Papers Presented to Local Branches

PROGRESS OF PHARMACOPŒIAL REVISION.*

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Professor Gathercoal is responsible for my presence in Chicago at this time and I appear before you with pleasure. The making of a Pharmacopœia is constructive work by a large and representative committee and it is not *my* Pharmacopœia.

As the final work of the Revision of the Pharmacopœia approaches, it must be understood that several questions are in abeyance. At the beginning of the work of revision, it was realized that the Ninth Revision would be for several reasons the most important in the history of the work. The passage of the National Food and Drugs Act and State legislation have enlarged greatly the scope and usefulness of the Pharmacopœia and of course the responsibilities of revision are much greater.

At the Pharmacopœial Convention held in Washington it will be remembered that a recommendation was made that publicity should be given to all changes in standards and descriptions before the issue of the work. The principle of this recommendation was mainly to give to manufacturers, dealers, pharmacists, and physicians a full opportunity to comment and criticise. This principle of publicity has been in force in the United States for a number of years. When a law is proposed in Congress, or even after it has passed one or two branches of the Government, it has become the custom to invite parties interested to attend what is called a "hearing" before a congressional committee, the object of which is to obtain information from all sides as to the practical enforcement of the law. In this way important amendments may be made to the law and this may now be termed one of the principles of the American form of government, and it is most essentially different from acts passed in a parliament, a reichstag, or the mandate of an emperor. In republican forms of government throughout the world, hearings and consultations with experts and interested parties are being recognized as essential to good government.

In the Revision of the United States Pharmacopœia, hearings have been already held; in fact, the present Pharmacopœia is being thoroughly revised in public. When Dr. Charles Rice published the Digest of Comments on the two previous Pharmacopœias, he foresaw the advantage of gathering criticisms and comments from all sides. This he published in book form and anyone interested could procure a copy by applying to him. The Eighth Revision has had the advantage of a Digest of Comments published by the Public Health Department of the Government by which the principle of publicity was greatly extended.

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Of course, it will be impossible to embody every bit of advice which is now in the hands of the Chairman of the Committee of Revision. Many of these show great variance of opinion; individual likes and dislikes abound. Many of the comments and criticisms are founded on insufficient knowledge and experience, as anyone could easily suppose would be the case—an increase in one or the other ingredients, a different mode of filtering, the elimination of a tendency to precipitate, the preference for a different flavoring, and other changes of minor importance.

The present Committee of Revision were confronted with an enormous task and now the work of making a selection, which, in their opinion, is the best, is occupying much attention and an embarrassment of riches confronts the Committee. In former years, when the Pharmacopœia was once issued it was the habit to wait five years before making any material change through the publication of a supplement. Of course, any errors were corrected immediately, but very few additions or changes in admissions or deletions were ever made; but ten years is entirely too long to wait for a new Pharmacopœia and it is proposed to make changes in the future more frequently in order to keep the Pharmacopœia abreast of the times. This will undoubtedly be done in the future, but we must attend first to the issue of the new Pharmacopœia as promptly as possible before a definite decision is made as to this part of the work.

The most important questions now pending are the tests for volatile oils, for whisky, and a few additions and deletions. The scope of the Pharmacopœia has occupied a great deal of time and there are a few subjects still awaiting final decision. The inclusion of Mercuric Chloride Tablets with a selection of the most desirable form for their administration to prevent possible accidents is the question of the hour. A decision has been reached to admit these tablets, but the best way to prevent the disastrous accidents which have been so industriously set forth in the public press has stimulated the inventive faculties of manufacturers to such an extent that the Committee is confronted with a great mass of detail. Manufacturers have vied with each other in putting upon the market many forms of tablets and a great variety of containers. The subject is exceedingly important.

One of the latest duties referred to the Committee of Revision has been the formulating of an official declaration of what constitutes a poison. Undoubtedly this question has been before the world for centuries.

A poison, in the common acceptation of the word, is a substance that produces a deleterious action upon life; but this definition is too broad and general to be serviceable in food and drug legislation—a lawyer would like to have a more specific definition. The Pennsylvania Pharmacy Law defines a poison under Section 10 as follows: "A poison in the meaning of this act shall be any drug, chemical or preparation, which, according to standard works on medicine or materia medica, is liable to be destructive to adult human life in quantities of sixty grains or less." The danger in specifying sixty grains or any definite figure lies in the fact that the limit cannot be justly or accurately fixed. Why not make it sixty-five grains or a hundred? Would a substance not be a poison if it were proved that cases were recorded in standard works on medicine or materia medica if sixty-five grains or one hundred grains have been safely administered? And

again there comes the question of idiosyncrasy; some patients will tolerate enormous doses of a substance which would prove fatal to others even if administered in one-half the quantity. Would it be just to prosecute anyone under such circumstances? If a definite figure is adopted, injustice will be sure to follow, and yet it must be admitted that there is great necessity in having a definite figure. The Revision Commitee must thrash out this question and reach a decision. This illustration furnishes a type of some of the problems which require settlement and, which ever way the question is settled, criticism is sure to follow.

The admission to the Pharmacopœia of substances known as protected, proprietary, or patented, has caused considerable discussion. It is universally admitted that a pharmacopœia should not advertise the products of one person, firm or corporation. Unjust discrimination would be charged and a precedent would be established and other persons, firms or corporations would demand recognition. How could a pharmacopœia provide tests for an article over which they have no control? The manufacturer would change at any time his tests or even the color of his product as often as he wished and make the pharmacopœial tests obsolete. But suppose the manufacturer of a protected substance consents to its introduction into a pharmacopœia under tests which he approves; he is virtually abandoning his control. The obstacle here is an insurmountable one, for no manufacturer yet has consented to forego the profits which he is enjoying from his protection for the sake of encouraging his competitors. The sole object of patenting or copyrighting the name is to gain profit by excluding competition. In our present Pharmacopœia, acetphenetidin was introduced as a coined word to avoid the use of the protected name "phenacetin." The manufacturer made no objection officially because his patent had a very short time to run and the question was met by marketing it under both names. This case was exceptional, but if a manufacturer had fourteen years protection ahead of him, it would seem to him a foolish piece of business to surrender his profits for the questionable honor of having his product admitted to the Pharmacopœia and losing the complete control of the tests for proving the identity and purity which would follow the surrender and opening the door for unlimited competition.

I will be glad to answer any questions which I can and receive whatever suggestions you may offer and they will be sent to the appropriate sub-committee for consideration. In work of this character an individual member of the Committee cannot hope to have his ideas always adopted. The combined judgment expressed by a majority vote must prevail. This method of revision, while both Republican and Democratic, is also Progressive.

Systematic methods of procedure in working out the detail are used, and, as the final days of revision are here, definite decisions must be reached. Let us hope that errors of judgment will be absent when the book appears. While discussion has been free and very earnest and impressive arguments have been used by individuals, the Chairman is glad to report that an excellent spirit and feeling exists in the Committee as expressed through the official circulars, letters and bulletins.