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A Guide to the U.S. Pharmacopeia and the USP DI

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3 A USER'S GUIDE TO THE DRUG COMPENDIA

An Overview

by David K. King, M.D., F.A.C.P.

New Year's Day 1994 marked a turning point in Medicare payment for off-label drugs used to treat cancer. Beginning January 1, 1994, citation in any one of the three compendia assures that Medicare must pay for a chemotherapy or biological agent for that indication. Passage of the law was hailed as a great victory for cancer patients, bringing much needed uniformity to the care they can receive throughout the nation.

In passing the law, Congress joined California, Georgia, Illinois, Indiana, Massachusetts, Michigan, New Jersey, New York, North Carolina, and Oklahoma, which had passed versions of the uniform model legislation on off-label use developed by the Association of Community Centers (ACCC). Recently, Alabama, Connecticut, Maryland, Ohio, Rhode Island, and Virginia were added to the list of states passing similar legislation.

Passage of this federal law, however, will not directly affect local insurers. That is why ACCC will continue to press for passage of this legislation at the state level to help eliminate unnecessary and arbitrary calls by some state regulated insurance carriers.

The passage of state and federal laws requiring the use of the three compendia has focused attention on how drugs come to be included in these publications. To better understand the three drug compendia, *Oncology Issues* asked representatives from the U.S. Pharmacopeia, the American Medical Association, and the American Society of Hospital Pharmacists to explain the history, objectives, and contents of their publications.

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A Guide to the U.S. Pharmacopeia and the USP DI

by Keith W. Johnson

The basic mission of the United States Pharmacopeia (USP) when it was founded in 1820, was to establish standards (or, at that time, recipes or formulas) for drug preparations in the United States. This standards-setting process continues today; manufacturers must meet the standards specified in the USP and the National Formulary (NF)–standards that are legally enforceable by the Food and Drug Administration (FDA) by Congressional mandate. The USP and NF are recognized by federal and state laws, as well as by many foreign countries, as the primary sources of industry standards. In meeting the needs for public standards, USP continuously reviews and revises existing standards to account for new data and technology, and develops standards for new products, including genetic and biotechnology products, such as interferons.

Eligible organizations that may appoint delegates to the quinquennial meeting of the USP Convention (the next one will be in March 1995) include the U.S. Colleges of Pharmacy and Medicine; state pharmaceutical associations and medical associations; national professional and scientific organizations, such as the American Medical Association (AMA) and the American Hospital Association; and federal agencies, such as the FDA, the Public Health Service, and the Department of Health and Human Services. In addition, there are positions for consumer and international representatives, as well as a small percentage of at-large members who are appointed because of their special knowledge and expertise. It is anticipated that delegates to the 1995 Convention will consider expanding the delegate pool to better reflect drug standards and drug information issues and needs as they exist today.

The USP, however, is a public interest group; it does not represent industry, medicine, pharmacy, or any other special interest group. It represents the public in its need for unbiased standards of drug quality and information.

The database reflecting USP's drug information activities was initiated in 1977. After three years of development, the first edition of *USP Dispensing Information (USP DI)* was published (1980). The information is under constant review. The official and most up-to-date *USP DI* information is in fact that found in the electronic database maintained at USP headquarters. New information is added to this database daily and is the basis for print and electronic applications provided by USP itself and by

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numerous vendors. New print publications are released annually (with monthly updates).

In general, the AMA *Drug Evaluations* and the *USP DI* can be considered complementary rather than competitive. The *USP DI* provides in-depth information about each specific medication, while the AMA publication focuses on comparative therapies or the use of a drug for a particular patient. For instance, is drug A better than drug B for a particular condition?

THE REVIEW PROCESS

USP DI is developed and finalized by USP's Committee of Revision, which is comprised of 114 of the top scientists, physicians, pharmacists, and other health care providers in the country, and its 33 medical specialty, professional practice, and consumer interest advisory panels, which are comprised of approximately 650 experts. The process is public, however, and all interested parties have the opportunity to comment.

USP DI is developed within parameters established by the Drug Information Division (DID) Executive Committee. These parameters are reviewed annually. For example, a new category of information for pharmacogenetics has recently been added. Using these parameters, DID staff drafts monographs based on product labeling and the medical literature. These drafts are reviewed by ad hoc experts, who have a special knowledge about the drug being reviewed; drug manufacturers; and experts on USP's various advisory panels.

Once the advisory panels reach an initial consensus (often after several rounds of reiterative review), the proposed drafts are identified as ready for public review in the *USP DI Review*. The drafts are then made available for public review by all interested parties. Suggested changes are again reviewed by DID staff, the advisory panels, ad hoc experts, and manufacturers. When the advisory panels and the Committee of Revision reach a final consensus, the changes are released to the electronic *USP DI* database. Final decisions rest with the elected Committee of Revision and its advisory panels, not USP staff or any special interest group.

CANCER TREATMENTS

In the 1994 database approximately 20 percent of the overall indications that *USP DI* listed as accepted therapy fell outside of FDA labeling. This percentage is considerably higher for drugs used in the treatment of cancer and when a drug includes unlabeled doses and pediatric uses. However, the USP is conservative about adding new unlabeled indications to the *USP DI*. Before new unlabeled indications are deemed acceptable for addition to the *USP DI* database, the literature must clearly document these uses, and USP advisory panels must support the findings. The USP does not evaluate unproven methods of cancer treatments, such as the highly controversial immunoaugmentative therapy. However, the organization is exploring a program that would develop unbiased information sheets that describe what is known about each method in question. These sheets could be used by both patients and providers.

Combination cancer therapy is routinely addressed in *USP DI* monographs. Accrual of such treatment regimens is difficult because of the rapidly changing knowledge base and the unique problems this presents in terms of consensus generation.

OTHER PUBLICATIONS

USP also produces a companion volume to the *USP DI Volume I (Drug Information for the Health Care Professional)* called *Advice for the Patient (USP DI Volume II)*. This information volume is written in easy-to-understand language that can be used by most patients. The information is set up so that providers can photocopy the monographs (permission granted with certain limitations) and use in patient education programs. This database in turn serves as the basis for many other patient-oriented programs, including USP's "Patient Drug Education Leaflets" (both standard and easy-to-read), AMA's "Patient Medication Instruction" sheets, NCI's bilingual chemotherapy leaflets, and the Consumer Union's *Complete Drug Reference*, which is available to the general public.

Another publication provided by USP is the *USP Dictionary of Drug Names*, an annual compilation of drug nomenclature.

FUTURE PLANS

USP's drug information activities are under constant review for potential change and expansion. Major initiatives relating to information for the health care professional include the development of drug utilization review (DUR) guidelines and the addition of information on drugs of choice and therapeutic alternatives. New initiatives on the patient information side include development of pictograms and the development of a system allowing the creation of personalized drug information sheets for patients that are based on the disease treated, sex, specific drug/dosage form used, educational level, and language. In addition, new print and electronics applications are under development.