THE REVISION OF THE UNITED STATES PHARMACOPŒIA.*

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The work of revising the United States Pharmacopœia is fast approaching completion, but, of course, it is impossible to announce a date of issue, because some pending and very important questions must be settled. It is expected, however, that printing in "galley" will begin July 1st.

Until 1906, the United States Pharmacopœia was accepted by the country as authoritative, when any one needed to use it for their benefit, but not authoritative when its tests interfered with what men called "business." This anomalous position was changed when the Food and Drugs Act made the Pharmacopœia the standard and the law of the land. The United States Pharmacopœia is only one out of thirty pharmacopœias used by other countries throughout the world.

The idea of an International Pharmacopœia, which would be authoritative, is regarded now as a dream of the future, but there is no good reason why all of the Pharmacopœias should not unite upon tests and rubrics, and, probably, the doses of medicines. The great difficulty in framing an International Pharmacopœia would be in selecting the articles of the materia medica and the preparations. The medical profession cannot be brought into harmony throughout the world with regard to the use of remedies against disease, and those found in an International Pharmacopœia would not be adequate, and it can readily be seen that such a book would be a very small one; as far as the United States is concerned many well-known and largely-used indigenous drugs would not be accepted by Germany, Russia, Japan, Austria and many other nations. A Pharmacopœia can never be an exploiter of new and untried remedies. That is not its function, and the book must contain a selection of drugs and medicines which are used in the various sections of the country, irrespective of special localities. Its title is the "Pharmacopœia of the United States of America." Internationalism is a grand idea and our fancy is tickled at the thought of one Pharmacopœia being used throughout the world, but the situation is not unlike that of universal peace, the disarmament of nations, and Church unity. It must be clear to everyone that, at this time, we are not ready for the culmination of these great movements. But there is no good reason why an earnest effort should not be made to induce the pharmacopœias of the world to accept as many subjects as possible upon which they can all agree; instead of an International Pharmacopœia, it would be much more practicable for each nation to have its own Pharmacopœia, with its own materia medica and pharmacy made to suit the people of the country, with an *international agreement on Standards*. This view seems to be substantially accepted by International Congresses, and every Pharmacopœial Commission hereafter will be expected to fall into line and at least make all of the very powerful and active remedies conform to one strength as, for instance, the fixing of the International Standard of arsenical preparations at one percent. An International Committee is at work endeavoring to frame tests for chemicals

*Read before New York Branch.

and assays, which will enable a physician to prescribe the best-known and most largely-used chemical substances of uniform purity throughout the world.

I am expected to speak more particularly of the present revision of the United States Pharmacopœia. It occupies a unique position; no Pharmacopœia of the world is revised upon the same plan. Pharmacopœias of the larger countries in the old world, are revised through a commission appointed by the Emperor, King, Queen, or ruler, but in the United States, the initiative comes directly from the people, and the medical and pharmaceutical professions, through a decennial convention, assembled at Washington, composed of delegates from all parts of the United States. Each body sends representatives who are believed to be most capable of determining the policy and general principles which should control the next revision. It has not been deemed wise to place the revision of such a work in the hands of men who belong to one political party, indeed your Chairman has never asked, and he does not know, how five men out of the fifty-one voted in the last presidential election, and if he did, it would make no difference in assignments of appointments. The reason given for the small honorariums or sums of money paid for services, has been the fear that money considerations would induce unworthy persons to make extraordinary political efforts to obtain control of the book to reward their friends or punish their enemies. The United States Government has been well represented in this revision, through its laboratories and the coöperation of the head of the Bureau of Chemistry, of the Department of Agriculture, Dr. Alsberg, and Dr. J. F. Anderson, Chief of the Hygienic Laboratory of the Marine Hospital Service. Several of the members of the Committee of Revision have official Government positions. It cannot be said that the Committee is not representative of the various branches of the healing art. The General Committee of 51, elected by the Convention of 1910, elect 15 of its members to have charge of the immediate revision. Each of these men become Chairmen of the Sub-committees and these Sub-committees are chosen for their especial fitness for the subject. Several of the members of the General Committee are on more than one Sub-committee. When the Executive Committee have reported on any branch of the work, the votes, in detail, from each member are reported, so that each member knows what is going on in each Sub-committee. The Executive Committee and the Chairman, both, have the right to appeal for a decision to the General Committee of Revision for a settlement. General questions, not falling immediately within the purview of a Sub-committee, have been referred to the General Committee directly. In this way, the concensus of opinion is obtained. This is a new plan for pharmacopœial revision, and is based upon the well known custom of deliberative bodies, and in fact, the principles underlying the Constitution of the United States.

The spirit which actuates both Committees and the Chairman is to get the best, without fear or favor. Publicity has been a prominent feature in this revision. For the first time in pharmacopœia building have the changes and standards and tests, been published in advance of the approval of the final text. This has been done to permit any one to frame a criticism or propose an improvement. This world-wide criticism or comment must have a limit fixed for the reception of comment or criticism, naturally, or the book would not appear for several years,

as it would be impossible to produce a work which could satisfy every criticism which could be made. Errors must, of course, be corrected whenever found and at once, but it is hoped, that with 50 or more experts reading proof, that every error will be detected before final printing.

The final draft on admissions and deletions must soon be forthcoming. There have been many admissions and more deletions. This subject has been thrashed over for nearly four years. The Convention disapproved of the admission of patented or proprietary preparations, mainly on the ground that everything in the Pharmacopœia should be free and open to all and that the Pharmacopœia should provide tests of identity and purity. If a manufacturer or owner will permit his synthetic or specialty to be introduced into the Pharmacopœia, he should sign an agreement giving to the Pharmacopœia such permission, otherwise he could secure whatever advertisement would come from the introduction of his specialty, and he might make any change in the appearance or the standard of strength or purity and the Pharmacopœia would have to frame standards and tests to suit the preparation sent out by the manufacturer. If the Pharmacopœia should introduce a synthetic without such an agreement, it would be possible for the manufacturer to have good grounds for a lawsuit and to demand an accounting and obtain damages for such loss as he believes he has sustained. In this connection a case was settled in Holland as follows:

"An action had been commenced by the Bayer Company, of Elberfeld, against a firm of wholesalers in Holland, for selling Aspirin Tablets which were not of their manufacture, thus infringing their trademark 'Aspirin.' The defense made to this action was that Aspirin was now included in the Dutch Pharmacopœia, and that, therefore, the word had come into public use and whatever rights Messrs. Bayer had previously, had now lapsed. The action was carried up to the High Court of Appeal in Holland, and Messrs. Bayer won their suit, the wholesalers being mulcted in damages, the Courts deciding that notwithstanding the word appears in the Dutch Pharmacopœia, Messrs. Bayer are still legally entitled to the word 'Aspirin' as their trademark."

If the Pharmacopœial Committee should decide to ignore the rights of an owner, and should introduce a synthetic without an agreement with him, no matter whether it was introduced under another name, the courts would rule in favor of the manufacturer or owner of the protected substance. Inasmuch as physicians can continue to prescribe the protected substance without let or hindrance, is it worth while, merely for the sake of seeing a synthetic in the Pharmacopœia to take such a step? The manufacturers of synthetics who have been consulted, have uniformly failed to give such permission and some have declared their intention of defending their rights through legal processes. An exception would probably have been made by an owner or manufacturer in a case of a patented or protected article, where the patent had a few months or probably a year to run, and, seeing a very moderate profit ahead, he might take advantage of the Pharmacopœia's introduction and give permission. The present Pharmacopœia, under the name of Acetphenetidin, admitted the extensively used and valuable phenacetin. These statements are made in order that you may understand the reasons which govern the Revision Committee in its decisions.

The Ninth Revision will differ from all those which have preceded it, mainly because much assistance has been rendered by manufacturing chemists and others, who have freely tendered their laboratory facilities and the services of their chemists, in trying out tests and standards and in perfecting detail. While this has greatly increased the correspondence, the time has been well spent because of the many valuable suggestions received. It has been necessary at times to arrange for hearings and conferences, and the effort has been made to invite every manufacturer or dealer having a special interest in the subject, to attend the hearings. A Committee of manufacturers was appointed, who were asked to get together, reconcile their differences and send a final draft to the Sub-committee. The Executive Committee of the U. S. P. did not accept every item in the report, but they did accept about 80 percent of the recommendations.

Conferences of the General Committee and the Executive Committee, have been held at the annual meetings of the American Pharmaceutical Association, and special conferences have been called in Philadelphia, of Sub-committees, with experts a number of times. In addition to this, the Committee has had valuable assistance from the local branches of the A. Ph. A. and State Pharmaceutical Associations. All of these communications have been tabulated, recorded and sent to the Sub-committees. In the preparation of the final text, by a system of collecting and recording by modern methods with card indexes, alphabetical lists and the valuable help of collaborators are grouped together, so that the editor may catch any suggestion which may correct an error or improve a process. Unlike many books, such as commentaries and text-books, a Pharmacopœia reflects the views of many persons, and is not in any sense the work of one man. It is constructive work and is republican, democratic and progressive. The plan is essentially American. There is a President and a Board of Trustees who have, during the work of revision, been kept in touch and have been supplied with circulars and the Executive Committee Letters. The Board of Trustees have the entire charge of financial affairs, making of contracts for the publication, and authorizing expenditures, but the work of revision is, of course, in the hands of the General and Executive Committees. The General Committee might be likened to the House of Representatives, and the Executive Committee, to the Senate. The Sub-committees have a parallel, in the Committees of the Senate and House of Representatives. The special Committees report to the bodies having the appointing or elective power.

For the first time in the history of Pharmacopœia making, the U. S. P. is using a method of publicity by printing before the issue of the book, in the pharmaceutical and medical journals, an abstract of the changes and standards, in order that these may be considered by all parties interested. These, must all be sent to the Chairman of the Committees of Revision before July 1st, the time fixed for beginning the printing. Any very important changes or errors discovered after July 1st, should be sent to the Chairman by telegraph.

It is not the intention, in the future, to wait for the usual period of ten years, to issue a supplement, and any addition or deletion which may become necessary, will be published, so that the book may be kept more fully abreast with the times. In this way, it is believed that the criticism made of the present and previous

pharmacopœias of being out of date, will be obviated, for the U. S. Pharmacopœial Convention is an incorporated and continuous body, each Convention taking over the property and effects of the previous Convention, new officers and committees being elected or appointed every decade.

The plan of revision has been worked out with the intention of providing the elements of stability and responsibility, and the experience of members gained in revision work, is a valuable asset in avoiding mistakes and errors of judgment. New men are elected to the Committee of Revision by the Convention, and a proper balance is sought to be maintained. Whatever criticism of this revision may be made in the future, it can never be said that every effort has not been made to have the work representative of all sections of the country.

The pharmacopœia is essentially a book of standards. Many men of many minds have contributed to its pages. It differs from ordinary books. It does not appeal to the sympathies or passions of men. It is a book without a plot. It advocates no propaganda, for *it*, itself is the propaganda. There is no exploiting of fads, no graft, no disposition to resent constructive criticism, and, now that the work is nearly finished, the Chairman declares that the sole object has been to provide pure, unadulterated, effective medicines of uniform quality, for the alleviation of pain and treatment of diseased conditions in the human race.

The lecture was illustrated with lantern slides as follows:

1. Text of the U. S. P. VIII.
2. Sub-committee No. 6 Bulletin, showing the first step in the revision—compiled criticisms and foreign standards.
3. Sub-committee No. 6 Bulletin, showing the first draft of modified text. Underlined portion differs from the U. S. P. VIII.
4. Sub-committee No. 6 Bulletin, showing the second re-drafted text as proposed for submission to the Executive Committee.
5. The Sub-committee report, as submitted to the Executive Committee.
6. Text submitted to the General Committee, for criticism and suggestions.
7. Publicity. Published Abstract of proposed changes in the text.
8. A page of the Report on Miscellaneous Galenicals, as submitted to the General Committee.
9. Circular-page, illustrating proposed text for type processes for fluidextracts.
10. Circular-page, showing a report on Inorganic Chemicals.
11. Circular-page, showing a report on Botany and Pharmacognosy.
12. Circular-page, showing a report on Assays.
13. Page, showing abbreviation and synonym to be inserted.
14. Page, showing proposed line-numbers for the U. S. P. IX.
15. Page, showing proposed paragraph numbers.
16. Page, showing proposed change in type for formulas.
17. Proposed title page, for the U. S. P. IX.