empowered by the government to choose drugs warranting official recognition and to establish their standards for purity and strength.

In this country, a group of experts, the Committee of Revision of the United States Pharmacopeia, are selected by and from those physicians, pharmacists, chemists, and pharmacologists who represent all organizations having a recognized interest in drug standards. These experts are elected by a democratic process at each Decennial Convention of the United States Pharmacopeia. They, then, serve until their successors are elected at the next convention.

The National Formulary Committee, likewise, is composed of experts selected by the American Pharmaceutical Association without political or governmental interference.

The Congress has recognized the finished work of these two groups—the United States Pharmacopeia and the National Formulary—as establishing the legal standards for drugs in the United States. Supplementing these two books of legal standards are New and Nonofficial Remedies and Accepted Dental Remedies. The former represents those drugs meeting the qualifications as to nature, use, claims, and so forth imposed by the Council on Pharmacy and Chemistry of the American Medical Association. Accepted Dental Remedies lists those meeting the requirements of the Council on Dental Therapeutics of the American Dental Association.

These four books, U.S.P., N.F., N.N.R., and A.D.R., are true examples of democracy in action and ones of which we, as a free people, can rightfully be proud.

As in all democratic institutions, however, freedom imposes with it a responsibility, and those who help establish policy and guide the affairs of these books must keep this great public responsibility constantly in mind. Each of the five symposium members is intimately concerned with one of these official or standard books and the policy and program governing them. Each is, in fact, a key individual concerned in each instance. That each one has recognized his responsibility not only to the public but to the professions concerned in this work is evidenced by his presence at the symposium.

The United States Pharmacopeia

By LLOYD C. MILLER, Ph.D.

Specifying standards of quality and purity for drugs, the United States Pharmacopeia is published every 5 years by a permanent organization which was first created in 1820. The organization consists of a board of trustees, a panel of officers, a permanent secretariat, and a revision committee of 60 experts.

Members of the revision committee are selected for their knowledge of all branches of medicine, chemistry, and pharmacy which conceivably can contribute in an important way to the technical work of revising the list of drugs included in the Pharmacopeia and their standards. The work of the committee is organized and directed from permanent headquarters in New York City.

The revision committee consists of 20 experts in medicine and 40 experts from the pharmaceutical and allied professions. The primary responsibility of the 20 physicians is to determine what drugs represent the best practice and teaching of medicine. It is the responsibility of the 40 other committee members to determine how pure and potent these drugs shall be and to provide methods by which these qualities may be determined.

Of course, the specifications vary according to the nature and end use of the drug. A crude drug used as the starting material of a pharmacopeial item is far different from a drug intended for intravenous administration.

The Pharmacopeia must concern itself not only with the quality of the drug but with its packaging and storage so that its initial quality will not be modified. This concern extends, of course, to the nature of the containers and the length of time the drug is safe for use if it is subject to deterioration.

The Pharmacopeia has other ancillary functions, but its main purposes are to determine

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what drugs shall be given pharmacopeial status and how pure must these drugs be.

U.S.P. Function

How much does the United States Pharmacopeia influence drug therapy trends now?—is a question which defies answering in definite terms. An answer is important in determining whether the Pharmacopeia is doing enough or might do more. This question has never been made the subject of an opinion poll, nor is it likely to be, but a fairly sound estimate is possible by looking closely at these accepted facts:

1. The official (United States Pharmacopeia and National Formulary) drugs are emphasized in teaching students of medicine and students of pharmacy. Their familiarity with the official drugs is bound to increase the use of U.S.P. drugs. Conversely, drugs which do not have official listing are less favored because they are less well known.

2. The official drugs are of a standard quality which is not subject to unannounced changes dictated by whim or trivial considerations. Only after careful study and often extensive investigation in the laboratory are revisions in the U.S.P. standards made.

3. Within limits imposed by the patient's need, the official drugs are the agents of choice in those cases covered by such health insurance plans as the Blue Cross. Many health insurance contracts call for payment only for the official drugs. In some ways, this represents a handicap imposed for convenience, but it gives the United States Pharmacopeia a real responsibility. The branches of the Government which procure drugs in quantity—the Armed Forces, the Public Health Service, and the Veterans Administration—all draw heavily upon the United States Pharmacopeia.

4. The official drugs are generally less expensive than the nonofficial drugs because most of their research and development costs have been charged off over the years since their introduction. Relatively few of them are subject to patent control so that all the forces of competition are brought to bear on keeping down the cost of manufacture and distribution.

5. Under the new Food, Drug, and Cosmetic Act of 1938 as well as under the original act of 1906, the Congress directs the Food and Drug Administration to utilize the United States Pharmacopeia and the National Formulary to insure quality, purity, and potency of drugs moving in interstate commerce. In consequence, most of the individual States similarly direct their boards of pharmacy to use the official compendiums as the basis of their regulatory activities. It is an outgrowth of this adoption of the United States Pharmacopeia and the National Formulary that led to a serious complication. It arises from the fact that in many States the official drugs may be sold only under the direction of a qualified pharmacist. Strong forces are working to extend the marketing outlets of many well-established drugs so that they may be sold, for example, in grocery stores. Since obviously few grocery stores are interested in employing a pharmacist, there is much pressure to modify existing "restrictive sales" provisions. Although the United States Pharmacopeia takes no sides in this controversy, the backwash from it lapped at the very foundation of the authority on which rests the whole pharmacopeial program in this country.

Wisconsin Decision

A case arose which has been passed upon by the Supreme Court of Wisconsin since the date of this symposium. The validity of the Wisconsin State Pharmacy Act was challenged on the grounds that its dependence upon the United States Pharmacopeia constitutes delegation of legislative authority to a body not responsible to the Wisconsin State Legislature. In ruling against this challenge, the court quoted an 1873 Pennsylvania decision as follows:

". . . the true distinction . . . is this: The legislature cannot delegate its power to make a law; but it can make a law to delegate a power to determine some fact or state of things upon which the law makes, or intends to make, its own action depend. To deny this would be to stop the wheels of government. There are many things upon which wise and useful legislation must depend, which cannot be known to the law-making power and must, therefore, be a subject of inquiry and determination outside of the halls of legislation."

Experts on constitutional law look upon this decision as most important in establishing the authority of the United States Pharmacopeia as well as the validity of this aspect of not only the pharmacy acts of the 48 States but of the Federal Food, Drug, and Cosmetic Act.

Subcommittee on Scope

All the five functions noted above emphasize the importance of the selection of the drugs which make up the Pharmacopeia. This emphasis justifies elaborating upon this primary responsibility of the revision committee.

The scope of the Pharmacopeia, by which is meant the contents so far as individual drugs are concerned, is the responsibility of the Subcommittee on Scope, one of the 10 subgroups of the Committee of Revision. The subcommittee includes the 20 physicians of the committee and 5 of the pharmacists who are more intimately familiar with prescription practices. The physicians represent such specialties as surgery, anesthesiology, endocrinology, and others.

It was natural for each physician to take the responsibility of heading a panel of fellow specialists to bring to the subcommittee a synthesis of opinion of what drugs are required in the best practice of his particular specialty. Thus, literally hundreds of physicians were polled for advice on what drugs they felt were essential or at least highly valuable in their practice. In conducting these surveys, it proved difficult to convey to the individual physician what the Pharmacopeia represents; many had little or no previous knowledge of it.

The United States Pharmacopeia may now wield a great influence on the quality of drugs which the physician uses, but until physicians generally come to look upon it as an authoritative guide to the best drugs, it will not be wielding the maximum influence in trends in the use of those drugs.

Pharmaceutical Information

How, then, can we get the physician's attention to a greater extent? Obviously, we should not ask for it until we deserve it and are prepared to keep it. We shall not deserve the physician's confidence until he can feel that the Pharmacopeia offers an indispensable and unique service.

Our greatest opportunity for serving the medical profession, I believe, lies in creating a pharmaceutical information bureau. We might begin by compiling data on the therapeutic usefulness of the new drugs, particularly those whose status is controversial.

It has been suggested that eventually our files should contain information on every Pharmacopeial drug. While this information would be primarily for the Subcommittee on Scope, it should be made available freely to all requesting it.

It has also been suggested, and even strongly advocated, that the United States Pharmacopeia publish a handbook of this kind of information for physicians. The suggestion was rejected by the U.S.P. Convention of 1950, and there is no thought now of attempting to disseminate the information broadly in such a fashion.

One practical difficulty in setting up such a service would be keeping it within bounds. The U.S.P. office cannot be expanded without limit to perform the extra work. It would be unwise to increase markedly the price of the Pharmacopeia to finance the project when its sales represent our only substantial source of income. It would be feasible to offer the information service to all requesting it, but to mail literature to nearly every owner of a current edition would be prohibitive in cost. It might be possible to dispense the information more economically through existing publications in the form of periodic reports.

In this connection, we might set up a register of the brands and trade names of the official drugs. Complete information on these is generally unavailable, although the annual editions of the *Drug Topics Red Book* and the *American Druggist Blue Book* give a great amount.

To increase the influence of the United States Pharmacopeia in these directions, it would seem necessary to create a more widespread awareness of what conformance with U.S.P. standards guarantees to the general public, to the medical profession, and possibly, even to the pharmacists. This order of listing corresponds directly to the difficulty of reaching groups involved, and inversely to the need for information. The general public has little awareness of the Pharmacopeia whereas to the pharmacist

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.

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