

The United States Pharmacopeia

Current applications to pharmacy practice

by Patrick Martin

The United States Pharmacopeia (USP) is the official standards-setting organization for quality and control of all prescription and over-the-counter medications, dietary supplements, and other health care products sold and manufactured in the United States. It is an independent, nonprofit public health organization, and the only non-governmental pharmacopeia in the world. The organization is funded through its publications, most notably the *United States Pharmacopeia – National Formulary (USP/NF)* (the *National Formulary* being acquired from the American Pharmacists Association in the early 1970s and combined into one official compendia). Much of the published work of USP is developed by professional volunteers representing pharmacy, medicine, nursing and other health care professionals as well as academia, government, the pharmaceutical industry, health care plans and consumer organizations.

USP began in 1820 with the intent of establishing harmonization in drug preparation and compounding, a standard activity performed with significant variation by practicing physicians and pharmacists of the day. However, the age of industrial pharmaceutical manufacturing replaced this activity by health care providers, and the USP adjusted its standards accordingly, placing an emphasis on analytical techniques aimed at verifying substance integrity.¹ This has left some practicing pharmacists today questioning the value of USP to their practice.

USP is so much more than just an official standards-setting organization (first recognized as the official compendia by the United States government in the 1906 Pure Food and Drug Act). Its mission is to promote the public health by developing

and disseminating quality standards and information for medicines, health care delivery, and related products and practices. It has evolved progressively with setting standards for newly approved medications and new manufacturing processes, especially those involved with biopharmaceuticals. In addition to its standards and verification activities, USP is involved in initiatives promoting patient safety and reducing medication errors. Other recent initiatives also reaffirm the relevance of the *USP/NF* to contemporary pharmacy practice. This article discusses these initiatives and their benefit to practicing pharmacists.

THE PHARMACISTS' PHARMACOPEIA

Recognizing that the current *USP/NF* is aimed primarily at pharmaceutical manufacturers, USP created a reference designed specifically for practicing pharmacists and pharmacy students, called *USP Pharmacists' Pharmacopeia*, the first edition of which was published in 2005. It contains drug and dietary supplement monographs, general chapters, compounding specification references and legal statutes. Drug monographs are abridged and only contain information related to pharmaceutical dispensing, such as storage and packaging. More than 120 official compounding monographs are also included. All general chapters related to pharmaceutical compounding and others related to topics such as weighing and measuring, labeling, dosage forms, and sterility testing are incorporated as well.²

According to USP, it is the organization's intention that the *Pharmacists' Pharmacopeia* serves as a comprehensive reference on multiple aspects of pharmacy practice, including regulatory compliance, helping to promote best practices in pharmaceutical dispensing and providing new perspectives on key issues that affect the pharmacy profession and practice.² The

last component is particularly interesting as it involves articles by USP experts on a broad range of pharmacy-related topics.

Another advantageous component of the *Pharmacists' Pharmacopeia* is the chapter on selected *Pharmacopeial Forum (PF)* stimuli. The *PF* is the USP publication that contains all proposed revisions for the *USP/NF*. The *Pharmacists' Pharmacopeia* contains those revisions that are relevant to pharmacy practice. As further revisions are still underway for Chapter <797> *Pharmaceutical Compounding – Sterile Preparations*, the *Pharmacists' Pharmacopeia* serves as a great tool for pharmacists to stay up-to-date with regulations that govern their practice.

In its two years of publication, the *Pharmacists' Pharmacopeia* has failed to capture significant attention, perhaps due mainly to lack of knowledge about its availability. However, it contains all pharmacy-relevant information from *USP/NF* with additional useful information not found within *USP/NF*. At nearly one-third the retail cost of an edition of *USP/NF*, pharmacies may want to consider the *Pharmacists' Pharmacopeia* as a less expensive alternative. It can be purchased from USP online at WWW.USP.ORG/PRODUCTS/PHARMACISTS/PHARM/.

MEDICATION ERRORS REPORTING PROGRAM & MEDMARX®

In an effort to reduce medication errors and enhance patient safety, USP has developed two medication error reporting systems. The Medication Errors Reporting Program is an online program that allows health care providers to report potential or actual medication errors on a confidential or anonymous basis. The program is operated by USP in cooperation with the Institute for Safe Medication Practices (ISMP). All reports are analyzed and any potential health hazards are forwarded to the FDA in conjunction with the MedWatch Program.³ Online forms can be found at WWW.USP.ORG/HQI/PATIENTSAFETY/MER.

MEDMARX® is a subscription-only, Internet-accessible database designed to track medication errors and adverse events in hospital settings. It is designed as a quality improvement tool which facilitates productive and efficient documentation, reporting, analysis, tracking, trending and prevention of adverse drug events.⁴ The

program is unique in design by allowing users access to data from other subscribing organizations for comparative analyses.

To help consolidate the data from these two programs and disseminate the findings to health care providers, USP's Center for the Advancement of Patient Safety (CAPS) established a monthly newsletter, *CAPSLink*, available as a free email subscription. The newsletter focuses on various topics, including errors associated with a particular class of medications or care setting or a common cause of error, such as look-alike, sound-alike drugs.⁵ An archive of past *CAPSLink* newsletters can be found at WWW.USP.ORG/HQI/PATIENTSAFETY/NEWSLETTERS/CAPSLINK/.

Pharmacists in any practice setting will find useful information in this newsletter. In addition to the case reports explaining the errors, the newsletter also contains recommendations and guidelines from USP's Safe Medication Use Expert Committee and other organizations including the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), the Joint Commission, the Agency for Healthcare Research and Quality, the Institute of Medicine, and FDA. These recommendations include strategies on how to manage and minimize future medication errors.

The Center for the Advancement of Patient Safety also publishes annual MEDMARX[®] Data Reports that are available for purchase from USP. These reports are much more in-depth and present data collected over extensive time periods. Each report focuses on a unique issue. The most recent report summarizes 1998-2005 medication error findings from perioperative settings. Other reports have focused on medication errors in other hospital settings such as intensive care units and radiological services. Reports have also been published on medication error findings associated with the use of various technologies, including computerized prescriber order entry and automated dispensing devices. The types of information found in each report include types of medication errors, causes, contributing factors, products involved and actions taken.⁴

DIETARY SUPPLEMENT VERIFICATION

Of particular interest to community pharmacists might be USP's relatively recent venture into dietary supplement verification. In 2002, an estimated 38.2 million adults used herbal medications or dietary supplements.⁶ Even more important is that a large segment of this population may be using these products with the intent to treat a specific condition. With such a large demand for these products, pharmacies should be encouraged to purchase dietary supplements of the highest quality on par with standard prescription medications. As pharmacists, it is our mission to promote safe medication practices. If patients choose to self-treat with herbals and dietary supplements, we must respect this decision and be able to offer safe products.

A dietary supplement that is awarded the USP Verified Mark assures pharmacists of a high quality product based on four important safety components: 1) that the labeling of the product is accurate and all ingredients are present in the amount specified; 2) that the product is free of harmful contaminants; 3) that the dissolution of the product is sufficient for human use; and 4) that the product was made under good manufacturing practices. USP maintains this assurance for all verified products via random off-the-shelf tests and periodic audits of manufacturing sites for continued compliance with good manufacturing practices.⁷ Without the USP Verified Mark, there is no assurance of the quality of the dietary supplement.

SUMMARY

USP is a multi-faceted organization that operates in cooperation with a large number of patient-safety organizations. The main concern of USP has always been the patient, and all initiatives developed by the organization strive to maintain that patients receive the right drug in an appropriate manner. Pharmacists should keep in mind that many programs, such as *USP Pharmacists' Pharmacopeia*, are designed specifically for pharmacy settings, and should make attempts to utilize them for the benefit of their patients. ●

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tive diagnostic and classification criteria. In patients with more severe disease, various systemic treatments are available in addition to topical therapies, and many patients use combination therapy to achieve adequate control of their psoriasis. Lack of head-to-head comparisons of treatment options and unique considerations of individual agents complicate therapy selection for many clinicians. Available evidence supports the use of phototherapy where available and newer biologic therapies in addition to traditional systemic oral agents. A patient-specific approach should be used to weigh efficacy, safety and cost factors when selecting appropriate regimens for treatment of moderate to severe psoriasis. ●

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