



*2005–2010 Resolutions
Adopted at the 2005 USP Convention*

March 13, 2005

Public Monographs and Reference Materials

USP resolves to work with appropriate stakeholders to contribute to the public health and patient care by eliminating barriers to expanding and updating public monographs in *USP–NF* and, if needed, developing reference materials for all legally marketed therapeutic products in the U.S.

Executive Summary

The resolution addresses the importance of gaining a full complement of new and updated monographs in *USP–NF* in a timely way. Where needed, the portfolio of official USP Reference Standards will expand commensurately. The background discusses some of the challenges facing USP and its efforts to expand the number of official monographs in *USP–NF*, its efforts to up date existing monographs, and its efforts to develop the reference standards required by modern monographs.

Background

The goal of USP is to develop public standards (monographs and official USP Reference Standards) for all therapeutics products legally marketed in the U.S. The goal of 100% coverage is constrained by several factors, including reluctance of Sponsors to submit Requests for Revision and constraints that limit FDA’s ability to work optimally with USP, such as limits on information that can be provided to USP under the Freedom of Information (FOI) Act. For biologicals and biotechnological products, the situation is further complicated by complexity of the products and the methods used to fully characterize them.

These various constraints over time have led to a gap between the number of articles legally marketed in the US (Rx and OTC drugs) and the monographs in *USP–NF*. *USP 28–NF 23* has more than 4,000 monographs of synthetic and semi-synthetic active ingredients and dosage forms, excipients, biological and biotechnological products, and dietary supplements. Even though this number is large, USP still needs to develop about 2,000 monographs to eliminate the gap. In addition, there is a need to update approximately 800–1000 current monographs to bring them up to today’s scientific standards.

For manufacturers, a public monograph and associated official USP Reference Standard, developed based on modern metrologic principles, provides a safe harbor. For practitioners and patients, it is a critical part of the triad of quality, safety, and efficacy information, the latter of which appears in product labeling. Taken together, the USP monograph is a key part of the triad that allows public scrutiny and promotes accountability.



A. New monographs

USP will initiate a number of approaches, all designed to optimize the collaboration among USP, FDA, and industry, to reduce the gap for new monographs. These strategies include providing assistance and incentives to specific manufacturers to encourage submission of information (Requests for Revision) to support new monographs, working with the Stakeholders' Forums to encourage general collaborations with USP in monograph development, and increased collaboration with FDA. Streamlining the work between Sponsors and USP staff while maintaining an appropriate period of time for review and comment will be necessary. The need for different procedures and acceptance criteria for certain tests, which USP terms the 'flexible monograph,' can impose a burden of working with multiple manufacturers to conclude a comprehensive monograph. In addition, a variety of campaigns need to be launched to promote the awareness of benefits that practitioners and patients, manufacturers, FDA, and compounding professionals can derive from the availability of modern ingredient, dosage form, and preparation monographs. Finally, USP and FDA should explore mechanisms for ensuring synergy between USP and FDA with regards to our common goal to clearly communicate regulatory requirements and interpretations of the official compendium (including status of informational (interpretative) chapters found at <1000> and above).

B. Updating existing monographs

USP must also continuously evaluate the current monographs and update them, where necessary, to replace older tests and procedures, cumbersome procedures, procedures requiring unsafe reagents, non-stability-indicating assay procedures, insensitive tests for impurities, and other outmoded approaches. Replacement will occur through modern instrumental and other techniques, with addition or deletion of tests to make standards consistent with best practices and requirements. USP is committed to incorporating advanced analytical procedures to aid in identifying and subsequently controlling, the levels of trace toxins, such as mercury. A close collaborative relationship with FDA and Sponsors is essential for the success of these efforts to update existing monographs. Just as product labeling is updated frequently based on new information and new uses, so too should the quality component expressed in a public USP monograph be updated to reflect advances in pharmaceutical knowledge, toxicological data, and analytical capability.

C. Reference standards

Physical reference standards are required for many of the procedures included in a modern *USP-NF* monograph and are provided solely for such use. This need is represented in the ever-expanding official USP Reference Standards collection. This collection is composed of highly characterized specimens of drug substances, excipients, impurities, procedural standards and calibrators, and compendial reagents. The increasing needs of stakeholders in different areas of pharmaceutical and biotechnological procedures require expansion of the current portfolio of official USP Reference Standards and create a need for new lines of reference standards. This ensures that techniques used for analytical and bioanalytical procedures are functioning properly,

giving added confidence to the results of tests. The feasibility and advisability of developing new lines of official USP Reference Standards, including procedural standards, authentic visual references, references for functionality testing, genetic testing, ancillary materials, limit tests for ancillary materials, and reagents will be evaluated. This evaluation will include a review of existing standards.

Resources

Because the resolution calls for reducing the turn-around time for new monographs and revisions to become official, major efforts will be required in different areas in USP. These efforts will call for an increase in staffing and continued modernization and streamlining within USP operations and laboratories. However, reducing turn-around time is ultimately expected to conserve resources. USP will have to expand its collaborative work with government, industry, and academic laboratories to maintain an optimal cohort of official USP Reference Standards.



Integrity and Safety of Therapeutic Products

USP resolves to work with stakeholders to continue to develop packaging, shipping, distribution, and storage standards and practices that ensure the integrity and safety of all therapeutic products through the distribution and dispensing system. USP further resolves to support educational and allied activities at all levels of distribution, dispensing, and administration (manufacturer through patient) concerning the integrity and safety of therapeutic products.

Executive Summary

Despite the impressive array of efforts in the 2000–2005 cycle, much work remains to be done to fully complete the needed General Chapters and allied monograph statements that help ensure the integrity of therapeutic products as they move from point of manufacture or compounding to point of use. Special issues for further consideration include the increasing complexity of ingredients and dosage forms and, as a consequence, the need for better packaging and improved distribution practices. This effort requires knowledge of the responsibilities, needs, and capabilities of all participants in the distribution system including state and national regulatory authorities.

Background

The work of the USP Packaging, Storage, and Distribution (PSD) Expert Committee during the 2000–2005 cycle resulted in a number of new and revised General Chapters dealing with a wide variety of issues. The PSD Expert Committee added standards to address concerns and issues observed for moisture- and temperature-sensitive preparations. Some of these added packaging and storage statements to monographs, together with consideration of the types of primary packaging and packaging materials used to protect Pharmacopeial articles. A framework for these General Chapters appears on page 2193 of *USP28–NF23*. At this time, approximately eight of the General Chapters have been finalized and two more are in development, and two are moving through the *PF* public process.

To aid in the revision process, USP formed the USP Project Team on Packaging, Storage and Distribution under the auspices of the Prescription/Non-Prescription Stakeholder Forum in an advisory role to the PSD-EC. The Project Team identified critical risk points encountered during distribution of a therapeutic article from the point of manufacturer to point of use by a consumer or patient, and categorized them as high, medium, and low. The Project Team also published a *Stimuli* article [*Pharmacopeial Forum* 29(3), May–June 2003, pages 864–870] to address these risk points. The *Stimuli* article is available on request. Recommendations to correct some of these risks were:



- Improvement of processes to change primary container without supportive data
- Improvement of downstream dissemination of information from manufacturer to repackager or pharmacist by:
 - Requiring labeling statements for repackaging/dispensing in blisters and bottle; in some cases statements exist for bottles only.
 - Improving the types of instructions on the bottle to allow repackagers to repackage exactly as the manufacturer requires.
- Improvement of repackaging guidance/requirements in General Chapters and removal of inconsistencies in bottle and blister repackaging (USP has a requirement of one year beyond-use date for dispensing pharmacists and FDA has six months for contract repackagers).
- Encouraging the use of higher barrier packaging for moisture-sensitive products.
- Expansion of general chapter <671> *Containers–Permeation*
 - To include classifications that will tie blisters to bottle specifications.
 - To consider the Moisture Vapor Transmission Rate/Unit concept instead of the per day/per liter concept.
- Education of drug sales representatives to properly store physician samples in representatives’ car trunks.
- Evaluation of child-resistant mechanisms—their use often causes medicines to be stored in a compromised state. PSD recognizes the involvement of the Consumer Product Safety Commission (CPSC) and the importance of the Poison Prevention Packaging Act (PPPA) of 1970.
- Processes to discourage shipping of medication via mail with no temperature or humidity control in place (irrespective of repackaged or original container).
- Promotion of education for proper storage and handling of medications in homes
- Additionally, USP has engaged in workshops and open conferences to provide education to manufacturers/practitioners, and has disseminated current information about available standards.

Resources

Activities described in this resolution would be assigned to the 2005–2010 Packaging and Distribution (P&D) Expert Committee. Additional support could be provided through the Stakeholder Forum and Project Team system, which is formally acknowledged by a Bylaws amendment. Staff support for this Expert Committee can be managed by the current infrastructure and funding would be provided under the budget of the Department of Standards Development. Storage standards will be addressed during the development of individual monographs in collaboration with the P&D Expert Committee.



New Science and Technology

USP resolves to work with appropriate stakeholders to track emerging sciences and technologies, and when appropriate, to develop information, best practices, and standards that have direct applications to the public health and patient care.

Executive Summary

The emergence of new sciences and the development of new technologies have accelerated. The impacts of these new technologies on the healthcare industry as well as patients and regulatory agencies need to be monitored. Standardization of new technologies done too early in their developments can stifle advances. However, it is also important to ensure that these new technologies are understood by practitioners; therefore, relevant information should be made available on the state of the art and the best practices that are being shaped by researchers in academia, government, and industry.

Background

For the purposes of this discussion, these sciences and technologies include but are not limited to new analytical and bioanalytical technologies, process analytical technologies (PAT), biotechnologies, gene and cell therapies and tissue engineering, genomics and proteomics, nanotechnologies, and other emerging sciences and technologies.

The traditional role of USP has been, since 1820, to develop public standards for drug substances and products to ensure the quality, identity, strength, potency, and purity of medicines. This traditional model called for USP to follow the development of new sciences and technologies by becoming involved in their application after they were fully developed and matured.

In the past 25 years the pace of the development and emergence of new sciences and technologies has required USP to change its original paradigm and become proactively involved in any new and emerging sciences and technologies that have direct or indirect applications to the healthcare of the public. USP recognizes that standards and information about these emerging technologies is lacking and that USP's expanded and diversified stakeholders are looking to USP to provide needed guidelines, such as best practices. This is particularly true in the fields of genomics and proteomics, which can lead to personalized medicine, as well as nanotechnologies. New technologies are also used diagnostically. The need for standardization is becoming more acute since development of applications of the emerging sciences/technologies is occurring in a broad range of settings, e.g., research institutes, academic laboratories and hospitals, and small entrepreneurial companies.

New Analytical and Bioanalytical Techniques: This area of development applies to non-complex as well as complex molecules. It is possible that USP's activity would be a combination of existing approaches to facilitate the characterization of products, their identities, potencies/strength, and impurities content. The use of rapid throughput techniques including the utilization



of microarrays, genetic probes, and bioinformatics techniques to capture, analyze, and report results and discoveries also will be considered. Because development of these new technologies will displace the classical and current techniques in the short- and long-term, USP must facilitate rapid updating of monographs and General Chapters as a means of facilitating both development and control.

Process Analytical Technologies (PAT): PAT has emerged as a way to help ensure final product quality by increasing analytical testing at the production line, possibly using a complicated array of chemometric, modeling, and statistical techniques, which leads to an increased understanding of the critical aspects of the manufacturing process. This concept is not new, especially in the biotechnology industry, because it is based on continuous validation of the process. What is new is the application of PAT to monitor a set of critical parameters that are predictive of both characterization and end-product specification data. The endorsement of this technology by FDA has resulted in the emergence of PAT in a variety of applications. When appropriately implemented, PAT may lead to a more efficient use of inspectional resources, elimination of unnecessary supplements, and reduction of end-product testing by the quality control laboratories. It is uncertain, however, whether the science of PAT is sufficiently evolved to meet these objectives, and it is uncertain whether the objectives are in accord with modern metrologic principles. USP will continue to monitor the use of PAT, publish information on the best practices, create General Chapters for PAT techniques, and continuously monitor its evolution as a means of ensuring good quality therapeutic products.

Gene and Cell Therapy and Tissue Engineering: Although not yet fully matured, this area of development offers great hope as a means of maintaining health and treating disease. USP has published a best practices general information chapter and is developing standards for ancillary materials for use in these therapies. USP will continue to develop strategies and tactics to monitor and become involved in these developments.

Biotechnology: Although biotechnology emerged about 30 years ago, its full potential in the area of therapeutics has yet to be realized. USP has monitored developments in this area and particularly in the area of biotechnology-derived products, developing a number of monographs for these products. However, development of monographs for biotechnological products is complicated by the complexity of the products and the methods used to fully characterize them. The combination of biotechnology with other emerging sciences and technologies for the development of diagnostics as well as therapeutics is evolving into new technologies, and USP will follow these associated developments carefully.

Genomics, Proteomics, and Metabolomics: The elucidation of the human genome and the potential applications to treat disease and maintain health constitute hallmark breakthroughs in medicine. Genetic analysis provides the capacity to select drug therapies that are best fit for the person's disease and metabolism, and application of this ability is expected to become more routine. It may be possible to develop therapies that can only be used in certain patients with appropriate genotypes, and these therapies may be marketed with pharmacogenetic "kits" to determine who should use the therapies. These "kits" may warrant USP standards.

Understanding genetic defects resulting in disease also lays the basis for gene therapies that will correct the defects.

But genes are not the full story. Their expression into proteins and the structure and function of these proteins are the area of science now labeled “proteomics” and the interaction of proteins in metabolic pathways is called by some “Metabolomics”. Technologies that will determine the level of a given expressed protein or the activity of a critical metabolic pathway could possibly substitute for the determination of gene variants related to disease in a given patient and direct the practitioner toward a specific treatment. These technologies and their application to the diagnosis and treatment of disease may well warrant USP standards.

Nanotechnology: Nanotechnology is the ability to analyze, evaluate, manipulate, and control specific materials at the nanoscale. The use of nanotechnologies in medicine includes the in-vivo collection of information about biological processes and interaction with organic and inorganic substances and pathogens for the diagnosis, prevention, and treatment of disease and injury. Advancements in the fields of physics, biology, engineering, chemistry, and medicine will allow the applications of nanotechnologies to the healthcare of the public. The American National Standards Institute (ANSI) and the National Institute of Standards and Technology (NIST) have begun to establish nomenclature and a terminology structure and have begun discussions about standards to support the new industry. A National Nanotechnology Initiative represents a federal research and development program that coordinates multi-agency efforts. In September 2004, the National Cancer Institute (NCI) announced a major commitment to nanotechnology for cancer research in the form of a \$144 million, 5-year initiative. The NCI program is designed to bring the application of nanotechnology to clinics for the treatment of cancer. NCI also announced the creation of a Nanotechnology Characterization Laboratory to standardize preclinical characterization of nanomaterials and has proposed expanding its collaboration with FDA. In addition to initiatives within these organizations, more than 30 start-up corporations are involved in the development of applications of nanotechnologies to identify, diagnose, and treat various diseases, especially cancers.

Resources

Monitoring the relevant developments could be done within USP’s current structure of Expert Committees, Advisory Panels, and Advisory Bodies. As the new technologies are developed and applications to pharmaceutical care become practical, the need for additional specialized Expert Committees and additional staffing could become critical.

Compounding Standards and Education

USP resolves to expand its work with appropriate parties involved in compounding, including practitioners, FDA, state boards of pharmacy, and other regulatory authorities, to support and disseminate information about science-based compounding practice.

Executive Summary

Potential efforts may include:

- standards for compounding procedures, processes and documentation (such as *USP* General Chapters <797>, <795>);
- monographs for compounded preparations, including standards for analysis;
- educational resources for practitioners, schools of medicine, pharmacy, and veterinary medicine in the area of compounding.

USP proposes to work in conjunction with pharmacy associations, the Pharmacy Compounding Accreditation Board, the National Association of Boards of Pharmacy, Colleges of Pharmacy, and State Pharmacy Associations to further advance standards for compounded preparations.

Background

During the 2000–2005 cycle, USP developed General Chapters <795> *Pharmaceutical Compounding—Nonsterile Compounding*, and <797> *Pharmaceutical Compounding—Sterile Compounding*. These General Chapters were deemed critical because the Supreme Court struck down the compounding provisions of the Food and Drug Administration Modernization Act (FDAMA) of 1997. These chapters have been recognized by national accrediting organizations. Partly in response to the Supreme Court decision, the creation of these two General Chapters, and partly as a means to help USP continue to develop compounding preparation monographs, USP held two compounding Stakeholder Forums and compounding workshops. These conclaves allowed interaction between USP and pharmacists, FDA, representatives from state boards of pharmacy and many others to consider current and proposed approaches to compounding. Three well-attended compounding workshops were held during 2004 to provide guidance on the new and existing compounding standards in *USP–NF* and to assist compounding pharmacists in implementing the requirements in their facilities. In addition, USP has compiled a list of approximately 1,000 compounded preparation monographs that need to be developed for inclusion in *USP–NF*. Some of these monographs were in various stages of development by the two 2000-2005 compounding pharmacy Expert Committees, with laboratory support from the USP Research and Development Laboratory. In November, the congressional appropriation committees included language in the conference report to the fiscal year 2005 appropriations legislation encouraging FDA to establish a private sector partnership “to help assure significant expansion of USP [compounding] monographs and other relevant guidelines.”



USP–NF compounding preparation monographs will provide a standardized process for pharmaceutical compounded preparations. Although all compounded medications may not be prepared according to pre-existing monographs, the availability of a science-based practice that establishes a scientifically determined beyond-use date provides validity to the compounding process.

During the 2000–2005 cycle, USP established an internship program for pharmacy students at several Colleges of Pharmacy. Interested students spent three months working at USP focusing on pharmacy-related topics, including development of monographs for compounded preparations.

Resources

Additional funding and staff will be required to develop the approximately 1,000 monographs that are lacking. Federal funding for this effort might be available, and USP could work collaboratively with all stakeholders to utilize these additional resources appropriately.



Standards for Nomenclature and Labeling

USP resolves to collaborate with appropriate partners to continue to establish standards for labeling and nomenclature that support the safe and proper use of therapeutic products, including but not limited to initiatives that:

- **Provide references for the identification of multi-ingredient products;**
- **Address recurring medication errors, particularly in the area of look-alike/sound-alike names, labeling, and packaging;**
- **Reduce medication errors, particularly in the area of look-alike/sound-alike names, by encouraging the use, in the practice setting, of only the generic names for new single-active-ingredient products marketed after January 1, 2006; and,**
- **Encourage the uniform use of *USP–NF* dosage form nomenclature.**

Executive Summary

This resolution encourages USP to:

- Conduct careful environmental scanning to understand the various governmental and nongovernmental groups that are actively engaged in naming conventions that involve therapeutic products;
- Convene groups to help FDA, USP, the U.S. Adopted Names (USAN) program, and International Nonproprietary Names (INN) achieve optimal ingredient and dosage form names for drugs and biologics;
- Continue active and positive support of USAN and INN.

Background

A review of the preface to the first edition of USP in 1820 emphasizes the importance of clear, useful names for the materia medica of the United States. This need continues to this day and is even more important, given the complexity of modern drug substances and drug products. Drug substances, including biologics and biotechnological products, dosage forms, and devices, all need clear, unambiguous, and useful names that are well-defined for many reasons.

Manufacturers, regulators, compounding professionals, policy makers—and certainly practitioners and patients—benefit from a standardized approach to how therapeutic products are named.

USP's experience with its reporting programs shows that both sound alike and look alike brand and generic names are capable of causing serious and life-threatening medication errors. Many solutions are proposed and in progress to reduce medication errors, but surely the goal of the original pharmacopeia in the U.S. for providing clear, useful names is one of the most logical and useful of these solutions. In the 2000-2005 cycle, the excellent work of the USP Nomenclature and Labeling Expert Committee and dedicated staff have advanced the general goal of clear, useful names for compendial articles. In addition, USP is a partner in the United States Adopted Names (USAN) Council, together with the American Pharmacists Association, American Medical Association, and FDA. USAN has progressed in this cycle to provide better,



more rapid service to manufacturers seeking names for active ingredients. USAN staff has worked with increasing success in this cycle with their International Non-proprietary Names (INN) counterparts at the World Health Organization. FDA staff has worked fruitfully with USP and the Nomenclature and Labeling Expert Committee with a high degree of success over many years to develop good, useful dosage form names. The importance of this activity should not be undervalued. It is the basis for a coherent ‘materia medica’ of a nation. Without these partnering activities, an understanding of the therapeutic products available in a marketplace would prove chaotic if not impossible. Yet, despite the impressive work of USAN, INN, USP, and FDA, there is much that needs to be done.

Naming (and labeling) standards should also address multi-ingredient drug products, particularly as they relate to different brands of the same formulation. For example, the antispasmodic, Donnatal®, contains atropine, hyoscyamine, scopolamine, and phenobarbital. Another brand could be available as ‘Antispasmol’ the ingredients of which may not be readily known by pharmacists and physicians, and drug references may not include information on this brand. Yet a third brand name could be derived from these same ingredients, ‘Bella/atro/pheno.’ The absence of standardized naming requirements allows for infinite possibilities and subsequent confusion. As wholesalers change suppliers, the pharmacy receives different products, so ‘Antispasmol’ may no longer be available from the pharmacy. When the patient visits the physician, a refill of ‘Antispasmol’ is written. Because the pharmacy no longer stocks that brand, there is no reference to determine the ingredients in that formulation.

Auxiliary labeling is another component of nomenclature and labeling that impacts the safe and proper use of therapeutic products. Although auxiliary labeling is intended to provide the patient with additional information to help the patient use therapeutic products safely and properly, a patient’s health literacy may affect how the patient understands and adheres to that labeling. As USP and stakeholders move forward in this initiative to establish standards for nomenclature and labeling, consideration should be given to auxiliary labeling.

The increasing emphasis on an electronic medical record has resulted in a host of governmental and non-governmental standards-setting bodies that are working to standardize many aspects of medical care, which surely includes pharmaceutical care. An understanding of “who is doing what” has become an increasing challenge. USP has a continuing, critical role in ensuring the safe and proper use of medicines, which is impacted by nomenclature and labeling.

Resources

The resource implications for this effort are within the capability of current USP staff, assuming active collaboration and assistance from partnering organizations. The resolution might specifically be associated with an advisory body convened by USP to conduct the necessary environmental scanning and become a convening body for interested stakeholders. The end result of the effort might be a report (white paper) to guide further actions.



USP International Presence

USP resolves to continue to work with international governmental and nongovernmental bodies to increase the impact of its public health programs internationally. Furthermore, USP resolves to provide assistance to improve regulatory mechanisms and to build capacity to monitor drug quality for countries that lack appropriate resources.

Executive Summary

USP staff sees opportunities to expand its role internationally to reflect the growing need and demand for USP technical support, products, and services. Activities include official compendia and authorized publications with translations where needed, official USP Reference Standards, technical leadership in drug quality assurance for bilateral and multilateral global health initiatives, training in testing methods, laboratory operations, SOP development, product sampling for surveillance of the marketplace outside the United States, verification programs, and pharmacopeial education programs, as well as USP's drug information and patient safety programs.

Background

Access to good-quality, safe, and effective medicines is a significant problem—approximately one-third of the global population lacks access to affordable medicines of good quality. This is a specific and devastating problem for patients with HIV-AIDS, malaria, or tuberculosis. As a non-governmental institution, USP can work freely with various stakeholders and constituencies to expand its existing products and services to achieve its mission of promoting public health. Increasingly, good health relies on access to medicines and also the infrastructure to deliver them. Through the efforts of the World Health Organization (WHO) and its regional offices such as the Pan American Health Organization (PAHO), many countries are now positioned to build systems that allow for both pioneer products and fully interchangeable multisource (generic) products, building on regulatory and compendial systems that have evolved in many countries, including the U.S. These new approaches should reduce reliance on “similar,” with uncertain safety, efficacy, and quality. Dissolution is increasingly relied on to document bioavailability and bioequivalence; dissolution techniques and procedures in *USP–NF* are frequently used.

Due to disparities in resources and infrastructure around the world, USP recognizes that different countries and regions require different approaches to meet local needs for good quality, safe and effective medicines. This does not mean that a lower level of standards should be used outside the U.S., but that countries with less-developed regulatory and scientific capacity will require technical assistance to be able to use *USP–NF* standards effectively to ensure the quality of medicines they produce, import, and export. USP has been working in developing countries since 1992 through the support of the U.S. Agency for International Development (USAID). In FY04, the current USAID-funded program provided technical assistance to 17 countries in Africa, Asia, and Latin America. By expanding USP's Global Assistance Initiatives, USP will work with



partner organizations such as USAID, WHO, World Bank, and others to provide technical assistance to help countries build their own capacity to monitor drug quality and improve regulatory mechanisms. USP will provide technical leadership in drug quality assurance to global efforts such as Roll Back Malaria, the Global Fund for AIDS, Tuberculosis, and Malaria and the President's Emergency Plan for AIDS Response, and others.

Other USP activities can contribute to promoting public health internationally. Verification programs offer an important opportunity to couple the monograph and official USP Reference Standard with one-on-one assessments of specific articles to help ensure their quality. USP's experience with its dietary supplement product and ingredient verification programs provides valuable experience to build pharmaceutical ingredient and dosage form verification programs in other parts of the world. USP's pharmacopeial education programs provide highly useful information to manufacturers, purchasers, retailers, and government testing laboratories to expand understanding of the uses and limitations of compendial testing. Also in this cycle, USP has worked to develop strong partnering capability with other governments, pharmacopeias, and manufacturers. USP is working with the other pharmacopeias of the Americas (Argentina, Brazil, and Mexico) in the Pharmacopeial Working Group (PWG), which is hosted under the Pan American Network for Drug Regulatory Harmonization of PAHO. USP has created Quality Communication Groups (QCGs) in Canada, China, India, and several Latin American countries. Taken together, these create opportunities for further debate and, most importantly, action to ensure good-quality, safe, and effective medicines everywhere. Although this resolution focuses primarily on USP's core pharmacopeial services, USP's public programs for drug information and safe medication use can be equally important depending on need.

This resolution will provide the framework for moving forward on focused international strategies including but not limited to:

- Providing USP standards and technical support globally;
- Ensuring that USP has a voice to influence medicine quality and use globally;
- Assisting in the protection of U.S. citizens from substandard imported bulks and dosage forms;
- Contributing knowledge (through data) about the nature and extent of adverse events, sharing solutions for medication error prevention, and offering a reporting program infrastructure for countries in need.

Resources

Although USP's current staff can manage international activities, this resolution would require staff to determine the feasibility and advisability and resource requirements to set up and operate international sites and coordinate all activities to ensure that they meet the operating standards of USP as an organization. USP's volunteers, Board of Trustees, and staff will be called upon to address policy, science, business, and resource issues in a deliberative, inclusive, and comprehensive approach to align with USP's mission domestically and abroad and need to ensure its financial viability and growth. This will be a multi-year approach to thoughtfully increase capabilities, focus execution, and measure both public health and business impact goals.



International Harmonization

USP resolves to continue its efforts to harmonize compendial standards with the Pharmacopeial Discussion Group (PDG) and other pharmacopeias.

Executive Summary

USP is encouraged to continue its work in the PDG to reduce conflicting or redundant requirements, while continuing to uphold the strength of the *USP–NF* revision process, with the overall objective of facilitating development of public standards and analytical procedures acceptable in the major pharmaceutical markets of the world. These efforts should ensure that terminology remains current with advancing technology and, whenever reasonable, is harmonized with other pharmacopoeias beyond the PDG. As part of this effort and to the extent feasible and appropriate, USP is encouraged to work with regulatory and industry partners to advance understanding in how a harmonized document from PDG is adopted in the U.S. and other countries and regions.

USP also is encouraged to explore the feasibility and advisability of improving its partnering activities with other pharmacopeias of the world, including 1) the WHO's International Pharmacopeia, 2) the important pharmacopeias of Mexico, Argentina, and Brazil, in the Americas, through the work of PWG in PANDRH, and 3) other pharmacopeias of the world, such as the Chinese, Indian, and Russian Pharmacopeias, as a means of optimizing the work of the pharmacopeias in assuring access to good quality medicines and, ultimately, good pharmaceutical care for all.

Background

Since 1989, the USP has worked through the Pharmacopeial Discussion Group (PDG) to harmonize excipient monographs and general chapters to assist manufacturers in major pharmaceutical markets of the world. PDG consists of the European Pharmacopoeia, the Japanese Pharmacopoeia, and the USP, with the World Health Organization (WHO) functioning as an observer. Eleven of the general chapters chosen for harmonization were identified by the Q6A Expert Working Group of the International Conference on Harmonization (ICH) as critical to the long term utility of the Q6A Guideline entitled *Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances*. The PDG effort has resulted in harmonization of 29 excipient monographs and 20 general chapters, nine of which are included in Q6A. To date, the PDG effort might be termed an experiment or 'pilot' effort. The experiment has had many useful and valuable indirect outcomes, not the least of which is increased communication and understanding among the three participating pharmacopeias about their own systems, resources, staffing, and capability. A key difference lies in their governance. The Japanese Pharmacopoeia operates fully within the central government system of Japan, although a private character arises through the work of the Society of the Japanese Pharmacopoeia. The European Pharmacopoeia is an intergovernmental pharmacopeia operating under the Council of Europe. The USP is entirely private in character. The three pharmacopeias operate in countries with different cultures, laws, regulatory bodies, and manufacturing groups.



That the PDG has made progress within their different systems is a testament to the wisdom, commitment, and courage of the participants. Yet despite this commitment, progress has been slow, as evidenced in the numbers of general chapters and excipient monographs harmonized through the process. And even these numbers do not tell the whole story, given that partial harmonization of many of these general chapters and monographs has occurred. For excipients, the pace of harmonization was accelerated through participation of an industry group termed TriPEC, which is composed of representatives from the International Pharmaceutical Excipient Councils of Japan, the U.S., and Europe. Participation from other pharmaceutical manufacturing groups has occurred but at a less rapid rate. In reviewing this 15 year experience, there are certain beneficiaries. For example, global manufacturers benefit from pharmacopeial harmonization. It is less certain whether the primary beneficiaries of a pharmacopeia—namely practitioners and patients—benefit at all, although benefit might occur if harmonization achieved lower drug prices and facilitated international trade in medicines.

PDG is not the only point at which pharmacopeial harmonization occurs. In Europe, pharmacopeial harmonization now involves approximately 35 countries of the Eurasian landmass through the efforts of the European Pharmacopeia. In the Americas, USP supports a Pharmacopeial Working Group (PWG) of the Pan American Network for Drug Regulatory Harmonization (PANDRH) sponsored by the Pan American Health Organization (PAHO). The PWG functions to coordinate the work of the four active pharmacopeias in the region: Argentina, Brazil, Mexico, and USP. Progress in the Americas effort is slow and is accorded a somewhat low priority in PANDRH. In other regions of the world, many changes are occurring for the pharmacopeias, with advancement in some countries of pharmacopeial approaches and support.

Resources

USP's current staff can manage ongoing international pharmacopeial harmonization activities; however, some additional resources will be required to organize and maintain extranet sites for the PDG and PWG. USP may form some advisory bodies or panels to address some of the issues and challenges encountered in its harmonization efforts. As with all USP initiatives, continuing commitment is subject to EVP-CEO direction, Board oversight and budgeting approval.



Drug Information Programs

USP resolves to work with interested parties to develop information programs concerning therapeutic products for special patient populations in need of targeted information.

Executive Summary

Under the Medicare Modernization Act, USP was given the responsibility to develop and revise the Model Guidelines. The Model Guidelines are a list of drug categories and classes that drug plans may use to design the structure of their formularies for the Medicare prescription drug benefit. To address this legislative requirement, USP can create important information to support the Centers for Medicare and Medicaid Services (CMS) in its implementation of the new Part D drug benefit. USP also may create information programs concerning therapeutic products for Medicare beneficiaries and other special patient populations including but not limited to the elderly, children, pregnant women, ethnic groups, and mentally retarded and developmentally disabled patients, and for veterinary products for animal use.

Background

In the current cycle and at the direction of USP's Board of Trustees, USP discontinued its contribution of content to the *USP DI Volume I* and *Volume II*, which became fully the responsibility of Thomson Healthcare. For the period commencing December 2003 and terminating December 31, 2006, USP has agreed not engage in any manner in the manufacture, publication, sale, license, distribution, or promotion of any competing drug information products.

In May 2004, USP began fulfilling requirements stipulated under the Medicare Prescription Drug, Improvement, and Modernization Act (MMA). MMA provides a new Part D drug benefit for Medicare beneficiaries and calls for USP to develop a list of drug categories and classes in consultation with interested parties. MMA also asks that USP maintain this list based on new information about covered Part D drugs. USP created a new expert committee, the Model Guidelines Expert Committee, and convened four Advisory Forums to support the efforts of the Expert Committee. Phase I of the cooperative agreement with the Centers for Medicare and Medicaid Services (CMS) was completed December 31, 2004 with the delivery of documents to CMS, including the USP Model Guidelines and the Comprehensive Listing of Drugs in the USP Model Guidelines.

USP has a regulatory role to revise the Model Guidelines. Section 1860D-4(b)(3)(C)(ii) of the MMA provides that USP should "revise such classification from time to time to reflect changes in therapeutic uses of covered part D drugs and additions of new covered part D drugs." To address this, USP can create important information to support CMS in its implementation of the new Part D drug benefit. At the appropriate time and with due regard to the continuing agreement with Thomson Healthcare, USP can re-enter the drug information marketplace, using its MMA work as a means of assisting Part D beneficiaries, CMS, and Congress in helping provide optimal pharmaceutical care. This work can readily extend to other beneficiaries,



specifically all practitioners and patients who benefit from authoritative, credible, unbiased drug information.

Resources

USP anticipates continuing work with CMS to support the revision of the Model Guidelines under the law. Following the completion of the non-competition agreement with Thomson Healthcare, additional resources for other information programs, including expansion of patient population-focused drug information, could be identified through the USP planning process. Pending this further planning effort, resources utilization is expected to be low.



Promoting Safe Medication Use and Disposal

USP resolves to work with appropriate constituencies to continue to develop programs to promote safe medication use and disposal.

Executive Summary

In order to accomplish the first element of this resolution, USP's will rely on its two medication error reporting programs and its traditional standards-setting activities, which uniquely position the organization as a valuable resource on safe medication use practices. To optimize the impact of these activities, USP resolves to develop additional educational products and programs to convey best practices in medication safety to healthcare practitioners, students, consumers, and others interested in advancing patient safety. Activities that may be explored include development of a core curriculum of safe medication management and development of a compendium of safe medication use standards.

The second part of the resolution will be addressed through partnering with other stakeholders to assess the environmental and public health impact of the disposal of medications to determine the extent of these issues and whether USP can make a unique contribution towards addressing them.

Background

Based on two robust reporting programs, MEDMARX and the Medication Error Reporting (MER) Program for medication errors and on other standards-setting activities, USP issues practice recommendations, develops medication-safety products, publishes in the healthcare literature, conducts educational programs, and produces healthcare process or practice standards. These activities are intended to foster safe medication use practices by students of the health professions, healthcare practitioners, patients, and consumers. As one example of such standards, USP's General Chapter <797> *Sterile Compounding* sets official practice standards that have been widely endorsed and are used by the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) as part of an accreditation process for hospitals and health systems.

Educational programs and curricula based on USP's work are needed for students of the health professions in order to build awareness of risk-prone processes and practices and to foster the development of competencies in safe medication use. The need for development of interdisciplinary educational approaches that are based on actual medication errors involving students, residents, and interns has been recognized at the national level in healthcare, but few resources have emerged.

USP also has issued numerous recommendations for medication error avoidance in diverse healthcare settings by various healthcare professionals, and has targeted these recommendations to certain populations. A standard compendium that could be used by healthcare professionals and regulatory bodies as a means of promulgating best healthcare practices would be beneficial. USP believes that a discussion about the value of such a compendium—particularly in light of the numerous, disparate organizations now creating such standards—would be highly valuable.



Partnering with leading patient safety-related organizations, USP would explore the development and dissemination of a compendium of standards and information that could reduce harm to patients and advance patient safety.

The second part of this resolution deals with the safe disposal of medicines, which is important for preserving the environment. Findings from a 2002 US Geological Survey have reported pharmaceutical contaminants, including nonprescription drugs, in 81% of US streams, antibiotics (48%) and other prescription drugs (32%). Though the clinical relevance of these findings awaits further studies, proper disposal of medications may ease the burden placed on our environment.

National policies on drug disposal/recycling/pollution prevention seem to be directed solely at the internal generation of waste by the medical care industry—not by the public. USP will seek to work with others to determine the public health impact of these issues and explore potential solutions in which USP might play role, such as, the promulgation of definitive guidelines or national standards on the proper and environmentally safe disposal of pharmaceuticals.

Resources

Additional resources and/or structural changes within USP and the Council of Experts will be needed for this expanded effort. The creation of a compendium for good healthcare processes and practices would be a major effort requiring careful volunteer and staff consideration.

USP will approach the second half of this resolution under the direction of the Board of Trustees. Considerable resources may be needed to assess the nature and extent of the problem, as well as how USP might develop guidelines or standards in this area. An advisability and feasibility study may be recommended as a first step.

Evidence-based Methodologies and Algorithms for Decision Support Used in E-Prescribing and Pharmacy Computer Systems

USP resolves to work with appropriate stakeholders to continue to develop evidence-based methodologies and algorithms for decision support in areas such as drug–drug interactions, and to expand efforts to other alerts and recommendations for use in e-prescribing technologies and pharmacy computer systems.

Furthermore, USP resolves to explore the feasibility and advisability of extending this approach to other information domains in the interest of the public health and patient care.

Executive Summary

Computerized health information systems can contribute to the care received by patients in a number of ways. Not the least of these is through interactions with healthcare providers to modify diagnostic and therapeutic decisions. The current systems, which include e-prescribing technologies and pharmacy computer systems, vary significantly. USP's efforts to develop evidence-based methodologies and algorithms for decision support also could provide support for standardized data sets that ensure uniform information availability for e-prescribing and pharmacy computer systems. This resolution, in conjunction with the recommendations established by a USP Computerized Prescriber Order Entry (CPOE) Project Team and the results of a drug-drug interaction project from the Therapeutic Decision Making Expert Committee will provide the framework for developing minimum standards that would outline the essential and minimum safety features needed for e-prescribing software, CPOE, computerized pharmacy systems, and other technologies.

Background

The explosion of medical and biological information has made it clear that innovative advances in storing, retrieving, and interpreting information are essential for health professionals and scientists. Practitioners can no longer expect to master comprehensively the information in their areas of expertise. Instead, they must increasingly rely upon problem solving strategies and the ability to access systematically the information required for thoughtful patient care. Computerized health information systems (i.e., e-prescribing, computerized prescriber order entry), can contribute to the care received by patients in a number of ways. Not the least of these is through interactions with health care providers to modify diagnostic and therapeutic decisions. These include: 1) processes that respond to certain types of clinical data by issuing an alert informing caregivers of these data's presence and import, (2) programs that critique new orders and propose changes in those orders when appropriate, (3) programs that suggest new orders and procedures in response to patient data suggesting their need, and (4) applications that function by summarizing patient care data and that attempt to retrospectively assess the average or typical quality of medical decisions and therapeutic interventions made by health care providers.

Key domains that are integral to decision support are:

- Drug-allergy
- Drug-drug interactions (prescription and OTC)
- Drug-laboratory values
- Drug-patient characteristics:
 1. age
 2. weight
 3. diagnosis
- Default doses
- Maximal dose checking
- Drug-pregnancy
- Drug-food
- Drug-herbal/vitamin

No established standards have been set for the computerized systems currently in use in the U.S. or for the data on which automated recommendations are made. These systems vary significantly and unless standards for data and decision algorithms are established, the computerized systems may have the propensity to create additional medication errors instead of actually reducing them. According to a recent report from the USP Center for the Advancement of Patient Safety's MEDMARX Program, mistakes associated with computer entry were the fourth leading cause of medication error in 2003, but they were the seventh leading cause in 2000.

Content for computerized systems must be evidence based. Staff sees opportunities for USP in the area of decision support rules using evidence-based content for computerized e-prescribing, pharmacy systems, and other computerized systems as developed through modern technology.

The concept paper on CPOE by the USP Computerized Prescriber Order Entry Project Team #17, chaired by David Bates, M.D., and the evidence emerging from the drug-drug interactions project of the Therapeutic Decision Making Expert Committee (TDM EC), chaired by Elizabeth Chrischilles are rational approaches to understanding the significance of science-based consensus in the development of content for computerized systems that have great potential to improve practitioner prescribing. These projects were both initiated in the 2000–2005 cycle and the concept paper on CPOE is available upon request.

CMS recently published their proposed rule on e-prescribing and the prescription drug program. USP should consider working with CMS and all other interested stakeholders during the new cycle on the resolution.

Resources

USP's current staff can manage the current activities of the Project Teams and the SMU and TDM Expert Committees. Expanding work into other domains would require additional funding and staffing resources, as well as possible additional expert committees.



USP Convention

Using the recommendations of the Resolution 18 Committee to the Board of Trustees, USP charges the Council of the Convention, as an ongoing responsibility, to review the purpose, role, and composition of the Convention membership and examine the voting procedures used during the Convention.

Executive Summary

This resolution focuses on recurring issues related to the representation within the Convention. It expresses the reality that the organizations that are eligible for membership often do not take advantage of the opportunity, and conversely, those who wish to be part of shaping USP's agenda for the future and who are primarily affected by that agenda, often have no, or minimal, opportunity for representation.

Establishing the Council of the Convention (CoC) as recommended by the ad hoc Committee on Resolution 18 and charging the CoC with a review of the composition and structure of the Convention creates an opportunity for an in-depth assessment of the current phenomenon by the parties most interested and vested in the outcome. The issues related to Convention composition and structure are many and complex, and they go to the very heart of USP's credibility and authority and are best discussed in a deliberative and inclusive approach.

In addition to the above, the CoC also is charged with evaluating the current procedures for voting during the stated meeting and making recommendations for improvements.

Background

The issue of representation in the USP Convention garners a significant and continuing amount of attention from the organization. USP has many stakeholders. They include the pharmaceutical industry, healthcare professionals, regulatory agencies of the US government, and organizations around the world interested in improving the quality of medicines. As USP has changed and evolved through time, so has the interest of its various constituencies — new initiatives create new partners. For example, the outcome of a study on the composition of the Convention conducted during the 1990–1995 cycle resulted in an expansion of the Convention membership in 1995 to include additional professional, international, governmental, and trade organizations. The expansion resolution created the current structure of *constitutionally named* and *invited* organizations.

USP has attempted during the 2000–2005 cycle to enhance its relationships and interactions with various constituencies outside the every five-year meeting. The largest beneficiary of this effort has been the pharmaceutical industry through USP's system of stakeholder forums and project teams.



In 2000, two resolutions dealt with the Convention—one called for the inclusion of constituencies under-represented in the Convention (Resolution 17), and another called for a committee to study the frequency of Convention meetings (Resolution 18). The members of the ad hoc Committee on Resolution 18 in reviewing the intent of the resolution recommended to the Board of Trustees that a Council of the Convention (CoC)* be established to serve as a communications conduit to and from the Convention. The ad hoc Committee felt that the issue was not necessarily the frequency of meetings but that the Convention membership had to be engaged on a more regular and personal level.

Specifically, the recommendation was that the CoC would be advisory to the governing bodies of the organization, i.e., Council of Experts and Board of Trustees. Thus, an amendment to the Constitution and Bylaws is being proposed that creates the Council of the Convention. During its deliberations, the ad hoc Committee on Resolution 18 also acknowledged the need for an in-depth evaluation of the purpose, role, and composition of the Convention and recommended that such a study be undertaken in the next cycle. It was thought that the CoC, if established through the proposed Constitutional amendment, could conduct the assessment.

The assessment of voting procedures used at the Convention was raised in the context of the final vote on resolutions where parliamentary procedures are used. Considering the relative facility with which the newly-instituted computerized election of the Council of Experts, Officers, and Trustees was conducted, it was thought that improvement also could be made to this part of the voting process in which the Convention engages.

* It is anticipated that the Council of the Convention will be a group of up to 25 members, who reflect the current Convention membership.

Resources

USP staff can support the activities of the Council of the Convention through its current structure. Funding for the projected semi-annual meetings of the CoC would be budgeted through USP's budgeting process and is expected to compare to the financial support required by an Expert Committee activity.



Expanded Outreach

USP resolves to expand its efforts to engage stakeholders who are affected by USP standards, but who have not been fully involved in USP processes, including but not limited to groups concerned with Human Biologics, Animal Health, Biotechnology, and Device Manufacturers, in USP committees and programs.

Executive Summary

This resolution directs USP not only to continue its outreach efforts but also to expand them so that interested stakeholders who have not participated in these activities in the past are encouraged to participate in the 2005–2010 cycle. USP has reached out to many of these additional stakeholders in the past but with little success. This resolution recommits USP to its efforts to encourage such groups to participate in the future. The resolution emphasizes that USP's processes, which lead to the establishment of compendial standards, must be transparent and participative and attempt to engage all who are affected by such standards.

Background

USP historically has involved stakeholders in standards development by eliciting input into the standards-setting process itself. This participative approach strengthens the credibility and authority of USP standards. At various times, however, certain stakeholders may be more involved in USP activities than others.

During the 2000-2005 cycle, USP created several Stakeholder Forums and 20 Project Teams. Both of these initiatives were designed to provide interested stakeholders additional opportunities to provide feedback to USP regarding a wide variety of activities. For example, the Prescription/ Non-Prescription Stakeholder Forum is composed of representatives from such diverse organizations as the Pharmaceutical Research and Manufacturers of America, Generic Pharmaceutical Association, International Pharmaceutical Excipients Council, Parenteral Drug Association, Food and Drug Administration, and others. This stakeholder forum meets twice a year with the chair position rotating among members. These meetings have resulted in valuable input regarding USP activities.

As a further example, Project Team 1 provided significant input about the development and refinement of the Flexible Monograph approach that helps to ensure that pharmacopeial standards do not exclude from the U.S. market any company with an approved product.

Another example is Project Team 15, which identified the critical control points in the drug product distribution chain, and evaluated the risks associated with each point. The distribution pathway begins at the point of manufacture and continues to the end user or patient. Risks were categorized as low, medium, and high, and the high risk areas were the subject of a *Stimuli* article [*Pharmacopeial Forum* 29(3), May–June 2003, pages 864–870]. High risk areas included, physician samples stored in sales representatives' car trunks, lack of supportive data



for beyond-use dating, child-resistant mechanisms, shipment via mail without temperature control, and storage and handling of medicines at the patient level.

Strategically, USP will continue to expand its outreach to and involvement of stakeholders from all segments of an issue. In concert with USP's overall strategic approach of obtaining the broadest consensus possible, the groups noted in the resolution will be encouraged to increase their involvement. Others groups' involvement will be sought as needs arise.

Efforts may include:

- Educating new and existing stakeholders about the importance and application of USP standards and programs to stakeholders' work;
- Providing USP Pharmacopeial Education courses and other information about:
 - *USP–NF* General Notices
 - *USP–NF* General Chapters
 - *USP–NF* Monographs
 - General USP activities
- Publishing articles in stakeholder journals and participating in stakeholder meetings and educational conferences, possibly providing USP exhibits at trade shows;
- Recognizing, as appropriate, stakeholder industry standards; and
- Utilizing web-based technologies and other resources as a means of increasing participation and involvement in USP activities.

Resources

It is anticipated that this activity would be conducted under the aegis of USP's Stakeholder Forums and Project Teams structure, the funding for which would be addressed within USP's annual planning and budgeting processes.



Organizational Outreach

USP resolves to expand its efforts to engage pharmacy and other healthcare practitioner organizations in discussions related to USP's public health program activities. Efforts should be made to continue this dialogue on a regular, periodic basis to help build understanding among all organizations.

Executive Summary

This resolution proposes a more robust and directed interaction between USP and its practitioner constituencies, specifically including but not limited to pharmacy practitioner organizations.

Discussions could include:

- USP's plans for activities related to the medication-use process, including the extent to which those plans may touch on the roles of the full range of participants in that process (i.e., manufacturers, distributors, physicians, pharmacists, nurses, hospitals, community pharmacies, other pharmacy outlets, regulatory bodies, payers, and others).
- Initiatives among practitioner organizations related to improving the medication-use process.
- The role of USP in supporting pharmacy practitioner organizations such as the Joint Commission of Pharmacy Practitioners in activities that focus on pharmacy practice with a view to avoiding redundancy in activities.
- Opportunities for collaboration among USP and pharmacy practitioner organizations in improving the public health.

This type of outreach should be extended beyond pharmacy practitioner organizations to other healthcare practitioner organizations or coalitions.

Background

USP's mission is to promote the public health and benefit practitioners and patients by disseminating authoritative standards and information developed by its volunteers for medicines, other healthcare technologies, and related practices used to maintain and improve health and promote optimal healthcare delivery.

The mission of most practitioner organizations includes the improvement of professional practice through means such as education, publications, research, and advocacy.

With missions that are so closely intertwined it is not surprising that USP activities can sometimes affect practice and there is potential that such initiatives may overlap with the activities of practitioner organizations.

When USP selects issues related to pharmaceutical care for its attention, there should be meaningful dialogue with national pharmacy and other practitioner organizations. (Although many individual healthcare professionals are involved in USP affairs, this does not achieve the



same outcomes as the engagement of practitioner organizations.) With such engagement of practitioner organizations USP would benefit in the following areas:

- Broad-based input, derived from the strategic planning efforts of practitioner organizations, into the establishment of USP's public health agenda,
- Advice on the full range of issues related to the medication-use process that may merit USP's attention,
- Efficient methods of communicating USP initiatives (including calls for review of proposals and dissemination of final decisions) to practicing healthcare professionals,
- Insight into effective ways to foster change in professional practice,
- Coordination with practice-improvement initiatives conducted by practitioner organizations,
- Identification of opportunities to marshal resources from multiple sources in the pursuit of improvements in the medication-use process, and
- Opportunity to avoid redundancy and confusion.

Resources

It is anticipated that this activity would be conducted under the aegis of USP's Stakeholder Forums and Project Teams structure, or as an advisory body to the USP. The funding would be addressed within USP's annual planning and budgeting processes.