REPORT OF COMMITTEE ON U. S. PHARMACOPOEIA, AMERICAN PHARMACEUTICAL ASSOCIATION.*

A number of the members of the committee responded to the call of C. H. LaWall, Chairman of the Committee of Revision, for suggestions and criticisms, which accounts in a measure for a somewhat shorter report. The purpose of this report is to briefly call attention to a number of features which should be considered by the next Pharmacopoeial Convention. Extended discussions do not seem necessary.

THE ALCOHOL PROBLEM.

There probably has not been a single question that has received more consideration in matters pharmacopoeial than alcohol. The present nation-wide movement to limit the use of alcohol to very restricted lines is well recognized and receives the approbation of both the medical and pharmaceutical professions. The present Pharmacopoeial Committee deleted from the last revision of the Pharmacopoeia not only a number of preparations which would lend themselves to beverage purposes, but also such as were beverages in themselves. Even whiskey and brandy were eliminated. In other instances the percentage of alcohol was materially reduced. It is believed the time is now at hand when additional reductions in alcohol content should be made wherever practicable. At a meeting in Washington during the war for considering a restricted use of alcohol it was contended by some that the alcohol content of the present Pharmacopoeial products could not possibly be reduced; others believed some reduction might be effected in some cases. Whatever our personal views may be in these matters there is no question but that existing conditions should, and must, receive very careful consideration and appropriate action. It is not a theory that confronts us but a condition. Every effort should be made to reduce the percentage of alcohol to the amounts necessary for extracting medicinal principles, or keeping the medicaments in solution, or preserving the preparations, etc.

METHODS OF ANALYSES.

It is self-evident that no method of analysis should be included in the Pharmacopoeia which will not give fairly concordant results in the hands of experienced workers. Any other course is liable to lead to complications under existing laws and the trade generally. If a method is used which is liable to material variation and commodities are handled on the basis of the results obtained by such methods, it can readily be seen that not only may manufacturers be penalized and chemists liable to censure but a considerable amount of monetary loss may result. The variations should not exceed the limits prescribed by the present Pharmacopoeia or such limits as may be adopted in a future revision. No method should be considered for possible inclusion which in a try-out varies more than 20 percent in the hands of skilled workers.

ONE MAN METHOD.

In the past it has happened that a method worked out by a single individual has been adopted without giving it thorough consideration. It is not believed that a one-man method should be adopted in a book that has the standing in law the Pharmacopoeia has. Furthermore, it is not believed desirable to adopt any method that has been tried out only in one laboratory. All methods should be carefully and fully tried out by a number of workers before receiving recognition.

CHANGE METHODS AND STANDARDS.

If the present Pharmacopoeia provides a good standard and good methods for determining such a standard they should not be changed unless better ones are at hand. They should never be changed for individual or personal reasons. A frequent changing of methods and standards is an economic loss. They require manufacturers to adjust products on a new basis and the analyst is compelled to spend time and material to become acquainted with the new elements involved. It can readily be seen, therefore, that changes in methods and standards cost time, money and labor, and unless something is to be gained, the loss seems unnecessary.

BIOLOGIC TESTING.

More and still louder criticisms of this form of testing are in evidence. What has been said above in conjunction with methods of analysis, generally, applies to this form of testing

*New York meeting, 1919.

drugs. Every possible effort should be made to establish methods of biologic testing of drugs which will give fairly concordant results in the hands of skilled pharmacologists.

DEFINITIONS TO BE CAREFULLY CHOSEN.

When it is recalled that the various food and drug laws cover everything between the covers of the Pharmacopoeia, it can be readily seen how important it is to carefully formulate definitions. If, for example, a definition for asafoetida prescribes that this drug comes from a given source, this portion of the standard contained in the Pharmacopoeia in and of itself may control the purity of the drug. In the past it has happened that asafoetida was adulterated with resinous material which would provide the amount of alcohol soluble material called for by the Standard but it was clearly established by tests other than those contained in the Pharmacopoeia that the asafoetida was actually adulterated and contained material which was not derived from the plant source called for by the definition in the Pharmacopoeia. Such products based on the definition alone are not asafoetida. Another case that comes to mind is an alleged balsam of Peru which complied with all of the tests prescribed by the U. S. Pharmacopoeia, excepting that defining the source of the commodity.

If the definition should include a geographic source, this, of necessity, if the law is strictly construed, would constitute a part of the standard. It is therefore plainly evident that no geographic name should be used unless it is carefully established that such a term is needed in order to secure the proper quality of drug.

LIMITS OF ASH, STEMS, WORMY AND INFECTED MATERIAL SHOULD BE CAREFULLY PROVIDED.

The present Pharmacopoeia provides ash limits in a goodly number of drugs. Some of these should be carefully revised. The question of limiting the presence of stems and other foreign materials should also receive additional careful consideration. In some instances (belladonna leaves; ipecac root) a larger percentage of stems may be included because such stems contain material amounts of the active ingredients and lessen the expense of the drugs. Wormy material or material contaminated with excrement of vermin, insects, etc., is not specifically covered. These features should also be carefully considered and made parts of the standards. It is perfectly true that when such drugs are powdered or made into the finished preparations the ultimate consumer will not be any the wiser but it is manifestly unfair to take advantage of the consumer because of his ignorance of matters of this character. He should be protected.

LIMIT TESTS.

In the case of chemicals, many limit tests are introduced. Some of the wording of these tests is very obscure, involved and unsatisfactory. For example, in the case of testing for chlorides after setting out a method of procedure we find that the personal equation is liable to enter into the ultimate conclusion very materially. The acceptance or the rejection of a chemical may depend upon such indefinite adjectives as "turbidity," "opalescence," "faint precipitate," etc. One chemist may have formulated in his mind what a "slight turbidity" might mean; another analyst might have an entirely different idea in his makeup. Cases have actually occurred where disputes have arisen regarding the quality of chemicals because of these indefinite elements. It is believed that when such terms are used methods should be provided for determining how to arrive at them so that different chemists working in different laboratories could readily inform themselves as to what the terms actually mean.

ARTICLES TO BE INCLUDED.

This is one of the difficult points to determine upon. The drugs included in the Pharmacopoeia are intended for the use of the medical profession in the treatment of the sick. Physicians or groups of physicians have different conceptions as to the value of various drugs. One is satisfied that a given drug gives excellent results in his practice; another feels equally positive that the drug is of little use. The function of the Pharmacopoeia is not to determine whether or not one physician or a set of physicians is correct. Its primary purpose is to provide standards which will insure that uniform and reliable drugs are placed in the hands of the medical man for the treatment of his patients. It is believed the day will come and is near at hand when the number of drugs used by the medical profession will be materially reduced, but until such time does arrive it is believed that the members of the medical profession should have a large voice in the drugs to be recognized by the Pharmacopoeia.

INTERVAL BETWEEN TIME OF ISSUE AND TIME OF BECOMING EFFECTIVE.

The last decennial revision of the U. S. Pharmacopoeia had hardly reached the hands of druggists, manufacturers and analysts before it became effective. It is clearly evident that such a short interval of time is inadequate for the trade, analysts and others to adjust matters affected by the new publication. The conditions existing at the time the last Pharmacopoeia became effective compelled those in charge of the enforcement of the Food and Drugs laws to take upon themselves the responsibility of not enforcing the standards contained in the book until the trade had had sufficient time to adjust itself to the new conditions. In some cases this required at least a year. It is believed that at least a year should elapse between the time the next edition of the Pharmacopoeia is placed on the market and the time it becomes effective. This would enable the trade and all others affected to adjust themselves to the new standards. They would then not be entitled to the excuse so often met with that the new book had been thrust upon them so suddenly that they had not been able to adjust themselves to the new standards and requirements. It is believed that such a course as the one outlined above would be fair and just, not only to the trade, but also to the chemists, the physicians and the consumer.

DO MOST OF WORK BEFORE NEXT CONVENTION.

It is believed to be a mistake to practically discontinue activities after the book has been made available. It is believed the work should be as aggressive between the time the new edition appears and the time for the next Pharmacopoeial Convention as any other time in the revision of the publication. If such a course were adopted the Committee would be prepared, to a large extent, to place it in the hands of the newly-appointed organization to proceed on definite plans and lines based on the results provided by the work of the former Committee. It is believed that such a course would materially reduce the length of time now necessary to issue a new edition.

PAY FOR WORK AS FAR AS POSSIBLE.

This feature is considered not with the idea of criticizing the excellent work done in past years voluntarily, but with a view of calling attention to the fact that it is asking too much of many of the busy men to give up a large amount of time to the work and receive no compensation therefor. Some can afford the time and labor only at the expense of health. In many instances the workers would not accept remuneration under any circumstance, but they often can ill afford to give the time for it. It is, therefore, believed that the best way to solve this problem is to employ suitably paid workers and exact from them due returns for the compensation revision.

IMITATIONS AND SUBSTITUTES.

Proprietary preparations through advertising and merit at times gain for themselves a useful place as remedial agents. In some instances an effort has been made to introduce into the Pharmacopoeia what might be called an imitation or a substitute. It is believed that if a manufacturer or dealer through investigation, expenditure of money and time produces a product which is of value to the public and especially the sick he is entitled to some consideration both morally and legally. After a given time it should become public property. In no case should the Pharmacopoeial Committee introduce into the Pharmacopoeia what might be looked on as a substitute or an imitation for such product. Attention at this point is called to the fact that the Food and Drugs Act forbids the placing on the market of imitation drugs.

SCIENTIFIC LITERARY EDITOR.

The wording of the methods of analyses, the limit tests and standards are sometimes obscure, indefinite or susceptible of more than one construction. All this should be rectified. It is believed that a large part of these shortcomings can be eliminated by having everything carefully edited, keeping in mind particularly brevity, clarity and definiteness.

NOMENCLATURE.

All names should be carefully chosen so as to avoid confusion and mistakes. Ferric Phosphate means a definite chemical but this name in the Pharmacopoeia refers to a mixture of iron phosphate and sodium citrate. In short, everything introduced into the Pharmacopoeia should be made as definite and specific as possible.

Respectfully submitted,

L. F. KEBLER, *Chairman*