 'B. & M.,' in that it is said the condemnation of these bottles would in principle establish a decision which would in substance destroy the life of the business.

Now to come more directly to the exact issues of fact which you are to decide in this case, I point out to you that to establish its contention the Government must prove to your satisfaction by a preponderance of the evidence, that is by the more weighty evidence looking both to quantity and quality thereof, two things, as follows: (1) That the articles were shipped in interstate commerce. This is admitted by the claimant so that it need give you no further concern. (2) That the representations contained on the labels of the cartons and on the bottles and in the booklets, or some essential part thereof, as contained in Exhibit B filed with the libel and above referred to, are false and fraudulent.

The exact issue of fact, therefore, that you have to determine in this case and the only issue of fact so to be determined is whether these bottles of 'B. & M.' are falsely and fraudulently misbranded. But I call to your particular attention that the Government does not establish its case here unless they prove to you that the alleged misbranding is both false and fraudulent. It is not sufficient for the Government merely to prove that the branding is false. It must also prove that it is fraudulent because that is the requirement of the Sherley amendment to the food and drugs act which I have above quoted to you with respect to misbranding which relates to the curative and therapeutic effects of the drugs.

Now you should separately consider in this case all the testimony submitted both for the Government and for the claimant with respect to these two questions as to whether, first, the branding is false, and secondly, if so, is it also fraudulent. Somewhat different considerations apply to these two alleged facts. It is possible that you may reach the conclusion that the branding is false but not fraudulent. If so, then your verdict should properly be for the claimant. But if you reach the conclusion of fact that the branding is both false and fraudulent, then your verdict should be for the Government.

I will make some reference to the testimony in the case dealing on the question as to whether the branding in this case, or some essential part thereof, is false—that is to say, is the representation made to the public on the labels of the bottles and cartons and in the booklets, incorrect and erroneous? Here the matter is to be considered apart from the question as to whether it is also fraudulent. A misrepresentation may be made either innocently or fraudulently; that is, it may result from misinformation or accidentally or inadvertently or even from negligence. It may be false but nevertheless honest. It is in this sense that we are dealing with the word 'false' as applied to the subject matter.

Now the first thing for you to determine is what, in substance, is the claim or representation made for 'B. & M.' prominently displayed on the labels of the bottles and the cartons containing them and on the outside cover of the booklet in the following: 'B. & M. Formerly called B. & M. External Remedy For External Applications, Inhalations Antiseptic, Stimulative, Soothing, Penetrative, Volatile, Alkaline In the treatment of Tuberculosis, Pneumonia, Bronchitis, Influenza, Colds, Croup, Rheumatism, Lumbago, Acute and Suppurative Skin Infections.'

"It is entirely clear, therefore, that 'B. & M.' is conspicuously recommended, to the public as a remedy for all these numerous diseases. The question at once arises as to what is the fair meaning of this representation. The word 'remedy' as thus used is to be taken in its common and ordinary meaning—that is to say, in the meaning that would naturally be attributed to it by the public and particularly those persons who would be inclined to purchase and use it if they were suffering, or thought they were suffering, from any of the diseases mentioned. The primary signification of the word 'remedy' as defined in Webster's New International Dictionary, edition of 1932, is as follows:

That which relieves or cures a disease: any medicine or application which puts an end to disease and restores health.

The word 'remedy' does not import a guarantee of a cure but it does necessarily imply as here used a substantial curative tendency with respect to the diseases mentioned. The interior text of the booklet, on page 5, states as follows, under the caption of 'What we claim for "B. & M."'

We claim that B. & M. alleviates much suffering and that it has remedial and therapeutic effect in appropriate cases of various afflictions in which we recommend its use. \* \* \* We do not claim that B. & M. will make any one live forever or that it will have remedial effect in every case.

In other places the booklet, in support of the recommendations of 'B. & M.' cites numerous specific instances of cures or substantial recoveries of patients suffering from the diseases mentioned as a result of the use of 'B. & M.' Taking the booklet as a whole and bearing in mind the nature of the subject matter and the purposes for which the booklet is written, it seems entirely reasonable to conclude that the recommendation of 'B. & M.' as a remedy for these diseases was designed to be understood by the public and would naturally be understood by the public in the ordinary meaning of the word 'remedy' which, as already defined, is that it has curative tendencies for the diseases for which it is recommended. I have been asked by the claimant in this case to instruct you that the recommendation of 'B. & M.' as a remedy means no more than that it has some palliative or alleviative effect in the treatment of the diseases; that is to say, the word 'remedy' as here used implies no more than that 'B. & M.' will do some good in the use of the diseases as, for instance, by relieving or abating some of the symptoms accompanying the disease, such as pain and physical suffering from the disease. But I think you can very reasonably find from the booklet that the representation to the public goes beyond this and is, in effect, a representation that 'B. & M.' has a substantial curative effect or tendency towards arresting the disease and restoring the patient more or less fully to normal activity. However you have each received and read, or will have opportunity to read, the booklet as a whole and to the extent, if any, that the representations made on the labels and in the booklet as a whole are uncertain or doubtful you can draw your own conclusions as to what is the substantial representation therein made to the public, reading and interpreting the language used in its ordinary and common acceptance.

"Now when you have determined what is the fair meaning and import of the representations made with respect to the use of 'B. & M.' for the diseases mentioned, you should ask yourselves whether, as a result of consideration, of all the testimony in the case, the representations so made to the public are true or substantially false. For your convenience only, I will now make, as far as I possibly can in view of the great volume of the testimony in this case, a succinct summary of the more important testimony submitted on both sides bearing on this issue of fact. On behalf of the Government you have heard the testimony of numerous medical and scientific witnesses which in effect purports to give you practically the whole field of knowledge and scientific and professional consensus of opinion on this issue and in substance it is that there is no basis in medical or other pertinent science in support of the claim that 'B. & M.' is a remedy for the diseases mentioned, or any of them. And the opinions and information thus given to you are supported by the respective witnesses from the fullness of their knowledge and personal experience, and the reasons for their statements have been given to you at great length. These witnesses include experienced analytical chemists, a competent and experienced doctor of medicine who is specializing in the field of pharmacology, which is the science or profession dealing with the effect of drugs upon animal and human bodies, physicians in general practice, and specialists in

the study and treatment of tuberculosis. Most of these witnesses are graduates of, and some are now professors in their respective subjects in the best known medical colleges and universities of this country, including the Harvard Medical School, the Johns Hopkins University, and the University of Maryland. To recall to your recollection only a few, these witnesses included, among others: Doctor Geiling, professor of pharmacology in the Johns Hopkins Medical School; Doctor Grollman, assistant professor of physiology, Johns Hopkins University; Dr. L. L. Barker, former professor of medicine, Johns Hopkins University and for many years widely engaged in consulting and bedside practice of general medicine in Maryland and elsewhere; Dr. James H. Sever, professor of orthopedic surgery, Harvard University; Dr. Victor F. Cullen, superintendent Maryland State Tuberculosis Sanitarium, Sabillasville, Md.; Dr. John B. Hawes, graduate of Harvard Medical School, specializing in tuberculosis; Doctor Floyd, also of the Harvard Medical School, specializing in tuberculosis and connected with the Boston Health Department; Dr. Lawrason Brown, graduate of Johns Hopkins University, for many years superintendent of Tuberculosis Hospital, Saranac, N. Y.; Dr. Gordon Wilson, professor of medicine, University of Maryland; Dr. Samuel Wolman, graduate of Johns Hopkins Medical School and for many years specializing in tuberculosis.

"The substance of the testimony of these witnesses, if believed by you, is that there is no known medicine which has or could possibly have the substantial curative effect claimed for 'B. & M.' for the numerous and several diseases recommended or for any of them and in many cases the witnesses testify that they are not giving merely their individual opinions based on their own scientific and professional knowledge and experience, but are stating the consensus of medical opinion upon the subject. The chemical analysis of B. & M. shows that it contains 50 per cent water, 40 per cent of turpentine oil, 5 per cent ammonia gas and small quantities of proteins (egg), carbolic acid, thiosinamine, and some salicylates. These witnesses were informed of the constituent element or drugs composing 'B. & M.' and were familiar with the several drugs and the effect thereof as applied and used for the various purposes in medicine and expressed the opinion that the drugs either separately or in the combination in which they are found in 'B. & M.' could not possibly have the effect claimed. Two of the witnesses specializing in tuberculosis, Doctor Cullen and Doctor McMurray, of the Davidson County Tuberculosis Hospital at Nashville, Tenn., testified that at the request of the Department of Agriculture a year or two ago they experimented with the use of B. & M. in the treatment of patients suffering from tuberculosis at their hospitals and found no beneficial effects whatever in any of the cases. Counsel for the claimant criticizes the adequacy and sufficiency of the use of B. & M. as actually used in these experimental cases. You have heard the testimony of these witnesses and will yourselves be the judges of the fairness and sufficiency of the tests made by them of B. & M.

"The testimony submitted on behalf of the claimant in this case in support of the remedial effect claimed for B. & M. consists of the testimony of Doctor Martin, who is the only physician testifying for the claimant, and the testimony of Mr. Rollins, chief executive officer of the claimant, and of Mr. Johnson, the president and counsel in this case for the B. & M. company, the latter testifying to personal experience of B. & M. as to a few of the less serious diseases mentioned and the testimony of certain laymen who were suffering from, or thought they were suffering from, some of the diseases mentioned. The reports and studies of Fenwick and Pease are not to be considered in this connection, as they are not supported by any legal evidence as to the statements or conclusions therein. You should carefully consider all this testimony submitted on behalf of the claimant and give to it such weight as you think it is entitled to in view of all the testimony in the case. You have seen and heard Doctor Martin testify. He is not a specialist in tuberculosis but is a Boston physician engaged in general practice. For many years he has been regularly on an annual salary of at first \$600, and now \$900, a year from the claimant corporation for medical advice which is given mainly in the form of correspondence with customers using or proposing to use B. & M. Doctor Martin testified to numerous and very remarkable cures effected by B. & M. in his personal practice. You heard his testimony as to what knowledge he had of the constituent drugs used in B. & M. You may have thought it was not very full or accurate. He was unable to submit any definite statement of how B. & M. accomplishes the results which he says he has noted. He submits a tentative theory of his own which finds no support in the whole field of medicine and scientific knowl-

edge as testified to by the Government witnesses. He is the only medical witness who undertakes to justify the claims made for B. & M. You should carefully consider his testimony and give it such weight as you think it is entitled to. You should also consider the testimony of Mr. Rollins bearing in mind that he is, of course, the most directly interested party in this controversy and the fact that he has had no scientific or medical education. He testifies to very many remarkable cures made by B. & M. according to his own personal observation. He has also submitted his theory and belief as to how B. & M. works and accomplishes the wonderful results claimed by him for it. It is fair to him that you consider that as a layman he has, of course, had the greatest opportunity to observe the use of B. & M. in actual experience. He, more than any one else, is in direct contact with the users of B. & M. Whether he is competent to diagnose and correctly interpret the diseases which he has mentioned in the cases of various patients and to reasonably interpret the effect of the use of B. & M. in the several cases, is to be determined by you and you can also consider, in weighing his testimony, the fact of his great personal interest in this controversy. You should also consider for whatever weight you think it may have, the testimony of the other laymen who, as witnesses, have testified to the effect they have noted in the personal use of B. & M. in various diseases from which they were suffering or thought they were suffering. About 20 lay witnesses testified for the claimant in this case as to various beneficial and curative effects from the use of B. & M. In connection with their testimony you can properly consider whether, in view of their lack of medical knowledge, they were competent to properly diagnose their own cases and to correctly interpret the effect of the use of B. & M. You can also consider the testimony submitted by the Government in rebuttal with respect to many of these cases in which tuberculosis was the disease dealt with, which is to the effect that the witnesses referred to, who thought they had been cured from tuberculosis by the use of B. & M., according to the testimony of Doctor Wolman, the tuberculosis expert who examined them during the trial, are still suffering from tuberculosis; and in some cases the Government has offered death certificates showing that persons said to have been cured of tuberculosis have shortly thereafter in fact died from tuberculosis.

"Very shortly summarizing the effect of the conflicting testimony on this issue, it is that the whole consensus of medical opinion is that B. & M. is substantially worthless in the treatment of the diseases mentioned; and as against this consensus of medical opinion the testimony of the claimant in support of the claims made for the remedy consist only of the testimony of Doctor Martin and the lay witnesses who testified from personal experience. This latter testimony the claimant refers to as empirical knowledge as contrasted with the scientific knowledge on the part of the Government. The claimant seeks to justify its representations to the public principally on this empirical knowledge. But you may consider that this so-called empirical knowledge with respect to tuberculosis is contradicted by some empirical and scientific knowledge contained in the testimony of Doctors Cullen and McMurray who used B. & M. in some 40 cases of tuberculosis without beneficial result. You may consider that the results of the use of B. & M. as observed by a competent and experienced specialist in tuberculosis are more valuable than the testimony of laymen based on their own untrained experience. And in this connection reference may be made to the statement in the claimant's booklet on page 5 as follows:

We expect better results invariably where the use of B. & M. is combined with other care and treatment by a skillful, conscientious and open-minded physician.

You can, of course, consider whether Doctors Cullen and McMurray are skilled, conscientious, and open-minded physicians.

"In reaching your determination on the issue of fact as to whether the claims made for B. & M. are false, you are, of course, not bound to accept the consensus of medical opinion as stated by the Government's witnesses. And you are not to be governed in any way in your decision by the fact that the United States, as represented by the Department of Agriculture, has decided to prosecute this proceeding. On the contrary, you are entitled fully to consider what weight the claimant's testimony on this issue has with you. If you reach the conclusion that the matter is one really of two schools of thought and that there is very substantial basis for the claims made and that the whole matter at issue is really only one of controverted opinion, then you should properly find for the claimant on this issue because where there is a substantial

difference of opinion between people who on reasonable bases think differently about a matter, that difference of opinion only can not be made the basis of a finding that the claims for the remedy are false. In any event, the Government having brought the charge has the burden of proving to your satisfaction by a preponderance of the evidence that the representations made are in fact false. I point out to you, however, on this issue, that there is here no mere conflict of opinion between two schools of medicine. The difference of opinion here is not between two groups of scientists holding opposing views, but (with the exception of the testimony of Doctor Martin for what value you attribute to that) the difference is between a practically nation-wide scientific knowledge on one side, and personal observation of a comparatively few laymen on the other side. I think you can very reasonably reach the conclusion in this case on this issue that after making all allowance for the good faith of these lay witnesses (which on this issue for the sake of the particular inquiry may be assumed) there still remains a field in which statements as to curative properties may be downright falsehoods and in no sense mere expressions of judgment. But however that may be, the issue is for you to determine from all the testimony in the case, giving the respective contentions such weight as you think they are entitled to.

"If you reach the conclusion that the representations as to B. & M. are substantially true, then your verdict should properly be for the claimant. But if you reach the conclusion that these claims are substantially false, then your next inquiry must be whether, in addition to being false, they are also fraudulent, because it is only in the event you find that the claims as made are both false and fraudulent that you can properly find a verdict for the Government and against the claimant.

"And here I must instruct you further as to what is the legal meaning of the word 'fraudulent' as here used. I have pointed out to you that the food and drugs act as originally passed and as construed by the Supreme Court did not prohibit even false branding of drugs in matters relating to their curative or therapeutic effects and to repair this omission Congress in 1912 by what is known as the Sherley amendment, amended the law to prohibit misbranding of drugs with respect to their curative or therapeutic effects, and prohibiting such misbranding in interstate commerce if the misbranding was false and fraudulent. This amendment of the law came before the Supreme Court of the United States for consideration in 1915 in a case entitled 'Seven Cases v. United States,' reported in 239 U. S. 510. The Supreme Court, by Mr. Justice Hughes (now Chief Justice), sustained the validity of the amendment and in discussing the law plainly explained the effect of the amendment and the force of the word 'fraudulent' as therein contained. It was there said:

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. 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. \* \* \* It cannot 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.

"It is clear from this pronouncement of law by the highest authority that to find the actions of the claimant fraudulent in this case you must find that they involved bad faith. And it is equally true that this bad faith may be inferred from all the circumstances in evidence. In this case the claimant is a corporation. As such it is, of course, an artificial being created by the law. But in determining whether its representations to the public are fraudulent you must look to the knowledge or lack of knowledge of its several officers who acted in the matter of making these representations to the public. If some of these officers knew, or must be held from the circumstances to have known, that the representations were substantially untrue, then the corporation has acted in bad faith and you can find in that event that the representations were both false and fraudulent. It is not a sufficient defense to the claimant in this respect to establish merely that one or more of these officers has an honest



opinion as to the truth of the representations. If any of them who acted in the matter within the scope of their authority and who had a substantial part in the making of the representations to the public did not honestly believe in the representations and had information and knowledge that the representations were untrue, you may find that the claimant corporation did not act in good faith but fraudulently. Now it is a sufficient defense to the corporation to show that one of the officers, to wit, Mr. Rollins, alone had a bona fide opinion as to the representations; nor is it a conclusion on this issue that Mr. Rollins states that he does not believe in the claims as made. You have a right to look at all the facts and circumstances in the case to determine whether the representations as made were in fact known to be false or if not actually positively known to be false then were made in reckless disregard of the truth which could have been ascertained upon reasonable inquiry from authoritative and reliable sources. Fraud in its very nature is difficult to define in any all-inclusive way. Here we are dealing with fraud in its relation to the state of mind of the officers of this claimant corporation. The fact that they say they were acting in good faith does not conclude the matter. You have a right to examine and determine from all the circumstances whether their statement as to their opinion is to be accepted and believed by you. If you find that they were in fact acting in good faith and with no intention to deceive the public, then you should find for the claimant in this case. If, however, you find that the statements made by them were made with knowledge of their falsity or recklessly made without reasonable grounds for making them in defiance of known authoritative information which was reasonably available to them and the failure on their part to make said reasonable inquiry, then you may find that they were acting in bad faith and fraudulently. The claimant should not be convicted of fraud merely because it advocates the theory of medicine which is not indorsed by the medical profession but it is equally true that when he fraudulently represents a medicine as a remedy he can not escape the consequences of his fraud by the mere fact that some one may honestly believe in the theory that he fraudulently and dishonestly exploits. The fact, therefore, if you find it to be so, that numerous persons who are laymen believe in the efficacy of this remedy is not a justification for the claimant in this case if its officers did not act in good faith. It is for you to determine from all the evidence in the case whether the statements of any of them are false and fraudulent. If you believe that the drug is so absolutely worthless, for example, for tuberculosis, pneumonia, bronchitis, influenza, or any of the diseases for which it is recommended to have a curative effect and that the claimant must have known it, then you would be justified in finding that the statement with reference to such disease or diseases is both false and fraudulent.

"The accepted legal meaning of the term 'fraudulent' includes false statements made in reckless and wanton disregard of their truth or falsity. Therefore, if you believe from the evidence that any one of the therapeutic claims made for B & M was false and was made by the claimant with a reckless and wanton disregard as to whether it was true or false, you may find a verdict for the Government.

"As I have said, you are to determine in the light of these principles of law whether the claimant has acted fraudulently or in good faith in the matter of these representations. You must consider all the testimony in the case on this point. It has taken a very wide range and comprehends the whole history of the relation of Mr. Rollins and the claimant corporation to this medicine. It is impossible to review it in detail but I shall endeavor to make a condensed summary or outline of the more important facts of the case bearing on this issue of fraud or good faith. And I think they will be clearer in perspective if they are stated largely chronologically.

"Mr. Rollins had no relation to B. & M. until after about 1913. For some years prior thereto he had been a court stenographer in Massachusetts. He knew a man named McClelland who owned the formula for B. & M. McClelland invited Rollins to become treasurer for his company. From McClelland, Rollins learned that in McClelland's association with a race track he had met a Doctor Burns (whether Burns was a doctor of medicine or a veterinarian is not entirely clear from the evidence), from whom he obtained the formula. Mr. Rollins understood that Burns was a medical man, a Cleveland doctor, and had two formulas for liniment, one for horses and one for men. Apparently B. & M., which is a coined phrase named after McClelland and Doctor Burns, was being sold by McClelland to the public as a liniment and possibly for other



purposes. Mr. Rollins says he used it on his hand for rheumatism which aided him in his court work as a stenographer. Later he used it on a member of his family for tuberculosis with very effective results. This member of his family was his daughter who has not testified in the case nor has there been any medical testimony as to her condition. I think that is true, although I am not absolutely certain about it. Mr. Rollins said he was impressed with the efficacy of the medicine and learned from personal experience of its beneficial effects in very serious cases of tuberculosis, rheumatism, pneumonia, etc. He thereupon began to acquire stock in McClelland's corporation and in a few years had bought out all the stock. The sale of the preparation to the public for a wide variety of diseases, including all those mentioned in this case and numerous others, principally including infantile paralysis, was continued. In 1920 Mr. Rollins' company, then known as the National Remedy Co., was prosecuted for false statements or misbranding in the Boston municipal court and found guilty on two counts out of many, and fined \$10. The opinion of the municipal court judge has been produced in evidence and found in effect the good faith of Mr. Rollins in that case. The quotation from the opinion in that case is carried on page 22 of the booklet in this case. Reference was made by the judge to the testimony of a Mr. Philbrick as justifying the claimant in some of its statements in that case, with regard to the effect of the use of B. & M. by Mr. Philbrick for a disease with which he was alleged to be suffering. The Government offers evidence in this case that about a year later Mr. Philbrick died from another disease which is among those for which B. & M. is recommended. Mr. Rollins knew of this fact. The quotation from the opinion is still carried in the booklet without reference to the specific cause of death of Mr. Philbrick. In 1919 the Government filed a condemnation proceeding similar to this against B. & M. in the District Court of New Hampshire. The case was tried in December, 1922. The jury found a verdict for the claimant. For reasons to be hereinafter stated, I must instruct you that the finding in this case is not conclusive in this present case nor a bar to its maintenance by the Government. It was, however, a finding that as of that date, to wit, 1919, the goods were not subject to condemnation either because the representations at that time were not false or fraudulent or neither false nor fraudulent. The result of this decision was perhaps naturally to fortify Mr. Rollins's belief that he had been vindicated. He continued to sell the preparation to the public and while the financial returns had been smaller up to that time, they shortly thereafter very materially increased. In recent years the gross sales of the business have amounted to \$130,000 to \$140,000. In 1931 the amount was \$110,000. The net profits have been approximately as follows: 1923, \$5,000; 1924, \$5,000; 1925, \$10,000; 1926, \$22,000; 1927, \$7,200; 1928, \$22,000; 1929, \$8,000; 1930, \$6,000; 1931, a loss of \$13,000. If these figures are not accurate they can be corrected by counsel. That is in accordance with my notes.

"In addition to this, Mr. Rollins's personal salary has varied from \$1,200 to \$10,000, and still in addition to this, since 1924, or 1925, the corporation has paid out extraordinary expenses for scientific investigations of nearly \$100,000, and for legal expenses approximately \$25,000.

"In 1929 the Government filed another libel condemnation proceeding against B. & M. in this district court of Maryland. After the case had been set for trial the Rollins company, which had intervened as claimant similarly as in this present proceeding, withdrew its claim and consented to a judgment of condemnation which was accordingly entered. At that time the claimant was represented by Mr. Johnson, now acting with Mr. Yost as trial counsel for the Rollins company. It was stated by Mr. Johnson that the reason for abandoning the test in that case was due to an unexpected discovery that there was a misstatement in the booklet, or claimant's literature, with regard to the percentage of the phenol coefficient (carbolic acid) present in the preparation and that this was due to an error made by one Fenwick, who was a pharmacist advising the Rollins company. It was, however, at that time pointed out to claimant's counsel that if the only change that was to be made was to correct this relatively minor error, another proceeding would promptly be brought and tried out on the full merits. Mr. Johnson then stated that it was the intention of his client to substantially revise its literature and claims so that there could be no cause for complaint by the Government and that steps would immediately be taken to accomplish this. Thereafter the Rollins company engaged the services of the Pease Laboratories at New York, a commercial laboratory said to be headed by Doctor Pease who is said to be a doctor of

medicine and who has wide experience in dealing with the Department of Agriculture in matters of this kind. Claimant contends that it has substantially altered its literature and that the present booklet is very different in the claims made from that previously made. On the other hand, the Government contends that there is little substantial change in the claims as made in the respective booklets. You have both booklets before you and can consider this point for whatever value it may have to you in determining this issue of fraud or good faith. Mr. Johnson also had various interviews with representatives of the Department of Agriculture in which he endeavored unsuccessfully to obtain their approval of the new literature. They warned him before its publication that it would be unsatisfactory and that any one issuing it would have heavy responsibility to justify it. Nevertheless new literature having been prepared or editorially supervised by Mr. Pease, was published and this proceeding has followed.

"You are also to consider on this issue of fact that Mr. Rollins testifies that he endeavored in good faith in the early days of his relationship with B. & M. and his control of the preparation, to have it adopted by the medical profession and have it used in various hospitals and sanitariums. He says it was refused by practically all for different reasons but mostly he attributes the refusal to use it to the fact that it was a proprietary medicine and therefore he charges in substance prejudice or lack of good faith of the medical profession in not adopting it. And you should also bear in mind the testimony of Mr. Rollins that during all the years he has been selling B. & M. he has had numerous testimonials from people suffering with tuberculosis and other diseases testifying to the efficacy of B. & M. This, he contends, has fortified his own opinion as to its usefulness. During the New Hampshire trial of 1922 Mr. Rollins was fully advised from the testimony of numerous scientists and doctors that in their view the remedy was worthless. There was also testimony in the case from certain laymen as to its efficacy. In addition to this testimony, medical and lay, Mr. Rollins admits that he was generally advised by physicians from time to time that the remedy was worthless. He discredited their opinion as of no value because he contends that it was based on prejudice against proprietary medicines or ignorance as to what B. & M. would actually do. He has steadfastly maintained his own opinion about the matter. He reluctantly accepted some diminution of the extent of his claims as set out in the booklet now on trial as compared with previous editions. He maintains vigorously that he is entirely right in his claims for B. & M. and that the medical profession as a whole is entirely wrong. He refuses to give any weight to their views. He maintains his own opinion despite practically universal medical opinion to the contrary, seeking to justify his opinion of what he calls empirical knowledge that is derived from actual experience from the use of a drug.

"You should also consider what is the weight and effect, if any, as bearing on this issue of good faith due to the fact that the Rollins company has in recent years paid nearly \$100,000 for alleged scientific investigations to demonstrate the efficacy of B. & M. in accordance with Mr. Rollins' own views, or to establish scientifically similar views. In 1924 Mr. Rollins employed a man named Fenwick, now recently dead, who was a pharmacist, to study the effects of B. & M. scientifically. And it is said that Fenwick performed various experiments on animals and devised a special apparatus for the purpose of testing the germicidal effects of B. & M. This apparatus has been shown to you by one of the witnesses. It is referred to in the present booklet. Mr. Rollins states that he received voluminous reports from Fenwick from time to time and these reports, or some of them, have been offered in evidence. Mr. Rollins contends generally that his opinion is to some extent confirmed or justified by these reports. Mr. Rollins says that his company paid Fenwick for compensation and for disbursements over a period of several years, about \$80,000 for this work. Mr. Rollins further admits that these scientific investigations as reported by Fenwick were not clearly understood by him. Some of the reports, or what purport to be copies thereof, have been offered in evidence. Their genuineness and other effect in this case bearing on the issue of good faith alone can be considered by you. It is not claimed that Fenwick had any medical experience or that he experimented with the drug on human beings. The Government contends that Fenwick's experimental data is of no value whatever and could not reasonably have been relied upon by the Rollins

company. While Fenwick was originally said to have been employed merely as a chemist by the Rollins company, it also appears that later he was called by the company, its Director of Research, and the large sums of money paid him would seem to indicate that he was in a very substantial sense an employee and agent of the corporation. Whether, under all the circumstances, Mr. Rollins or his corporation was substantially justified in making their statements in reliance upon anything Fenwick had said or done is for your determination, bearing in mind all the circumstances of the case including those already specially referred to.

"You will also bear in mind that the present booklet is said to have been prepared by Doctor Pease and a large amount of it, and particularly all of it under the head of scientific evidence, is the work of his laboratories based in part upon Fenwick's work and apparatus and that other parts of the booklet were under the editorial supervision of Doctor Pease. You can also consider the form and arrangement of the booklet in this case with respect to the matter in large type with reference to the treatment of various diseases and the so-called scientific evidence in small type. You can consider whether this scientific data thus arranged was for the purpose principally of being superficial impressions to the laymen or whether it has any real value to B. & M. with regard to the diseases for which it is recommended. In this connection you can bear in mind the testimony of Doctor Martin, claimant's medical adviser, that he does not understand the purport of the so-called scientific data and that in substance it was placed in the booklet, as he understood it, merely for advertising purposes and in effect that it really means nothing substantially to the laymen. You may possibly conclude that the effect of this arrangement of the booklet with reference to the so-called scientific evidence is to be impressive, rather than really informative. In this connection you can consider the testimony of the Government's witness to the effect that the scientific data is of no value as applied to the effects of B. & M. on the human being in view of entirely different conditions. All this has some bearing on the question of the good faith of the claimant in publishing the booklet. As to its weight in this connection you must be the judge of it.

"Another consideration of possibly even greater importance in this case is the nature of the claim made for B. & M. and the suggestion, at least, in the booklet as to the belief of Mr. Rollins as to how it works. You should consider this as bearing on the issue of good faith and real belief on the part of Mr. Rollins in the light of much common knowledge with respect to tuberculosis which is one of the diseases prominently and conspicuously mentioned in the booklet and as to which much of the testimony has related. You have been told that the tuberculosis germ was discovered about 1881 and as applied to tuberculosis of the lungs, this germ fastens itself within the lungs and becomes encased in a waxy capsule. Medical testimony is all to the effect that there is no known drug which, taken either externally or internally, can penetrate within the lung encased as it is, in sufficient quantities to destroy it. And that therefore, there is no medical remedy having any substantial curative effect for tuberculosis. The disease is widespread, is a great scourge, many people are infected with it, it is itself infectious and a great danger to the world. In recent years it is common knowledge that many millions of dollars have been spent in the treatment and cure of tuberculosis. Many hospitals have been established for the care of its patients. Much of this work has been charitable and philanthropic as well as Governmental. Hundreds and thousands of physicians have been seeking for the best method of cure. Complete rest, nourishing food and similar treatment is the only effective remedy according to the established medical opinion. Now in the light of all this knowledge, you should consider what is the claim that is made by Mr. Rollins as to how B. & M. works as bearing on his good faith. He says in the booklet that he cannot prove how it works but that he believes it works by penetrating through the skin and to some extent by inhalation through the mouth and that it reaches the germs encased within the lungs and draws the poisonous bacilli out through the body and through the skin in the form of eruptions or blisters, from which the poisonous matter is discharged. He contends further that B. & M. is a remedy for any germ disease within the body except possibly brain diseases and that the remedy if used long enough and as directed and applied to the skin will penetrate through the skin and in some way reach the germs wherever they are in the body. But that this cannot be accomplished with diseases of the brain on account of the thickness of the skull. Furthermore, he says the eruptions

on the body will appear only over the seat of the poisonous infections even though B. & M. is applied to other parts of the body. Medical testimony is to the effect that blisters on the body from the use of B. & M. result from the constituents of turpentine and ammonia in the substance. Now you will consider as bearing on the issue of good faith whether Mr. Rollins under all the facts and circumstances of the case honestly believes that the medicine will work this way. It is not sufficient for him or for other agents of the corporation merely to say that they believe it. The question is whether to find that they do honestly believe it. The theory advanced by Mr. Rollins is characterized in substance by medical witnesses as practically impossible. Doctor Geiling, eminent pharmacologist, testifying for the Government, says it is pure nonsense. Doctor Barker said the idea was purely medieval. Even Mr. Rollins admits he has no knowledge that the medicine does work in this way or what properties of the combination known as B. & M. are causative of this alleged result. He says it is a pure mystery to him but he knows it does so work. You will consider whether this claim which, after all is the one that Mr. Rollins originally had and which he has persisted throughout the last 15 years, is made honestly by him and is honestly believed in by other agents of the corporation with regard to the claims made to the public, or whether under all the facts and circumstances the idea is so fanciful, unsubstantial, unsupported by known scientific information, that it is incredible that any reasonable man should actually believe it in face of the fact that he also is perfectly well-informed as to the practically unanimous medical and scientific opinion to the contrary. In this connection you should also bear in mind, as said by the Supreme Court in the case from which I have quoted, that:

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.

"You can also consider the fact that it is, of course, to the financial advantage of Mr. Rollins to make these representations to the public and that sufferers from diseases that are hard to cure naturally look for help from any source from which it is thought obtainable but they are naturally credulous and generally hopeful and eagerly receptive to suggestions as to cures when their doctors can not themselves give them much hope.

"You can also consider testimony in specific cases offered by the Government tending to show a lack of good faith with respect to certain particular points or statements in the booklet. Time will not permit an enumeration of these particular instances which the Government sets up as specific badges of fraud. The testimony with regard to most of them is conflicting and you should consider the testimony of the claimant with regard thereto as well as that of the Government. Reference may be made particularly to one conspicuous illustration involving the relations between Mr. Rollins and a Mrs. Merchant, to which several hours of testimony were devoted. Mrs. Merchant, you will recall, was a sufferer from tuberculosis and claimed to have been cured by the use of B. & M. Her testimony was included in one of the booklets and continued until 1927. It is a very comprehensive and thorough testimonial. Many people who were presumably prospective customers for B. & M. wrote to her about it. She replied to them. The correspondence consisted of possibly an average of several letters a day over a period of several years. Mr. Rollins was advised of this correspondence. During this time from time to time, he made presents to her aggregating in all over \$1,100. He says that much of this was given purely as charity in her later years or when she again became ill and destitute. While she claims to have been cured of tuberculosis by the use of B. & M., the Government offers in evidence a death certificate showing that she died from pulmonary tuberculosis. Mr. Rollins disputes the accuracy of this cause of her death and attributes it to cancer of the rectum. He says her attending physician told him that that was the cause or one of the causes of her death. In the close of the correspondence Mr. Rollins suggested to Mrs. Merchant's son that he supposed the cause of death was cancer of the rectum and that it would be detrimental to his company if the real cause of death was tuberculosis. He inclosed a check to the son as a gift. The implication from all this should have your consideration. Mr. Rollins contends he was acting throughout in entire good faith.

"Another case that has been specifically mentioned by the Government as indicative of fraud but denied in testimony submitted by the claimant, is that of Agnes Lovejoy who was referred to by name in some of the earlier booklets as cured of tuberculosis of the joints by the use of B. & M., which disease is

also referred to specifically in the present booklet, and Mr. Rollins says that the Lovejoy case, although not specifically named in the booklet, was in his mind as a basis for that recommendation. But the Government contends that the Lovejoy case was the one which was involved in the Boston trial and the claimant continued to make statements of the case after Doctor Sever testified that Agnes Lovejoy was cured before discharge from the hospital and before the use of B. & M. The present booklet refers to certain cures of tuberculosis treated with B. & M. by Mrs. Hammond. The Government has offered testimony tending to show that B. & M. had no substantial part in the treatment of the majority of these persons so referred to. This again is disputed by the claimant and the testimony is conflicting. The method of treating customers of B. & M. by correspondence is advanced by the Government as indicative of reckless actions in the treatment of diseases by the claimant and as suggestive of lack of good faith by reason of its recklessness. You can also consider that in the early days around 1915, Mr. Rollins stated that B. & M. was cordially recommended for various diseases by three doctors whom he named. Two are now dead and one called as a witness by the Government has testified that Mr. Rollins has either grossly exaggerated or entirely misstated the effect of his statements to him, Mr. Rollins, as to the effect of the use of B. & M. His testimony is categorically denied by Mr. Rollins. The case of a Mrs. LaPierre as alleged to have been cured of tuberculosis by the claimant is cited despite the fact that her death certificate shows she died of tuberculosis May 3, 1914. Mr. Rollins disputes this.

"You can also consider the fact that Mr. Rollins and Mr. Johnson, to a lesser extent, after hearing all the medical testimony in this case maintain their position and their opinions and in substance give no weight or effect whatever to the Government's testimony as affecting their views. Arguments in favor of their respective positions over this are made by both parties. The Government contends that such an attitude is evidence of reckless disregard of the very highest and most authoritative and informed medical opinion without adequate basis for rejection of it. The claimant relies on the circumstance as indicative of their persistent and consistent good faith. The jury can make their own inferences in this respect. The jury may also consider what inferences are to be drawn from the failure of the claimant to call Doctor Pease as a witness in this case. As he has not been called as a witness it is clear that the jury cannot consider the scientific work that he is said to have done in support of the claimant's position. The fact that he did the work and made the reports and was paid \$15,000, for the work by the claimant is relied upon as showing their good faith with respect to the claims contained in the booklet. While Doctor Pease has not in fact been called as a witness, claimant's counsel states that he was in court during the taking of the Government's testimony for a week or more and that they fully expected to call him as a witness in this case. They expressed great surprise and disappointment that he refused to stay and testify. The Government in the closing days of the trial upon learning definitely that the claimant did not expect to call Doctor Pease as a witness, obtained a special order for him to be summoned. His business is in New York and his home is near by. It is reported that the summons has not been served on him. In the absence of any other testimony with regard to Doctor Pease the jury fairly can not consider anything other than the bare fact that he is not called as a witness for the claimant. This fact is a matter of argument and possibly inference which may be addressed to you by counsel for the parties respectively. In connection with the good faith of the claimant in relation to Doctor Pease and whether the claimant was justified in relying upon his reports and experimental work, you can consider all the facts and circumstances in the testimony. It appears that Doctor Pease was first employed by Mr. Johnson as an expert witness to testify in court in support of the claim. Later, after the claimant determined to change its literature, Mr. Johnson says he employed Pease to advise them generally with regard to what claims they could justly make. Claimant contends that as a result of this it substantially changed this booklet. The Government contends there is no substantial change. You have both booklets to compare in this respect. You may bear in mind that the essential nature of the claims for B. & M. was advanced many years ago by Mr. Rollins, and his company, long before their contact with Doctor Pease.

"There are some other matters in this connection that you should bear in mind, particularly in weighing the testimony offered by the claimant in sup-

port of its good faith. The law does not presume that statements, even though extreme, are fraudulently made. The burden of proof is on the Government to show that they were fraudulent by a preponderance of the evidence. The claimant has spent large sums of money for laboratory work and scientific investigations. This has already been mentioned in another connection and is possibly susceptible of different interpretations as applied to the results of the work in this case. Claimant contends that the large sums paid for this work indicate its right to substantially rely thereon and that it would not pay such large sums for work if they did not believe the work honestly represented results of bona fide work done by those who submitted the reports. You can also consider on behalf of the claimant for whatever you may think they are worth in the testimony the large number of testimonials received by the claimant as to favorable results from the use of B. & M., and you may consider the results of personal use by Mr. Rollins of the drug upon himself for various ailments, some of a virulent nature, and in which he says B. & M. has cured him and that he relied upon B. & M. for this purpose without calling in any specialist to treat him for the infections, consulting only Doctor Martin. During the progress of the trial the Government has called for numerous papers from the claimant and the latter contends it has supplied any and all data from its files so called for. Certainly it has supplied a great deal of such information voluntarily. You may also consider that one of the agents of the corporation, Mr. Rollins, is not a highly educated professional man but is a person of only ordinary intelligence but in this connection you should also bear in mind that this comment is not applicable to other agents of the corporation whom you may find to have had some substantial part in making the representations to the public. You can also consider in this connection what has already been said on the subject that the claimant says it relies upon what it believes to be competent and outstanding scientific advisers in the preparation of its literature and accepted the advice of such advisers, particularly Doctor Pease, to the extent of subordinating or somewhat abating its views or contentions in statements which Mr. Rollins believed to be true with reference to the merits of the drug.

"It is not possible even in this lengthy charge to review all the evidence in this case bearing on the issue of fraud or good faith. In the last analysis it is a question of fact for you to determine from all the facts and circumstances in the testimony. I again summarize it briefly by saying that if from all the facts and circumstances you determine that the agents of the corporation acted in good faith and with no intention to deceive the public and that the honest conviction that their statements were true and that this conviction is not merely a reckless assertion but a bona fide belief founded on reasonable basis, then you should find that the statements were not made by the claimant and you should find for the claimant. If, on the other hand, you are satisfied by a preponderance of the evidence that the statements as tested by the above principles of law defining fraud were in fact fraudulent and if you have also found the statements to be false, then you should find a verdict for the Government.

"I will say a word to you with regard to the effect of the New Hampshire case tried in 1922. I previously stated that you were not to regard that case as a bar to this proceeding. I have, however, admitted the important papers relating to this case into evidence for whatever bearing they might have on the state of mind of the claimant's officers with regard to fraud or bad faith. Ordinarily a case tried between the same parties involving the same subject matter and decided on its merits is a bar to further litigation on that same case. But in my opinion the case now being tried is not the same case as was tried in New Hampshire because the legal issue that was there tried was the relation of the literature then published to the drug and involved, among other issues, necessarily the issue of fraud or good faith as of 1919 on the part of the claimant. This case arises and is tried more than 10 years after the New Hampshire case. It is contended by the claimant in this case that the booklet has been entirely rewritten. Therefore, there has been a change in the subject matter, but perhaps even more importantly in this case, the developments during this period of 10 years may make a very great difference from the standpoint of whether what was claimed in good faith by Mr. Rollins in 1919 can still be said to have been claimed in good faith by the claimant in this case as of 1931. To some extent there has been a change in the officers of the company, many things have happened since 1919, much additional information has been obtained or has been available to the claimant in these 10 years, other cases have been brought and disposed of, including the 1929 case in this court,



negotiations have taken place between the claimant and the Department of Agriculture, and generally speaking, it is entirely possible that the facts and circumstances relating to fraud or good faith of the claimant in 1931 may differ vastly from those existing in 1919. And as to the 1929 case disposed of heretofore in this court, it also, in my opinion, is not an estoppel as against the claimant because it appears that although that case was abandoned by the claimant yet there was no trial on the merits.

"There are some general considerations which I think are reasonably implied in what I have already said but which it may be just as well to express to you. There has been some testimony in this case on behalf of the claimant and some expressions of counsel for the claimant in which possibly it might be inferred that this is a case of a medical profession against the Rollins company. That is, of course, not true. Anything that has been said along this line is to be properly understood only as in criticism of the testimony of doctors who testified as witnesses for the Government. The proceeding is by the United States Government and not at all by the medical profession. The medical testimony is that of witnesses only.

"The proceeding is not for the purpose of completely stopping the sale of B. & M. It is aimed only at the condemnation of B. & M., which is sold to the public under representations that it is a remedy for specific and particular diseases complained of in the Government's libel, which had been heretofore mentioned. It is not contended by the Government that B. & M. may not be properly sold as a liniment and used for such purposes. It is also not contended that it may not be sold for various skin troubles such as athlete's foot, or for sprains, bruises, or insect bites. It is not contended by the Government that B. & M. has no curative qualities in the way of destroying the germs with which it can come into contact. Therefore, your verdict in this case if it should be for the Government will not prevent the sale of B. & M. for the treatment of diseases which are not complained of in the libel. But if you find that the claims are false and fraudulent with respect to any one or more of the diseases so mentioned, then your verdict should be for the Government. It is not necessary for the Government to show that the claims are false and fraudulent with respect to all of the diseases complained of. If it is false and fraudulent as to any one, that is sufficient.

"In determining whether the claims are false and fraudulent you may take into consideration the fact that when an individual or company puts out a drug intended for use by persons so credulous as those suffering from disease such individual or company is assuming a great responsibility and extreme caution should be exercised in informing the public of the curative or alleviating properties of the drug. Great and lasting injury to the health of individuals may result if misstatements are made as to its curative effects by inducing its use in incipient stages of diseases upon which it has no effect, which, if taken in time, might by proper treatment be cured. Knowing and realizing this as every owner of a proprietary medicine must, if he is a person of intelligence, it is for you to say whether or not he should not first ascertain just what its curative and therapeutic effect is upon the diseases for which it is recommended. In this connection and in this case you can consider whether the investigation originally made when the drug was put on the market was sufficient and reasonable or insufficient. You can also consider what has been done in the way of scientific investigations by the claimant in later years and whether the results of this investigation reasonably justified the continuance of the claims as modified and as now made. The testimony shows that large sums of money have in recent years been paid by the claimant for alleged scientific data. You can consider the source from which this information was obtained by the claimant and whether it was selected with reasonable judgment and good faith as authoritative and reliable. It is said by the claimant that the investigations have still not been completed. You can consider whether the claimant has acted reasonably in reference to its claim of good faith in putting out the product before these investigations have been completed, or whether, consistent with its claim of good faith, it should have waited the results of the full investigation before selling the drug to the public under the representations made. In this connection, you may also bear in mind claimant's testimony to the effect that he believes the investigations that have been made are sufficient to justify the claims as made. This case does not involve in any way the right of any person to buy what medicine he pleases and use it for what he pleases. Or, as expressed by counsel for the



claimant, the case does not involve, nor does it deny, the right of self-medication. Nor does the law prohibit a man or corporation from making any medicine he wants to and sell it to the public if he honestly tells the truth about it.

"I have been asked by the parties to give you certain specific instructions. In the charge which I have given you I have covered most of the matters about which specific instructions have been asked by the parties but a few may not have been expressly referred to and I will now cover them.

"You are instructed that you cannot infer that a statement is fraudulent merely because it is false. The Government must prove both by a preponderance of the evidence. With reference to statements in booklets other than those involved in this present case, you are instructed that a verdict for the Government must be based only upon false and fraudulent statements contained in or upon the cartons, bottle labels, and booklets involved in the present seizure and complained of in the libel in this case, and particularly Exhibit B filed with the libel. Any evidence of statements in the booklet has been admitted only upon the evidence of the intent of the claimant in the issuance of the present booklet and your verdict, if against the claimant, should not be made on the basis of statements in former booklets alone. You should not base a verdict for the Government merely upon your own belief that the statements in the booklet in the present case are false and unfounded. If you believe that the claimant was even grossly in error in making the claims, that is not sufficient. You must find that the statements were made fraudulently within the principles above outlined. The point of time as of which you must find that the statements in the booklet were false and fraudulent is the time of the shipment of the particular articles in interstate commerce which was in this case on or about August 1931. As I have said, the burden of proof is on the Government to establish both the falsity and the fraud claimed by a preponderance of the evidence. If after considering all of the facts of the case the minds of the jury are in a state of equipoise on either the question of fraud or the question of falsity, then your verdict must be for the claimant; that is to say, if you find the evidence on each side on either of these questions is equally weighty, then the Government has not established the affirmative by a preponderance of the evidence. In considering the preponderance of the evidence you are not limited to the mere number of witnesses on a particular issue, but you may consider the quality and quantity of testimony bearing on the issue. You are instructed that your verdict, if for the Government, must not be based upon false and fraudulent statements in the booklet which do not relate to the curative or therapeutic effects of B. & M. You are also instructed that in determining the question of fraud or good faith the agents and officers of the claimant corporation are not necessarily to be held to the standards of knowledge of a physician, and the question to be determined is not primarily what a physician or scientist would believe but what the claimant's agents having charge of the matter honestly believe, bearing in mind also, however, as I have said, that the manufacturers of medicine sold for serious diseases are in a position to have and should have superior knowledge upon the subject to that of the general public and must be held to good faith in their statements accordingly. In considering the two issues of falsity and fraud or good faith presented, you are to consider the carton, bottle label, and booklet in their entirety and all that is contained in them as bearing upon the good faith of the representations of the claimant.

"In considering whether B. & M. is a remedy as recommended in the treatment of the diseases mentioned and complained of by the Government, you may consider the effect which the different drugs acting together, or in combination with each other, will have on the human body, but you must also consider the effect of the application as a whole and the manner in which the directions call for its application so that its usefulness, if any, of one or more of the ingredients of B. & M. if separated from the other in the treatment of diseases, is no conclusive proof of the remedial value of B. & M. in the treatment unless good derived from the application of the whole is less than the harm caused thereby.

"In considering the effect of the reports of Pease and Fenwick, as I have heretofore indicated, they are to be considered by you only on the question whether or not the claimant acted in good faith and you must not accept such reports as any proof whatsoever of the scientific truth or accuracy of the

theories or statements made in these reports, Fenwick having died before having testified in this case and Pease not having been called as a witness.

"Finally, gentlemen, if your verdict is for the Government, when called upon by the clerk for your verdict, you will be asked, 'Who shall speak for you?' and you shall say your foreman, and the foreman will then be asked for your verdict, and if it is for the Government, you will say, 'We find for the Government.' If, on the other hand, you find for the claimant, then the answer will be, 'We find for the claimant.'

"I am very sorry indeed, gentlemen, to have had to enlist your further attention to this lengthy charge. The case, as you know, is a highly important one. I am sure that you all have but one desire, and that is to render a public service in the interests of impartial justice in accordance with your very best judgment about all the testimony in this case, to which I noted you have listened so very attentively, sometimes under circumstances of not too comfortable conditions as to weather or otherwise.

"Gentlemen, and counsel of the bar, to the extent that all requests for instructions submitted by the respective parties are not covered in the charge, they are hereby rejected, and exceptions noted on behalf of the parties respectively.

"Of course, it is the usual practice in the Federal courts if counsel desire to take exceptions to the charge as given, they must be specific, that is, to the particular parts of the charge."

Mr. YOST. May we confer just a minute on that question, your honor?

The COURT. Yes. Gentlemen of the jury, we will take a recess for 10 minutes.

Mr. YOST. Your honor, there are just two exceptions. While the reference to them may be involved in the prayers, there were so many prayers I should like to make these specific exceptions: In the first place, I should like to except to what we consider the broad definition which the court has given to the words "remedy" and "therapeutic." Our idea is that they are susceptible, properly, of a narrower construction.

The COURT. Well, is that all you want to say on that?

Mr. YOST. Yes.

The COURT. I have very carefully considered that and I will have to stand by the instruction I gave to the jury on it. Exception noted on that point.

Mr. YOST. Secondly, your honor has referred to knowledge of the several officers of the corporation as constituting the knowledge of the corporation, and then you have referred, of course, to the testimony of Mr. Johnson as president. It is undisputed that at the time this literature was issued, and at the time of these seizures, Mr. Johnson was not president of the corporation. The issue in this case is the intent at the time of these seizures, and I think that that fact, as a matter of law, should be pointed out to the jury because I do not think that Mr. Johnson's intent now has anything to do with the question, has any bearing upon the question of the intent of the corporation at the time the literature was issued, and the seizures in this case made.

The COURT. Well, I leave that issue as to who were the officers of the corporation at that particular time entirely to the jury.

Mr. YOST. Of course, there is no evidence to the contrary, your honor, I take it.

Mr. SOBELOFF. Yes, there is, and I will point it out.

Mr. YOST. And that is a matter of argument, I assume. I know of no other evidence. Your honor also uses the phrase at one point that the manufacturer of a drug must use "extreme caution." We think that is further than the decisions go, and that he is only answerable for reasonable care and good faith, rather than extreme caution.

The COURT. Now, let me consider that a moment: I think I would say to the jury on that that the amount of care that must be exercised is, of course, that which is reasonable in the light of the recommendations made, and the nature of the disease for which the recommendation is made, how serious it is, how serious may be the consequences of a mistake, or of a wrongful representation. As applied to some of the diseases in this case, it is clear that they are highly dangerous to the community, to the individual, and the proportion of care that must be exercised must be in proportion to the nature of the thing that is done in the way of representation. From my point of view care which would be reasonable in one connection might be regarded as extreme care in a less important matter. I attach no particular importance to the use of the word

"extreme" as used. I think, probably, your view that it must be reasonable, but reasonable in the light of the subject matter to which it is applied, is probably the correct one, and the jury is so instructed.

Mr. YOST. On the question of res adjudicata, I understand your honor's ruling to be that while the New Hampshire case established the fact that at that time there was no bad faith, or no falsity, either one or both, that that did not necessarily conclude the present litigation, because there is a change in the literature and that, therefore, different issues are involved. I take that to be a ruling on your honor's part that, as a matter of law, the issues are different. We are of the opinion that the difference in the booklets, as to whether there is any substantial difference in the booklets, and, if so, whether the claims in the 1919 literature are broader than the claims in the present literature, and, therefore, substantially cover the present claims, should be left as a question of fact to the jury. I am not quite certain whether, under your honor's instructions, you meant to leave that open to the jury or not, or whether you have ruled on it as a question of law.

The COURT. Well, at the earlier stages of this case I suggested, for consideration of counsel, possibly, the testimony could be limited on the issue of good faith, particularly as to matters arising since 1919. Apparently, counsel for the claimant did not take that view of it, because they themselves decide to put in evidence facts and circumstances prior to 1919. I, therefore, thought it was unnecessary to make any further distinctions about that case except to say that in my opinion it is not res adjudicata as to this.

Mr. YOST. And there was one further extract from the charge: Your honor emphasized, I thought somewhat negatively, from the claimant's standpoint, to the jury that they might consider that as the result of their finding, or, should they not find for the Government, they might consider the dilemma in which sufferers from certain diseases might be left by being misled into using something that would not be of any help to them, without in any way offsetting that by a positive statement that, of course, if the remedy has any therapeutic value, in the minds of the jury, and they find for the Government, they might at the same time be depriving the public of a remedy that might be helpful to them. In other words, I think the negative emphasis was placed on that matter.

The COURT. I think whether the matter is affirmatively indicated is dependent on the view that the jury takes of the facts. In the first part of the charge I said that the case, in my opinion, is a very important case, according to both the contentions of the Government and of the claimant, that the result would be likely to affect, importantly, the health, if not the lives of a great many people. The Government's contention is that the continued sale of this preparation to the public under the recommendations made tends to induce sufferers from some very serious diseases, particularly tuberculosis, to rely upon the remedy, which the Government says is of no value, and to neglect proper medical advice which might be of real help, while the claimant's contention in this case is that the remedy is so wonderfully efficacious that it ought to be used by every physician for the treatment of these major diseases, including tuberculosis, and if the B. & M. company can not sell it for use in the treatment of tuberculosis the public will be deprived of a very valuable remedy. Now, whether those two things are true is an issue in this case.

Mr. YOST. That is all I have, your honor.

Mr. SOBELOFF. The charge is satisfactory to the Government. We have no exceptions, and in view of the very complete review of testimony which is contained in your honor's charge, at the request of both the Government and the claimant, a good part of what I would have said in my opening argument becomes unnecessary to say. I am perfectly willing, if it is agreeable to the court and the claimant, to waive my opening argument.

The COURT. Whatever counsel for the claimant desire to say as to that is, of course, agreeable to the court. I am rather disposed myself to suggest that in a case of this importance, which has taken so long to try, probably it would be more satisfactory both to the jury and to counsel for the claimant, to have the Government make at least some opening argument. You do not waive your concluding argument?

Mr. SOBELOFF. No, sir.

The COURT. I think it is better to have the opening argument made to the jury. Now, gentlemen, as to the practical question of time: The case has taken so long to try, there has been so much testimony, that I am in no dispo-

sition at all to unreasonably, if at all for that matter, limit counsel, but I have indicated that I thought that three hours on each side, is, perhaps, enough for counsel to cover the case in argument. Unless I hear some dissent from that view, I think we can proceed on that assumption, citing quite a legal precedent for similar conditions that, in the appellate courts, while counsel are permitted to take that length of time, they are not obliged to do so. Proceed, Mr. Sobeloff.

Counsel for the Government and claimant thereupon delivered their final arguments, at the conclusion of which the court further instructed the jury.

The COURT. Gentlemen, you are now ready to retire to your room. The clerk will give you, as is customary in all cases, simply the papers in this case; that is the libel papers. There are two cases consolidated, but they are treated as one, and there is no real difference between them, except they are two different seizures here in Baltimore made at two different times. I think I will not ask the clerk to give you any other papers than that unless you ask for them. If you want other papers, you can ask for them from time to time; but to start with I should think that the request should come from you, if you want anything more than just the ordinary papers. \* \* \*

"Of course, you will remember, gentlemen, in addition to this charge as given yesterday morning, there has been one or two things said since then. You will recall them, I think. The principal thing was that this morning I called to your attention that as to Mr. Johnson the evidence showed that he was not president of the company at the time the shipment was made. And it resulted from that, in view of other testimony, that the inquiry particularly with regard to good faith of the officers of the company resolves itself into an inquiry as to Mr. Rollins in that connection, in connection with which, however, you should consider from the standpoint of the claimant corporation as a whole, what information and knowledge and notice it had by virtue of what it learned from Mr. Johnson's activities in the case as its counsel. But in testing the good faith of the individuals, it must ultimately substantially in this case relate to Mr. Rollins.

"However, you will bear in mind that the claimant is a corporation, and if the evidence shows the lack of good faith on the whole, you can consider all the evidence with regard to it.

"Now, is there any other paper you would like to have, gentlemen?

The FOREMAN. Your honor, in the matter of rendering the verdict on behalf of the jury, the mere statement of the verdict for or against the claimant or for or against the Government is sufficient for the court?

The COURT. Yes. The procedure will be this: When you have agreed upon the verdict, you will advise the bailiff, who is your officer in charge, that you have agreed. You need not say any more than that. And then the court will be advised, and you will come in court. The clerk then will call off the jury list and see that you are all here. And then he will ask you if you have agreed. If you have, then he will ask, "Who shall speak for the jury?" And the response is, "The foreman." And then he will ask you, "How do you find your verdict in this case, for the Government or for the claimant?" And your reply will be in accordance with your verdict as you have reached it.

The FOREMAN. There is some question relative to the specifications, whether you eliminated two and three. I think you said you did.

The COURT. Yes.

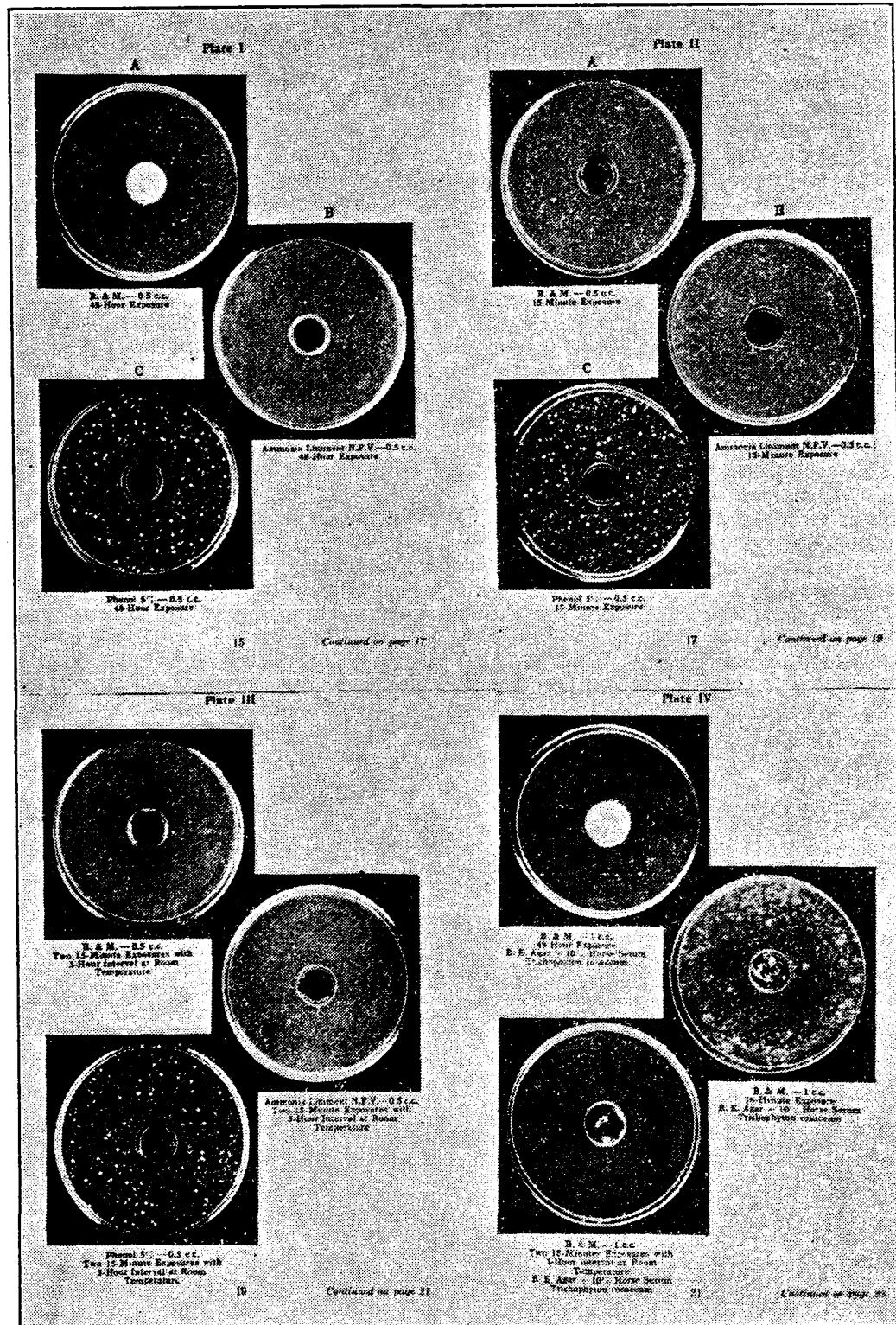
The FOREMAN. I wanted to get clear on that one point.

The COURT. They are out of the case. You need not bother with them at all in the form of your verdict. The only charge that is the basis of the condemnation in this case, as sought by the Government, and defended by the claimant, is contained in paragraph four. And that is the one that you have heard about, the alleged misbranding as false and fraudulent.

On July 19, 1932, the jury returned a verdict for the Government. On July 28, 1932, a motion for a new trial having been withdrawn by the claimant, the court entered a decree ordering the product condemned and destroyed.

The extracts from the labeling which the libels charged to be false and misleading and which were dismissed by the court, were as follows. Exhibit A (booklet cover) "For External Applications, Inhalations, Antiseptic." \* \* \* [p. 1] An Antiseptic \* \* \* Application \* \* \* For Antiseptic Applications \* \* \* [p. 6, 7] Mr. F. E. Rollins, who controls the manufacture and sale of B. & M., believes that B. & M. applied to the skin and inhaled as directed, actually penetrates to the seat of the infection and kills the germs themselves. He is not a physician or a scientist. He has formed this

opinion from his own personal experience on himself, by observation of others, and from what he has been told. We want to say frankly that we are not now able to prove by scientific and legally-competent evidence that this is true. Neither has it been demonstrated to our satisfaction that it is not true. Con-



sequently, while we believe it, yet we desire clearly to be understood as making no claims or representations that B. & M. acts that way. \* \* \* [p. 9] B. & M. under laboratory conditions of testing, will kill certain disease-producing germs commonly employed to study antiseptic action—germs of a kind

more than ordinarily resistant to antiseptics and the use of which in such tests has the approval of certain Government officials. B. & M. contains certain ingredients which will act antiseptically as just stated, even after they have penetrated through jellies and animal membranes, such as freshly-killed guinea pig skin, which are frequently employed in the making of such laboratory tests. \* \* \* We do not claim that the conditions inherent in and surrounding the laboratory methods of study are identical with those which exist when B. & M. is applied to the human body. No tests thus conducted could ever hope to duplicate exactly all the variable and changing conditions of natural use. Laboratory tests of these types avoid some at least of the variabilities which exist in people of different body tendencies, past disease histories and unlike conditions of health and disease. These tests serve also to measure the germ-killing effects as compared with those resulting from like testings of other perhaps longer known germicides such as carbolic acid, or preparations of somewhat similar types, which are made according to professionally approved methods and have had legal federal and state recognition for considerable periods. Of still greater importance is the fact that the results of these types of researches can be expressed in relatively precise or graphic forms so that the reader may gather for himself some ideas as to the ways in which B. & M. acts under the conditions of such investigations. Some of the methods thus employed are quite commonly used by modern laboratory investigators, both in official departments having statutory regulation powers over the sale of foods and drugs and in educational and other institutions. Others of the methods were developed by those who have been intensively endeavoring to reveal the scope and limits of germ-killing action of B. & M. and some of the ingredients used in its preparation. \* \* \* [p. 11] B. & M. is recommended to be applied to the skin in its fluid state and without dilution and obviously its first effects result from these direct applications. Hence when the germ-killing powers are subjected to appropriate testing, the results first to be shown should be those obtained from the direct application of B. & M. to germs. The following tabulation shows the number of a certain type of germs found to be still capable of growth in a cubic centimeter (about fifteen drops) of the testing mixtures of B. & M. and water dilutions, after exposing several million of these germs at the temperature of the human body to these mixtures for the number of minutes indicated at the top of each column of the results. The culture of the germs employed in this test is one having federal official recognition and was obtained from a severe case of infection.

"TABLE I

" [Tabulation of Results of Test with B. & M. for Germicidal Powers when Direct Contact Exists with the Germs]

Product tested	Dilution	Number of germs per c c. (15 drops) surviving after:			
		15 sec.	30 sec.	1 min.	3 min.
B. & M.-----	(Undiluted.....)	1,700,000	600,000	950,000	230,000
	1:2.....	4,000,000	3,500,000	1,100,000	1,100,000
	1:5.....	42,000,000	33,000,000	22,000,000	10,000,000
	1:10.....	96,000,000	48,000,000	46,000,000	36,000,000
Control.....	(Water).....	92,000,000	84,000,000	86,000,000	87,000,000

Product tested	Dilution	Number of germs per c c. (15 drops) surviving after:		
		5 min.	10 min.	15 min.
B. & M.-----	(Undiluted.....)	92,000	16,000	00
	1:2.....	700,000	260,000	140,000
	1:5.....	12,000,000	3,200,000	1,000,000
	1:10.....	24,000,000	12,000,000	4,800,000
Control.....	(Water).....	78,000,000	77,000,000	79,000,000



"These results indicate a speedy and progressively destructive effect of B. & M. upon this species of germ during the first fifteen minutes of contact between them and even when the B. & M. is diluted several times with water. B. & M. is recommended to be used without dilution on the skin except in rare cases and then only with an equal amount of water. As a spray for the nose and throat the dilution recommended is one part to 10 parts of water. Even in this latter dilution the B. & M. solution has a pronounced destructive effect upon the germs in 15 minutes under the conditions employed. Keeping in mind that B. & M. is applied like an ointment or liniment, and it is recommended to be applied full strength repeatedly at each spreading period, usually several times a day, there are presented next the results of a series of tests using a culture of the germ above referred to as from a severe case of suppurative infection and the disease producing powers of which were determined by federal officials. The method of testing is well recognized and the products tested in comparison with B. & M. have legal and official recognition. The germs of this culture are sown in a solidified jelly containing ten per cent of the albuminous fluids of horse blood and possessing a standardized power of promoting growth of these germs when incubated at an appropriate temperature for a given time. The nutrient jelly is solidified in shallow glass plates with removable covers and a hole or cup is made in the center of the jelly into which the B. & M. or the other products used for comparison are placed in measured amounts before starting the incubation. If the antiseptic or germicidal ingredients can penetrate into the jelly before the germs can grow into visible mounds [p. 13] or colonies then there will be zones around the hole or cup showing no spots or colonies of germ growth. The characteristics and the width of these zones of clear jelly will permit the reader to compare the germ affecting powers of the preparations thus tested. \* \* \* Obviously from the results occurring under these conditions, as shown by the plates, B. & M. exhibits marked power of preventing the growth or killing these pus-producing germs. \* \* \* It may be claimed that taking two days for action constitutes too long a period to indicate practical efficiency under the usual conditions of use. In the next series of tests, the time period of contact of these products in the cups in the jelly was reduced to 15 minutes and double the amounts of each of the products were placed in the cups. After 15 minutes, all of the B. & M. and other products which could be, were carefully removed from the cups and then the plates were incubated for 48 hours with the results shown in Plate II. B. & M. is recommended for repeated application. In Plate III are the results of another series of three photographs with two applications of each of the three products three hours apart and left in the cups for 15 minutes each and then removed as far as possible. \* \* \* While these results might not be considered as constituting proof that the antiseptic ingredients of B. & M. would penetrate into the tissues of the human skin to the same degree as they do into the germ nutritive jelly, other lines of scientific research go further towards indicating penetrative power. Scientists devoting much time to B. & M. problems developed a form of apparatus in which the germs of disease inoculated into a moving portion of blood without the colored cells, i. e., the serum, or a moving flow of beef broth standardized to promote the growth of the germs, are brought into contact with an animal membrane covering the outlet of a jar containing the B. & M. or other products under investigation. Thus the flow of germ-containing blood serum [p. 23] or broth passes one side of the animal membrane and on the other side of the membrane is the application of the B. & M., the official liniment or other product being tested. There is no possibility of interchange of fluids except through the animal membrane. The temperatures of the serum or broth and of the membrane at the point of treatment are substantially those of the skin of the human being. The culture of germs used in the first series of such tests employing this Membrane Penetration Apparatus was the same as already mentioned as having a degree of infection power recognized by federal officials. The time period of such contact of each of the flowing fluids with the membranes having one of the products under test on the opposite side has been six hours. Chemical and germ tests of samples of the infected fluids were made at hourly intervals or oftener. In Table II will be found the results of two tests in which B. & M. was the product placed on the upper side of the animal membrane of parchment, in this case Goldbeater's skin. In test (A), the infected circulating fluid was undiluted blood serum taken from a normal horse. In test (B), the infected fluid was standardized nutrient beef broth.



"TABLE II

"Tabulation of Results showing the number of surviving Germs in (A) Circulating Infected Horse Serum and (B) Circulating Infected Beef Broth, after Flowing Over Animal Membranes with Undiluted B. & M. on the Opposite Sides of the Same.

Time in Contact		pH	Test A Numbers of Surviv- ing Germs	pH	Test B Numbers of Surviv- ing Germs
Start of test.....	acid	6.7	3,200	6.5	3,900
1 hour.....	neutral	7.0			
2 hours.....		9.1	3,100	10.2	3,000
3 hours.....		9.1	3,400		1,200
4 hours.....	alkaline		3,200		10
5 hours.....			3,000		0
6 hours.....		9.3	810	10.2	0
			290		0

\* \* \* [p. 25] Thus in tests with this apparatus there have been found not only substantial reductions in the numbers of living germs in the circulating broth or serum, amounting in some cases to evidences of complete sterility within six hours or less, when B. & M. was employed, but chemical tests applied to small samples of the flowing fluids at fixed time periods during the investigation give conclusive evidence of penetration through the membranes of volatile alkaline ingredients of these products. It was remarked earlier that the germ employed in the tests, the results of which have been reported was one of more than ordinary powers of resistance to antiseptics. It was deemed advisable to make a short series of comparative tests with B. & M., Ammonia Liniment and phenol (carbolic acid) solution upon germs of a less resistant type but none the less of a kind capable of producing skin and other infections. Such a germ is technically described as a hemolytic streptococcus. There are presented next the results of such a series of tests conducted in the Membrane Penetration Apparatus already mentioned.

"TABLE IV

"Tabulation of results showing the Number of Surviving Germs in Circulating Horse Serum Infected with a Hemolytic Streptococcus after Flowing Over Animal Membrane with B. & M., 5 per cent solution of Phenol (carbolic acid) and Ammonia Liniment (N. F. V.) on the Opposite side of the same.

"Numbers of Surviving Germs After Treatments Indicated

Time in contact	B. & M. (Undiluted)	Phenol 5 per cent	Ammonia Liniment (Undiluted)
Start of Test.....	4,000	2,900	2,900
1 hour.....	630	1,800	1,650
2 hours.....	0	1,500	140
3 hours.....	0	380	0
4 hours.....	0	0	0
5 hours.....	0	0	0
6 hours.....	0	0	0

"Thus there has been developed a body of evidence of the power of certain ingredients of B. & M. quite readily to penetrate animal membranes. A conservative scientific point of view may not perhaps warrant a claim for a like result in the living human being; however, there would appear to be no reason to doubt the power of penetration of some of the antiseptic factors of B. & M. well into the layers of living skin. \* \* \* The question will naturally be raised, do B. & M. fumes possess antiseptic powers and if so are such effects due to the ammonia used in its production, or to some other volatile ingredients or both? It was considered desirable to determine whether the fumes liberated under certain conditions from B. & M., possessed stronger antiseptic powers than the fumes from the official ammonia liniment or an ammonia solution in water of the same general strength. Accordingly a frequently used system of testing fume antiseptic effects was employed. In it the germs of the species, race and virulence first mentioned above were soaked on to filter paper strips; these were confined in sealed glass jars in each of which was the same amount of one

of the products already mentioned (B. & M., Linimentum Ammoniae N. F. V., and also a watery solution of Ammonia carrying the same amount of free ammonia as B. & M.). At various time periods of exposure of the germ-laden strips of paper to the fumes of these products, a strip was removed from a jar and the number of living germs on the strip determined by the usual laboratory methods. The results as shown in Table V are most interesting.

"TABLE V

"Tabulation of Results Showing the Numbers of Surviving Germs on a Strip of Filter Paper Infected and Exposed to the Fumes from B. & M., Ammonia Liniment N. F. V., and a water solution of Ammonia containing the same amount of Free Ammonia as in B. & M.

Product Used	Number of Germs per Strip Surviving After:			
	5 minutes	10 minutes	15 minutes	30 minutes
B. & M., Undiluted.....	1,500,000	1,200,000	350,000	210,000
* * * *	*	*	*	*

Product Used	Number of Germs per Strip Surviving After:			
	1 hour	2 hours	6 hours	24 hours
B. & M., Undiluted.....	5,000	0	0	0
* * * *	*	*	*	*

"B. & M. fumes did not kill as many germs at the start as did the fumes from the Ammonia Solution, but they soon caught up \* \* \* It might not be scientifically sound to conclude from these results that the fumes arising from B. & M. as applied according to directions would destroy in the same length of time, the same numbers of the same race of germs in the membranes and their secretions, of the nose, throat, and of the tubes of the lungs in the living human being. The living conditions are not necessarily the same. The full strength of fumes in each of the jars might be very irritating [p. 29], especially to the membranes of the nose, particularly if inhaled for the same long periods of time. However, the body defenses as a rule need but little added help to exclude or overcome the germs after they have gained entrance into the tissues. If now germs are even but slightly injured by antiseptics, the powers of resistance of the tissues may be much supported. If the injuries to the germs are repeated frequently, and if the living tissues or their secretions around the germs are rendered more or less unsuited for the further growth or existence of the germs, the balance between germs and body resistance may be readily turned in favor of the latter by even traces of antiseptics frequently applied and especially if these antiseptics are alkaline in character and can exist in small amounts in the tissues and fluids of the body and aid in the correction of the abnormal states created by the growth of the germs in the body. By all laboratory methods of determination of antiseptic efficiency published here, B. & M. has shown superiority over Linimentum Ammoniae N. F. V., and over the effects of the equivalent solutions of ammonia in water. The results of these tests also bring out that the fumes from B. & M. are not as concentrated as to either alkalinity or antiseptic potency at the first stages of their volatilization as they are in the second stages, indicating a more balanced or controlled distribution of the effective fumes than the results from the fumes of the official liniment or that ammonia solution in water. The fumes from B. & M. may be expected therefore to be less quickly and easily dissipated into the atmosphere when employed practically and exert their effects over longer periods through opportunities for inhalation than those of the official liniment or plain ammonia water, containing the same amount of free ammonia, as B. & M. Thus the fumes of B. & M. do not have the same capacity at the outset for nasal membrane irritation but possess longer and more effective antiseptic and alkalizing influences than the other two products. To these superiorities, the investigations show it to possess greater penetrative power of its antiseptic constituents in the presence of nutrient jelly or of animal membranes."

The extracts from the labeling which the libel charged were false and fraudulent and which were sustained by verdict of the jury were as follows: Exhibit B (booklet) "B. & M. (Trade Mark) Formerly Called B. & M. External Remedy For External Applications, Inhalations, Antiseptic, Stimulative, Soothing, Penetrative, Volatile, Alkaline. In the Treatment of Tuberculosis, Pneumonia, Bronchitis, Influenza, Colds, Croup, Rheumatism, Lumbago, Acute and Suppurative Skin Infections. \* \* \* B. & M. (Trade Mark) Formerly Called B. & M. External Remedy For External Use An Antiseptic Alkaline Application Penetrative \* \* \* Respiratory—Circulatory—Stimulative. For Antiseptic Applications and Volatile Alkaline Stimulative Inhalations. In the Treatment of Colds, Influenza, Laryngitis, Bronchitis, Croup, Pneumonia, Pulmonary Tuberculosis, Rheumatism, Lumbago, Acute and Suppurative Skin Infections. Forword \* \* \* its efficiency demonstrated empirically in 1913. \* \* \* The successes (some of them amazing) which have resulted from the use of B. & M. during the past generation \* \* \*

"There is one kind of advertising which never fails, and that is the relief of sickness and suffering before one's very eyes. Upon that kind of advertising, B. & M. depends more than upon anything else. \* \* \* [p. 5.] We are obtaining much information concerning some of the ways in which B. & M. works to do the good which we know from actual and practical use that it has done. We can show some features of it now. Meanwhile, shall we have to wait for centuries—like the doctors did before they prescribed quinine for malaria—until the doctors can prove just how the active principles of B. & M. work, before they will let their patients use it? \* \* \* We base the claims which we make partly upon what we regard as reliable empirical information and partly upon technical scientific findings. \* \* \* What We Claim For B. & M. We claim that B. & M. alleviates much suffering and that it has remedial and therapeutic effect in appropriate cases of the various afflictions in which we recommend its use. We expect better results invariably where the use of B. & M. is combined with other care and treatment by a skilled, conscientious and open-minded physician. We do not claim that B. & M. will make any one live forever or that it will have remedial effect in every case. How B. & M. Works. From unquestionable scientific authority we learn that 'the processes of immunity are essentially chemical processes. . . . We do not as yet know exactly how the various reactions of immunity are established.' The present chemistry of immunity is recognized by what is accomplished, that is to say by empiricism—in the face of almost complete ignorance as to how it is accomplished. [p. 6.] Just so, experience justifies us in saying that we know many things which the use of B. & M. accomplishes even though we cannot yet prove how it does so. Our scientific investigations to date are in accord with medical authority that 'immunological defense against many diseases is a chemical defense against a chemical attack.' It is definitely provided that infinitesimal quantities of certain substances give extraordinary results which are sometimes uncannily specific. Does B. & M. do its work this way? We do not know. But we do know that the use of B. & M. as directed brings about chemical reactions in the human body. \* \* \* Germ Diseases. Tuberculosis and many other diseases are known to be caused by germs and are infections. To learn how to control such diseases, we must find out how to prevent the access to and the growth of germs within the body. Theoretically, a simple way of stopping the course of an infectious disease would be to find and administer some substance which will kill the germs but will be relatively harmless to the tissues of the patient. Science is eagerly searching for such substances. The chemo-therapeutic experiments today which promise the best results are said to be those which consider the disinfecting power of drugs, their germ-growth-preventing power both within and without the human body, and the ease or difficulty in penetrating to where the infecting germs are. Mr. F. E. Rollins, who controls the manufacture and sale of B. & M., believes that B. & M. applied to the skin and inhaled as directed, actually penetrates to the seat of the infection and kills the germs themselves. He is not a physician or a scientist. He has formed this opinion from his own personal experience on himself, by observation of others, and from what he has been told. We want to say frankly that we are not now able to prove by scientific and legally-competent evidence that this is true. Neither has it been demonstrated to our satisfaction that it is not true. [p. 7.] Consequently, while we believe it, yet we desire clearly to be understood as making no claims or representations that B. & M. acts that way. We are spending and shall continue to spend thousands of dollars in research in an effort to find out as much as possible of

the truth. But we do contend that the thing of immediate importance is not so much to find out how B. & M. works. The real question of importance to a sufferer is to find out whether or not it does the work, no matter how. Mr. Rollins became interested in the manufacture and sale of B. & M. only after and because he was convinced that it had saved the life of one who was very near and dear to him and who had been given up to die by the family physician before she used B. & M. Mr. Rollins is equally sure that he, himself, would have been dead years ago if he had not freely and persistently used B. & M. upon occasion. Within three months of this present writing he was suffering from a virulent infection with hemolytic streptococci (and that germ is as bad as it sounds). He applied B. & M. even after it was torture to do so because of the eruptions on his skin which had followed its persistent use. Skin eruptions are always to be expected when B. & M. is used persistently. To-day, at the age of seventy-nine, he is in active personal management and control of the F. E. Rollins Company. Every business day he is at its office and elsewhere directing its affairs. \* \* \* Sparing use is useless. The sparing use of B. & M. will not bring satisfactory results. It must be used freely and persistently. We do not say this in order to sell more B. & M., but because the results reported to us show that this is true. We have paid many thousands of dollars for scientific investigations (more than \$20,000 during the year preceding the writing of this pamphlet) and they confirm it. We would much prefer that people should not use B. & M. at all rather than that they should fail to get satisfactory results from its use. [p. 8] We are both altruistic and selfish. We do want to sell B. & M. But we have no desire that any one should buy it unless he gets more than his money's worth. Just as a pure selfish business proposition, it would be bad business to hold out expectations which would not be fulfilled. Our business must continue to grow because of satisfied users or not at all. We repeat: There is one kind of advertising that never fails, the relief of sickness and suffering before one's very eyes. Those practical results as noted are supported by the many published scientific reports of investigations on animals and human beings of the effects of some of the principal ingredients in B. & M. These ingredients must be employed in adequate amounts and repeatedly over full periods of the existence of the body conditions which they can alleviate. Physicians also find it difficult to get people to employ remedies which must be applied with religious devotion over considerable periods and in full amounts. That is one reason why powerful remedies for quick action are sought while those of milder kinds giving the better results when taken over long periods are not favored; and yet some of the diseases treated cannot be effectively influenced in short periods nor can the patients stand powerful doses. Let us repeat, B. & M. should be used freely and frequently in acute diseases of short duration and freely and with devoted persistence in those conditions lasting into weeks and months. We would much prefer that people should not use B. & M. at all rather than that they should fail to get satisfactory results from its use.

"Scientific Evidence. [p. 9] There are certain things which have already been brought forth by the scientific research and investigation which have been done for us. In accompanying pages there will be found as careful statements concerning some of these laboratory studies as words in common use will permit. Such language is not that of the scientist nor can we interpret the results of such scientific work as necessarily or exactly those which will take place when B. & M. is used practically. Such studies help us to see ways in which B. & M. acts and especially as to the way it works in the laboratory as compared with other agents. B. & M. under laboratory conditions of testing, will kill certain disease-producing germs commonly employed to study antiseptic action—germs of a kind more than ordinarily resistant to antiseptics and the use of which in such tests has the approval of certain government officials. B. & M. contains certain ingredients which will act antiseptically as just stated even after they have penetrated through jellies and animal membranes such as freshly-killed guinea pig skin, which are frequently employed in the making of such laboratory tests. B. & M. possesses certain ingredients which tend to nullify or to neutralize the acid materials or conditions which develop during and often precede the onset of certain germ infections. The need to neutralize these effects of the growth of certain disease germs in the body tissues is one of the reasons for recommending the free and persistent use of B. & M. for as long periods as these infections last. We are causing further and more elaborate scientific investi-

gations of B. & M. to be made. The results of these investigations taken in connection with reliable empirical information will control all literature which we shall issue in the future. We are determined to make no statement or claim which can justly be criticized. Technical Investigations. In the following pages we will present in as simple language as possible, with photographic reproductions, the results of some of the technical investigations made with B. & M. We do not claim that the conditions inherent in and surrounding the laboratory methods of study are identical with those which exist when B. & M. is applied to the human body. No tests thus conducted could ever hope to duplicate exactly all the variable and changing conditions of natural use. Laboratory tests of these types avoid some at least of the variabilities which exist in people of different body tendencies, past disease histories and unlike conditions of health and disease. These tests serve also to measure the germ-killing effects as compared with those resulting from like testings of other perhaps longer known germicides such as carbolic acid, or preparations of somewhat similar types, which are made according to professionally approved methods and have had legal federal and state recognition for considerable periods. Of still greater importance is the fact that the results of these types of researches can be expressed in relatively precise or graphic forms so that the reader may gather for himself some ideas as to the ways in which B. & M. acts under the conditions of such investigations. Some of the methods thus employed are quite commonly used by modern laboratory investigators, both in official departments having statutory regulation powers over the sale of foods and drugs and in educational and other institutions. Others of the methods were developed by those who have been intensively endeavoring to reveal the scope and limits of germ-killing action of B. & M. and some of the ingredients used in its preparation. [p. 11] B. & M. is recommended to be applied to the skin in its fluid state and without dilution and obviously its first effects result from these direct applications. Hence when the germ-killing powers are subjected to appropriate testing, the results first to be shown should be those obtained from the direct application of B. & M. to germs. The following tabulation shows the number of a certain type of germs found to be still capable of growth in a cubic centimeter (about fifteen drops) of the testing mixtures of B. & M. and water dilutions, after exposing several million of these germs at the temperature of the human body to these mixtures for the number of minutes indicated at the top of each column of the results. The culture of the germs employed in this test is one having federal official recognition and was obtained from a severe case of infection.

"TABLE I

"Tabulation of Results of Test with B. & M. for Germicidal Powers when Direct Contact Exists with the Germs.

Product Tested	Dilution	Number of Germs per c c (15 drops) surviving after:			
		15 sec.	30 sec.	1 min.	3 min.
B. & M.-----	Undiluted-----	1,700,000	600,000	950,000	230,000
	1:2-----	4,000,000	3,500,000	1,100,000	1,100,000
	1:5-----	42,000,000	33,000,000	22,000,000	10,000,000
	1:10-----	96,000,000	48,000,000	46,000,000	36,000,000
Control-----	(Water)-----	92,000,000	84,000,000	86,000,000	87,000,000

Product Tested	Dilution	Number of Germs per c c (15 drops) surviving after:		
		5 min.	10 min.	15 min.
B. & M.-----	Undiluted-----	92,000	16,000	00
	1:2-----	700,000	260,000	140,000
	1:5-----	12,000,000	3,200,000	1,000,000
	1:10-----	24,000,000	12,000,000	4,800,000
Control-----	(Water)-----	78,000,000	77,000,000	79,000,000

\* To those especially interested in studying in further detail the procedures followed in such tests, copies of the full reports will be forwarded on request.

"These results indicate a speedy and progressively destructive effect of B. & M. upon this species of germ during the first fifteen minutes of contact between them and even when the B. & M. is diluted several times with water. B. & M. is recommended to be used without dilution on the skin except in rare cases and then only with an equal amount of water. As a spray for the nose and throat the dilution recommended is one part to 10 parts of water. Even in this latter dilution the B. & M. solution has a pronounced destructive effect upon the germs in 15 minutes under the conditions employed. Keeping in mind that B. & M. is applied like an ointment or liniment, and it is recommended to be applied full strength repeatedly at each spreading period, usually several times a day, there are presented next the results of a series of tests using a culture of the germ above referred to as from a severe case of suppurative infection and the disease producing powers of which were determined by federal officials. The method of testing is well recognized and the products tested in comparison with B. & M. have legal and official recognition. The germs of this culture are sown in a solidified jelly containing ten per cent of the albuminous fluids of horse blood and possessing a standardized power of promoting growth of these germs when incubated at an appropriate temperature for a given time. The nutrient jelly is solidified in shallow glass plates with removable covers and a hole or cup is made in the center of the jelly into which the B. & M. or the other products used for comparison are placed in measured amounts before starting the incubation. If the antiseptic or germicidal ingredients can penetrate into the jelly before the germs can grow into visible mounds [p. 13] or colonies then there will be zones around the hole or cup showing no spots or colonies of germ growth. The characteristics and the width of these zones of clear jelly will permit the reader to compare the germ affecting powers of the preparations thus tested. The photographic results of three such plates are shown in Plate I. The first (A) represents the results when one-half cubic centimeter (about seven or eight drops) of B. & M. undiluted was introduced into the hole or cup. The second (B) illustrates the results from the introduction into the cup of the same amount of a liniment described officially as *Linimentum Ammoniae* (U. S. P. IX and N. F. V.). (This is the nearest type of product to B. & M. which has official and legal recognition as having pharmaceutical and therapeutic properties. The amount of ammonia introduced into this official liniment is in excess of that employed in the making of B. & M.) The third (C) illustrates the results from the same amount of a five per cent solution of Phenol (carbolic acid) introduced into the cup. All these plates were incubated for germ growth at a temperature of the human body for forty-eight hours. Obviously from the results occurring under these conditions, as shown by the plates, B. & M. exhibits marked power of preventing the growth or killing these pus-producing germs. This is in contrast to the failure of the official *Ammonia Liniment* to penetrate into the germ growth promoting jelly with any obvious restraint of formation of mounds or colonies of these germs of special approved type. While carbolic acid in a five per cent solution does penetrate and obviously prevents the growth of the colonies in a definite zone, the effect is not the same as shown for the B. & M. It may be claimed that taking two days for action constitutes too long a period to indicate practical efficiency under the usual conditions of use. In the next series of tests, the time period of contact of these products in the cups in the jelly was reduced to 15 minutes and double the amounts of each of the products were placed in the cups. After 15 minutes, all of the B. & M. and other products which could be, were carefully removed from the cups and then the plates were incubated for 48 hours with the results shown in Plate II. B. & M. is recommended for repeated application. In Plate III are the results of another series of three photographs with two applications of each of the three products three hours apart and left in the cups for 15 minutes each and then removed as far as possible. \* \* \* While these results might not be considered as constituting proof that the antiseptic ingredients of B. & M. would penetrate into the tissues of the human skin to the same degree as they do into the germ nutritive jelly, other lines of scientific research go further towards indicating penetrative power. Scientists devoting much time to B. & M. problems developed a form of apparatus in which the germs of disease inoculated into a moving portion of blood without the colored cells, i. e., the serum, or a moving flow of beef broth standardized to promote the growth of the germs, are brought into contact with an animal membrane covering the outlet of a jar containing the B. & M. or other products under investigation. Thus the flow of germ-containing blood serum [p. 23] or broth passes

one side of the animal membrane and on the other side of the membrane is the application of the B. & M., the official liniment or other product being tested. There is no possibility of interchange of fluids except through the animal membrane. The temperatures of the serum or broth and of the membrane at the point of treatment are substantially those of the skin of the human being. The culture of germs used in the first series of such tests employing this Membrane Penetration Apparatus was the same as already mentioned as having a degree of infection power recognized by federal officials. The time period of such contact of each of the flowing fluids with the membranes having one of the products under test on the opposite side has been six hours. Chemical and germ tests of samples of the infected fluids were made at hourly intervals or oftener. In Table II will be found the results of two tests in which B. & M. was the product placed on the upper side of the animal membrane of parchment, in this case Goldbeater's skin. In test (A), the infected circulating fluid was undiluted blood serum taken from a normal horse. In test (B), the infected fluid was standardized nutrient beef broth.

"TABLE II

"Tabulation of Results showing the number of surviving Germs in (A) Circulating Infected Horse Serum and (B) Circulating Infected Beef Broth, after Flowing Over Animal Membranes with Undiluted B. & M. on the Opposite Sides of the Same.

Time in Contact		pH	Test A Numbers of Surviv- ing Germs	pH	Test B Numbers of Surviv- ing Germs
Start of test.....	acid	6.7	3,200	6.5	3,900
1 hour.....	neutral	7.0			
2 hours.....		9.1	3,100	10.2	3,000
3 hours.....		9.1	3,400		1,200
4 hours.....	alkaline		3,200		10
5 hours.....			3,000		0
6 hours.....			810		0
		9.3	290	10.2	0

"In Table III will be found the results of one test in which Ammonia Liniment (N. F. V.) was the product placed on the upper side of the animal membrane.

"TABLE III

"Tabulation of Results showing the Numbers of Surviving Germs in Circulating Infected Horse Serum after Flowing Over the Surface of the Animal Membrane (Goldbeater's Skin) with Ammonia Liniment on the Opposite Side of the Same.

Time in Contact		Reaction as pH	Numbers of Surviv- ing Germs
Start of test.....	acid	6.8	4,900
1 hour.....	neutral	7.0	
2 hours.....		9.0	4,500
3 hours.....		10.6	3,600
4 hours.....	alkaline		4,200
5 hours.....			2,900
6 hours.....			3,100
		10.6	3,100

"[p. 25] Thus in tests with this apparatus, there have been found not only substantial reductions in the numbers of living germs in the circulating broth or serum, amounting in some cases to evidences of complete sterility within six hours or less, when B. & M. was employed, but chemical tests applied to small samples of the flowing fluids at fixed time periods during the investigation, give conclusive evidence of penetration through the membranes of volatile alkaline ingredients of these products. It was remarked earlier that the germ employed in the tests, the results of which have been reported was one of more than ordinary powers of resistance to antiseptics. It was deemed advisable to make