it is a reference text which he studied intently in his student days.

There is little glamour in the U.S.P. program. It does not lend itself to popular magazine articles, and even the most gifted Chautauqua speaker could scarcely work up any enduring enthusiasm over it. This is a real handicap in getting favorable publicity.

However, we have two avenues for disseminating information about the Pharmacopeia and for eliciting helpful comments on its program. One of these is the direct contact with those immediately concerned with drugs and drug standards, particularly the regulatory agencies and the manufacturing pharmaceutical houses. The second avenue of approach is in professional forums.

The swiftest way of enhancing the influence of the United States Pharmacopeia will be to enter on a campaign to reach every medical and dental student in the United States at some time during his 4-year course of study. This may be done in a short lecture which can also cover the functions of the Food and Drug Administration and the other government agencies concerned with drugs. It is particularly important for physicians to get a clear picture of these interrelationships. Obviously, it is out of the question for any one person to tell the story in every medical and dental school. Perhaps the best approach is to commission some faculty member, probably the professor of pharmacology or medicine, to give the lecture for which material could be provided from the U.S.P. office.

Another way of reaching physicians would be through the committees on hospital formularies in every hospital. These committees now represent sources of assistance to the United States Pharmacopeia but would offer ideal channels for the influx of information.

Summary

The United States Pharmacopeia can and should do more to improve the intelligent use of the best therapeutic agents available to physicians through pharmacists. It can succeed in this effort by judicious expansion of its present facilities to create an information center for the use of pharmacy and medicine. Suggestions along this line will be welcomed.

The National Formulary

By JUSTIN L. POWERS, Ph.D.

The present status of the National Formulary stems from the authority derived from the Federal Food, Drug, and Cosmetic Act of 1938. The act states in part that the term "drug" means "articles recognized in the official United States Pharmacopoeia, the official Homeopathic Pharmacopoeia of the United States, or the official National Formulary, or any supplement to any of them . . ."

Section 501 (c) of this statute requires that drugs purporting to be those listed in the National Formulary must conform to the standards of strength, quality, purity, and identity prescribed by that compendium. All determinations of these standards must be made in accordance with the methods described therein. Variations from these standards are permitted only when the identity of a drug is unchanged, and certain labeling requirements of the act are met.

The same section of the act confers authority upon the Administrator of the Food and Drug Administration to prescribe tests where none have been provided or where those described are, in his opinion, insufficient. Before this provision can be invoked, a complicated procedure spelled out in the act must be followed. Not once in 13 years has the Food and Drug Administration found it necessary to invoke this safeguarding provision that gives the right to take away from the National Formulary and the United States Pharmacopeia a part of their standard-making functions. I think this is a significant point in establishing the role of the National Formulary in maintaining sound drug standards.

Dr. Powers is chairman of the Committee on National Formulary, American Pharmaceutical Association, Washington, D. C.

Another section of the act declares that a drug shall be deemed misbranded if it purports to be a drug recognized by name in an official compendium unless it is packaged and labeled as prescribed therein.

Basis of Admissions

Admissions of drugs to the National Formulary are based upon their therapeutic value, the extent of their use, or both. When therapeutic value is a consideration, admissions to the 10th edition of the National Formulary will be based on the advice and recommendations of a special committee of medical consultants.

Where extent of use is the principal criterion for admission, it is determined by a consideration of trends in drug therapy, by information obtained from prescription ingredients, by extent-of-use surveys conducted by the National Formulary and others, and by a study of drug market reports.

Prescription surveys which report results only in terms of types of drugs used in compounding and dispensing are of little significance to the Committee on National Formulary of the American Pharmaceutical Association in determining extent of use. These surveys usually report that a large percentage of the prescriptions studied are for "specialties," a small percentage are for U.S.P. drugs, and a still smaller percentage are for N.F. drugs. These reports have the added disadvantage of creating an incorrect impression about the role of the official compendiums in developing and maintaining sound standards for drugs.

Of greater service are surveys such as that by J. S. Mordell, in which the incidences of occurrence of drugs in prescriptions are recorded in terms of official names in addition to the restricted names. We all know that many official drugs are distributed under one or more trade-mark names, but they are still official drugs because in their labeling they purport to be items whose names and standards appear in the official compendiums. We sometimes forget that an official drug by any other name than an official name is still an official drug and must comply with official standards. We are finding the information in Mordell's comprehensive study useful in deciding on deletions from the ninth edition of the National Formulary.

In contrast to the basis of admissions to the National Formulary, the United States Pharmacopeia has followed a more conservative policy. In general, its scope has always been restricted to drugs selected by representatives of the medical profession and believed by them to possess the greatest therapeutic merit. Extensive duplication of drugs having essentially the same action in any single therapeutic classification has been avoided as far as feasible. This selectivity has prevented the inclusion of many drugs of therapeutic value or extensive use, or both, and is responsible for the origin and development of the National Formulary.

Two Valuable Services

The National Formulary performs a unique service by providing official standards for extensively used and therapeutically effective drugs not covered by the Pharmacopeia. It may establish specifications for widely used drugs such as rutin or vitamin E concerning the utility of which medical opinion is divided. It provides for the continuance of official standards for drugs deleted from the United States Pharmacopeia during periodic revisions. Many of these drugs continue to be used extensively for many years after losing their Pharmacopeial status. We believe the ultimate consumer is entitled to assurance of the integrity of drugs in these categories through the protection offered by official standards. During periods of shortages of critical materials used in the manufacture of dosage forms, as when glycerin was scarce during World War II, the National Formulary has been instrumental in developing official specifications for safe and satisfactory replacements.

The National Formulary also performs a distinct service to pharmacists and pharmaceutical manufacturers by providing specifications for the procurement of drugs used in dispensing, prescription-compounding, and manufacturing, and in formulas and working directions for the preparation of dosage forms.

We are conscious that the official compendiums ought to be made more useful to the practicing pharmacist. I believe this can be accomplished best by furnishing certain background information which he can use in his everyday practice. Plans have been formu-

lated for doing this in subsequent revisions of the National Formulary by the device of an appendix, the content of which cannot be construed as constituting official standards.

New and Nonofficial Remedies

By R. T. STORMONT, M.D.

The Council on Pharmacy and Chemistry of the American Medical Association was organized in 1905 to serve the medical profession by providing authoritative information about therapeutic agents.

At first the council was primarily concerned with the problem of exposing quackery in the field of therapeutics. Secret remedies, promoted under false or grossly exaggerated claims, provided a major target of attack. After the enactment of laws providing for more stringent regulatory control over drugs, the council tended to devote its efforts more toward the encouragement of a constructive program of rational therapeutics. This is reflected by the fact that the annual publication, New and Nonofficial Remedies, is generally regarded as the major contribution of the council toward advancing the science, if not the art, of medicine.

What is the exact nature of the information contained in New and Nonofficial Remedies? At present the book consists of two major divisions. The first section deals with general statements on broad classifications of preparations and monographs describing the actions, usage, and dosage of specific council-accepted drugs. The second section contains physical descriptions, tests for identity and purity, and methods of assay for the active ingredients and dosage forms of those council-accepted drugs for which official standards are not yet available. Thus, the importance of New and Nonofficial Remedies in developing and maintaining sound drug therapy trends would appear to be self-evident. However, there are certain points which deserve some emphasis.

Dr. Stormont is secretary of the Council on Pharmacy and Chemistry of the American Medical Association, Chicago.

Physician's Guide

Nomenclature of drugs is a rather important, though admittedly somewhat tedious, matter. The council always desires to cooperate with pharmaceutical manufacturers in the selection of generic or nonproprietary names for new drugs. The council encourages manufacturers to submit proposed generic and trade names for new products even before they are ready for the market. The early adoption of nonprotected designations for medicinal agents tends to obviate a certain amount of needless confusion in the literature. Usually such names are subsequently adopted by the United States Pharmacopeia and the National Formulary.

A drug which is accepted for inclusion in New and Nonofficial Remedies must be marketed and promoted in conformity with the rules of the council. The advertising and labeling must not contain claims unacceptable to the council. It is the responsibility of the drug manufacturer to submit the evidence necessary to convince the council that any proposed claims are justified.

The average physician today does not have the time or facilities to evaluate new drugs himself and to determine their proper indications for use, contraindications, limitations, and hazards. Not infrequently he finds it most difficult to study authoritative reports of the developments in therapy which are published in medical journals. He may or may not obtain reliable and useful information from a drug detail man or from promotional copy. Under these circumstances New and Nonofficial Remedies serves as a most useful reference volume or guide for rational therapeutics.

Some drug manufacturers and physicians have wondered why relatively few mixtures have been accepted for inclusion in New and Nonofficial Remedies. Obviously, it is the right and duty of a physician to know the essential composition of the drugs he prescribes. He also wishes to know if the mixtures are unnecessarily complex. He must be mindful of the fallacy of routinely prescribing unnecessarily