# Section on Pharmacopoeias and Formularies

Papers Presented at the Sixty-Second Annual Convention

## CHAIRMAN'S ADDRESS—SECTION ON PHARMACOPOEIAS AND FORMULARIES.

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As this address is being written your Chairman faces the peculiar position of not knowing whether he is to deliver a call for renewed activity to a virile and promising branch of the Association, or whether he is to be called upon to preside at the obsequies of a dead or dying Section. Today the life of the Section hangs in the balance; before the Council, prosecution and defense have presented their cases and the verdict is awaited.

The Chairman has earnestly protested against the discontinuance of the Section, as he believes that it is an advantage to the Association to retain the divisions of work already established, increasing them perhaps, if necessary, so that the annual meeting will include adequate consideration of every important branch of pharmaceutical activity.

Instead of arbitrarily selecting three or four general heads as "Scientific," "Practical Pharmacy," etc., with the hope that the Chairman entrusted with the preparation of programs will cover all departments within the scope of pharmacy, it would seem to be a better plan to divide the same time between two or three Chairmen, each selected for his knowledge and interest in a specific branch of the work. Can it be expected that a chemist as Chairman would develop a program covering the latest developments in Materia Medica and Pharmacognosy, or a pharmacognist be interested in galenical preparations or prescription difficulties? Yet this is what has been seriously advocated.

Those familiar with the history of the Section know that it was proposed by the late Professor Oldberg whose large experience gave him the comprehensive vision which recognized the value of assembling pharmacopœial and formulary material, and developing year by year special programs covering this field. The Section was created by resolution of Council in 1912 and has officially enjoyed two years of life, a preliminary meeting having also been held during the Denver meeting three years ago. Whether the motion to abolish the Section has prevailed in the Council will probably be known by the time this Section meets and congratulations or condolences will be in order.

Whatever the decision, however, the importance of guide and reference books of the character here under consideration will not be lessened. So long as pharmacy exists a standard collection of formulas with tests and other related information for medicinal or prophylactic use, will remain an essential, so that, even in the midst of these uncertainties, a few guiding principles may well be laid down.

One task before the Section is the listing of the best available books containing formulas. This has already been started; a list mainly of foreign books having been presented a year ago by Mr. Raubenheimer and published in the Journal. The Secretary this year promised a more comprehensive collection of titles.

It would be of much value if this list when published would include a brief outline of each book, indicating its scope and purpose, price and publisher, and it should include, in addition to pharmaceutical preparations as usually understood, veterinary medicines, household recipes, business and scientific formulas, etc.

This field may also be enlarged (when the Association establishes permanent headquarters) through the Section's assistance in collecting the actual books, either by exchange for our National Formulary, or through donation or purchase. In this way a valuable collection of pharmacopœias and formularies will be made available for the officers of the Association and others. There has evidently been no attempt in the past to start such a collection, and your Chairman would suggest that, in anticipation of the establishment of headquarters, the proper parties be instructed to enter into correspondence with authors or publishers of such books, with a view of effecting an exchange with the new N. F. IV.

The main purpose of this Section lies in its possibility for constructive work. Its activities throughout a period of years should materially assist in the improvement of existing books and in the development of many new formulas and processes. The Section may encourage the improvement of existing standard formulas, the proposal of new or improved tests and assays for establishing the standard character of preparations, and the perfecting of new preparations useful in the field mentioned.

Before this Section, have been presented the reports from all established committees at work in associated fields—Pharmacopœia, National Formulary, Unofficial Standards, Recipes for Household or Scientific Use, etc., and the value of collecting these allied subjects before one interested audience and of affording an opportunity for discussion must be recognized.

Our own publication, the National Formulary, with the Fourth Edition enters upon a new era. For the first time it has been revised with the purpose in view of serving as a standard under the Food and Drugs Act. Standards have been established for such preparations as lend themselves to assay, and all articles entering the formulas have been carefully defined, if not already standardized by the U. S. P.

Although a privately owned book, it now becomes a part of the National Law, and it will require much wisdom on the part of the Committee in charge, and of the Association Council to establish the policies which are to control it.

The importance of the National Formulary has also greatly increased because of the inclusion in this edition of many largely used preparations formerly official in the U. S. P. The Association has assumed the authority of republishing these formulas, but it cannot claim thereby any exclusive control over them. This fact compels a broad and liberal attitude toward this question.

With the increased importance of the National Formulary another policy should become well-defined, i. e., the exclusion of any formula which can be said to imitate a proprietary or widely-advertised product. When years of medical

use have proven the efficacy of a certain type of preparation, and many pharmaceutical houses and retail pharmacists are manufacturing products of that type, there can be no fair criticism of the National Formulary if it publishes a formula of the same general character for the purpose of establishing a standard strength. The guiding principle here, however, should be "A high grade pharmaceutical product, offered upon its own merit and with a distinctive flavor and appearance."

Your Chairman would recommend that this Section go on record as approving such a policy for the Association in the preparations of the National Formulary.

The question has many times been asked "What sharp distinction now exists between the U. S. P. and N. F. " With the new policy for the N. F. IV in which basic substances used in formulas are included and standardized there is even less difference between the two books to the casual observer. There remains, however, this important difference: To the U. S. P. is conceded the right to first choose from the entire field of materia medica those substances or preparations, in the eligible class, which, in the opinion of the Revision Committee are most useful in the practice of medicine. The chief purpose of the N. F. from its inception has been to provide standard formulas for those substances used in medicine which the U. S. P. thought it unwise to include. Even this classification is too broad, for there are many substances and preparations used in medicine which will not be found in either the U. S. P. or N. F., so that in reality the N. F. is the second selection. As to the relative merits of many of the articles left for the N. F. there is a vast difference of opinion and often it has been by but a small majority that the decision was reached to include or exclude preparations from both books. This, of course, may be expected since medicine yet depends largely upon empiricism for its conclusions concerning the merit or demerit of many products, and this very condition demands a book occupying the place now held by the N. F.

Every member of the Association should do his utmost to perfect this important publication so that the Association may occupy an honorable and helpful place in the advancement of medicine during this era. As much as is possible the question of financial return to the Association from the sale of the book should be subordinated, especially if it is suggested that this income be used for the general work. The Association can hope to retain the honorable, but unusual position of control and ownership of a National standard only so long as the policies guiding the Association are free from pure commercialism; it must prove that it is worthy of the trust. A portion of the income from the sale of the book should be used for the establishment of a laboratory where, before the next edition is needed, some of the problems which have arisen during the current Revision may be solved. This would be a worthy and suitable use for a portion of the profits, and it should not be forgotten that at least the expense of adequate Revision should be provided for.

One feature of the sessions this year which should prove interesting to the members of the Association, and which should be helpful to both the U. S. P. and N. F. Revision Committees is the exhibit to be held on Friday. A number of the members of the Association have prepared specimens of new or modified

formulas using the proposed methods, and they have reported their experience with each preparation.

Your Chairman desires to express his appreciation of the immediate response given to his appeal for assistance in getting up this Exhibit, and takes this opportunity of thanking all of those who have contributed.

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## REPORT OF THE COMMITTEE ON THE U. S. PHARMACOPOEIA.*

The publication of four parts of the first proof of the U. S. P. IX has given this committee some material for consideration during the past year. The strenuous efforts, however, of the National Committee of Revision of the U. S. P., and of the committee on the National Formulary to complete their respective works has continued to absorb to a considerable extent the available energy of the majority of the members of this committee. We have, however, managed to review the first three parts of this first proof, and have forwarded as rapidly as possible the results of our deliberations direct to the Chairman of the Committee of Revision. We have hoped in this way to place our suggestions before the National Committee, at a time when they would be in a position to consider them.

A few of the comments that this committee has made which have a general bearing, we desire to present at this time in our report.

The use of the term "Melting Point," which is generally understood to mean a definite temperature, is inappropriate when used to designate a range of melting points for a given substance which may extend over several degrees of temperature.

The word "should" is not emphatic enough for use in expressing a requirement, and its use in this sense in the Pharmacopœia ought to be greatly curtailed.

Since the U. S. P. is a legal standard the plea has been made that its language be as free as possible from relative qualifying words of the character of "faint," "slight," "moderate," "about," etc., unless the same be properly defined in an appropriate place.

When an article of different origins is considered it is undesirable to place the different descriptions under one title, as is offered in the case of Salicylic and Benzoin, etc.

The use of the term "absolute Alcohol" to indicate an alcohol which is absolute, in one part, and not absolute in another part of the book, is confusing.

It seems highly desirable that the tests in the U. S. P. be discriminated into "identity or description tests" and "purity requirements."

With reference to standards, there seems to be a desire on the part of those who use the U. S. P. simply as a legal standard to set the purity requirements high and to have the tests very exacting, whereas those who may be amenable to its provisions seem to advocate a somewhat lower purity requirement with tests less exacting. To harmonize these two interests is undoubtedly a difficult matter. One also notes the desire of the Chemist to introduce special testing apparatus like the polariscope, spectroscope, refractometer, platinum ware, etc. On the other hand the druggist does not see his way clear to acquire these, even though he may have the time and ability to use them. Consideration should therefore be had for him in this effort to secure proper standardizations. Where no method of preparation is given for an article, refined methods of valuation would seem desirable; but in the case of the various preparations which may be

* Presented to Section on Pharmacopœias and Formularies, August, 1914.