

opinion the doctors who were present spread the information among those in their own sections who did not attend the meeting. It would be an easy matter to interview these doctors and re-impress them relative to the preparations which they had seen displayed at their annual meeting. Less than \$100.00 had been spent and the results were well worth while.

Chairman Hunsberger said that the lesson from Mr. Webster's paper suggests that each pharmacist secure a copy of the "Epitome" and take this along when he interviews local physicians.

Emil Roller said that the pharmacists in New York had to contend with a large number of detail men who visited the physicians and left samples with them. These preparations the physician dispensed. Not only does this interfere with the work of the pharmacist, but it may do injury to the physician's practice by leading the patients to self medication.

W. Bruce Philip called attention to the members that some manufacturers were putting out preparations under U. S. P. and N. F. names that are deficient as far as strength is concerned and sometimes as to solvent. He referred, among other preparations, to non-alcoholic elixir for simple elixir and half-strength elixir I. Q. and S. In his opinion a strong stand ought to be taken against such practice. It is true that these preparations have labels which indicate that they differ from the U. S. P. and N. F. formulas, but the physician and the patient are apt to overlook this information. He had visited quite a number of drug stores and found that even the druggists were not aware of the fact. **Mr. Stanbury** inquired whether such things could be legally done in this country. **Mr. Philip** advised that such preparations could be sold provided the label stated the difference in strength. However, the fact that the preparation was less expensive because of content the salesman could offer them at a lower price than obtained for the U. S. P. or the N. F. article. **Mr. Stanbury** stated that in Canada a B. P. preparation must conform in every respect to the strength of that formula.

Dr. Stanbury referred to the bootleg druggist. He said that he was practically extinct in Canada. That the Pharmacy Act had been amended so that after the second offense his license is automatically suspended for a year and can only be restored by giving State evidence that he would observe the law. A license fee is required to keep alcohol on the premises. He expressed appreciation of the reception accorded him by the members.

Chairman Hunsberger stated that it was a pleasure to have **Secretary Stanbury** attend the convention. Referring to the treatment meted out to the bootleg druggist in Canada, he said, "It is a harsh but a deserved treatment." In his opinion, we in this country are a little too lenient in handling matters of that kind.

With reference to the labels which had been spoken of he remarked that he had a startling experience within a year—relative to a tincture of digitalis which, supposedly, was three times the official strength. If it really was three times the strength of the U. S. P., it is apparent that the preparation is dangerous. A preparation should be in accord with the implied or designated standard.

P. Henry Utech said he was trying to evolve a resolution that might cover the requirement. The resolution might disapprove of the practice of manufacturing firms in offering for sale pharmaceutical preparations that in a way are substitutes for U. S. P. and N. F. preparations. **Chairman Hunsberger** said that the resolution might state that such preparations be no stronger nor weaker than those of the standards. He called attention to the fact that three members of the Committee on Resolutions were in the room and they might take up the matter for the purpose of formulating a resolution. **Mr. Utech** so moved; this was seconded and carried.

SOME NOTES ON THE HISTORY OF THE PROPRIETARY ASSOCIATION.*

BY ERVIN F. KEMP.

In the presentation of a "history" it is probably necessary that some figures and dates, as well as some names, be given; though the true history of a commercial trade association is not so concerned with dates and names and figures as it is with motives and accomplishments.

* Section on Historical Pharmacy, A. Ph. A., Philadelphia meeting, 1926.

This is particularly the era of commercial trade organizations. Under our Government, commercial trades are forced to be interested in matters of government, and especially in legislation, both State and national. The association contact is necessary if a manufacturer is to know his obligations and duties and realize his opportunities, privileges and rights.

Whether you know it or not, or whether, knowing it you realize its import or not, the government under which we live has undergone, in the last decade or so, a rather complete revolution. Nothing but the shell of the old government remains.

We are now governed by bureaus; the commercial trade organization is the concomitant of the government bureaus.

There are, in the United States, according to Federal census, only 1363 manufacturers of proprietary medicines doing an annual gross business of \$5000 or more. Of these only 363 manufacturers do \$100,000 or more of annual business. The total annual output was \$177,683,403.

In 1882, when the Proprietary Association came into being, there were 563 establishments manufacturing proprietary medicines, with a total annual output of \$14,682,494. Not 50 of them were capable of being run as profitable, separate businesses. Many of them were merely adjuncts to wholesale or retail establishments; and in the census from which these figures are taken did not segregate the group into sub-groups based upon annual output.

Erior to 1882 the proprietary manufacturing trade had no organization. It was loaded down with onerous burdens. It still had to meet the stamp tax imposed during the Civil War emergency; it paid a tax on alcohol used as a material of manufacture. It had other problems, and no way to meet them jointly.

Groups of manufacturers had, for years, met informally, but in June 1882, the organization of an association known as "The Manufacturers and Wholesale Dealers in Proprietary Articles of the United States" was perfected. Its avowed purpose was covered in a section of its by-laws, as follows:

"The object of this Association shall be the mutual protection of the rights of its members to the respective Trade Marks that they may own or possess; to establish such mutual coöperation as may be required in the various branches of the trade; to unite in reducing such burdens as may be oppressive; to facilitate and foster equitable principles in the purchase and sale of our merchandise; to establish and maintain uniform commercial rates; to acquire and preserve for the use of its members such business information as may prove of value to them; and to adjust controversies and promote harmony among its members."

Its program was to straighten out trade disputes, to meet legislation emergencies, then consisting of a bill now and then in a State Legislature, to secure the repeal of the Civil War Stamp Tax and to secure tax-free alcohol for the manufacture of medicines and pharmaceutical specialties. The latter it is still fighting for, and intends to fight for until the tax is finally repealed.

Later the name of the organization was changed to "The Proprietary Association of America" and still later to "The Proprietary Association."

The first officers were:

President: Charles S. Crittenden, New York.

First Vice-President: John J. Thomsen, Baltimore.

Second Vice-President: Charles C. Goodwin, Boston.

Third Vice-President: John F. Henry, New York.

Fourth Vice-President: James S. Richardson, St. Louis.

Treasurer: Dr. Fred Humphreys, New York.

Secretary: S. R. Pinkney, New York.

The first list of members available is for 1885, when there were 76, of which about 50, either directly, by the original houses, or by their successors, are still members. The others have largely passed out of business, or been merged with existing houses, but the products manufactured by many of them are still represented in the Association.

In the nearly forty-five years of its existence, the Association has had 14 presidents, as follows:

Charles N. Crittenden,
F. Humphries, M.D.
R. V. Pierce, M.D.
Alfred B. Scott
R. E. Queen
Thomas Doliber
V. Mott Pierce, M.D.

E. C. DeWitt
H. B. Harding
D. S. Chamberlain
W. A. Talbot
Frank J. Cheney
A. H. Beardsley
Frank A. Blair

The expansion of the Proprietary Association came about gradually. In 1897, when the Association was 15 years of age, an attorney was retained to counsel the members, and advise them. From that action grew the present legal department, having the full-time services of an able attorney, whose duties have been greatly increased, not only by reason of the expansion of the trade, but principally by increasing legislative and regulating restrictions placed, not alone around the business of manufacturing drug products, but about practically all of the functions of business. Proprietary manufacturers, in addition to the problems peculiar to that business, have to meet all of the other problems confronting business as such.

The only incumbents of this position have been George L. Douglass, and his successor, at present in office, Harry B. Thompson.

The next step in the development and expansion was the appointment in 1905 of Ervin F. Kemp, as "Secretary of Committees." From this step developed the establishment of a legislative bureau, with the "Secretary of Committees" as the active man, charged with the task of securing and disseminating information from each State Capital, and from Washington, of proposed legislation, and regulations relating, in any way, to the drug-manufacturing industry. The Bureau has been conducted since that time, under the supervision of the "Secretary of Committees," whose title was changed to that of "General Representative."

In 1915, still another department was created, marking the most important forward step ever taken by the organization, and one of the most important forward steps ever taken by any commercial trade organization up to that time. It consisted of the amendment of the by-laws, by the inclusion of a section setting up certain "Requirements for Membership," and the reaction of a "Requirements Committee." The section of the by-laws is as follows:

To be eligible to membership in the Proprietary Association every article manufactured by the applicant or the member must comply with the following minimum requirements:

(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, 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 eucaïne; nor shall it contain opium or any of its alkaloids or their derivatives in greater proportion 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 should 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 disease or conditions which are generally recognized as incurable by the simple administration of drugs.

(6) The package either as to its 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 finds 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 preparation, 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.

These requirements present a minimum and not a maximum of the conduct of manufacturers represented within the Association.

Some background needs to be established for this action. The Food and Drugs Act was passed on June 30, 1906, and for several years thereafter a condition bordering on chaos existed in the trade. The Act, so far as it applies to prepared medicines, is a branding law; it provides that no drug shall be held out falsely or fraudulently, as to its therapeutic properties, or in any misleading manner with regard to its origin or composition.

It also requires the revelation of the quantity or proportion of certain drugs, if contained.

Its enforcement is lodged with the Secretary of Agriculture, the Secretary of the Treasury, and the Secretary of Commerce and Labor, with provision (in Section 4) that the Bureau of Chemistry shall examine specimens of foods and drugs to determine whether these products are misbranded or adulterated within the meaning of the Act. To facilitate the work there was created within the Bureau certain boards, which are wheels within wheels. One of them in the Board of Drug Control, which has immediate supervision over drugs.

Prior to the enactment of the law there had been no standards of any kind.

Manufacturers had accepted, as their therapeutic standard, the views and opinions, in many cases, of the originators of the formulas, usually doctors who, in their practices, had developed certain prescriptions. We all know that doctors do not always agree on therapeutic or curative properties of drugs or compounds of drugs. There was no one representing a medical consensus—no standards, no authorities.

The Bureau of Chemistry refused to instruct or advise; it cited and prosecuted. It held itself to be a law-enforcing, not a law-instructing body. Its Chief was a Czar, and the trade was at its wits' end. Manufacturers were willing to obey any proper law, and the Food and Drugs Act was a proper law, foreseen by far-sighted manufacturers to mean as much for the trade as it did for the public. They were unable to arrive at any basis of understanding. Their own medical advisers, their own research departments, could not guide them, for there was an arbitrary power which could not be consulted for a basis of understanding, but which would only prosecute. This has been changed largely by the attitude of this, and other associations.

It took some time to straighten matters out, and get the machinery of the law in working order, and in making it workable. Some litigation to the Supreme Court of the U. S. ensued, in which neither the Proprietary Association, directly, or any of its members had any part. The Supreme Court, in deciding in favor of an accused manufacturer and against the government, made the amendment of the Act necessary if it were to accomplish what its sponsors wanted to accomplish, and what our Association Attorney—George L. Douglass at that time—held that it did accomplish without amendment. However, the Shirley Amendment, so-called, followed, and the ambiguity of the law was cleared.

Upon organization of the Requirements Committee in 1915, Fred K. Fernald was designated Secretary. The services of a therapist and of a pharmaceutical chemist were engaged, and others engaged to act as consultants. Mr. Fernald served as Secretary until physically incapacitated, when Ervin F. Kemp was designated.

A call was immediately issued to members of the Association to make the submissions called for by the amended by-laws, and every member responded. Every label and every bit of printed matter was gone over and brought into line with the then understanding of the law, and the regulations created for its enforcement.

Since that time other complete examinations have been made, and, as a result of each, further advances were made, and a third subsequent examination, or a fourth in all, is now nearing completion; each having as its object the revision of labels to a compliance with the interpretation of the law as applied by the Board of Drug Control of the Bureau of Chemistry.

While citations of members of the Association have not wholly ceased, they have been reduced to a rarity.

The Requirements are not confined to the matter of labeling. They touch, among others, the subject of narcotics and alcohol. As to opium and its derivatives, the standard adopted was that of Section 6 of the Harrison Act, patterned after the so-called "Chicago Model Bill," adopted after conferences between all drug-trade organizations, and in the passage of which the Proprietary Association took its part. Opium or derivatives are practically unknown in packaged medicines manufactured by members of the Proprietary Association.

The requirement as to alcohol states that a medicine containing alcohol, if manufactured by a member of the Association, must contain no more 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."

In 1915, or four years before the passage of the Volstead Act, the Proprietary Association adopted its standard, in language almost identical with that of the definition of the Volstead Act. Although about 25 per cent of the preparations manufactured by the members of the Proprietary Association contain alcohol, no member has ever had a permit refused, revoked, or seriously questioned.

The Requirements Committee for eleven years has attempted to keep not only abreast of, but if possible, a little in advance of the requirements of the Bureau, which has been a difficult task, for, with one exception, the Bureau has made no advance announcement of its changed policies or of its field of investigation. The Committee has freely consulted the Bureau and has always sought to the very limit of its ability so to do, to so shape the course of the members of the Association that their items might not by even the most liberal construction be regarded as misbranded under the provisions of the Food and Drugs Act. It has not, unfortunately for all concerned, been able at all times so to shape the conduct of the members of the Association, through its advice and suggestions, as to avoid charges of misbranding; but wherever such charges have been made, both the manufacturer and the Requirements Committee, which in many cases has represented the manufacturer before the Bureau of Chemistry, have striven to learn exactly what is required by the Board of Drug Control of the Bureau of Chemistry and to comply therewith. In so doing, manufacturers have more than once yielded what they believed to be, what their technical advisers, and what the Committee on Requirements for Membership believed to be their rights.

This has been done in a spirit of coöperation which we believe generally has been appreciated by the Bureau of Chemistry and which generally has been more satisfactory to the Bureau than to the manufacturer.

The action of the Association voluntarily in adopting its requirements and in enforcing them has noticeably decreased the number of prosecutions and has at the same time kept the major portion of the trade, when reckoning in amount of business done, well in line with the requirements of the Bureau. It has seldom protested these rulings or any action of the Department, save and except the action of the Department in seizing goods in many instead of one jurisdiction. By multiple seizures, which we believe have been discontinued, except in cases of pressing emergency, the manufacturer was placed in a position where, right or wrong, he was unable to defend himself, found himself strangled by strong-arm methods, and virtually deprived of his day in court, if he sought to avail himself thereof.

We believe that the business of the manufacturers who have submitted to the processes of the Requirements Committee is to-day on as high a plane as that of any group of manufacturers.

We believe and maintain that no emergency exists in this group rendering necessary, advisable, or just, any method other than that of conference and discussion, whereby in any given case the manufacturer may learn first hand, or

through his designated agents, exactly what is required of him; and may then be given reasonable time in which to reshape his printed matter, without interruption of business.

The Food and Drugs Act under which we are all operating is plain in denouncing false and fraudulent misrepresentation of the therapeutic qualities of a prepared medicine. We maintain that the action of all members in our group has been such as to make impossible the proper lodgment of a charge of willful falsity or of fraud.

It is difficult to always meet changing conditions or always to correctly gauge the unwritten interpretation of the meaning of a law, but the members of the Proprietary Association, through its Requirement Committee, have endeavored at all times, as has been stated, to know and to obey not only the law, but to comply with the requirements and even with the opinions of those who are charged with its enforcement.

The present membership of the Proprietary Association is slightly over 200. This is less than ten per cent of the total number of manufacturers of proprietary medicines in the United States, but over sixty per cent of those in the groups doing more than \$100,000 gross annual business. It constitutes the largest, most powerful and influential group of manufacturers in the trade, and the gross business of the members is equal to about eighty per cent of the total dollar volume of the entire industry.

The governing body is an Executive Committee of sixteen members, including the officers; its present corps of officers is:

President:

Frank A. Blair,
Household Products, Inc.,
New York City.

Second Vice-President:

J. H. Howe,
A. H. Lewis Medicine Co.,
St. Louis, Missouri.

First Vice-President:

E. K. Hyde,
The Mentholatum Co.,
Buffalo, N. Y.

Secretary-Treasurer:

Charles P. Tyrrell,
Syracuse Medicine Co.,
Syracuse, N. Y.

EXECUTIVE COMMITTEE.

H. A. Beardsley,
Dr. Miles Medical Co.,
Elkhart, Ind.

Z. C. Patten, Jr.,
Chattanooga Medicine Co.,
Chattanooga, Tenn.

Dr. V. Mott Pierce,
World's Dispensary Medical Assn.,
Buffalo, N. Y.

B. Van R. Moore,
Pepsin Syrup Co.,
Monticello, Ill.

General Representative:

E. F. Kemp,
425 Star Building,
Washington, D. C.

H. Smith Richardson,
Vick Chemical Co.,
Greensboro, N. C.

J. A. Mitchell,
Wright's Indian Veg. Pill Co.,
New York City.

J. F. Hindes,
Emerson Drug Co.,
Baltimore, Md.

R. R. Land,
Dr. Kilmer Co.,
Binghamton, N. Y.

John F. Murray,
Wyeth Chemical Co.,
New York City.

Geo. H. Miller,
The Musterole Co.,
Cleveland, Ohio.

W. E. Weiss,
Sterling Products, Inc.,
Wheeling, W. Va.

Stanley P. Jadwin,
63-65 Cortlandt St.,
New York City.

General Counsel:

Harry B. Thompson,
422 Star Building,
Washington, D. C.