REPORT OF THE COMMISSION ON PROPRIETARY MEDICINES OF THE AMERICAN PHARMACEUTICAL ASSOCIATION FOR 1915–1916.*

General Approval of the Ten Declarations of the 1915 Report.—The 1915 report of the Commission presented ten declarations specifying the requirements to which proprietary package medicines should conform in order to render them suitable for direct sale to the general public. These declarations were approved by the American Pharmaceutical Association at its sixty-third annual meeting, San Francisco, August 9–14, 1915, were printed in the JOURNAL,[1] and later issued in the form of a reprint.

A member of this Association, Mr. W. A. Hover, brought the report of the Commission to the attention of the National Wholesale Druggists' Association at its forty-first annual meeting, at Santa Barbara, California, September 27 to October 1, 1915, which association approved all of the requirements except No. 8, which reads as follows:

Incurable and Contagious Diseases.—The preparation must not be advertised or recommended as a cure for diseases or conditions which are generally recognized as incurable by the simple administration of drugs, or for the cure of contagious or acute diseases the treatment of which properly requires the supervision of a qualified medical attendant.

While the N. W. D. A. seemingly approved the general purport of the declaration, it was thought that it might be construed to include affections which, though technically of an acute nature, might not be of sufficient gravity to necessitate the attendance of a physician.

In October, 1915, the Chairman was invited to a conference with a special committee of the Proprietary Association for a general discussion of the work of the Commission and of the ten requirements which it had proposed.

The Chairman accepted the invitation, and frankly explained to the special committee the purport of the requirements as he understood them, and the reasons which influenced the Commission to adopt them.

As a result of this conference the special committee made a report to the Proprietary Association recommending the adoption of a majority of the ten declarations as the standard to which remedies marketed by members of that association should be made to conform.

The Proprietary Association at a special meeting adopted the report of its special committee in the form of an amendment to its By-laws which reads as follows:

REQUIREMENTS FOR MEMBERSHIP AND PROVISIONS FOR ENFORCEMENT OF SAME.

(1) The preparation must be of such character as may reasonably be expected to bring about the results for which it is recommended. Statements on packages and elsewhere regarding composition, origin, place of manufacture, and name of manufacturer or distributor must be in exact accordance with the facts. Statements regarding therapeutic effects must neither be obviously unreasonable nor demonstrably false.

(2) The preparation must not be offered or intended directly or indirectly for use as an abortifacient nor for any other immoral or illegal purpose.

(3) The preparation must not contain cocaine or eucaine; nor shall it contain opium

* Presented and approved at the Sixty-fourth Annual Meeting of the American Pharmaceutical Association, Atlantic City, 1916.

[1] JOURNAL OF THE AMERICAN PHARMACEUTICAL ASSOCIATION, October, 1915, p. 1148–1167.

or any of its alkaloids or their derivatives in greater proportions than those specified in Section Six of the Federal Law, commonly known as the Harrison Act, and it shall also contain other active drugs in such proportions that when used as directed it will not be likely to create or satisfy a drug habit; provided that if specially intended for the use of babies or small children the preparation shall contain none of the drugs named in this section in any quantity.

(4) If the preparation contains alcohol the amount shall not be greater than is properly necessary to hold in solution in permanently active condition the essential constituents of the preparation and to protect against freezing, fermentation or other deleterious change, and the medication shall be sufficient to render the preparation unsuitable for use as an intoxicating beverage.

(5) The preparation must not be advertised or recommended as a cure for diseases or conditions which are generally recognized as incurable by the simple administration of drugs.

(6) The package either as to wrapper, label or accompanying literature shall contain no statement in conflict with the misbranding provisions of the Federal Food and Drugs Act.

(7) The preparation must be of such a character as not to endanger life or health if used in accordance with instructions accompanying the package.

(8) In order to secure the enforcement of these requirements and to take charge of the examinations necessary to that end, a Committee on Requirements shall be selected by the Executive Committee, with power to carry out the work as outlined by these requirements under such rules and with such salaries as may be determined by the Executive Committee, to which Committee may be appealed any findings of such Committee on Requirements. For the purpose of rendering all possible aid to the members in the work of conforming their preparations to the requirements, each member shall submit for examination to such Committee on Requirements, complete packages of his preparations, including all literature contained in such packages, with such information as may be necessary to determine the fact of compliance in all respects with such requirements. No member shall be obliged, under this provision, to reveal his formula.

It will be observed that the provisions of this by-law, while differing somewhat in language, in the main cover the same ground as the ten declarations approved by this association, and may be regarded as a distinct step towards the introduction of reasonable standards into the proprietary package medicine business.

Lately it has been unofficially reported that the Committee on Requirements provided for in the last section quoted above has been engaged in examining the products and literature issued by the members of the Proprietary Association, and that all members will be required to conform to the provisions of the new by-law or withdraw from the association.

The National Drug Trade Conference at its last session, held at Washington, D. C., December 16, 1915, also took the report of the Commission under consideration, and after a brief discussion, most of which was of a favorable character, referred the definitions and declarations of the report to a special committee with instructions to report thereon at the next session of the Conference.

In the *Journal of the American Medical Association* (December 25, 1915, p. 2210) there appeared a four-page review of the Commission's report, by Dr. Torald Sollmann. Dr. Sollmann's remarks are on the whole commendatory, though they express the idea that the report was not sufficiently radical in its recommendations. This review is an excellent presentation of the subject from the standpoint of one who is strongly opposed to the manufacture and general sale of package remedies, *i.e.*, of "patent medicines."

More or less discussion of the report has also appeared in the daily press. In the *New York Tribune* (Sunday, June 16, 1916), Samuel Hopkins Adams presented a lengthy, critical and generally commendatory review in which he says:

The report of the Commission on Proprietary Medicines of the American Pharmaceutical Association is the result of two years of careful, expert investigation. The motives inspiring it were to clean up false advertising for the good name of the pharmaceutical trade, and to improve conditions which had become a public scandal and a public danger. Their conclusions form a notable document in the campaign against the Great American Fraud. While it is by no means a radical or sweeping pronouncement, it strikes straight at the vital points of fraud and danger. If followed up, it cannot fail of far-reaching reform.

The Right of the Pharmacist to Deal in Proprietary Medicines.—A criticism offered to the 1915 report was that it dealt mainly with prohibitions, and that it did not contain any expression regarding the right of the pharmacist to deal in ready-made or package remedies intended for direct sale to the general public.

In explanation it may be stated that the Commission took it for granted that proprietary ready-made or package remedies would be recognized as legitimate articles of commerce, provided and so long as they conformed to the requirements laid down in the 1915 report.

To remove any misapprehension on this point, the Commission now offers the following declarations as expressing its views of the relations of the drug trade to the sale of proprietary medicines:

(1) *A Legitimate Field for Certain Proprietary Remedies.*—There is a legitimate field for ready-made or package remedies intended for the domestic treatment of common ailments, provided they are appropriate for use in the particular affections for which they are recommended, and are not deceptively labeled or advertised, or otherwise improperly exploited.

(2) *Traditional Right of the Pharmacist to Deal in Such Remedies.*—It is the professional right of the pharmacist, sanctioned by custom and tradition, to keep such remedies in stock, whether manufactured by himself or by others, and to supply them to the general public on demand. In meeting the demand for ready-made or package remedies, the pharmacist should refrain from usurping the proper functions of the physician, especially in regard to diagnosis.

Alcohol and Habit-forming Drugs in Proprietary Medicines.—One of the specific duties assigned to the Commission is:

" To inquire whether, and to what extent, the proprietary medicines commonly known as patent medicines, contain alcohol or habit-forming narcotic drugs in sufficient proportions to render them liable to create an alcohol or drug habit, or satisfy such habits when otherwise created."

Obviously it would be physically impossible for the Commission to examine all of the many thousands of package remedies on the market, and any judgment of their alcohol or habit-forming drug content must therefore be based upon the examination of a selected list of preparations.

Obviously also, such a list might be selected in such a manner as to give an entirely erroneous impression of the prevalence of alcohol and narcotic drugs, and show either a greater or less proportion of preparations containing these substances than would represent the average of the market.

To insure what might be regarded as a fair average list the following method was adopted:

There was first compiled a list of manufacturers of proprietary medicines located in various parts of the United States, including both the makers of widely advertised remedies and of those having only local or sectional repute. The list thus included both large and small producers of proprietary medicines.

After the list of manufacturers was completed, an effort was made to obtain as complete a list as possible of all the package remedies made by them, both liquid and solid, without regard to whether they contained alcohol or habit-forming drugs or were free from them.

From the labels of the preparations thus obtained there was compiled a list of those which were stated to contain alcohol or habit-forming drugs—as required by the Federal Food and Drugs Act—and the proportions in which these were stated to be present.

In this manner there was obtained a list of 1108 preparations believed by the Commission to be a fairly representative list of package remedies as manufactured and sold within the United States. Of these 1108 preparations, the labels of 308, or 27.79 percent of the total, carried a statement showing the presence of alcohol in proportions of 1 percent or over.

As a means of testing the accuracy of the above computation, the Commission this year obtained from the Chairman of the Committee on Requirements of the Proprietary Association a complete list of the preparations manufactured by that association and of the label statements of the proportions of alcohol and of narcotic drugs contained therein.

From this list it appears that a total of 1078 liquid and solid preparations are marketed by members of the Proprietary Association, of which 342, or 31.72 percent of the total, contain alcohol in proportions of 1 percent or more. Of these 342 preparations, 25 are of the nature of hair dyes, toilet creams, flavoring extracts, or general pharmaceutical preparations not strictly of the type commonly known as "patent medicines." Subtracting these we have a net total of 317 preparations, or 29.40 percent of the whole number which contain alcohol in proportions of 1 percent or over.

There is therefore a difference of 1.61 percent between the figures obtained by the Commission from the examination of a general list of widely selected patents and those obtained by an examination of the preparations put out by members of the Proprietary Association.

While the Commission does not contend for the absolute exactness of either calculation, it is inclined to the opinion that if all of the package remedies of the market could be examined the ratio of alcoholic to non-alcoholic preparations would not vary greatly from the figures set down above.

In a comparative study[2] of the alcoholic to non-alcoholic preparations of the United States Pharmacopœia VIII and National Formulary III, it was found that of 427 liquid and solid U. S. P. preparations, and of 575 liquid and solid N. F. preparations, 206 of the former and 274 of the latter contained alcohol in proportions of 1 percent or over.

Shown in tabular form the frequency of alcohol in proprietary package preparations as compared to U. S. P. and N. F. preparations is approximately as follows:

Proprietary package preparations, probably about.....	30 percent
U. S. P. (VIII) preparations	48.25 percent
N. F. (III) preparations	47.65 percent

It should be kept in mind that the above figures are intended only to show roughly the relative frequency of occurrence of alcohol in the classes of preparations compared, and have no bearing upon the average alcoholic content of the respective classes of compounds.

[2] J. A. PH. A., October, 1915, p. 1162–1163.

Permissible Alcohol Content.—Declaration No. 3 of the 1915 report, expressing the permissible alcohol content in popular package remedies, is as follows:

> If the preparation contains alcohol, it must be sufficiently medicated to prevent its use as an intoxicating beverage, and in addition to this requirement, the proportion of alcohol present must not be greater than is properly necessary to hold in solution in permanently active condition the essential constituents of the preparation, and to protect the preparation against freezing, fermentation, or other deleterious change.

It will be recognized by every one familiar with the manufacture of pharmaceutical preparations that the proportion of alcohol necessary to keep the " essential constituents " of a solution in " permanently active condition " or to protect it " against freezing, fermentation or other deleterious change " will vary constantly with the character and quantity of the substances in solution. Whether or not alcohol is present in excess in a given preparation can be determined only by an examination of that particular preparation.

The Proportion of Alcohol Required to Prevent Fermentation or Moulding.—During the past year experiments have been continued to determine the least proportion of alcohol necessary to prevent fermentation and molding in liquid preparations which do not contain other antiferments or antiseptics.

The liquids employed have been hydro-alcoholic tinctures of simple vegetable drugs, after removal of the original alcohol by evaporation.

After sterilization, the liquids were inoculated with pure cultures of yeast, or with the common mold *Penicillium glaucum,* and kept under observation at laboratory temperatures for periods of five to ten days.

When the inoculated flasks were kept closely stoppered, so as to prevent evaporation of alcohol or the entrance of adventitious organisms, it was found that the presence of about 13 percent by volume of absolute alcohol was sufficient to prevent fermentation—indicated by gas formation—and about 16 percent to prevent the growth of mold.

If the flasks were only loosely stoppered, so that evaporation of alcohol could occur, it was found that an initial proportion of about 17 percent of alcohol was necessary to prevent fermentation, and of about 19 percent to prevent the growth of mold, within a period of ten days.

It is intended to continue the experiments with a larger list of preparations, and under conditions of exact control, during the next year.

From the information already obtained it seems fair to conclude that a proportion of alcohol not exceeding 19 to 20 percent by volume should not be considered excessive in preparations of simple vegetable drugs, when used simply to prevent fermentation and molding during storage and shipment under commercially practicable conditions, and while under consumption by the purchaser.

The Proportion of Alcohol Required to Prevent Freezing of Hydro-Alcoholic Preparations.—The prevention of freezing during transportation or storage is a matter of very great importance to those who ship goods to the northern states during the winter season, and to those who store them for sale in such climates.

In the absence of dissolved substances, a mixture of 20 parts of alcohol and 80 parts of water will freeze at about 10 degrees above zero and a mixture of 30 parts alcohol and 70 parts water at about 5 degrees below zero (Fahrenheit scale). In the presence of dissolved substances, as mineral salts, vegetable extractives, etc., the freezing points of the liquids would, of course, be lowered below those given.

In the absence of considerable vegetable extractive or of other dissolved substances the presence of 20 percent by volume of alcohol is therefore not excessive as a protection against freezing of preparations shipped or stored in the northern states during the winter months.

Of course it does not follow that a preparation is unobjectionable simply because it does not contain more alcohol than is necessary to prevent fermentation, molding, or freezing, since the degree of medication might, nevertheless, be so slight, or of such a character, as to render the liquid capable of being used as a tipple.

The preceding statements do not, of course, refer to preparations in which a very high percentage of alcohol is necessary to hold the essential or important constituents in solution. Notwithstanding their high alcohol content, such preparations are usually less adapted for tippling purposes than the weaker ones.

Whether a preparation is or is not objectionable because of its alcoholic content is therefore a question that must be determined by an examination of the facts in each particular instance.

Habit-forming Drug Content of Package Remedies.—The examination last year of the labels of 1108 package remedies exhibited a total of 92, or 8.3 percent of the whole number, which contained opium or its alkaloids or derivatives, cannabis indica, or chloral hydrate, and mostly in proportions lower than those permitted by the federal anti-narcotic act. The examination of the labels of 1078 similar preparations this year exhibited only 61, or 5.65 percent of the whole number, which contained any one of the drugs named.

Of the five preparations examined this year which contained extract of cannabis indica, three were corn remedies which could not be used internally, and two were cough remedies not likely to be used in large doses or for any considerable length of time.

Of the four preparations which contain chloral hydrate one was a hair tonic, one an antiseptic lotion, one an application for eczema, and one a toothache remedy.

None of the preparations examined this year or last contained either cocaine or eucaine in any quantity.

Discussion of Formula Publication, Etc.—During the past year the Commission has devoted considerable attention to the discussion of the open formula proposition, and of other methods that have been proposed for the control of the manufacture and sale of package remedies.

The questions particularly considered with a summary of the answers thereto are presented below.[3]

(1) Will the open formula, *i.e.*, publication of the active ingredients on the label, be likely to increase or decrease the sale of proprietary medicines as a whole?

A majority of those answering believe the publication of the formula on the label would either have no effect on the sale of proprietary medicines, or would tend to increase their sale, since the principal condemnation of package remedies has been based upon the secrecy of their composition.

(2) Will the publication of the formula on the label be likely to change the legal responsibility of retail dealers, who have hitherto been declared by the courts

[3] Numerous members of the association have been requested to give the Commission the benefit of their advice. These answers will be given in full in a supplemental report. It is proposed to continue the discussion throughout the coming year.

not to be responsible for damage resulting from the use of proprietary medicines concerning the composition of which they were uninformed?

The respondents generally believe that a statement of the ingredients on the labels of package remedies would have the effect of making the pharmacist responsible for damage resulting from their use, in view of the fact that the courts have hitherto held them not to be responsible for the sale of remedies of which they did not know the composition.

(3) What benefit would the public derive from the publication of the formula of a proprietary medicine on the label?

There is a difference of opinion as to the benefit the purchaser would derive from reading the formula. Some believe he would be benefited because it would give him the opportunity of "reading up" on the drugs mentioned. Others, perhaps a majority, believe that the purchaser would either pay no attention to the printed formula, or, if he did, would be inclined to experiment with combinations of his own.

(4) If the formulas of proprietary medicines are not published, can the public be protected against fraud or injury by a proper system of inspection and analysis?

The answers are nearly evenly divided as to the sufficiency or insufficiency of inspection and analysis as a means of protecting the public against fraud perpetrated under the cover of secrecy.

(5) Instead of the requirement of the publication of all active ingredients as above stated, would it be advisable to require simply a statement of certain potent drugs, or of those deemed to be so active that the purchaser should be informed of their presence?

A majority of the answers seem to favor the publication of active or potent ingredients in preference to publication of the entire formula.

(6) If you believe the last proposition to be preferable to the publication of the complete formula, what definition would you propose for potent drugs; or, instead of a definition, what list of drugs would you propose for statement?

No list of potent drugs to be stated has been proposed to the Commission.

One answer favors the definition of potent drugs proposed by the Voluntary Conference for the drafting of a Modern Pharmacy Law.

(7) If you favor neither of the two main propositions above stated, namely, publication of the entire formula, or of potent ingredients only, what are your views as to a law requiring the communication of the active ingredients to some official bureau authorized to pass upon or approve or disapprove preparations offered for sale generally to the public?

The answers are almost unanimously opposed to the proposition to require the communication of the active ingredients to an official bureau authorized to pass upon, and either permit or forbid the sale of package remedies.

(8) If you approve the last proposition, would it be possible to draft a law that would prevent unreasonable condemnation of formulas by the official bureau, or to prevent sectarian prejudice from influencing its determinations? For example would a board composed of "old school" or regular physicians be inclined to pass or reject a Homeopathic remedy for rheumatism upon a statement of its contents?

A majority of the answers maintain that it would be impossible to provide a board or bureau that would be free from prejudice or that would not be likely to condemn the peculiar remedies of rival schools of medicine.

(9) Should such a bureau be composed of physicians exclusively or should pharmacy be represented in the membership, and to what extent?

A majority of those who have answered believe that such a bureau, if established, should have practical pharmacists among its members. One answer maintains that the inclusion of pharmacists on such a board would not improve its composition.

(10) Should a bureau charged with the duties above specified be municipal, state or national?

While a majority oppose the bureau idea altogether, they would regard a federal board as the least objectionable of the three.

It is the design of the Commission to take counsel with the entire membership of the Association upon the questions submitted before finally formulating its proposals for approval by the Council.

False Advertising the Basic Evil of the Package Medicine Business.—In its last report the Commission expressed the opinion that the greatest evil connected with the package medicine industry has been the falsity and extravagance with which its products have so frequently been exploited, and that many meritorious package remedies exist concerning which no criticism can be offered except as to the methods employed in their exploitation.

The Commission has not since discovered facts or arguments that would cause it to modify that opinion. It still believes that the enforcement of truth in advertising is the proper correction of the present evils in the package remedy business, and that except in so far as they may contribute to this end all other proposed plans of regulation will be futile.

Respectfully submitted,

The Commission on Proprietary Medicines,

MARTIN I. WILBERT, Washington, D. C.,
JOHN C. WALLACE, New Castle, Pa.,
CHAS. CASPARI, JR., Baltimore, Md.
THOMAS F. MAIN, New York, N. Y.,
JAS. H. BEAL, *Chairman,* Urbana, Ill.

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