THE PHARMACOPŒIA, BY THE PEOPLE AND FOR THE PEOPLE.*

E. FULLERTON COOK.[1]

The Democratic Character of the U. S. Pharmacopœia.—When in 1820 Dr. Lyman Spalding realized the fulfilment of his plans for the establishment of a Pharmacopœia for the United States of America, he had also laid a foundation for future revisions which insured its democratic character.

The principles of the founders, namely, that the Pharmacopœia should be representative of all parts of the Nation and in the best interests of all of its people, has been loyally maintained during the century which has followed. Repeatedly during the one hundred years of its existence, the extent of its representation has been widened.

In 1920 the delegates participating in the Convention were from most of the great medical organizations of the United States, governmental and private, from every division of pharmacy, including National and State organizations, and educational and other scientific groups; and also from the National Chemical and Dental Associations, a total of 130 different bodies being represented.

These delegates, in Convention assembled, laid down the general principles under which the U. S. P. X was to be prepared and also elected the Committee of Revision. Here, too, the number of members has been extended far beyond that needed by the originators and greatly in excess of any other pharmacopœial commission of the world, the better to represent all parts of the Country and to insure the help of experts in each of the varied arts and sciences upon which the Pharmacopœia is based.

But even the 51 members of this large Committee were not content to hold within their own councils the honor of collecting data, comments and criticism and of preparing new texts and tests; they called to their help numerous other organizations and individuals.

For instance, the U. S. Public Health Service annually compiled the world literature related to the Pharmacopœia, also the faculties in a number of colleges of pharmacy made comparative studies for the Revision Committee of the texts for many chemicals, as published in the more important foreign pharmacopœias. An advisory committee of a dozen experts was organized in the Bureau of Chemistry at Washington and assisted throughout the revision, experts in the Bureau of Standards checked all tables and much physical data; an advisory committee of the N. A. R. D. reviewed the pharmaceutical texts, and much assistance was rendered, especially in assays and tests, by the Scientific Sections of the AMERICAN PHARMACEUTICAL ASSOCIATION and the American Drug Manufacturers' Association.

But a distinctive feature of the Tenth Revision was the election of auxiliary members to the sub-committees. There were many specialists other than members of the Committee who were associated with scientific organizations who welcomed an opportunity to assist in the revision and secured this privilege through nomination by the Sub-Committee Chairmen and subsequent election as auxiliary members to the sub-committees with which they were especially qualified to serve.

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* Read at the 1927 meeting of the New Jersey Pharmaceutical Association.

[1] Chairman of the Committee of Revision, U. S. P. X.

There were three auxiliary members on the biological sub-committee, fourteen in the chemical groups, four assisting in bio-assays, fifteen in botany and pharmacognosy, three in nomenclature, fifteen on the galenical sub-committees, etc.

Furthermore, all important changes proposed by the revisors were subsequently published in the JOURNAL OF THE AMERICAN PHARMACEUTICAL ASSOCIATION, seven separate sections appearing, and free reprints were offered to all, the announcements in connection with this publicity appearing each time in the general pharmaceutical press.

When the time came for final proofs, these were offered to about 250 experts in the Country and sent in duplicate in pamphlets of 64 pages each, one copy to be returned to the Chairman of the Committee. Every comment or criticism received as the result of this extensive publicity was compiled and considered before the book was finally printed.

No favoritism was shown, no one who was willing to help in the U. S. P. X revision was ignored and the experts of the entire Country were invited to assist at all stages of the revision. For an indication of the splendid response to this democratic program of revision one need but turn to the Pharmacopœia and read the long list of those who made the book (pages v, vi, lv and lvi). It includes the names of the majority of those who are prominently before the Country as experts in the many related fields.

Recently the Committee of Revision called upon the research workers of the Country to assist in solving many unsolved pharmacopœial problems and the interest and response has been most gratifying.

The Scope of the Pharmacopœia.—This phase of the Pharmacopœia will always be of the first importance and interest. The principles underlying its determination were established in the First Edition and have been kept prominently before each committee for one hundred years.

The first words of the Preface of the First U. S. Pharmacopœia of 1820 show clearly the ideals of the founders and it could have readily been adopted as the guide for the Sub-Committee on Scope in the Tenth Revision. It reads, "It is the object of a Pharmacopœia to select from among substances which possess medicinal power, those, the utility of which is most fully established and best understood." "The value of a Pharmacopœia depends upon the fidelity with which it conforms to the best state of medical knowledge of the day."

Still quoting from the Preface of the 1820 Pharmacopœia we find: "With a view of discriminating between articles of decided reputation or general use, and those, the claims of which are of a more uncertain kind, the Convention determined to refer to a secondary list, such substances as were deemed of secondary or doubtful efficiency, retaining only on the principle list articles which might be considered of standard character."

Such was the guiding principle in 1820; let us see what was the "general principle" adopted by the 1920 Convention. On page xliv, U. S. P. X, is found:

Object and Scope of the Pharmacopœia.—The object of the Pharmacopœia is to provide standards for the drugs and medicines of therapeutic usefulness or pharmaceutic necessity sufficiently used in medical practice throughout the United States and its possessions."

In referring to the Scope of the U. S. P. X, the statement is made in the

Preface (pages ix and x) that "The Sub-Committee on Scope—acting in accordance with the General Principles of the Convention—primarily decided admissions upon approved therapeutic value or pharmaceutical necessity."

In a recent criticism by Rusby on the Scope of the U. S. P. X this statement was erroneously quoted as "proved therapeutic value" which is an entirely different matter and one not at any time serving as a guide to the Sub-Committee on Scope.

In comparing the principles of the two revisions, separated by 100 years of scientific progress it is gratifying to find this complete harmony in ideals and purposes between the two committees. Truly, to again quote Rusby, "The general object and function of the Pharmacopœia are the same as they were originally, in spite of changes in method and detail, resulting from changed conditions."

One detail, resulting from changed conditions, namely, the vision of Charles Rice in establishing the NATIONAL FORMULARY, and the passage of the National Food and Drugs Act, in 1906, has in 1920 placed the equivalent of the secondary list of the first Pharmacopœia in the NATIONAL FORMULARY, which leaves the Pharmacopœia free to keep pace with the current medical sciences and stand as the combined medical and pharmaceutical representative of our modern materia medica.

To make this relationship more perfect, as the two books are now linked by the law and have informally and harmoniously worked together for two decades, it might be possible to create officially a liaison committee, consisting of representatives from both Revision Committees, and thus more fully bring about this desirable end.

This policy has produced a Pharmacopœia which is to-day receiving the approval of not only the leaders in the medical and pharmaceutical sciences of the United States but of the world.

These principles must stand if we are to keep the Pharmacopœia abreast of the tremendous advances of to-day in the protection of the health of our people.

The past twenty-five years have been evolutionary in their study and use of drugs in the treatment of diseases but the value of many substances is now fully established through combined clinical, pharmacologic and biochemical evidence and a new confidence is being developed, based upon a scientific foundation. The Pharmacopœia of the United States should "conform to the best state of medical knowledge of the day," to again quote the U. S. P. 1820, and should therefore closely follow the wisest and latest developments in the treatment of disease.

In reaching decisions on Scope the Sub-Committee adopted a systematic and conscientious policy. Its personnel consisted of the seventeen members of the Revision Committee nominated by the medical members of the Convention, also the President of the Convention, and in addition, Messrs. Beringer, LaWall and Seltzer.

The Sub-Committee members in personal conference immediately considered all articles official in the U. S. P. IX and unanimously accepted about 500 titles. The remaining titles were then studied in related groups, their merits or demerits discussed, information collected by questionnaires or from literature and a decision finally reached, by vote. The list of proposed deletions were then published in the medical and pharmaceutical press and all comments or criticisms received were published in the official Circulars.

A feature of the agreement on Scope, in the General Committee, was that all

objections to the decisions of the Sub-Committee on Scope would be reviewed by a "Referee Committee on Scope" which was to consist of all physicians on the General Committee, a total of 21.

Every decision concerning which there had been any unfavorable comment, with the recopied criticism in full accompanied by the author's name, was placed before this Referee Committee on Scope and a vote taken for reconsideration.

If at least 5 votes out of the 21 were cast for reconsideration, the title was to be carefully reviewed and discussed and again voted upon. Out of the 133 titles reviewed, 49 received 5 or more votes for reconsideration. After sufficient time for discussion and study a new vote was taken. This resulted in ten additional titles being admitted to the U. S. P. X. The work of this Referee Committee alone covered about 150 pages of Circulars and extended over two and one-half years.

The work of the original Sub-Committee on Scope was continued for almost five years and called for over 400 pages of Circulars. These official Circulars are available in many parts of the Country and copies have been filed in the National Museum at Washington, the Medical Section and with the office of the Secretary of the A. PH. A. and anyone who is interested in the reasons for decisions on this important question is invited to study these original documents where much will be found which is illuminating.

If errors of detail have inadvertently crept into the decisions on Scope, as is quite possible, these must be corrected.

A valuable confirmation of the work of the Sub-Committee on Scope has just been published in the report of the Commonwealth Fund on "Basic Material for a Pharmaceutical Curriculum."

This study of 17,577 modern prescriptions from every section of the United States and representing 40,610 individual items, establishes evidence which will be a surprise to many, namely that of all ingredients used by physicians in these prescriptions, 74.29 per cent were official in the U. S. P. IX, 7.19 per cent were from the NATIONAL FORMULARY IV, 10.29 per cent were proprietary and 8.23 per cent were not now standardized but mostly from one of the former U. S. P. or N. F.

A study of the U. S. P. X shows that about 72 per cent of the substances prescribed are now official, about $2^1/_2$ per cent being among those titles deleted.

One hundred and ninety-one articles official in the U. S. P. IX were not admitted to the U. S. P. X. The Commonwealth report gives valuable facts with reference to these. In the more than 17,000 prescriptions carefully analyzed 98 of these deleted articles were *not once* prescribed, 29 others were called for *1 or 2 times*, 16 of the titles were prescribed *3 to 5 times* and 22 *six to ten times*. The remaining 27 titles *are listed below:*

	(Times prescribed.)
Acidum Hydrocyanicum Dilutum	26
Acidum Nitrohydrochloricum Dilutum	42
Ammonii Iodidum	32
Aqua Hamamelidis	23
Camphor Monobromata	64
Cerii Oxalas	101
Diacetylmorphina	45
Diacetylmorphinæ Hydrochloridum	101

(These two substances were first admitted but later deleted on legal grounds)

Extractum Ergotæ (the Flindextract was retained)	58
Extractum Gentianæ (the Compound Tincture was retained)	25
Extractum Hydrastis (the Fluidextract was retained)	11
Extractum Opii (powdered Opium and the Tincture were retained)	27
Fluidextractum Viburni Prunifolii	13
Pulvis Aromaticus	13
Quininæ Salicylas (nine quinines were retained)	17
Sparteinæ Sulphas	11
Strontii Bromidum (four bromides were retained)	78
Strychnina (two strychninine salts were retained)	11
Syrupus Acaciæ	49
Syrupus Hypophosphitum	38
Tinctura Arnicæ	20
Tinctura Cannabis (the Fluidextract and Extract were retained)	16
Tinctura Gelsemii	43
Tinctura Hydrastis (the Fluidextract was retained)	13
Zinci Phenolsulphonis	28

Scope, therefore, is one of the large research problems of the Committee of Revision, and physicians and pharmacists who are in a position to contribute personal knowledge concerning the present-day use and therapeutic approval of medicinal agents which are not now in the U. S. Pharmacopœia, are earnestly urged to contribute such information to the work of the Committee.

THE THEORY AND ART OF PHARMACOPŒIA REVISION; A REPLY.

BY HORATIO C. WOOD, JR., M.D.

In the June number of the JOURNAL appears under the above title an article by Dr. Rusby in which he attacks the work of the Revision Committee especially those operations which belong to the Sub-Committees on Scope and Nomenclature. As I was Chairman of the former and a member of the latter, may I be permitted to call attention to some of the inaccuracies in Dr. Rusby's paper.

It is unfortunate that he has not read the Pharmacopœia more carefully, for if he had done so, he would have been spared the chagrin of condemning the Committee for deeds which it never committed. For example, he accuses us of having deleted oil of chenopodium without sufficient justification; as a matter of fact this drug was admitted into the U. S. P. X. He deems very unfortunate the "relegation of *Rhamnus Purshiana* which is purely Latin to serve as the official English title;" whereas the adopted English title is Cascara Sagrada, *Rhamnus Purshiana* being given as a synonym for the Latin name. Most unfortunate of all his misquotations, however, is the statement that we rejected all "articles unless their therapeutical usefulness has been *proved*." Such a principle was never suggested in the work of the Sub-Committee on Scope and, I feel sure, if it had been would have been regarded by most of the members as a ridiculous proposition. Apparently Dr. Rusby's mistake in this connection has arisen from a careless reading of the preface (see page x of the U. S. P.) in which occurs the statement that this Sub-Committee "primarily decided admissions upon approved therapeutical value." There is a vast difference between the meanings of the words "proved" and "approved."