The United States Pharmacopeia and the Anesthesiologist

The publication in June 1965 of the seventeenth revision of the United States Pharmacopeia marks the 145th year of the availability of this valuable compendium. It is regrettable that many physicians are unaware of its existence or know little of its nature, scope and usefulness. All physicians, and anesthesiologists in particular, should be familiar with its contents.

In 1817, Dr. Lyman Spalding of New York City urged the Medical Society of the County of New York to take steps to create a National Pharmacopeia, by means of a plan whereby northern, middle, southern and western districts of the United States would first draft pharmacopoeias and then compile their respective efforts into a single pharmacopeia. The general plan succeeded, and the first United States Pharmacopeial Convention assembled in Washington, D.C., on January 1, 1820. However, pharmacopoeias were submitted to the Convention only by the northern and middle districts, these were reviewed and consolidated, to provide the basis for the first United States Pharmacopeia, which was published December 15, 1820, with Latin and English versions on facing pages.

The first Pharmacopeia was the result of discussion and cataloging of drugs and other substances possessing medicinal powers, the utility of which had been established and the physiological activity recognized. The first Convention recommended the inclusion of substances that conformed to the best state of medical knowledge of the day, in a compendium that has since been known as the U.S.P.

Before adjournment, the 1820 Convention adopted a Constitution and Bylaws, with provisions for subsequent meetings of the Convention and a revised Pharmacopeia every ten years. In 1900, publication of U.S.P. supplements was initiated. In 1940, the rapid increase in the number of drugs introduced led the Convention to direct publications of a new U.S.P. revision at five-year intervals.

The U.S.P. convention is a legally incorporated, nongovernmental, nonprofit agency which derives its funds from private sources, the chief of which is the sale of the Pharmacopeia. In 1906, when the Food and Drugs Act became law, Congress designated the Pharmacopeia as the agency to establish standards of strength, quality and purity of medicinal substances. This policy continues. Some states maintain similar policies. A medicinal substance referred to as "official" indicates that a drug is listed and described in detail in a monograph in the U.S.P.

At the present time, the "Convention" delegates its work in the interim between decennial meetings to an elected board of trustees and officers. The Committee on Revision is composed of 60 members. Members of this committee are nominated by various scientific and educational groups concerned with medicine and drugs. For the past several decades an anesthesiologist has been an elected member.
of the Committee on Revision. In addition to physicians, the present composition of the committee includes chemists, pharmacists, pharmacologists and other scientists concerned with drugs. The Committee on Revision is divided into various subcommittees composed of specialists. These subcommittees are responsible for providing data, information and advice on the standards, usefulness and other aspects of drugs.

Of primary interest to anesthesiologists is the subcommittee on Scope. Members of this subcommittee are appointed to serve as chairman of advisory panels drawn from various specialty groups to provide detailed knowledge and expert opinion. The member of the Committee on Revision serving as chairman of the Anesthesiology Panel is Dr. John Adriani of New Orleans. Serving on the panel are Drs. Emanuel M. Papper of New York City, David A. Davis of Chapel Hill, North Carolina, Francis F. Foldes of New York City, Leroy D. Vandam of Boston and Arthur S. Keats of Houston, Texas. The Committee on Revision and the various specialty panels serve for ten years. The Committee on Revision prepares two revisions of the Pharmacopeia each decade. The panels and Pharmacopeial staff are now beginning to assemble the eighteenth revision which will be available in 1970.

The activities of the Committee on Revision preparing the seventeenth revision were influenced by the Kefauver-Harris legislation enacted in 1962. The approach of the majority of clinicians, formulary committees and others responsible for policies concerning the use, procurement and dispensing of drugs has in general been conservative, but this legislation has accentuated this conservatism. The history of the development of the United States Pharmacopeia reflects a continued conservatism in categorizing and recommending standards of purity of drugs. Much thought and deliberation were expended in determining adequate standards for drugs. The Kefauver-Harris Amendment to the Food, Drug and Cosmetics Act created problems in nomenclature. A drug may be known by its chemical, generic, proprietary, or nonproprietary name. The amended law stipulates that only the generic names of medicinals are acceptable. Previous revisions included other names in addition to the generic. The omission of synonyms would lessen the usefulness of the compendium. Therefore, a separate chapter on nomenclature has been added which includes a tabulation of synonyms.

The rapid increase in the number of available drugs has created problems in devising suitable names for new drugs. In 1961 the Pharmacopeial Convention and the American Medical Association combined their efforts in this difficult task. In 1964, the American Pharmaceutical Association joined this group and a committee was formed. The present committee is called the United States Adopted Name Council (USAN).

As a new drug gains widespread acceptance and becomes a valuable therapeutic agent, it is placed before the Committee on Revision for consideration for admission to the U.S.P. Data concerning the drug are referred to one or several panels, the members of which are familiar with and have a direct interest in the use or dispensing of the drug. The panel votes to adopt or deny admission. The final decision to admit or reject is made on the consensus of the Subcommittee on Scope. Those drugs already listed are given careful consideration for retention or deletion from the compendium. In selecting drugs from a group of several of similar action, the one which is the most effective and least toxic or noxious is selected. Drugs which have been deleted from the compendium but which are still considered to be useful are, in many cases, included in the National Formulary (N.F.). The N.F. is a compen-
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The importance of being familiar with the contents, scope and utility of the U.S.P. cannot be overemphasized. Such information may be of value when deciding which compound of a group of several is the most effective and least noxious. Data in the monographs are of value to formulary committees, and to those preparing specifications for the purchase of drugs on a contractual basis. The fact that U.S.P. standards and recommendations have been met may also be helpful in medico-legal situations concerning dosage and usage.

New inclusions in U.S.P. XVII of interest to anesthesiologists are: Bemegride, chlorpromazine, ethyl chloride, halothane, lidocaine, metaraminol, methamphetamine, methylergonovine, plasma protein fraction, and succinylcholine. A drug once included and dropped may be readmitted if there is a new use, or another dosage form or renewed interest in an old use. Ethyl chloride has been readmitted for topical use by recommendation of other specialty groups but not by anesthesiologists. Compounds deleted are amphetamine, amylene hydrate, barium hydroxide lime (Baralyme), blood group specific substance A&B, apomorphine, chloroform, dibucaine, dihydromorphinone, ephedrine sulphate (injectable), levallorphan, meperidine, mephentermine, meprobamate, opium tincture, opium powder, papaverine, piperocaine, thiamylal, tolazoline, trimbromomethanol, trimethophran camphorsulfonate, and vinyl ether.

Anesthesiologists should have access to and refer to this latest Revision.

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