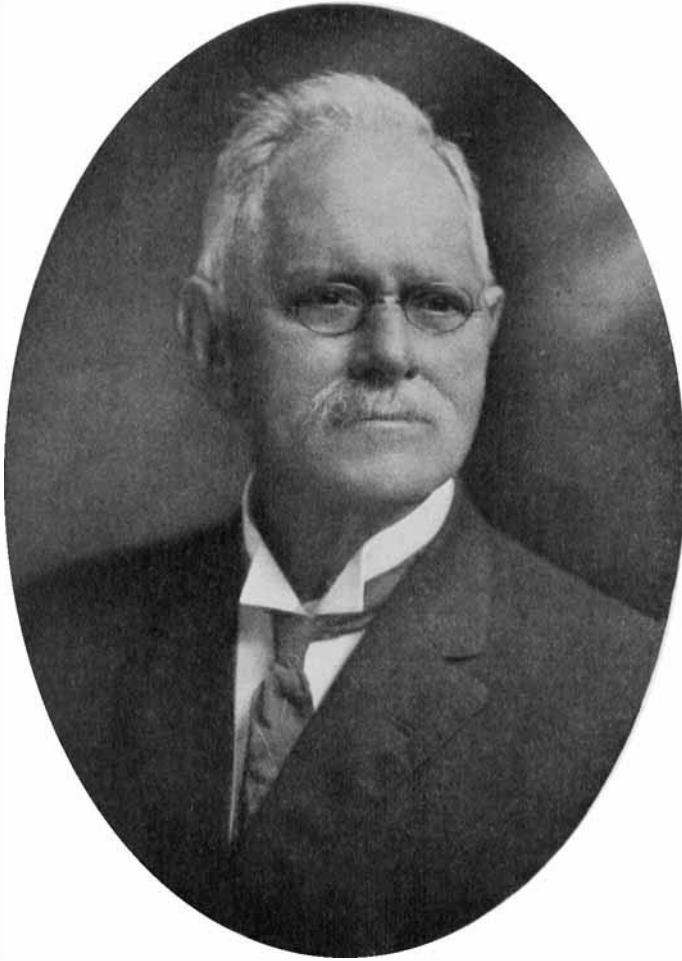


FABIUS CHAPMAN GODBOLD

**Honorary President of American Pharmaceutical Association
1915-1916**



FABIUS CHAPMAN GODBOLD



The Journal of the American Pharmaceutical Association

Volume IV

OCTOBER, 1915

No. 10

Office of Publication, 63 Clinton Building, Columbus, Ohio.

Subscription, \$4.00 per annum, within the United States. To Canada, \$4.35. To other foreign countries in Postal Union, \$4.50 per annum. Single copies, 35 cents.

Entered at the Postoffice at Columbus, Ohio, as Second-Class matter.

Papers and communications for insertion in the JOURNAL should be sent to the Editor, E. G. Eberle, 63 Clinton Bldg., Columbus, Ohio. Subscriptions should be sent to the Treasurer, H. M. Whelpley, 2342 Albion Place, St. Louis, Mo.

The Association does not accept the responsibility for the opinions of contributors. Offensive personalities must be avoided.

H. C. Godbold, Honorary President American Pharmaceutical Association

1915-1916

The subject of this brief sketch, Fabius Chapman Godbold, was born in Franklin County, Mississippi, July 7, 1842, and here he grew to manhood. Mr. Godbold served for four years in the Confederate Army and after the close of the war made New Orleans his home, engaging in the drug business in 1866 and continued actively therein in that city until 1913, when he retired.

A few years more and the half century mark of service in pharmacy would have been reached and in that period Mr. Godbold encouraged every movement that contributed for its advancement in the State of his adoption. It was largely through his efforts that the Louisiana Pharmacy Law was enacted and he was honored by appointment when the first Pharmacy Board under its provisions was created, serving as secretary for twenty-one years. He is a charter member and Ex-President of the Louisiana Pharmaceutical Association.

When the National Association of Boards of Pharmacy was organized, he at once took active part in the work and in 1906 at the meeting in Indianapolis was chosen President. He has also taken an active interest in the National Association of Retail Druggists, contributing his efforts and encouragement.

He joined the American Pharmaceutical Association in 1887 and until a few years ago Mr. and Mrs. Godbold were regular attendants at the annual conventions. Mr. Godbold has served the Association in various capacities, holding the Chairmanship of the Council, 1909-1910. The honor which has now been conferred, that of Honorary President of the American Pharmaceutical Association, comes to him as a reward of long and faithful service in the Association and for its advancement.

REPORT OF THE COMMISSION ON PROPRIETARY MEDICINES OF
THE AMERICAN PHARMACEUTICAL ASSOCIATION.*

The duties assigned to the Commission on Proprietary Medicines of the American Pharmaceutical Association are :

- (1) "To inquire into and to report to the Council from time to time upon the general subject of proprietary medicines in their relations to pharmacy, medicine and the public health.
- (2) "To inquire whether, or 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.
- (3) "To inquire whether, or to what extent, the commonly advertised patent medicines contain potent drugs in sufficient proportion to render them dangerous in the hands of the laity.
- (4) "To inquire into the extent to which patent medicines are fraudulently advertised, or differ in composition or origin from the claims made for them, or the extent to which they are advertised for the use of diseases for which no cure is known to medical science."

The scope of the functions above imposed is sufficiently comprehensive to include practically every phase of the proprietary medicine question which the Commission may choose to consider, and since the number of proprietary medicines on sale in the United States is estimated at 40,000 to 50,000 items, (inclusive of the large number used by the medical profession, but exclusive of the thousands of druggists' "own make" preparations, usually of only local reputation) it will be seen that the task assigned to the Commission is by no means a trivial one.

While the literature relating to proprietary medicines is of enormous volume,—if much of the printed matter relating to this subject can be dignified by the name of literature—a very large proportion of it is of so controversial a character that it may be dismissed at once as of little value, consisting in large part of sweeping general assertions against or in favor of proprietary medicines, the sifting of which results in a vast amount of chaff and very little wheat.

The policy of the American Pharmaceutical Association has always been distinctly unfavorable to the increased use of proprietary medicines, including both those supplied for the use of the medical profession and those intended for direct sale to the general public, and long before the American Medical Association began its active campaign against them the former association had repeatedly placed itself on record in opposition to the multiplication of ready-made medicinal agents, for the reason, aside from other considerations, that the use of such forms of medication has a tendency to reduce the dispensing pharmacist from the

* Presented to the Council of the A. Ph. A. at the 63d annual convention of the Association, San Francisco, August 9-14, 1915.

rank of a compounder of drugs and medicines to that of a mere dealer in the merchandise of other manufacturers.

Not only does the use of proprietary medicines tend to reduce the legitimate compounding profits of the pharmacist when they are dispensed by him on the order of the physician, but the readiness with which such medicines lend themselves to dispensing by physicians, and the avidity with which physicians have availed themselves of this quality have combined to relieve the retail pharmacist of a great deal of dispensing business, though in theory he is the legalized distributor of medicinal agents.

In the case of the proprietary medicines which are advertised and sold directly to the general public, the situation as it affects the retail pharmacist, is equally unsatisfactory. Even when the advertised prices are obtained the retailer's profit on such articles is only moderate, and when they are sold at cut prices, as is frequently the case, the percentage of profit is usually less than the net percentage cost of doing business.

While the American Pharmaceutical Association has never formally recognized the right of proprietorship in medicinal agents, the American Medical Association, on the other hand, has yielded to the necessities of the situation, and through the action of its Council on Pharmacy and Chemistry has placed the stamp of legitimacy upon numerous patented or protected chemicals, or other articles of proprietary origin. In granting such recognition, however, certain conditions and regulations are imposed which tend to effectually guard the financial and professional interests of the medical profession, and which brand with professional disapproval all proprietary remedies likely to reach the hands of the laity otherwise than through the physician or on his prescription.

Among the most useful of these regulations of the Council on Pharmacy and Chemistry are:

Rule 3, which prohibits the recognition of any medicinal agent that is advertised directly to the general public. Only insecticides, germicides, disinfectants, and non-medicinal foods are excepted from this rule, and these are excepted only when they are not advertised as curative agents.

Rule 4, which prohibits the recognition of any article whose label, package, or accompanying circulars contain the names of the diseases for the treatment of which the article is said to be indicated.

(This rule does not apply to remedies with which self medication is obviously improbable, such as vaccines and antitoxins, nor to cases where similar immediate heroic treatment is indicated.)

Rule 8, which excludes from recognition all articles whose names are suggestive of the diseases or pathological conditions for which they may be used, or which are suggestive of therapeutic indications.

Since without direct advertising (prohibited by Rule 3) the general public would not learn of the existence of proprietary remedies, and would not be likely to purchase them without information as to the affections for which they are intended, (the giving of which information is prohibited by Rules 4 and 8) it follows that if these rules could be given the force of law and universally enforced, the sale and use of proprietary medicines, except under the direction of qualified physicians, would be reduced to a negligible quantity.

While these rules are admirably adapted to conserve the financial and professional interests of the physician, their application to remedies intended for sale to the general public could hardly operate otherwise than to still further contract the small volume of business left to the pharmacist by the dispensing physician.

Druggists' own make preparations and those produced by cooperative companies are clearly within the category of proprietary medicines if they are recommended to the laity for self-medication, and hence must be subject to the same rules regulating advertising and labeling. If the right to bring ready-made remedies to public attention and to state on the labels and wrappers what they are to be used for be denied, the sales of such articles would soon decline to the vanishing point. Whether in such case physicians would enthusiastically begin the writing of prescriptions is a question which one druggist should be able to answer as well as another. The risk is with the druggist, and it is not surprising that he should hesitate to approve a step which would mean a certain reduction of income on the chance of an uncertain gain from another source.

Unfortunately the problems involved in the use of proprietary medicines, especially those known as patent medicines, have too frequently been discussed from a purely partisan standpoint, and in a manner better calculated to cloud judgment than to illuminate it.

1. Too many inconsistent and self-contradictory arguments have been presented in behalf of the same proposition. For example, thousands of analyses have been published tending to show that proprietary medicines are not the result of great and wonderful discoveries made by their manufacturers, but that, on the contrary, they are in many cases combinations of well known and commonly used drugs, recognized by the medical profession as valuable remedies when properly applied. This is a good argument to explode the fanciful claims frequently made for proprietary medicines, but it has been largely nullified by sweeping general statements to the effect that all proprietary medicines are dangerous or worthless, which immediately prompts their defenders to inquire why they should be considered dangerous and worthless if they are practically the same as the combinations used by physicians, and why a given mixture should be considered a valuable and efficient remedy when dispensed by or on the order of a physician, and dangerous and worthless when put up in a carton with printed label and wrapper.

The net result of such contradictory arguments is only to weaken the faith of the public in the efficiency of medicines in general, and to have the impression that proprietary remedies are at least as good as any others, since none of them amounts to very much.

2. While condemning proprietary remedies which are widely advertised, and have a general sale, pharmacists have not hesitated to recommend their "own make" preparations of similar character in their place, from which the customer is likely to infer that the opposition to the advertised remedy is prompted mainly by the fact that it does not return as good a profit as the home compounded mixture.

The argument that the own make preparation is non-secret, has but little weight with the average layman. He reasons that all he wants to know is what the mixture is good for, and that his information will not be advanced by a statement of

ingredients of whose separate qualities and medicinal value he knows little or nothing.

3. While declaiming against proprietary medicines as a class, pharmacists have not hesitated to continue to stock and sell them, or to recommend them by the recital of cases where they have been used with apparent benefit.

In this respect the physician has been as inconsistent as the pharmacist. Thousands of registered physicians are also the owners of drug stores, but we have yet to learn of a physician druggist,—though there may be such—who does not carry a full line of popular patent medicines for sale to all who ask for them; nor would it be difficult to show that many physicians have used and continue to use such remedies in their private practice.

4. In most of these discussions only minor emphasis has been placed upon the fact that the greatest evil of the patent medicine industry is the falsity and extravagance with which its products have been exploited. This is the basic evil of the patent medicine business and the point where it is most vulnerable, and an attack upon this evil needs no argument for its justification.

Numerous patent medicines are mixtures which have some merit if properly applied in cases for which they are adapted; the evil is not in the remedies themselves but in the method of their exploitation. Sweeping general assertions of the absolute worthlessness of patent medicines, besides being untrue, have a contrary effect to the one intended, as for example, the following, attributed to a prominent antagonist of proprietary medicines, "Every advertised cure for disease is a fraud. Its vendor is a quack; his publisher an accomplice; his patron a dupe. One rule covers the field, if it's medical it's a fake," "An honest and meritorious medicine could not live," "A real cure couldn't make office rent," etc. Most people have used patent medicines sometime in their lives, and when they read such statements as the above are inclined to suspect that the whole campaign against ready-made remedies is insincere and prompted largely if not wholly by selfish motives.

DEFINITIONS FOR PROPRIETARY MEDICINES, ETC.

One of the first tasks attempted by the Commission was the adoption of a set of general definitions to serve as a basis for its deliberations, and this has proved to be by no means as easy and simple as it might appear.

The definitions finally decided upon, though formulated only after considerable thought and consultation of authorities, are not assumed to be perfect, and suggestions for their further improvement will be welcomed.

Proprietary Medicine—A judicial definition of proprietary medicine found in the case of *State vs. Donaldson*, (41 Minn., 80-83) is as follows:

"It is a matter of common knowledge that what are called 'patent' or 'proprietary' medicines are prepared for immediate use by the public, put up in packages or bottles, labeled with the name and accompanied by wrappers containing directions for their use, and the conditions for which they are specifics. In this condition they are distributed over the country in large quantities and sold to consumers in original packages, just as they are purchased by the dealer, without any other or further preparation or compounding."

It is evident from the language employed that the learned judge had in mind only the class of preparations commonly known as "patent medicines," and the definition therefore is properly applicable only to that class of proprietaries.

The definition adopted by the Council on Pharmacy and Chemistry of the American Medical Association, reported in *New and Nonofficial Remedies*, is as follows :

"The term 'proprietary article,' in this place shall mean any chemical, drug or similar preparation used in the treatment of disease, if such article is protected against free competition, as to name, product, composition or process of manufacture by secrecy, patent, copyright, or in any other manner."

The latter definition possesses the advantage of compactness, with substantial accuracy, but does not set forth the factors of proprietorship with sufficient detail to meet all of the requirements of the Commission.

The essential feature of proprietorship is the special ownership claimed or assumed by the manufacturer of the exclusive right to manufacture and sell the mixture, or the exclusive right to the use of the name or title under which it is sold, and this is the feature which the Commission has sought to emphasize in the following definition :

"In its widest sense, a proprietary medicine is any drug, chemical or preparation, whether simple or compound, intended or recommended for the cure, treatment or prevention of disease, either of man or of lower animals, the exclusive right to the manufacture of which is assumed or claimed by some particular firm or individual, or which is protected against free competition as to name, character of product, composition or process of manufacture by secrecy, patent, copyright, trade-mark, or in any other manner."

Classification of Proprietary Medicines—The most obvious classification of proprietary medicines is, of course, into ethical preparations, or those which are advertised only to the medical profession, and non-ethical or patent medicines, or those which are either advertised directly to the general public, or named or advertised in such a way that in course of time the public will become acquainted with their properties, and thus be lead to purchase them direct, without the advice of a physician.

While it is simple enough to make a distinction between the two classes on paper, it is much less simple to make a practical application of the distinction.

While in theory physicians prescribe and use only those of the first class, as a matter of fact they frequently prescribe and perhaps still more frequently use those of the second class, though usually with the precaution of removing the label, or transferring the medicine to another package so that its proprietary character is not recognizable.

Bearing upon the difficulty of distinguishing between ethical and non-ethical preparations is the following extract from an editorial in the *Journal of the American Medical Association*, (Vol. 64, p. 530) :

"When the Council on Pharmacy and Chemistry was started we announced that we did not see any clear line of demarcation between 'patent medicines' and many so-called 'ethical proprietaries.' Time has not caused us to change our opinion."

To the same effect is the following extract from a letter by the Editor of the *Journal of the American Medical Association* to the Chairman of the Commission, which is quoted by permission :

"A 'proprietary' medicine is one that is owned and controlled by some individual, corporation or company. The name itself defines it. There is no difference between a 'proprietary' and a 'patent' medicine. The latter is a misnomer, but is generally applied to proprietary medicines that are advertised directly to the public. These are about the views expressed in *The Journal* on many and various occasions. At the very beginning of our propaganda work, some nine years ago, I brought out this point, and it raised a howl among the 'ethical' proprietary manufacturers. But as time has gone on I believe that the average doctor has begun to realize the same thing. Listerine used to be advertised in medical journals only ; it was then an 'ethical' proprietary. Now it is advertised in lay publications ; hence it is a 'patent' medicine. But I do not think it is any more a patent medicine now than it was ten years ago ; or that it was any more an 'ethical' proprietary ten years ago than it is to-day. So also with Antikamnia."

The distinction then between ethical and non-ethical proprietaries is not in the character of their composition, but in the manner of their exploitation. An otherwise ethical preparation exploited in a non-ethical way thereby becomes non-ethical, and this regardless of its composition or usefulness. Secrecy, while an element, is not the only element in determining the non-ethical character of a preparation, because not even the open publication of the formula will save it from being classed as non-ethical, if exploited to the general public, or if exploited in a non-ethical manner.

As stated by Editor Simmons in the letter above quoted, the term patent medicine is a "misnomer." It was applied originally to remedies protected by letters patent and sold in packages of distinctive form and size. Later the custom of taking out patents upon medicinal mixtures ceased, but the custom of selling them in packages of distinctive form and size continued, and so they have continued to bear the same designation as formerly. The term is now wholly inappropriate, but is apparently so firmly fixed in usage that it seems likely to persist as long as the class of remedies to which it is habitually applied continues in existence.

The distinction between the two classes of proprietaries finally approved by the Commission is expressed in the following definitions :

Proprietary Medicines Exploited in Accordance with the Requirements of Medical Ethics, or so-called "Ethical Proprietaries": Proprietary medicines, the active ingredients of which, with their proportions, are stated on the label or otherwise published, and which are not advertised to the general public, either through the public press, by accompanying circulars or in any other manner, and not accompanied by printed matter calculated to encourage their use by the laity without the advice of a physician.

"Proprietary Remedies Advertised Directly to the Public," or so-called "Patent Medicines": Proprietary medicines, whether of secret or open formula, which are advertised directly to the general public through newspapers, by circulars or in any other manner, and the packages of which are accompanied by printed matter specifying the affections, symptoms, or purposes for which the remedies are recommended, and directions for their use.*

* The terms "ethical" and "non-ethical" as employed in this report are intended merely to distinguish between remedies exploited in accordance with the rules of medical ethics regarding the advertising of medicinal agents, and those advertised to the general public in contravention of such rules. The terms have been used for want of better, and are not to be understood as implying any idea of relative merit.

Patented Medicines—While it is no longer customary to grant patents upon preparations which are mere mixtures of known remedial agents, it is still the custom to grant patents upon newly discovered chemical compounds which have an alleged use in medicine, and these derivatives of the tar barrel, or “German synthetics,” are among the most commonly used medicinal agents employed by the medical profession.

In order to distinguish these really patented products from the unpatented “patent medicines,” the following definition has been adopted:

“*Patented Medicine*”: Any proprietary medicine protected by an unexpired patent issued by the Government of the United States or by the government of any foreign country.

Drug Habit and Habit-Forming Drugs—One of the duties imposed upon the Commission is to determine to what extent “the proprietary medicines commonly known as patent medicines contain alcohol or habit-forming narcotic drugs in sufficient amount to render them liable to create an alcohol or drug habit, or to satisfy such habits when otherwise created,” which necessitates a clear understanding of the terms drug habit and habit-forming drugs.

While these terms are fairly well understood by medical authorities, attempts are sometimes made to stretch their application to an unwarranted extent. Some would class as a drug habit the taking of the same remedy for a recurrent ailment, although the drug was not used between the successive recurrences, and although there was no increase in the dosage required for relief. As one such correspondent puts it, “if a man in a malaria country takes quinine every time he has ‘the shakes,’ he has a drug habit, and quinine is the habit-forming drug.”

Such definitions are, of course, mere verbal plays upon the terms habit and habit-forming, and are not worthy of serious consideration.

If we examine a typical case of drug habituation we shall find certain elements constantly present:

1. Increased tolerance for the drug, so that doses can be safely taken that would have produced serious or even fatal results if taken before habituation was established.
2. The continuance of the drug after the occasion for which it was originally used has passed, for the sake of obtaining the physiological effects of the drug alone, or of avoiding the effects which would result from its discontinuance.
3. The sudden discontinuance of the drug produces a marked sense of discomfort, and may occasion serious functional disturbance.

After consultation of various authorities, the Commission has decided upon the following definitions:

“*Drug Habit*”: An acquired tolerance for quantities of a drug in excess of the normal, safe dose, and a craving or appetite which can be satisfied only by the continued use of such drug, or of some other drug of equivalent or similar physiological properties.

“*Habit-Forming Drug*”: Any drug or mixture the continued use of which leads to the toleration of quantities greatly in excess of the normal, safe dose, or to a constitutional craving or need for the drug, the sudden discontinuance of which occasions a marked sense of discomfort, and may cause serious or well-marked functional disturbance.

THE BRITISH PARLIAMENTARY COMMITTEE REPORT.

In 1914 there appeared the Report of the Select Committee of the House of Commons which had been directed to make a general inquiry into the trade in patent and proprietary medicines as conducted in Great Britain. The inquiry extended through three sessions of Parliament, during which thirty-three public sittings were held, 42 expert witnesses were examined, and more than 14,000 questions were propounded.

Nine of the witnesses were representatives of Government Departments, eleven were medical practitioners, five were public analysts, four were wholesale or manufacturing druggists, and nine were the manufacturers of proprietary medicinal preparations.

The printed report presents the conclusions of what was probably the most extended and complete investigation of the proprietary medicine industry ever made under official supervision.

While the report is entirely too long for presentation at this place, a brief synopsis of its principal features may be of interest.

The report presents a review of the laws of Great Britain and her colonial possessions, from which it would seem that in Great Britain there is much less control of the sale of fraudulent and dangerous medicines than is exercised in the United States through the operation of the Federal Food and Drugs Act, and of similar acts in most of the states.

Analyses of Secret Remedies—The difficulty of making accurate analyses of remedies containing vegetable extractives is considered and the conclusion reached that complete identification of the ingredients of a complex mixture may be impossible when drugs are used which do not contain constituents of well-marked chemical characteristics, and that of a mixture of vegetable extracts the maker "can truthfully say that the composition of his remedy cannot be discovered by analysis," and also that mixtures of "tinctures, infusions, decoctions, extracts, etc., may defy all chemical, microscopic, spectroscopic, olfactory or physiological analysis. While a mixture, therefore, may have a therapeutical value, it may also be made to defy the analytical exposure of a fraudulent claim of therapeutical value."

Classification of Proprieties—In the language of the Report: "Patent and proprietary medicines differ very widely in character. At one end of the scale is the valuable scientific preparation; at the other end is the mere vulgar swindle. Any useful consideration of them must therefore be preceded by some classification into distinct categories, as these may call for widely differing treatment in the public interest, corresponding to their differences of character."

Non-secret proprieties are divided into the three following groups:

1. "Genuine drugs originally produced synthetically, or extracted from crude compounds by skilled chemists and tested by therapeutists," the processes of manufacture of which are patented or the names of which are registered as trade-marks, represented by such examples as aspirin, adrenalin, and urotropin.

2. Remedies "that contain no new drugs, but are only new combinations, depending for their potable or assimilable qualities upon the skill with which they

are compounded," as "various emulsions of cod-liver oil or petroleum, and mixtures of bismuth with pepsin."

3. Non-secret drugs with secret excipients, or "known drugs with formula disclosed, mixed for purposes of convenient or elegant manufacture with minute quantities of medically inert substances, the nature of which is a trade secret."

Concerning the above three groups the report states: "It will be evident that unless some of the above drugs are such as should not be sold at all; unless it should be thought desirable to forbid unfounded claims of efficacy in curing disease; or unless any restriction of the multiplication of trade names be recommended, there is nothing in the above Class calling for interference in the public interest."

Secret Remedies—Secret remedies are classified under four groups which may be summarized as follows:

(1) "Household Remedies," often originally manufactured from a doctor's family prescription, and undoubtedly beneficial for uncomplicated ailments, * * * Except for the fact that often the advertisements of them recommend their use for cases they cannot benefit, thus causing the purchaser to run the risk of serious injury by delay in securing proper medical treatment, there is little or nothing to criticize in their sale."

(2) "Dangerous remedies and drugs for improper purposes," "which should not be sold at all, or which should be sold only on a doctor's prescription, or which should not be sold for the purpose for which they are offered."

(3) "Fraudulent remedies," "consisting of abortifacients, of alleged cures for cancer, consumption, diabetes, paralysis, locomotor ataxia, Bright's disease, lupus, fits, epilepsy, rupture (without operation or appliance), deafness, disease of the eye, syphilis, etc., together with electric belts, apparatus for supplying oxygen to the system, (other than by inspiration), 'ionized' waters," and the like. "There should be little difficulty in identifying remedies of this class, and their treatment in the public interest need involve no doubt or hesitation. They are, and are known by their makers to be, cruel frauds; and the sale and advertisement of them should be prohibited under drastic penalties."

(4) "Genuine simple remedies" which possess real therapeutic value, but "depending for their sale largely or wholly upon the extravagant promises they hold out to the purchaser," including such as "under the name of misbranding," are "now prohibited by law in the United States," and such as are "refused admission into Australia."

Concerning the latter the Report says: "This group presents obviously great difficulties in drawing the line between claims which are merely 'puffs' and claims which are fraudulent, but we regard it as beyond question that the public is defrauded on a large scale by promises which cannot possibly be fulfilled."

The report submits examples of questionable secret remedies and of the exaggerated and fraudulent claims made for them, and of "fake prescription proprietaries" under coined names especially designed to "deceive the public into the belief that they are not proprietary articles, but are familiar drugs, purchasable in small quantities at ordinary prices."

Examples of British nostrums of this class are "pure colorless kalamax," "salith leaves," "stallax," "pilenta soap," "jettaline," "allacite of orange blossom," "tennaline," "carmarole," etc.

The Trade in Abortifacients—Judging from the space devoted to the subject, abortifacients or alleged abortifacients are more numerous and are advertised and sold more openly in the United Kingdom than in the United States.

From the report it appears that these abortifacients are not commonly sold in the form of recognized proprietary medicines, but it is said that "simple aperient pills from reputable makers are frequently recommended in language suggesting that they are efficacious for this purpose," as, for example, the recommendation that "women suffering from any 'unusual delay' take 5 pills a day."

The Medical Profession and Secret Remedies—The Committee states that "so far as we have been able to discover, no scientific chemist and no qualified medical man, with rare exceptions, is connected with or employed in the manufacture of secret remedies such as those we have placed in Class B," (secret remedies) which is certainly contrary to experience in America, where a considerable number of medical frauds have been exploited by persons regularly licensed to practice medicine.

The report admits, however, "that many medical men give testimonials (with the use of their medical qualifications but without the use of their names) to proprietary and secret remedies."

The Publication of Formulæ—Perhaps the most unexpected feature of the report is the position which the Committee takes with regard to the publication of the formulæ of proprietary remedies. Considering that the personnel of the Committee was one which suggested the probability of a report unfavorable to the proprietary medicine business in general, and that the majority of the witnesses examined were those whose official positions or personal interests might prompt them to oppose the sale of secret medicines, it was anticipated that one of the recommendations of the Committee would be an unqualified pronouncement in favor of compelling the publication of formulæ of proprietary remedies. The conclusions of the Committee, are, however, quite the reverse, as will appear from the following:

"It has been strongly urged upon us, chiefly by witnesses representing the medical profession, that every remedy sold should by law be compelled to bear a label stating its exact composition. This is what is meant by 'exhibition of formula,' and witnesses advocating it came to us convinced that this simple change in the law would secure adequate protection of the public against injury and fraud."

"We have given long and careful consideration to this proposal, and we find ourselves unable to recommend it. In the first place it would beyond question inflict a grave hardship, sometimes amounting to ruin, upon proprietors of secret remedies, or the loss of their investments upon shareholders in limited companies. Any long established remedy in the lawful advertising and sale of which very large sums have been spent, would immediately be faced upon the market by a score of preparations advertised as made from the same formula and sold at a much lower price. An example was given to us of a remedy the proprietary rights of which were immediately destroyed by disclosure of its formula.

"The above would not, we are aware, be a conclusive argument against this pro-

posal if its adoption would really protect the public against danger and fraud. We are convinced, however, that such would not be the case. Any benefit resulting from exhibition of formula must obviously depend for its efficacy upon the intelligence and education of the intending purchaser. It could not in any other way afford protection to the purchaser or restrict the operations of the vendor, though incidentally it would enable a retail chemist to offer the same drug or mixture made up by himself, at a lower price. But to a large majority of purchasers a statement of composition or contents on the label would afford no information whatever. The disclosure that a remedy contains or consists of 'acetylsalicylic acid,' or 'hexamethylene-tetramine,' or 'phenolphthalein,' or 'taka-dias-tase,' or 'emplastrum plumbi,' or even 'acetanalide,' or 'potassium iodide,' would be meaningless to most people; indeed, the simplest substances might acquire distinction from being described in technical chemical language—soap, for instance, a large ingredient of the most popular aperient pills, posing as 'sodium oleate and stearate.' And if it be rejoined that the popular name should be required to be given, the answer is obvious that many of the most important drugs, such as most of those mentioned above, have no popular name. Further, an accurate statement of contents might be in itself misleading. For example, if 'Phosferine' were stated to contain phosphoric acid, almost every purchaser would believe that he was getting assimilable phosphorus."

"For these reasons exhibition of formula (except in the case of alcohol, poisons, and certain dangerous drugs) does not appear to us to be a proper, practical or effective measure."

Recommendations—The principal points of the final recommendations of the Parliamentary Committee are as follows:

"That the administration of the law governing the advertisement and sale of patent, secret and proprietary medicines and appliances be coördinated and combined under the authority of one Department of State."

"That there be established at the Department concerned a register of manufacturers, proprietors and importers of patent, secret and proprietary remedies, and that every such person be required to apply for a certificate of registration and to furnish (a) the principal address of the responsible manufacturer or representative in this country, and (b) a list of the medicine or medicines proposed to be made or imported."

"That an exact and complete statement of the ingredients and the proportions of the same of every patent, secret and proprietary remedy; of the contents other than wine, and the alcoholic strength of every medicated wine, and a full statement of the therapeutic claims made or to be made; and a specimen of every appliance for the cure of ailments other than recognized surgical appliances, to be furnished to this Department, such information not to be disclosed except as hereinafter recommended, the Department to control such statement, at their discretion, by analyses made confidentially by the Government Chemist."

"That a special Court or Commission be constituted with power to permit or to prohibit in the public interest, or on the ground of non-compliance with the law, the sale and advertisement of any patent, secret or proprietary remedy or appliance, and that the commission appointed for the purpose be a judicial authority such as a Metropolitan Police Magistrate sitting with two assessors, one appointed by the Department, and the other by some such body as the London Chamber of Commerce."

"That a registration number be assigned to every remedy permitted to be sold, and that every bottle or package of it be required to bear the imprint 'R N. ' (with the number), and that no other words referring to the registration be permitted."

"That in case of a remedy the sale of which is prohibited, the proprietor or manufacturer be entitled to appeal to the High Court against the prohibition."

"That the Department be empowered to require the name and proportion of any poisonous or potent drug forming an ingredient of any remedy to be exhibited upon the label."

"That every medicated wine, and every proprietary remedy containing more alcohol than that required for pharmacological purposes, be required to state upon the label the proportion of alcohol contained in it."

"That the advertisement and sale (except the sale by a doctor's order) of medicines purporting to cure the following diseases be prohibited:

cancer	diabetes	locomotor ataxia
consumption	paralysis	Bright's disease
lupus	fits	rupture (without operation
deafness	epilepsy	or appliance

"That all advertisements of remedies for diseases arising from sexual intercourse or referring to sexual weakness be prohibited."

"That all advertisements likely to suggest that a medicine is an abortifacient be prohibited."

"That it be a breach of the law to change the composition of a remedy without informing the Department of the proposed change."

"That fancy names for recognized drugs be subject to regulation."

"That the period of validity of a name used as a trade-mark for a drug be limited, as in the case of patents and copyrights."

"That it be a breach of the law to give a false trade description of any remedy, and that the following be a definition of a false trade description: 'A statement, design or device regarding any article or preparation, or the drugs or ingredients or substances contained therein, or the curative or therapeutic effect thereof, which is false or misleading in any particular.' And that the onus of proof that he had reasonable ground for belief in the truth of any statement by him regarding a remedy, be placed upon the manufacturer or proprietor of such remedy."

"That it be a breach of the law—

- (a) "To enclose with one remedy printed matter recommending another remedy.
- (b) "To invite sufferers from an ailment to correspond with the vendor of a remedy.
- (c) "To make use of the name of a fictitious person in connection with a remedy. (But it should be within the power of the Department to permit the exemption of an old established remedy from this provision.)
- (d) "To make use of fictitious testimonials.
- (e) "To publish a recommendation of a secret remedy by a medical practitioner unless his or her full name, qualifications and address be given.
- (f) "To promise to return money paid if a cure is not effected."

A PROVISIONAL STANDARD FOR PATENT MEDICINES.

In view of the extended work of the A. M. A. Council on Pharmacy and Chemistry upon proprietaries addressed especially to the medical profession, it is not likely that the Commission will greatly concern itself with this particular class of preparations, except perhaps in connection with their purely trade relations.

As regards non-ethical proprietaries, or patent medicines, the Commission has undertaken to formulate a set of tentative declarations setting forth certain requirements as a minimum standard which non-ethical proprietary medicines should meet in order to render them safe in the hands of the general public.

It should be noted that these declarations are put forward as provisional, and that they do not necessarily represent the final opinion of the Commission as to the requirements with which this class of preparations should be expected to comply.

The reasons for the adoption of some of these declarations will probably be sufficiently apparent without explanation. In the case of some others a brief review of the reasons which lead to their adoption may be of value.

Fraudulent Prescription Nostrums—Some ten or a dozen years ago, there appeared a class of proprietary articles, now commonly known under the title of "fraudulent prescription nostrums," which because of the cleverness with which they were advertised immediately became very profitable to their exploiters, and as a consequence increased in numbers until they have become a veritable plague to the drug business, both wholesale and retail. While differing in other respects, these nostrums possess the common characteristic of employing fanciful or coined names designed to conceal their proprietary character and to convey the idea that they are simple chemical compounds, or known vegetable drugs commonly found in drug stores and purchasable in small quantities.

One popular form of advertisement for these nostrums is a pretended prescription or formula, the name of the nostrum being cleverly introduced among a list of popularly known drugs, the combination either to be made up by the druggist or by the purchaser himself.

Many of these hypocritical formulas appeal to the feminine desire for personal beauty, and are exploited as the prescriptions of alleged medical specialists or as used by some famous stage beauty.

Chemical analyses of this particular breed of nostrums show that they are frequently composed of the most common and cheap ingredients, as table salt, baking soda, alum, borax, powdered soap, etc., tinted and scented to conceal their simple character, and usually sold at prices enormously in excess of their real value.

Admitting that certain of these combinations may possess some of the cosmetic or medicinal value claimed for them, the Commission is of the opinion that the plain hypocrisy of their exploitation is indefensible upon any ground of fair commercial practice, and has accordingly introduced into the list of requirements for proprietary medicines the following:

Prescription Fakes, Concealment of Proprietary Character—The preparation must not be named or advertised in such a way as to conceal its proprietary character and lead the purchaser to believe that it is a simple chemical or vegetable drug ordinarily purchasable in small quantities, instead of a proprietary mixture or substance.

Mail Order Medicines—Another class of proprietaries deserving of special mention are the products of what may be denominated as the "mail order prac-

tice of medicine." This scheme is usually worked in the name of a physician or company of physicians, operating either on their own account or in the employment of third persons, and consists in the use of newspaper advertisements or of purchased mailing lists to get into communication with prospective customers and then continuing the connection by means of mail correspondence. Pretentious symptom blanks are sent to the patient to be filled out, but no matter what the symptoms are, the case is treated by the sending of one or more stock mixtures which seem to fit every case.

If these ready-made mixtures were found in the stock of a drug store they would undoubtedly be denominated patent medicines, but if they were found in either wholesale or retail drug stocks they would be subject both to federal and to state food and drug laws, and to investigation and analysis by state food and drug departments. Masquerading as they do under the disguise of physicians' prescriptions they escape the wholesome control of these agencies, and as shown by the exposures in *Nostrums and Quackery*, have been the frequent instruments of fraud, and the means of disseminating habit-forming drugs.

Bearing upon this method of marketing, the Commission has adopted the following declaration:

Methods of Marketing—The preparation must be one which is regularly offered to the public through the usual trade channels, i. e., through regular wholesale and retail dealers in ready-made medicines, and thus subject to inspection by the authorities charged with the enforcement of state food and drug laws.

Alcohol Content—The purposes for which alcohol may be legitimately used in a medicinal preparation are to extract and hold the active constituents of drugs in solution in permanently active condition, or to prevent fermentation, moulding, freezing or other spoilage.

Whether or not an alcoholic medicine can be made to serve as a substitute for a beverage alcoholic liquor depends upon the degree and character of the medication, or upon whether or not the degree of medication is sufficiently great to render it impossible to obtain sufficient alcohol to produce the characteristic stimulation of that compound without taking an overdose of the remaining constituents.

This excess of alcohol in proportion to the degree of medication may be the result of design with the intention of selling an alcoholic stimulant under the disguise of a medicine, or it may be due to the fact that the medicating substance naturally possesses such low activity that it is difficult to include sufficient of it in the solution to prevent the predominance of the alcoholic effect. The latter is the case with numerous undoubtedly legitimate official preparations, such as many of the spirits, elixirs, tinctures, essences, etc., some of which, although the attempt is made to reduce their alcoholic content to the lowest degree consistent with pharmaceutical requirements, yet are capable of serving more or less perfectly as alcoholic substitutes.

In view of the fact that alcohol is a rather expensive ingredient to use in proprietary medicines, it may be assumed that when such remedies are issued in good faith the alcoholic percentage will be as low as the pharmaceutical requirements of the particular combination will permit. Conversely, it seems fair to

assume that when the alcohol percentage of a mixture is far in excess of pharmaceutical requirements, it is for the express purpose of making a preparation that will serve as a substitute for beverage alcoholic liquors.

In considering this question, use was first made of the investigations of the U. S. Commissioner of Internal Revenue in connection with the collection of the tax upon the sale of alcoholic liquors at retail, the results of which are issued from time to time in the form of printed lists of alleged medicinal compounds which are deemed so strongly alcoholic in proportion to the degree of medication as to bring them fairly within the class of alcoholic beverages.

The revenue list examined was dated June 6, 1914, and contained 287 titles of such preparations, with the names and addresses of their manufacturers.

Upon comparing this list with two of the largest wholesale price lists of proprietary medicines, there was found after the elimination of duplicates, a total of 14 preparations named in the price lists which were also included in the revenue list. In other words, 14 preparations recognized as proprietary preparations by the publishers of price lists of such preparations are also recognized as excessively alcoholic by the Commissioner of Internal Revenue.

Examination of several drug stocks failed to show the presence of any of this class of preparations on sale, and inquiries addressed to several wholesale druggists brought the reply that the great majority of the preparations contained in the Revenue Department circular were practically unknown to the wholesale drug trade, and that it was believed that they were mostly sold through the saloon trade, or were preparations of local character devised to evade local prohibitory laws, and ordinances, and not offered for sale outside of the localities in which they originated.

The subject was next approached by the examination of the statements of alcoholic percentage taken from the labels of 1108 proprietary preparations issued by the leading manufacturers of this class of goods within the United States, and believed to fairly represent the average of patent medicines handled by retail druggists. As these statements are required by the Federal Food and Drugs Act, and by similar acts in most of the states, it was believed safe to rely upon their substantial correctness. While it is, of course, possible that some of these statements were not correct, it is not thought likely that there was a sufficient number of misstatements to introduce any material error into the final result.

Of the 1108 preparations considered, three hundred and eight, or 27.79 percent of the total number, were stated to contain alcohol in proportions ranging from 1 percent upward.

A study of the proportion of alcoholic to non-alcoholic preparations recognized by the United States Pharmacopœia and National Formulary, yields the following:

Total number of U. S. P. preparations, liquid and solid, of galenical character	427
Number of U. S. P. galenicals containing more than one percent of alcohol	206
Percent of U. S. P. galenicals containing alcohol	48.24

A similar study of the titles of the National Formulary (third edition), most of which are for preparations which can be denominated pharmaceuticals, presents the following:

Total number of N. F. preparations of galenical character	575
Total number of N. F. preparations containing alcohol	274
Percent of N. F. preparations containing alcohol	47.65

In enumerating the U. S. P. and N. F. galenicals, definite chemical compounds, vegetable drugs, the several forms of unmedicated alcohol, unmedicated spirits, and unmedicated wines were omitted as not properly coming within the term pharmaceutical preparations, and therefore not properly comparable with proprietary medicines. Certain other U. S. P. and N. F. preparations which contain only trifling quantities of alcohol, such as syrup of tolu, etc., were also omitted.

No preparations were considered as alcoholic if the alcohol is removed in the process of manufacture.

While the study of the general subject of alcohol in proprietary medicines has not proceeded sufficiently to warrant any extensive generalizations, and is therefore reserved for further study, the Commission at this time offers the following declaration:

Alcohol Content of Proprietary Medicines—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.

Content of Habit-Forming Narcotic Drugs—Using the same 1108 preparations studied for alcoholic content, a similar study was made of their content of narcotic, habit-forming drugs, the data being taken from the statements on the labels made in accordance with the requirements of federal and state laws.

One fact developed was that not one of the labels mentioned the presence of cocaine in any quantity, a condition rather unexpected in view of the frequently published statement that this alkaloid is a frequent constituent of patent medicines. While undoubtedly there were formerly proprietary remedies containing cocaine, and that there still may be some that have not come to the attention of the Commission, it is not probable that a sufficient number of such preparations exist to constitute a serious menace.

Extract of Cannabis Indica was mentioned in three of the 1108 preparations, two of the three being corn remedies which could not be used internally, and the third a cough remedy in which the accompanying medication is probably sufficient to render it unlikely that the preparation could be successfully used to produce the narcotic effects of the Cannabis without taking an overdose of the other ingredients.

No one of the 1108 preparations was stated to contain chloral in any proportion, though it is possible that further search may develop the existence of chloral-containing medicines which are advertised to the general public.

The preparations, presumably not intended for internal use, stated to contain opium or one of its alkaloids in some proportion were as follows:

Injections for Gonorrhœa	2
Tooth-Ache Remedies	2
Liniments and Embrocations	5
Pile Remedies	8
Antiseptic Salve	1
Eye Salves and Eye Waters	10
	<hr/>
Total	28

In the above preparations the narcotic content was in excess of two grains of opium, or of one-fourth grain of morphine to the ounce in twenty instances, and not in excess of these proportions in five instances.

Whether any of the above 28 preparations would be capable of use internally so as to produce the narcotic effect of opium without an overdose of the other constituents has not yet been given consideration by the Commission.

The preparations admittedly intended for internal use, containing opium or a derivative were as follows:

Asthma and Bronchitis Remedies	2
Soothing Powders and Teething Syrups	4
Diarrhœa Cordials and Cholera Morbus Remedies	12
Cough and Cold Cures	21
Tablet forms, mostly for cough	3
	<hr/>
Total	44

Besides the above there were 15 preparations of miscellaneous character not easily classified with any of the preceding, which contained opium or one of its alkaloids.

Of the preparations plainly intended for internal use, seven contained opium in excess of two grains to the ounce, six of these being diarrhœa cordials, or cholera morbus remedies, in which the proportions ranged from 3 to 8 grains to the ounce, or materially less than the average opium content of the five diarrhœa mixtures of the National Formulary. The last one of these seven preparations was an asthma remedy, which was stated to contain $23\frac{1}{3}$ grains of opium to the ounce.

The largest proportion of morphine or its sulphate in any preparation for internal use was 1 grain to the ounce. In one preparation the alkaloid present was codeine, in the proportion of $11\frac{1}{34}$ grain to the ounce of tablets.

Heroin was reported in one cough syrup in the proportion of $1\frac{1}{19}$ grain to the ounce.

In the majority of cases the proportions stated to be present did not exceed the quantities permitted by the Harrison Law, namely, 2 grains of opium, $\frac{1}{4}$ grain of morphine, 1 grain of codeine, or $\frac{1}{8}$ grain of heroin to the ounce, and in many cases the proportions are considerably lower.

Of the four preparations for children's use which contained opiates, two contained 2 grains of opium, one contained $\frac{9}{20}$ grain of opium, and one $\frac{1}{4}$ grain of morphine to the ounce.

It is perhaps only fair to state that the statements of narcotic content were compiled before the enactment of the Harrison Law, and it is probable that if the packages now being issued were to be examined it would be found that those intended for interstate commerce would comply with that act.

Whether or not opium or its alkaloids, or the narcotic derivatives of the latter can be dispensed in combination with other active non-narcotic drugs in such a way as to prevent the use of the combination from leading to a drug habit is a question which the Commission expressly reserves for further study.

As a provisional measure the Commission has adopted the following declarations:

Content of Habit-Forming Drug—If the preparation is one which is capable of being used internally, whether recommended for internal use or not, it must not contain cocaine, nor shall it contain opium 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 proportion that the use of the preparation will not be likely to create a drug habit, nor satisfy such a habit when previously existing.

Remedies for Children's Use—If intended for administration to infants or children, the preparation must not contain cocaine, or opium or its alkaloids, or their derivatives, in any proportion whatever.

Of the remaining declarations, namely, those relating to the Activity of Proprietary Preparations, Immoral or Illegal Purposes, Incurable and Contagious Diseases, Conformity in Labeling to the Federal Food and Drugs Act, and to Advertising, the Commission deems them of such evident propriety that no commentary is needed, and therefore offers none.

The ten declarations provisionally adopted are as follows:

MINIMUM REQUIREMENTS WITH WHICH PROPRIETARY REMEDIES SHOULD COMPLY IN ORDER TO RENDER THEM SAFE FOR DIRECT SALE TO THE GENERAL PUBLIC.*

The following declarations are provisional, and subject to repeal, modification or expansion as the Commission may later decide.

(1) *Prescription Fakes, Concealment of Proprietary Character*—The preparation must not be named or advertised in such a way as to conceal its proprietary character and lead the purchaser to believe that it is a simple chemical or vegetable drug ordinarily purchasable in small quantities instead of a proprietary mixture or substance.

(2) *Methods of Marketing*—The preparation must be one which is regularly offered to the public through the usual trade channels, i. e., through regular wholesale and retail dealers in ready-made medicines, and thus subject to inspection by the authorities charged with the enforcement of state food and drug laws.

(3) *Alcohol Content*—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

* Approved by the Council of the American Pharmaceutical Association, San Francisco, August 10, 1915.

essential constituents of the preparation, and to protect the preparation against freezing, fermentation, or other deleterious change.

(4) *Content of Habit-Forming Narcotic Drugs*—If the preparation is one which is capable of being used internally, whether recommended for internal use or not, it must not contain cocaine, nor shall it contain opium 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 proportion that the use of the preparation will not be likely to create a drug-habit, nor satisfy such a habit when previously existing.

(5) *Remedies for Children's Use*—If intended for administration to infants or children, the preparation must not contain cocaine, or opium or its alkaloids, or their derivatives in any proportion whatever.

(6) *Activity of the Preparation, Cautions Against Misuse*—The preparation must be of such character that it will not be liable to endanger life or health when used in accordance with the accompanying instructions, and if the preparation is one which is liable to occasion injury when improperly used or when used to excess, the accompanying literature must bear instructions tending to guard against such improper or excessive use.

(7) *Immoral or Illegal Purposes*—The preparation must not be intended for use as an abortifacient nor for use for any other immoral or illegal purpose, nor must it be advertised or recommended either directly or indirectly as an abortifacient or for any immoral or illegal purposes.

(8) *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.

(9) *Conformity to the Federal Food and Drugs Act.*—Neither the label on the package nor any of the accompanying literature shall bear or contain any statement in conflict with the misbranding provisions of the Federal Food and Drugs Act.

(10) *Advertising Not Accompanying the Package*—Advertising not accompanying the package shall conform substantially to the statements on the label, carton, or in the accompanying circulars as to the origin, composition or character of the preparation, or concerning its curative or remedial value.

THE QUESTIONS OF SECRECY AND EXHIBITION OF FORMULAE.

One of the most common characteristics of the non-ethical proprietaries known as patent medicines is the secrecy of their composition, though, as previously stated, the open publication of the formula is not sufficient to place a preparation in the ethical class if it is openly offered for sale to the general public.

The question of secrecy is by far the most delicate and difficult one with which the Commission has to deal, and although considerable thought has been devoted to the subject no conclusion has been reached.

Which of the various propositions that have been offered for the regulation of secrecy, or whether any of them would be effective and practicable, are much disputed questions, and it would require an extended treatise to even partially summarize the opposing arguments.

Far too many alleged reforms consist merely in the substitution of a set of new

evils for an old one, and not infrequently we later discover that the exchange has been unprofitable.

It is the hope of the Commission to consider the subject of secrecy in patent medicines with such thorough deliberation that any policy it may propose will not be likely to lead to conditions worse than those sought to be cured.

Respectfully submitted,

CHARLES CASPARI, JR.,
THOMAS F. MAIN,
JOHN C. WALLACE,
MARTIN I. WILBERT,
JAMES H. BEAL, Chairman,
Commission on Proprietary Medicines.



R. S. LEHMAN, New York
Chairman of Section on Education
and Legislation



JOSEPH WEINSTEIN, New York
Chairman of Section on Practical
Pharmacy and Dispensing