



**Status of the 2005-2010 Resolutions
Adopted at the 2005 USP Convention**

December 2008

Resolution #1: 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.

Status of Resolution Implementation

March 2006:

Monograph acquisition is a formal staff position at USP and planned improvements to related databases and the standards workflow system tracking application are being implemented to increase efficiency. USP is currently operating under a one cycle review policy.

With respect to reference standards, USP has developed multiple approaches for the procurement and qualification of candidates for reference standards. The “routine path” is dependent upon donations from pharmaceutical manufacturers. Despite best efforts, the number of monographs/reference standards acquired through this “routine path” has not met expectations.

In order to increase the number of monograph/reference standards, an alternative, “non-routine” model has been developed. In this model, staff would obtain candidate bulk reference standards materials without a monograph and USP’s Research and Development Laboratory (RDL) would verify the Certificate of Analysis (COA) and characterization methods provided by the material supplier. Under this proposal, the bulk comes first and drives subsequent development of the monograph, reversing the normal order. As is consistent with USP’s standards development process, interested parties would have the opportunity to comment when the draft monograph is presented in *Pharmacoepial Forum*.

June 2006

Staff is working to amplify availability of monographs in *USP–NF* based on the Board’s request to explore opportunities to obtain monographs at the time of NDA approval.

September 2006

There are 230 new monographs currently in the USP pipeline; these are in various stages within the process prior to *Pharmacoepial Forum (PF)* publication. Since July 1, 2006, 35 new monographs have been published in (*PF*) for public comment and review. With respect to monograph revisions, there are approximately 1360 revisions in progress. Seven non-routine monograph analyses have been completed since July 1 with 40 projected for completion during this fiscal year.

The final count for new reference standards introduced in FY06 was 121, and there were 185 replacements for products depleted from the inventory by customer demand. Staff anticipates completing 120-150 new reference standard products in FY07.

January 2007

From July to November 2006, USP has acquired 69 new monographs (10 are for articles pending FDA approval and 3 are for articles legally marketed outside the US). In FY07, 47 new monographs have been published in *Pharmacoepial Forum (PF)* for public comment and review. With respect to revisions, approximately 1874 are in various stages in the process. (Please note that revisions, or changes, are counted individually; i.e., one monograph could contain multiple revisions.) Twenty-three non-routine monograph analyses have been completed since July 1.



Resolution #1 (continued)

January 2007 (continued)

In this fiscal year, 61 new reference standard items have been introduced and there have been 93 replacement lots for products depleted from inventory by customer demand.

April 2007

From July to February 2007, USP has received 108 new monographs (11 are for articles pending FDA approval and 4 are for articles legally marketed outside the US). So far in FY07, 58 new monographs have been submitted to *Pharmacopeial Forum (PF)* for public comment and review; however, 18 of the 58 are being held out because we have not yet secured reference standards for them. Six biologics/biotech horizontal monographs/chapters are in development at this time, four of which are in *PF*. A recent rules change for new monograph approvals has temporarily shifted staff emphasis to new monograph completion rather than revisions. This emphasis is expected to balance out in the next quarter.

Fiscal year to date there have been 103 new reference standard items introduced and 153 replacement lots for products depleted from inventory by customer orders.

June 2007

As of May 31, USP has received 160 new monographs, plus 4 for Food Chemicals Codex (19 are for articles pending FDA approval, 3 others are for articles legally marketed outside the US and also are pending FDA approval). To date 114 of the above have been submitted to *Pharmacopeial Forum* for public comment and review; however 30 have been held in abeyance until reference standards are available.

There have been 157 new reference standard items introduced in FY07 and overall product availability is at 99.4%.

December 2007

Through November of the new fiscal year 2008, USP has received 35 new monographs, and in the same period, 34 new monographs were submitted to *Pharmacopeial Forum* for public review and comment. These monographs have lead to the request for 45 new reference standard materials. Additionally, standards (documentary and reference materials) for ancillary products are advancing through the work of the General Chapters group with a completed chapter on Protein A and the reference material close to approval. There are five standards for articles legally marketed outside the US (articles for neglected diseases) on the USP website, and five others are in progress. There are 12 draft pending FDA approval standards on USP's website and 39 in active development. USP continues to work with stakeholders to improve the "pending standards" approach. Discussions have also begun with industry, FDA and other stakeholders regarding the possibility of a collaboration between USP and the EP to create harmonized drug substance monographs within a specified period after product approval.

Fiscal year to date there have been 30 new reference standard items introduced and 46 replacement lots provided. Reference standards product availability remains very high at 99.7%.



Resolution #1 (continued)

March 2008

In the course of the preceding half of the cycle, the USP has focused on identifying and completing a public standard for every article in public commerce. The focus is most evident in a number of changes in USP policy that are targeted at removing barriers to the creation of these standards. Two primary examples of these changes include *flexible* monographs and *pending* standards.

The flexible monograph reduces the need to create a single standard for items that are manufactured differently, with potentially different impurities and empirically different physical properties, but that have been shown to be bioequivalent by the FDA. The flexible monograph has been implemented in dozens of monographs in the past two years.

The pending standards approach allows the creation of monographs for generic products prior to final FDA approval. This approach reduces the time that a generic drug is available in the marketplace without a public standard. The pending standards approach has been used for just over a year and has already yielded more than two dozen monographs, with many more in development.

Other internal improvements have been implemented that speed the monograph creation and editing times significantly and increase the level of oversight and understanding of the progress of items in development. One internal improvement is the development and maintenance of the “pipeline” document from which the numbers reported in previous status reports were derived. Another improvement is the focus on completing revisions in a single public review cycle. These efforts have lead to record numbers of monographs being processed and delivered for publication in the *USP-NF*.

June 2008

USP recently has focused on “pending standards” and continues to work with stakeholders to improve the approach. The USP and the European Pharmacopeia have agreed to co-develop a number of monographs over the next several years, with the first monograph already underway. The USP has engaged in a significant redesign of the presentation style of the *USP-NF*. This presentation style was developed in conjunction with our stakeholders and is targeted for initial presentation in early winter of this year. To accomplish this goal, the initial conversion of the content is nearing completion, which is expected prior to the end of the fiscal year.

Through April, 2008:

- 109 new monographs were submitted to *Pharmacopeial Forum* for public review and comment,
- 5 standards for articles for neglected diseases on the USP website, and five others are in progress
- 30 pending standards on USP’s website, (4 have moved to Official standards in the *USP-NF*)S.
- 128 new reference standard items released
- 167 lots released to replace depleted inventory.
- Reference standard product availability remains at 99.6%.

Resolution #1 (continued)

September 2008

Through fiscal year 2008:

- 162 new monographs were submitted to *Pharmacopeial Forum* for public review and comment,
- 5 standards for articles for neglected diseases on the USP website, and five others are in progress
- 31 pending standards on USP's website, (4 have moved to Official standards in the *USP-NF*).
- 161 new reference standard items released
- 187 lots released to replace depleted inventory.
- Reference standard product availability remained at 99.6%.

December 2008

The Board of Trustees new strategic plan emphasizes USP's core compendial activities, which are embodied in Resolution #1. When the Resolution was adopted in 2005, USP estimated that approximately 2000 monographs were missing from *USP-NF*. As of 2008, USP has closed this gap slightly, but at the current pace, it is estimated that a complete *USP-NF* is still over 40 years away. Further, with the addition of Food Chemicals Codex, about 1000 missing, non-flavor, food ingredient monographs have been identified and there are likely about 1000 missing flavor monographs. In June 2008, against this backdrop, the Board approved the creation of a new department, Standards Acquisition, solely focused on acquiring new monographs and reference materials. Dr. Shawn Dressman, who joined USP in 1999 as a staff scientist, and most recently held the position of Director, Reference Standards Evaluation, has been hired to lead Standards Acquisition. The plan is to hire staff in Rockville, India, and China to support USP's global search for world-class monographs and reference materials.

The monograph redesign effort has reached a milestone with the presentation of redesigned monographs on the web site for a 90-day public review and comment period. The goal is to introduce the new format and collect comments on any corrections or clarification that might be needed prior to publishing the reformatted monographs in *USP 33-NF28* scheduled for November 2009. USP continued its work on the Prospective Harmonization Pilot Study with the European Directorate for the Quality of Medicines (EDQM)/European Pharmacopeia (EP) on the development of four drug substance monograph and their associated reference standards. USP completed technical review of four monograph submissions and submitted questions. EDQM will combine USP's questions with those of EDQM reviewers and present these to the monograph sponsors.

In September 2008, USP met with the USP-Indian Pharmacopeial Commission Monograph and RS Advisory Panel in Hyderabad, India. In 2008, companies represented on this panel have proposed about 20 new monographs and reference standard candidates to USP. Most of these are directed toward antiretrovirals, antimalarials, and anti-tuberculosis medicines.

In the first quarter of FY09:

- 35 new monographs were received
- 25 new monographs were submitted to publication in *Pharmacopeial Forum*
- 1 new draft Pending monograph was submitted for publication on the web site for public review and comment
- 31 new monographs published in the *Second Supplement to USP31-NF26* reached their official date on August 1, 2008
- 19 new Reference Standard items were released



Resolution #1 (Continued)

Projected Resolution Completion Date

No end date. This is an ongoing programmatic activity of USP.

Resolution #2: 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.

Status of Resolution Implementation

March 2006:

The Packaging and Storage Expert Committee (P&S EC) is working to incorporate the elements of this Resolution into its workplan. The P&S EC finalized Chapter <1079> *Good Storage and Shipping Practices*; however, a more controversial Chapter, < 386> *Environmentally Sensitive Preparations*, was cancelled. Instead, the Committee is evaluating certain content from Chapter < 386> for inclusion in other chapters and may seek to address other packaging and storage issues within other chapters. In an effort to engage stakeholders, the Product Quality Research Institute (PQRI) and the P&S EC have agreed to exchange members for their meetings, and packaging companies are observing. Any educational efforts will focus on pharmacists and be developed through consultation with current members of the EC and engage professional organizations; however, no formal activities are underway at this time.

September 2006

In the continual effort to incorporate the elements of the resolution into the work plan, the P&S EC began the extensive review and revision of chapter <661> Containers. To clarify the specialized content of the chapter, the chapter has been separated into two new chapters; sections relevant to plastic will remain in <661> but the title will be Containers–Plastics; sections relevant to glass were included in a new chapter <660> Containers–Glass. Chapter <671> Containers–Permeation is being revised to include standards and tests used to determine the functional properties of a container and will include several new test methods. Chapter <1178> Good Repackaging Practices has been revised so that it provides guidance and resources for repackagers of solid oral dosage forms. A new Chapter has been proposed—Chapter <681> Repackaging into Single-Unit Containers and Unit-Dose Containers from Nonsterile Solid and Liquid Dosage Forms.

January 2007

In addition to the ongoing work of the Packaging and Storage Expert Committee as noted above, USP staff is coordinating educational and outreach activities around the content of Chapter <1070> *Emergency Medical Services Vehicles and Ambulances— Storage of Preparations*. Staff will target healthcare provider organizations and others and will seek to raise awareness about the chapter and solicit input for future improvements in the requirements. Additionally, an ad hoc Advisory Panel under the aegis of the Safe Medication Use Expert Committee will analyze data associated with medication errors in the home and their relationship to proper storage and handling. Based upon their analysis, a patient education initiative could be developed.

April 2007

Nothing new to report.



Resolution #2 (continued)

June 2007

The Packaging and Storage Expert Committee is focusing efforts on reorganizing, clarifying, and expanding the focus of Chapters in the *USP* that relate to *Containers*. (See September 2006 status comment.) The EC has determined further work/separation is needed; e.g., creating additional chapters to cover plastic, glass, unit dose containers, etc. and also, addressing special issues presented by biotechnology products. Chapter <1078> *Good Packaging Practice* revision is under review by the EC. The EC is looking again at the issue of ambient storage temperatures for drugs in transit, to include data that might be collected about warehouse receiving practices of drug manufacturers. The idea of a “packaging compendium” was discussed.

December 2007

At its meeting in October, the Packaging and Storage Expert Committee was transitioning to new leadership after the departure of the chair. Discussions focused on advancing the previous workplan as described in the June Status Report, and included Chapter <1150> *Pharmaceutical Stability*, which addresses Climatic Zones, Chapter <1079> *Good Shipping and Storage Practices*, with consideration of RFID on biopharmaceuticals, and a general discussion on shipping and storage issues related to controlled cold temperature.

March 2008

The focus of this resolution is the better coordination of stakeholders and volunteers in the development of standards for packaging and storage. In the first half of this cycle, the USP has eliminated standards that increased the testing overhead for the industry where there were no resulting benefits to the patients. This was seen in the elimination of general chapter on *Environmentally Sensitive Preparations* <386>. Instead the USP has focused efforts on improving general chapters for good storage and shipping practices to include cold-chain management. These chapters will be presented later this year. To ensure that the chapter will meet the needs of the stakeholders and patients, USP volunteers and staff have made presentations to interested parties in public meetings and served as facilitators in the discussions that followed. The input from these discussions has been incorporated into the initial drafts of these important chapters. Further discussion of the chapters during their public comment period are planned in an effort to raise public awareness

June 2008

In follow-up to the June 2007 report, the Packaging and Storage Expert Committee has published revisions to <660> *Containers – Glass*, and <661> *Containers – Plastic*. They are in the process of developing General Chapter <662> *Containers – Metal* and <670> *Containers – Auxiliary Components* to complete the packaging suite of chapters. To address problems in packaging practices, they have proposed the addition of <659> *Preservation, Packaging, Storage and Labeling* which will cover drug pedigree and repackaging control strategies. This chapter is still in a conceptual stage, but progress towards a chapter is expected.

Resolution #2 (continued)

September 2008

The Packaging and Storage Expert Committee is nearing completion of the General Chapter <659> *Preservation, Packaging, Storage and Labeling*, which will cover drug pedigree and repackaging control strategies. A significant revision of <1079> *Good Storage and Shipping Practices* also is nearing completion. This revision will include practices commonly referred to as “Cold Chain” management.

December 2008

Correction to September’s update: General Chapter <659> does not cover drug pedigree and repackaging control strategies. The chapter will contain all the container and storage definitions that are currently in the Preservation, Packaging, Storage and Labeling section of General Notices. The definitions are also being updated, so that they are aligned with FDA and industry. It is Chapter <1178> *Good Repackaging Practices* that outlines best practices for repackaging, which was revised and became official in 2007. Chapter <1079> is in the final stage of editing and will be published in *PF 35* (3).

Projected Resolution Completion Date

This resolution is expected to continue throughout the cycle.

Resolution #3: 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.

Status of Resolution Implementation

March 2006:

Justification/approval for an advisory body has been completed. General make-up of the advisory panel (topic areas) was submitted to the Executive Committee of the CoE and was accepted. Staff is in the process of identifying appropriate experts. Beyond emerging sciences and technologies experts, staff is planning to expand the advisory body to include experts in discovery/development, drug information, quality of care, patient safety, health policy, and international health.

June 2006

Dr. James Akers, Chair of the Microbiology and Sterility Assurance Expert committee and a member of the Executive Committee has agreed to chair the panel. To assure broad consideration of topics relevant to USP, the Executive Committee has endorsed representation on the panel in the following areas: healthcare policy; personalized medicine/bioinformatics; new analytical and process technologies; general science; and standards setting. Experts will be sought who can speak broadly about the translation of basic science advances to activities suitable for USP.

September 2006

Staff has confirmed participation of 17 members of the Resolution 3 Advisory Panel, eight of whom will attend the Annual Scientific Meeting in Denver. Through presentations, experts will address four key questions:

1. How do you see your field evolving in the future in terms of healthcare — short term, long term, long range; most significant changes that could impact on the availability of medicines and their delivery?
2. How do standards relate to your field — what standards exist and how are they created; what standards are needed now and/or in the future; what will USP's role be?
3. From a grand challenges perspective, what are one or two things USP could do to transform health care?
4. Other thoughts?

January 2007

The following is the high level overview of areas of strategic interest for USP as determined by the Advisory Body convened at the Annual Scientific Meeting in September.

- **Biotechnology:** USP should position itself to help set new standards for using biotechnology as a tool for drug discovery and development, safety and efficacy evaluation, and clinical use and practice. USP should develop strategies to critically evaluate the technologies as they are developed.

Resolution #3 (continued)

January 2007 (continued)

- Pediatric Pharmacogenetics and Developmental Pharmacogenomics: Children are a population with unique issues. New technologies most applicable to pediatrics include Phenotyping probes, Disease-related biomarkers, and Genotyping/genetic testing.
- Public Health Policy: The needs of patients around the world are often overlooked. The problem of health has only recently been “medicalized” in developing countries, illustrated by mass malaria eradication campaigns. The relationship between information technology and medical treatment could be leveraged to improve care in the developing world. Regulation and the harmonization of standards should be a top priority. The need to register a product in every country hampers the ability to get the drugs to the people who need them.
- Economics of Health Care: The tension between what is potentially valuable healthcare and who is going to pay for it will continue to increase. USP could help determine uses of electronic records for diagnosis and treatment as well as accountability and post-marketing safety. The economics and politics of healthcare are determining the provision of healthcare around the world. USP should bring together stakeholders from around the world to obtain full input on worldwide issues. USP will need to maintain its independence as it makes connections to direct policy making.

April 2007

The next meeting of the Resolution 3 Advisory Panel will be held in conjunction with USP's 2007 Annual Science Meeting. The original panel members are in the process of developing a "white paper" which captures the concepts and ideas shared at the 2006 gathering. Staff is recruiting new members for the Panel since a rotating membership was originally envisioned in order to stimulate new concepts and diversity of thought.

June 2007

New members will be added to the Resolution 3 Advisory Panel during the summer of 2007 for participation in the next Advisory Panel meeting held September 25, 2007 during the Annual Scientific Meeting in Tampa, Florida.

December 2007

At the September 2007 Annual Scientific Meeting the “repopulated” Resolution 3 Advisory Panel convened to inform USP staff of recent advancements in new technologies and science. Panel members responded to questions posed at earlier Resolution 3 Advisory Panel meetings. (See September 2006 status statement for questions.) The Advisory Panel experts and topics covered were:

- William G. Feero, M.D., Ph.D., National Genome Research Institute — Molecular Medicine
- Steven Westwood, Ph.D., International Bureau of Weights and Measures — Metrology
- John M. Midgely, Ph.D., JMM International Consultants — Small Molecules
- Adrian F. Bristow, Ph.D., National Institute for Biological Standards and Controls — Biologics and Biotechnology
- David M. Eisenberg, M.D., Osher Institute, Harvard medical School — Dietary Supplements
- S. Suzanne Neilsen, Ph.D., Purdue University — Food Additives
- Melvin Koch, Ph.D., University of Washington — Process Analytical Technology



Resolution #3 (continued)

- Thomas Layloff, Ph.D., Supply Chain Management System — Supply Chain Management/Spectral Imaging
 - Peter Swaan, Ph.D., University of Maryland — Drug Transport
- Drs. Feero and Bristow also addressed ASM participants in the General Session.

March 2008

Plans for the 2008 Resolution 3 meeting will begin shortly after the March 2008 Spring Governance Meeting.

June 2008

The third meeting of the Resolution 3 Advisory Panel will occur at the September 2008 Annual Scientific Meeting, which has become the customary venue for this advisory panel. The composition of the advisory panel rotates based on USP's desire to understand new science and technology areas and this year a new chair will be appointed from among the members of the Council of Experts Executive Committee. (James Akers, Ph.D., chair of the Microbiology Expert Committee has chaired the advisory panel for the past two years. For 2008, the following areas will be targeted:

1. Knowledge Management
2. Biomarkers
3. Virtual Publishing
4. Metrology
5. Personalized Medicine
6. Drug Safety
7. Bioethics

September 2008

The third meeting of the Resolution 3 Advisory Panel will occur Tuesday, September 23, 2008, during the Annual Scientific Meeting. Dr. Michael Murray, member of the Executive Committee and Chair of the Safe Medication Use Expert Committee, will chair this meeting, replacing Dr. James Akers who chaired the past two meetings. Confirmed speakers include:

- Dr. Jennifer Hunter-Cevera, President, UMBI, to speak on biologics
- Dr. Willie May, NIST, to speak on metrology
- Mr. Hashim U. Yusufu to speak on Global Public Health
- Dr. Joseph Rodricks to speak on the recent IOM meeting on heavy metals

In addition, speakers for two other topics, microbiology and spectral libraries, have been invited to speak.

December 2008

The third meeting of the Resolution 3 Advisory Panel occurred as noted above, with the following speaker changes: Dr. Hashim Yusufu and Dr. Joseph Rodricks were unable to participate. Instead, Dr. Kurt Classen spoke about the recent IOM meeting; Dr. David Hussong spoke about Microbiology topics, and Dr. David Bugay spoke about Spectral Imaging. There will be one more meeting of the Advisory Panel in September 2009, in Toronto. A final white paper will be presented to the USP Convention.

Projected Resolution Completion Date

This resolution is expected to continue throughout the cycle with yearly advisory panel meetings.



Resolution #4: 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.

Status of Resolution Implementation

March 2006:

A meeting of the Compounding Stakeholder Forum (CSF) is scheduled for June 16, 2006. Among other topics associated with this resolution, CSF participants will discuss the value of an Education Project Team under the forum. USP, at the level of CEO and Chief Legal Officer, continues to participate actively as a member of the Pharmacy Compounding Accreditation Board (PCAB).

A *Guidebook* was developed by staff for Chapter <797> to help practitioners understand the proposed revisions to the chapter. This *Guidebook* is part of a comprehensive, multi-pronged campaign to engage practitioners and other interested parties in USP's standards setting activities.

Staff is evaluating the responses from two focus groups and a survey on the usefulness of the *Pharmacists' Pharmacopeia* and will make recommendations for improvements, as appropriate. USP is working with NIH to identify a mechanism to increase the number of USP monographs available for the pediatric population.

September 2006

The Compounding Stakeholder Forum held on June 16, 2006 was very successful and yielded valuable recommendations in a number of areas to improve the processes for USP's compounding standards setting activities; some specific to Chapter <797>. USP received 500 comments on the proposed revisions to Chapter <797>, and the comments are with the relevant Expert Committee for review. The public comment process for Chapter <797> was the first in which USP actively solicited comments from practitioners and used the USP website to disseminate the proposed revision and collect comments. USP has issued an RFP for two awards of \$60,000 each for research in compounding: (1) methods development and validation and (2) stability to establish beyond use dates for compounded preparations. The goal is to acquire data that will support development of compendial monographs for publishing in *USP-NF* and the *Pharmacists' Pharmacopeia*. USP donated four copies of the *Pharmacists' Pharmacopeia* to schools/colleges of pharmacy in the US and Canada. Staff from USP and the American Society of Health-System Pharmacists are exploring potential educational programs related to compounding.

April 2007

Review of comments to the proposed revisions to Chapter <797> continues through two advisory panels. USP continues to support the efforts of PCAB and donated copies of the *Pharmacists' Pharmacopeia (P2)* to all PCAB surveyors for their use when conducting surveys. USP will meet with APhA and NCPA leadership in mid-April to discuss future commitments for PCAB and USP compounding standards. Discussions at the Spring meeting of the National Alliance of State Pharmacy Associations indicate that many states are considering recognizing USP's compounding practice chapters, <795> and <797>, in their regulations. Currently, Georgia is the only state requiring compounding pharmacies to have the *P2* as a reference. A recent bill introduced by Senator Kennedy, which references USP, also calls for stronger



enforcement by FDA at the state level. Although the bill does not appear to be getting much traction, it has caused considerable concern among national pharmacy organizations. USP is monitoring its movement.

Resolution #4 (continued)

USP staff continues to evaluate an online, self-study curriculum on sterile compounding that could be used by both practitioners and students, and is currently reviewing a prospective partner for course development. Discussions continue with the American Association of Colleges of Pharmacy (AACCP) as a partner to promote the final program to colleges of pharmacy. USP is conducting a compounding survey which will be up on the website by April 1, 2007 to enlist the practicing pharmacists in gathering information about compounding practices and preparations being compounded. This information will be used to enhance the Pharmacists' Pharmacopeia.

June 2007

The compounding survey response time has been extended to July 1, 2007 to allow organizations to further encourage their members to participate in the compounding survey. This survey requires some thought on the part of the compounding professional and thus additional time has been requested by the Compounding Practice Expert Committee.

The review process to enable the publication of USP Chapter <797> in *USP 31- NF 26* is almost completed. There are a few outstanding sections still being reviewed and considered by the Sterile Compounding Expert Committee. These sections include: Disinfecting and Cleaning; and Environmental Monitoring. The two Advisory Panels convened to assist the Expert Committee in their deliberations have officially completed their advisory responsibility. The recommendations from the Radiopharmaceutical Advisory Panel were approved by the Committee while that of the Disinfecting and Cleaning Advisory Panel are under consideration. It is anticipated that the uncompleted sections will be published in the *Second Supplement* to *USP 31-NF 26*. A comprehensive outreach campaign will accompany release of the chapter, including organization briefings, workshops/webinars, press release and online access to the completed chapter in advance of actual publication.

The *Pharmacists' Pharmacopeia* will be published in the 3rd quarter of FY 08 and is currently being evaluated for new content.

December 2007

The new official Chapter <797> will be available on USP's website on December 3, 2007. Stakeholder briefings occurred during the week of November 26 to provide section highlights and information on publication and official dates, as well as information on the significant educational activities USP will provide in connection with the publication of the chapter. Eight webinars and three 2-day workshops are planned and a useful guidebook on the chapter will be offered. The *Pharmacists Pharmacopeia (P2)* 2nd Edition will contain the new official Chapter <797> along with all chapters referenced in <797>. The second edition of P2 significantly expands and enhances the content of the first, including standards and compliance documents from the Pharmacy Compounding Accreditation Board (PCAB).

March 2008

General Chapter <797> was published as a Revision Bulletin on USP's website on December 3, 2007 and will become official June, 2008. The commentary (which responds to 500+ comments) has also been posted. A series of seven 90-minute, web-based seminars (webinars) on different topics related to aspects of <797> will have been developed and will be presented to assist practitioners' understanding of the chapter, with the first webinar scheduled for February 21, 2008. In addition, 2-day intensive, hands-on workshops that provide in-depth analysis of current compounding issues, including the practical application of USP's General Chapter <797> will be offered.



Resolution #4 (continued)

There has been an effort to provide a complete set of resources for practitioners and others on USP's website through a new portal "Hot Topics" that includes the educational packages and additional publications related to Chapter <797>: *A Guidebook to General Chapter <797> Pharmaceutical Compounding—Sterile Preparations* and the *Second Edition of the Pharmacists' Pharmacopeia*.

The *Second Edition of the Pharmacists' Pharmacopeia* will launch on March 14, 2008 at the APhA Convention in San Diego, CA. USP will have a booth at this convention to announce the sale of the newly revised Second Edition. This reference book has been substantially updated and enhanced. It contains:

- 134 USP monographs for compounded preparations and 79 USP general chapters covering compounding, packaging, labeling and storage of pharmaceutical preparations
- New Chapter on Veterinary Compounding
- Over 500 monographs on preservatives, flavorings, and colorings from the Food Chemicals Codex
- Enhanced chapter on compounding support including 20 articles on the Basics of Compounding
- Expanded section on Legal Requirements and Laws applicable to compounding

USP staff provided organizational briefings about the new chapter to a numerous stakeholders, encouraged links to USP's website and is providing a 90-minute webinar overview of the chapter revisions to members of state boards of pharmacy and surveyors of the Pharmacy Compounding Accreditation Board (PCAB).

June 2008

Two USP <797> workshops have been conducted so far since the release of the chapter with a third scheduled later in June (estimate 200 total participants). The workshops are an in-depth analysis of current compounding issues and provide insight into pharmacy-related content from the USP *Pharmacists' Pharmacopeia* and the *USP-NF*. The workshops allow access to USP expert committee members and staff, who provide guidance, address questions regarding the chapter, and discuss current issues affecting facilities and practitioners. All workshops are ACPE accredited, and it is possible additional workshops will be conducted in FY09. In addition to the workshops, a total of seven webinars will be conducted in FY08 to educate healthcare practitioners and others about the newly released USP General Chapter <797>. Topics include contamination risk levels, immediate use, cleansing and garbing, and facility design. At this writing it is anticipated that 500 will have participated. Free sessions of the webinars and workshops are being offered to State Boards of Pharmacy and surveyors of the Pharmacy Compounding Accreditation Board.

The 2008 *Pharmacists' Pharmacopeia* was launched at the American Pharmacists Association Meeting in March.

The Pharmacy Compounding Accreditation Board (PCAB) has created an Accreditation Committee (AC) in its by-laws to make decisions regarding pharmacies' certifications. NABP and USP are permanent members of the AC — NABP will chair the group and USP will be entitled to name its member (staff). The remaining three seats on the AC will be elected by the PCAB Board. USP has submitted names of other candidates for consideration. USP also sits on the Nominating Committee for the AC.



Resolution #4 (continued)

September 2008

A third USP <797> workshop was conducted since the June report (approximately 200 total participants in all) See details about workshops in June 2008 report. An additional 16 workshops for calendar year 2009 are being planned in collaboration with the Star Compounding Center in Denver. This Center offers a state-of-the-art facility where participants receive hands-on training with sterile and non-sterile compounding techniques. As planned, seven live Webinars have been conducted reaching nearly 1,000 practitioners. Recordings of these Webinars will be available for purchase through USP beginning in September-October time frame that will allow the continuation of these educational offerings to anyone interested in this subject matter.

The Pharmacy Compounding Accreditation Board (PCAB) established an Accreditation Committee (AC) to review survey results and recommend accreditation to the Board. The AC is structured as follows: NABP Chair's the Accreditation Committee; USP staff holds the Vice-Chair position; 2 pharmacy representatives, and one physician representative. Nominated by USP, the physician representative is a member of the USP Dermatology Expert Committee, and a pharmacist-physician.

USP is seeking grant proposals for stability studies on eight non-sterile and eight sterile compounded preparations. Invitations to submit proposals by August 29, 2008 were sent to pharmacy schools and laboratories.

December 2008

The First and Second Supplements to the Pharmacists' Pharmacopeia have been published. In efforts to develop additional monographs for compounded preparations, four universities and one contract laboratory were awarded grants to complete stability studies on 16 compounded preparations. Eight non-sterile and eight sterile compounded preparations will be completed by June 2009.

Projected Resolution Completion Date

This resolution is expected to continue throughout the cycle.

Resolution #5: 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.**

Status of Resolution Implementation

March 2006:

A meeting was convened on December 21, 2005 and was attended by representatives from HL-7, United States Adopted Names (USAN) Council, FDA's Center for Drug Evaluation and Research and Center for Devices and Radiological Health, National Library of Medicine, WHO's International Nonproprietary Names, and USP's Nomenclature and Labeling Expert Committee. There was general consensus that organizations are inclusive in their activities and collaborative in their approach.

The Safe Medication Use (SMU) Expert Committee created three separate subcommittees to address the issues associated with nomenclature and labeling of products. They are Standards Development, Education and Training, and Data Analysis and Actions. The Standards Development subcommittee will focus on: *Tall Man Lettering* (mixed case lettering) for a specific list of medications as a means of distinguishing them; *Standardized Labels/Labeling*; i.e., format, style, and placement of information on labels of prescription drugs; and *Patient Safety Recommendations for USP Monographs* for safety-focused recommendations (i.e., labeling, packaging, storage, and handling) for individual/class *USP* monographs

September 2006

Proposed revisions to USP General Chapter <1121> Nomenclature were published on USP's website, and staff is actively soliciting practitioner comment through the website on the section of the chapter dealing with the USP Salt Nomenclature Policy, which was added to the chapter. Under the policy, the title for a dosage form monograph uses the name of the molecule on which dosing and monitoring are based. The Salt Nomenclature Policy is intended to:

- Standardize compendial monograph titles and definitions
- Achieve uniformity in expressing dosages
- Simplify prescription writing and pharmacy record-keeping
- Reduce the likelihood of medication errors by correlating the product name with the substance by which the product is dosed.

The comment period for Chapter <1121> ends 10/15. On a parallel track, USP will meet with FDA and members of the Nomenclature Expert Committee to discuss the implications of the change.

The Standards Development subcommittee of the Safe Medication Use (SMU) Expert Committee currently is collecting data on the value and effectiveness of Tall Man lettering as an approach to avoiding medication errors. The subcommittee also is conducting a similar survey on efforts by other organizations to standardize labels/labeling before developing its recommendations.



Resolution #5 (continued)

January 2007

Proposed revisions to the Salt Nomenclature Policy have generated considerable concern/interest from both practitioner and industry stakeholders. In the role of convener, USP brought together practitioner members from the Safe Medication Use Expert Committee and members of the Prescription/Nonprescription Stakeholder Forum so that industry could better understand the practitioner impact of the Salt Nomenclature Policy. The Nomenclature Expert Committee will finalize the Salt Nomenclature Policy in February. When it is published in Spring 2007, the *USP Dictionary* will include two enhancements — Unique Ingredient Identifier (UNII) Codes and a pronunciation guide developed by Dr. William Heller (former USP Executive Director).

Activities of the Safe Medication Use Expert Committee and its Subcommittees, as noted in September's update, also continue.

April 2007

The Nomenclature Expert Committee (NOM EC) discussed the Salt Nomenclature Policy in detail during their February 2007 meeting, but the policy has not been finalized. USP staff is developing a revised monograph naming policy and related implementation procedures for review by the NOM EC. After its approval by the NOM EC, this revised policy will be published in the *USP-NF*. Publication of the 2007 *USP Dictionary*, with the previously cited enhancements, is on schedule.

June 2007

USP's Safe Medication Use Expert (SMU) Committee Standards Subcommittee is currently spearheading a project to evaluate the awareness, use, and effectiveness of "Enhanced Lettering" in medication nomenclature. Phase 1 of the survey has been completed. An online survey tool was used with the goal to gauge awareness of "Tall Man Lettering." This survey was widely distributed to health care professionals of multiple disciplines; more than 1,700 responses were received. Currently the responses are being aggregated and analyzed. These data are to be summarized and presented to the NOM EC. The second prong will target directors of pharmacy, and will seek information about what drug pairs are currently being identified with "Tall Man Lettering," what presentations of letterings are being used, and where there is standardization.

The SMU at its recent meeting last May addressed several issues from the NOM EC, including Acetaminophen/Paracetamol, Labeling Gluten in Medications, Labeling Combination Products (which has significant implications for CPOE, EMR(s)/EHR(s), electronic references, databases, and more.

The revised monograph naming policy and related implementation process document were published on the USP web site as part of the revised general chapter <1121> *Nomenclature* which will be published in *USP 31-NF 26*.

Resolution #5 (continued)

December 2007

The Nomenclature Expert Committee (NOM EC) voted to adopt revisions to General Chapter <1121> *Nomenclature* related to salt nomenclature. This change allows for more consistency in the naming format of many drug products—including compounded preparations—over the long term, and helps to reduce the likelihood of medication errors involving these products. The change will have a significant impact on physicians, pharmacists, nurses and other health care providers, drug manufacturers and regulatory professionals, and vendors of drug information and pharmacy systems. Under the new naming policy, the titles of USP monographs for drug products and compounded preparations formulated with a salt of an acid or base will now use the active moiety—the molecule or ion responsible for the physiological or pharmacological action of the drug substance—for both the product name and the strength/dose. This differs from the salt nomenclature policy that USP had previously followed, which named a product based on how the strength is expressed. This new policy serves a number of practical purposes. Naming by active moiety offers more consistency among USP dose form monograph titles and definitions. The new policy is better suited for computer prescriber order entry (CPOE) systems because names will be shorter. In addition, there is a smaller chance of medication errors, e.g., switching a patient from an IV product to an oral product, because it is easier to determine the equivalent amount of a drug a patient is receiving when the dose is based on the active moiety instead of on the salt.

The NOM EC along with other related Expert Committees and a wide array of stakeholders are concerned about the use of suffixes that do not have consistent or understandable meanings. A Joint Subcommittee will be established regarding the nomenclature of drug products with modified release characteristics and the Joint Subcommittee will include membership from the NOM and Pharmaceutical Dosage Forms EC, the FDA, and others.

The 2006 Annual MEDMARX Report will address the issue of drug nomenclature due to brand and/or generic names that look or sound alike and the potential for medication errors.

March 2008

Revisions to General Chapter <1121> were published in *USP 31-NF 26* and included the newly revised Monograph Naming Policy for Salt Drug Substances in Drug Products and Compounded Preparations. The Nomenclature Expert Committee met on February 25-26, 2008 at USP Headquarters. The liaison for the Nomenclature EC attended the USAN Council meeting in Phoenix, Arizona in January and reported on USP activities regarding nomenclature.

The newest *MEDMARX Data Report: A Report on the Relationship of Drug Names and Medication Errors in Response to the Institute of Medicine's Call for Action. Findings 2003-2006 and Trends 2002-2006* was published in January. This report focuses on medication errors involving drug nomenclature as reported to either MEDMARX or the USP-ISMP Medication Errors Reporting Program. Analysis of more than 26,000 records with look-alike and/or sound-alike drug names indicates that the risk of a medication error increases with similar drug names. The report also includes a drug name pronunciation guide from the USP Dictionary of USAN and International Drug Names. Historical information about medication errors from the MEDMARX database are contained in the technical appendices. This report responds very directly to the intent of this resolution.

Resolution #5 (continued)

June 2008

The 2008 USP Dictionary of USAN and International Drug Names was published in April as part of USP's collaboration with AMA, APhA, and FDA in the USAN Council. A presentation on the USP naming process was requested at the INN Council. USP-FDA Subcommittee on Aerosols Nomenclature met on May 22nd to harmonize terminology between the groups. A USP-FDA Joint Subcommittee on Modified Release Dosage Form Terminology will meet in June to discuss variations of 'extended- release' formulations.

September 2008

As a complementary offering to this year's MEDMARX Data Report: *A Report on the Relationship of Drug Names and Medication Errors in Response to the Institute of Medicine's Call for Action* released this past January, USP created a web tool called a "Drug Error Finder" for patients and other stakeholders to locate look-alike and/or sound-alike drug names via the USP website. The tool will be launched August 25, 2008.

<http://www.usp.org/hqi/similarProducts/drugErrorFinderTool.html>

USP staff and Expert Committee Chairs, Tom Reinders (Nomenclature), Tom Foster (Biopharmaceutics), and David Long (Pharmaceutical Dosage Forms) are collaborating with the International Union of Pure and Applied Chemistry (IUPAC) to harmonize the IUPAC glossary of terms used in pharmaceuticals. It is important to provide consensus terms, considering the impact that IUPAC publications have in the international community. Dr. Chorghade is the leader of the Division VII task force working on two IUPAC glossaries. He welcomed long-term collaboration between IUPAC and USP. Dr. Chorghade is invited to the Nomenclature Expert Committee meeting, to be held in December to present a report on the glossary project.

December 2008

The Drug Error Finder, USP's web tool for locating look-alike and sound-alike drug names, is a popular USP page for visitors to USP's site. There have been more than 112,250 queries that could lead to further name changes where mix-ups have been identified and result in fewer medication errors. USP will maintain the Drug Error Finder, but it will not be updated.

Projected Resolution Completion Date

This resolution is expected to continue throughout the cycle.

Resolution #6: 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.

Status of Resolution Implementation

March 2006:

Publication of the Spanish translation of *USP–NF* continues; the *First Supplement* was released in March. Work is beginning on the Russian edition of *USP–NF*. The complete reference standards catalog has been translated into Mandarin and selected pages of the English version contain sections translated into Spanish, French, and German. The USP website is now available in Spanish, French, German, and Chinese.

Pharmacopeial Education classes have been held in Switzerland and Ireland so far this fiscal year, and planning progresses to hold classes in Turkey and Switzerland in the remainder of this FY, with possibilities also in Mexico, Canada, and Belgium. The International Council of Nurses (ICN) and USP collaborated on two projects; AMR (Antimicrobial Resistance) Fact Sheets and a Visual Inspection Tool to identify counterfeit drugs. Both of these instructional tools along with a video on Thin Layer Chromatography (TLC) made by USP staff with the help of the USP Research and Development Laboratory are available to any interested party. The TLC video introduces TLC testing and the benefits of its use in low-resource countries. USP staff continues to conduct training workshops in many developing countries on topics such as: principles of good laboratory practices (GLP), basic testing, and how-to-implement drug quality monitoring for antibiotic, antituberculosis, and antiretroviral medicines, dissolution, UV-spectrophotometry and high pressure liquid chromatography (HPLC), and practical application of good manufacturing practice (GMP) fundamentals.

USP opened its sales office in Basel, Switzerland in late 2005 and held the India site inauguration in February 2006. USP's Board of Trustees has recently approved development of a site in Shanghai, China. Regarding Latin American programs, USP continues to work with the External Quality Control Program (EQCP) in collaboration with the Pan American Health Organization (PAHO) and the Pan American Network for Drug Regulation and Harmonization. In collaboration with PAHO and EQCP, two rounds of external quality control testing will be conducted with the official laboratories in 21 countries in the region.

The International Health Expert Committee will work on revisions to monographs for neglected diseases (e.g., malaria) and develop new monographs and reference standards for articles legally marketed outside the US, as well as provide oversight of foreign translations of the *USP–NF*.

September 2006

USP staff is participating in the WHO initiative, IMPACT (International Medical Products Anti-Counterfeiting Task Force) to address counterfeit drugs worldwide. International Annual Scientific Meetings will be conducted in the next several months in Amman, Jordan and Cairo, Egypt. In addition, USP will conduct a symposium in China in October and a second European Stakeholder Forum in Basel in December. The Therapeutic Goods Administration of Australia will visit USP in late September to discuss future collaborations in standards setting as Australia and New Zealand combine their drug regulatory functions and name *USP* as a default pharmacopeia.

Resolution #6 (continued)

USP's China site building will be ready for occupancy at the end of October and its inaugural opening activities are planned for February 2007. USP continues to maintain its presence in Latin America through its participation in PANDRH and the External Quality Control Program (EQCP). EQPC's 23 labs completed a sixth round of proficiency testing. Asian and African activities have rendered 10 monographs for drugs approved outside the U.S. for malaria, tuberculosis and HIV/AIDS, including a submission of monographs for CoArtem by Novartis. USP DQI recently received funding (\$625,000) to conduct programs in Uganda, Madagascar, and Mekong countries.

January 2007

USP's China site is operating with a small staff, and opening ceremonies are planned for August 2007 before the FIP (Federation Internationale Pharmaceutique) World Congress in Beijing. USP will partner with colleagues in China to present a workshop prior to the FIP meeting as part of an Industrial Pharmacy offering. USP China staff has moved into the building and are providing technical support to industry, government, and pharmacopeia representatives.

Both directly and through the USP Drug Quality and Information program, USP staff is involved in a broad range of activities in Latin America. Working in collaboration with many groups USP has: helped lead the Good Laboratory Practices Working Group; participated in the Steering Committee for the Amazon Malaria Initiative; and participated in dissolution and bioequivalence workshops. Staff also is working with the Mexican Pharmacopeia (FEUM) and others to arrange a USP-FEUM annual science meeting in March 2007. USP is considering a site in Brazil.

In the Asian/African regions, USP staff and USP DQI provided training and technical assistance to a broad range of organizations interested in improving the quality of medicines. They participated in or provided:

- Technical assistance on GMPs to selected manufacturers in Bangladesh in a collaborative effort to increase sources of good quality zinc products for control of diarrheal diseases.
- A workshop on drug quality at a meeting of the HANMAT malaria network (Ethiopia, Eritrea, Sudan, Somalia, Yemen, Djibouti, and South Sudan).
- Training for the national drug quality control lab of Uganda and local pharmaceutical manufacturers on good laboratory practices and major testing methods.
- An Africa Regional Drug Quality workshop in Tanzania,
- A WHO Regional Workshop for National Malaria Control Programs in Manila,
- Facilitated a workshop in Danang, Vietnam on drug quality control and anti-counterfeiting for 86 representatives from the Ministries of Health, Trade, Interior, and Customs; police, prosecutor, and provincial health agencies; and national priority health programs.
- Traveled to Moldova to evaluate the drug information centers established by USP DQI a year ago at the National Institute of Pharmacy in Chisinau; the center will continue to provide services to the Ministry of Health.

Resolution #6 (continued)

April 2007

USP conducted a symposium on dissolution and bioavailability/bioequivalence of drug products in Lima, Peru, on February 1-2, 2007 – 150 attendees. USP is a member of the Good Laboratory Practices Working Group from PANDRH/PAHO, and participates in activities to improve the performance of the Official Medicines Control Laboratories in Latin American and the Caribbean. The Spanish translation of the *First Supplement to USP30–NF25* has been completed. An update from Geotar, the Russian publishing company handling the translation to that language, states that 30 % of the text has been translated to date. USP’s USAID activities for this quarter included the First Francophone Africa Regional Workshop on Pharmacovigilance, which focused on raising awareness about drugs safety, particularly for antimalarials, and the importance of effective pharmaco-vigilance programs. USP-DQI website redesign has been completed, which has enhanced search capabilities on the site.

USP DQI has provided an HPLC apparatus for the Official Medicines Control Laboratory in Bolivia and conducted a training workshop on HPLC and Good Laboratory Practices and use of the *USP–NF* at the OMCL in La Paz, Bolivia. International Standards monographs *Abacavir sulfate* and *Efavirenz* and Pending Standards monograph *Abacavir Oral Solution* were posted on the USP website marking the launch of this new initiative to provide easier access to high quality standards for drugs for neglected diseases. Two other monographs are under review. USP contributed \$30,000 to the Pharmaceutical Science World Congress 2007 which convenes under the aegis of the International Pharmaceutical Federation (FIP). This contribution categorized USP as a “sponsoring” organization garnering a large amount of visibility at this international conference.

June 2007

USP is working to establish two Advisory Panels in India in conjunction with USP’s MOU activities with the Indian Pharmacopoeia Commission. The topics include 1) Monograph and Reference Standard Acquisition and 2) Herbal Ingredients and Product Testing

On the anti-counterfeiting front, USP DQI participated in the 3rd Global Forum on Pharmaceutical Anti-Counterfeiting and represented USP at the first meeting of the WHO International Medical Products Anti-Counterfeiting Taskforce (IMPACT) Technologies Working Group in Prague, Czech Republic. Also, USP staff spoke at “Detecting Counterfeit Drug” workshop sponsored by York College, FDA, and USP on USP’s role in IMPACT and the use of Minilabs[®] for surveillance in the field. An experimental protocol has been developed at USP for use in a laboratory collaborative project (FDA and a commercial laboratory) to use near IR to detect counterfeit drugs.

USP DQI collaborated with WHO, UNICEF, USAID and the Johns Hopkins University Bloomberg School of Public Health in the development of the WHO publication *Production of Zinc Tablets and Zinc Oral Solutions. Guidelines for Programme Managers and Pharmaceutical Manufacturers*, which is intended to assist in the selection and procurement of quality zinc products for use in the prevention and treatment of diarrhea in children less than 5 years of age. The guidelines can also be used by pharmaceutical manufacturers to develop quality zinc products.

Resolution #6 (continued)

USP DQI jointly authored the review article, *The use of chlorhexidine to reduce maternal and neonatal mortality and morbidity in low resource settings*, published in the Intl Journal of Gynecology and Obstetrics May 2007(2); 97:89-94. USP DQI worked on the pharmacology and safety issues of chlorhexidine and also on the issues of programmatic implementation on the use of chlorhexidine as anti-infective agent in neonatal cord care. CHX is a simple, low cost, and easily available intervention that is now being incorporated in delivery kits and rolled out for use in neonatal cord care in the Asia region, starting with Nepal. USP DQI will provide technical assistance on GMP and product quality testing.

The Infectious Diseases Textbook developed by Smolensk Medical Academy of Russia in collaboration with USP DQI was published, distributed to regional USAID and WHO Offices and widely disseminated to hospitals, medical schools, and Drug Information Centers in Russia and Russian-speaking countries. The Moscow Sechenov Medical Academy, one of the leading medical schools in Russia, recently announced that they have made this textbook recommended reading for third and fourth year medical students. This is the third edition of the textbook, which now includes valuable and not readily available information on new medications, updates on new viral infections, quality assurance measures and new known side effects of medications. The book is also available by website and has reached 3 million medical professionals in Russia and neighboring countries.

December 2007

An MOU signed with Jordan officials allows development of proposal for USP to have a presence in the Jordanian Drug Control Laboratory. The third Annual Scientific Meeting was held in Jordan, with attendees from official medicines control labs from five countries (funded by USAID), senior officials from Egypt, and high level Jordanian FDA officials.

Time was spent with officials at Health Canada to explain the value of USP's verification programs in an effort to encourage reliance on this USP program.

An MOU was signed with Febrafarma to advance joint training and education opportunities as well as industry stakeholder forums. An HPLC workshop was conducted in Brazil for 80 members of Febrafarma as a first activity under the MOU.

Staff presented a symposium on antimicrobial resistance and anti-counterfeiting measures at the Congress of the International Pharmaceutical Federation (FIP)

Under the USAID grant USP staff facilitated a training course in Cambodia on 'Establishing Anti-Infective Drug Quality Monitoring Using Basic Tests' and tested 17 products from Cambodia in USP's Applied Compendial Research Lab. Presentations were given by USP staff at an ASEAN-U.S. Patents and Trade Office 'Workshop on Counterfeit Products' held in Bangkok, a poster on "Zinc Adjunct in the Management of Children's Diarrhea: Ensuring Product Quality" at the 25th International Congress of Pediatrics, a training workshop on control of bacterial endotoxins delivered to the official medicines control laboratory of Madagascar – this was the first USP DQI training on microbiology. Staff also conducted an anti-infective drug quality monitoring training workshop in Vietnam, a workshop in BA/BE in Cambodia, and presented at the USAID Avian Influenza Program Workplan Development Meeting in Thailand.

Resolution #6 (continued)

John Snow International/DELIVER Project –a five-year subcontract to provide quality control services for medicines purchased through DELIVER for the Presidential Malaria Initiative (PMI). USP’s role includes technical assistance in pharmaceutical QA/QC and post-marketing surveillance; prequalification of suppliers and verification of ingredients, preparation of monographs and reference standards for specified malaria drugs, and training local JSI staff in sampling and simple screening tests.

Population Services International/Gates Foundation Award – USP’s role will include facilitating stakeholder involvement at country level; training PSI’s in-country staff to sample drugs at a subset of outlets and to screen products using Minilabs®; identifying qualified laboratories for confirmatory testing; and preparing test result data for inclusion in project reports.

Work is underway to develop USP’s new site in Brazil. Plans are also being considered for expansion of the India site.

March 2008

China — USP anticipates a formal signing of the revised MOU with the Chinese Pharmacopoeia Commission during the inauguration activities in Rockville in early March. Shortly thereafter, it is anticipated that USP will sign a revised MOU with the National Institute for the Control of Pharmaceutical and Biological Products. Both of these MOUs strengthen USP’s collaboration with these bodies in China.

India — The India Annual Scientific Meeting was held in early February. Several hundred people participated during the several days of activities. Also, a revised MOU with the Indian Pharmacopoeia was signed. The Board approved expanding the India site during its December 2007 meeting and work has begun in contracting with architects, exploring various land and lease options, and more.

Brazil — An employee orientation program was specifically designed and provided to USP’s first three USP-Brazil employees, including the Vice President (i.e., the site manager). This program extended over two weeks and provided exposure for these new employees to all facets of the organization and introduced them to key contacts.

International Technical Assistance Programs — The DQI program published *Ensuring the Quality of Medicines in Resource-limited Countries: An Operational Guide*. This is a flagship publication of USP DQI in collaboration with its partners – WHO, Management Science for Health, PATH, Organon and 4 national medicines regulatory agencies. USP was represented at an IMPACT meeting in Lisbon in December and in Singapore in February. IMPACT is a world-wide consortium dedicated to combating counterfeit and substandard drugs.

Africa — An African Advisory Panel, supportive of the International Health Expert Committee, has been formed and has convened via teleconference. This group serves to provide input and insights to guide potential ways for USP to engage more in Africa.

Resolution #6 (continued)

June 2008

China — USP and the Chinese Pharmacopoeia signed a revised MOU on March 5, 2008 following the inauguration activities for the new USP headquarters in Rockville, MD. USP China expects to exceed the targeted 150 lab tests by year end. A new Pharmacopeial Education program was launched, and six new companies have submitted 7 ingredients for USP's Verification Program. MOU discussions continue between USP and the National Institute for the Control of Pharmaceutical and Biological Products (NICBP). USP and NICBP are targeting June 2008 for a MOU signing ceremony in Beijing.

India — The lease deed for the additional land for lab expansion has been finalized, and an ISO 17025 surveillance audit that was recently completed revealed "zero" non-conformities. 100% of the monograph redesign has been completed by site staff and are currently being reviewed at headquarters. India staff conducted six Pharmacopeial Education courses YTD.

Brazil — The completed USP building has been turned over to USP-Brazil staff, and the operating permit is expected by June 2008. There are currently eight staff members on board including all management positions. Four additional staff will be recruited in Q4 FY08. Advisory group candidates have been approved by USP's CEO. The site is expected to be at full operating status by July 2008. Official site inauguration ceremonies in Brazil are planned for the week of August 18, 2008.

Russia — A Memorandum of Understanding with the Russian FDA (Roszdravnadzor) is under development.

International Technical Assistance Programs —

- DELIVER Project /John Snow International – USP completed a verification audit of Guilin Pharmaceuticals and qualified the drug substances in question. Final report was delivered to USAID/JSI in April.
- Population Services International/Gates Foundation – USP has obtained a 5-year, \$1.3M obligation from PSI. USP staff attended the kickoff meeting in Kenya in April.
- USP has hired a manager to direct both PSI and JSI projects and to pursue other grant opportunities for USP.
- USP DQI has conducted tests on 908 products, and is currently working in 21 countries. To date, training workshops with Official Medicine Control Laboratories have been held in four countries: Jamaica in October 2007, Guatemala in November 2007, Bolivia in February 2008, and Paraguay in March 2008. The DQI work plan was approved by USAID in April 2008. A program manager and coordinator to support initiatives in Africa were hired in March 2008. USP DQI is working in Uganda to establish antimalarial drug monitoring programs, and with the National Drug Authority (NDA) to launch a pharmacovigilance program and adverse drug reaction reporting system.

Resolution #6 (continued)

September 2008

China— Four working groups have been established under the USP-ChP MOU (signed March 2008). A total of 136 monographs were proposed by ChP as candidates for potential collaboration in the next three years. A workplan for the first USP Chinese translation is being drafted, which projects publication by FY2011. A draft MOU between USP and The National Institute for Control of Pharmaceuticals and Biological Products (NICPBP) has been finalized. The primary focus of the MOU is on lab testing and reference materials. The scheduled signing of the NICPBP MOU is Q3 FY2009 at USP HQ in Rockville, MD. Three pharmacopeial education pilot programs were successfully completed in FY08, and included 263 participants. There are eight Chinese companies currently participating in USP verification programs, with seven additional companies in the pipeline.

India— There were nine pharmacopeial education classes conducted during FY08 that included 470 participants. PE is working towards a goal to offer one course per month, and plans to develop and use the GMP courses to train and simultaneously identify/qualify leads to grow the USP verification programs. Under the verification programs, analytical testing was completed on 18 products, 16 plants were audited, and document reviews were conducted on 3 Dr. Reddy's products through FY08.

Brazil— USP Brazil is ready for collaborative testing as of September 2008, and the site inauguration ceremonies and events were held during the week of August 18, 2008. Advisory group and stakeholder forum meetings also took place during this time. In addition to key USP staff members, representatives from various government agencies, associations, and industry organizations and companies were in attendance.

International Technical Assistance Programs —

- *Southeast Asia*
 - During the latest round of testing under the USP DQI antimalarial drug quality monitoring project, the Food and Drug Quality Control Center of Laos discovered three counterfeit antimalarial medicines in May. The samples – labeled as artesunate 50mg tablets – actually contained no active pharmaceutical ingredient. The Laos Food and Drug Department issued a recall, directing the Champasack provincial authority to confiscate all remaining stocks from those outlets, and also sent warning notices to all provinces in the country.
 - In collaboration with WHO and the Cambodia Department of Drugs and Food, a workshop was conducted in Cambodia in May for 45 participants to help establish a pharmacovigilance (PV) center in the country.
 - USP DQI presented drug quality monitoring data from Lao PDR, Cambodia, and Vietnam and demonstrated the use of GPHF Minilabs[®] to police, customs agents, and regulatory authorities from the Mekong Region during meetings organized by INTERPOL in July.
 - Sponsored through a USAID grant, USP Pharmacopeial Education staff and USP DQI will conduct several workshops in Vietnam and Laos for hospital and community pharmacists on HIV/AIDS medications. The workshop consists of three modules that cover HIV/AIDS care and prevention, quality of such medications, and their safe use. These workshops are being conducted in collaboration with several organizations interested in improving the quality of medicines. These organizations include HIV/AIDS control programs, national medicines regulatory authorities, schools of pharmacy, teaching hospitals, and drug quality control laboratories of both countries.

- *Sub-Saharan Africa*
 - In support of the expansion of the national pharmacovigilance program in Madagascar, USP DQI conducted a “training for trainers” workshop in June for 24 participants from 22 regions of the country. Forty-two additional regional trainers will receive training in the coming months. Training was also given to staff from the Antananarivo University Hospital, where USP DQI is helping set up a Drug Information Center – the first in the country.
 - In August, USP DQI launched drug quality monitoring projects in Ethiopia and Benin under the President’s Malaria Initiative (PMI). The projects focus on post-marketing surveillance and will include sampling and testing rounds performed by the national quality control laboratories of the countries. In late August, USP DQI conducted a training course on basic tests and sampling procedures for staff from the Drug Administration and Control Authority in Ethiopia.
- USAID/Deliver Project (JSI) – JSI updated USP on their intent to place future antimalarial drug laboratory testing up for competitive bid between USP and Northwest University in South Africa. A cost analysis of performing the laboratory testing was requested, completed, and presented to senior management.
- Population Services International Project – USP submitted the draft of the Drug Quality Assurance Study protocol for ACTWatch to PSI for review and comments.

December 2008

China — A USP delegation of nine staff members attended the third USP-ChP joint symposium in Tianjin November 6-7, 2008. The four MOU working groups held meetings to review progress on collaborative efforts and plans for future activities. Preliminary terms of the *USP-NF* Chinese translation efforts were agreed upon between USP and the ChP. The contract is currently under review by the ChP. Official signing of the MOU between NICPBP and USP is scheduled for March 2009. PE will work to build curricula and advance training opportunities locally, and consider working with ChP and NICPBP on these activities. ISO site recertification audits are scheduled for December 2008.

India — USP is currently in discussions with Pharmexcil regarding possible collaboration in conducting training programs and developing herbal monographs. There are also plans to conduct six collaborative training programs in FY2009. A meeting was held in September 2008 with the National Institute of Pharmaceutical Education and Research (NIPER), Mohali, to discuss organizing joint training programs to assist NIPER, Mohali with setting up a GLP compliance lab and collaborative testing of reference standards. NIPER has also expressed an interest in entering into an MOU with USP to support these activities. Three companies have signed on as verification program participants in Q1 FY2009. A total of eight on-site audits of verification program participants are scheduled to be conducted through Q2 FY2009. Pharmacopeial Education (PE) has been successful in reaching the goal to offer one course per month through October 2008. An ISO 9001: 2000 audit of USP-India was completed without any non-conformances being identified.

Brazil — The draft MOU has been submitted to the Sindicato da Indústria de Produtos Farmacêuticos no Estado de São Paulo (Sindusfarma) for final approval. The MOU will eventually replace the current agreement with Febrifar which is due to expire in June 2010. A joint Sindusfarma/Febrifar biopharmaceutics workshop was held September 15-16. All required licenses and permits for collaborative test work have been received at the USP-Brazil site as projected. The lab has also received all the necessary chemicals and reagents. Testing is scheduled to begin mid-November 2008.



Resolution #6 (continued)

The lab has accepted 12 new collaborative testing projects, which are expected to be completed by the end of December 2008. Three Pharmacopeial Education courses are scheduled for November 26-28. As many as 150 participants are expected.

Projected Resolution Completion Date

This resolution is expected to continue throughout the cycle.

Resolution #7: International Harmonization

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

Status of Resolution Implementation

March 2006:

With the advice and consent of the Board, an Advisory Body on Resolution 7 was formed, comprising representatives from the Convention membership and other interested parties. At the conclusion of Advisory Body discussion of the issues and additional feedback from members via email, a final document was submitted to the Board for consideration. In December 2005 the Board directed staff to communicate USP's continued commitment to work with the Pharmacopeial Discussion Group (PDG) of ICH, which was done via letter on January 25, 2006. Members of the Advisory Body also received copies of the final document and the letter USP sent to PDG.

June 2006

At PDG meetings in June 2006, USP indicated a general intent to carry on its harmonizing activities in PDG, to include work on non-excipient general chapters. In parallel, the ICH Q4B Expert Working Group continued to work on the ICH-requested guidance, but is focusing more on regulatory interchangeability. Regulatory interchangeability by ICH regulators is an important decision. By achieving mutual recognition of any one of the three compendial texts by any ICH regulatory agency, national reliance on a country's own compendium may be diminished. Neither PDG nor ICH Q4B indicated interest in improvements based on the USP Discussion Points.

June 2008

USP has forwarded a concept paper to the Pharmacopeial Discussion Group on ideas for process improvements along these lines:

1. General: science, strategy, and goals
2. Process
 - Secretariat
 - More frequent and effective communication among PDG partners
 - Inclusion of compendial experts in the harmonization process
 - Industry participation/support
 - Inclusion of other pharmacopeias in the harmonization process
3. Topics for Harmonization
 - General Chapters—immediate prospects
 - Drug Substances—immediate prospects

These topics will be discussed at the June 2008 PDG meeting in Portland, Oregon.

Resolution #7 (continued)

December 2008

Projected Resolution Completion Date

USP's activities on the Pharmacopeial Discussion Group will continue throughout the cycle based on the conclusions of the Advisory Body on Resolution 7. From time to time, highlights/enhancements to the process will be shared in this status report.

Resolution #8: 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.

Status of Resolution Implementation

March 2006:

USP held a consultation with a broad range of stakeholders in July 2005, which generated a number of ideas for potential roles for USP. As USP considers these recommendations, staff continues to conduct environmental scanning and to meet with organizations to discuss other potential collaborations. A follow-on meeting is planned for August 2006 and will include chairs of the Information Expert Committees. Corporate Development staff will evaluate all USP options with a view to developing a strategy for USP's involvement in drug information after January 2007.

Current drug information work focuses on the Medicare Model Guidelines and articles for the Annals of Internal Medicine.

September 2006

A second consultation on drug information was held on August 22, 2006. The USP Board of Trustees formed a Drug Information Task Force, which is working with USP staff and a consultant to assess the input from both consultations and come to a determination on USP's possible future role in drug information.

January 2007

USP staff and Model Guidelines Expert Committee have posted draft Version 3.0 of the Model Guidelines on the website for public review and comment. The final document is due to CMS by February 5. The non-compete restrictions of the Thomson agreement will end in 2006 and there is general support from participants of the Drug Consultations for USP to move back into drug information. USP's Market Research Group is concluding its work and staff, with oversight by the Board's Task Force, will assess USP's options.

April 2007

The second meeting of the USP's Health Alliance partners, to consider USP's potential reentry into the healthcare arena was held February 27, 2007. Representatives from the American Pharmacist's Association, American Medical Association and the American Nurse's Association attended the meeting. There were guest presentations from USP's Information Committee Experts working at the National Institutes of Health Drug Information Department and a guest representative from Consumers' Union presenting their Best Buy Drugs website. USP staff presented a Applied Drug Information website prototype for consumers and healthcare practitioners. The group will reconvene later this spring.

The latest Version 3.0 of the Model Guidelines, with associated documents, was delivered to CMS February 5, 2007. USP staff is reviewing the new contractual arrangements proposed by CMS for the annual contract renewal.

Resolution #8 (continued)

June 2007

USP and CMS have signed a new cooperative agreement for the creation of Model Guidelines Version 4.0 and associated documents. Work is in progress to create this third revision. The Model Guidelines Expert Committee met in conjunction with the Spring Governance Meeting in April. Individual Information Expert Committees will be meeting via teleconference in July to form recommendations that will be reviewed by the Model Guidelines Expert Committee during their August 6th meeting.

The final two vacant Information Expert Committee Chairs (Nephrology/Urology and Clinical Toxicology) have been elected. Orientation sessions will be completed in July 2007. With the addition of the Model Guidelines Expert Committee, there are now a total of 17 Information Expert Committees.

USP was invited to meet with the American Society of Health System Pharmacists (ASHP) on June 18 to discuss Resolution #8. ASHP expressed a desire to partner with USP on future drug information activities. Both parties agreed to form a task force to consider future options. USP staff recently attended a public hearing on patient Medication Guides. Staff is currently analyzing testimony presented during the meeting and other information to potentially draft comments to the docket (deadline July 12, 2007)

December 2007

Discussions are ongoing with ASHP on a potential collaboration on drug information for cancer therapies. Version 4.0 of the Model Guidelines (draft) is currently posted on USP's website for comment. The target date for delivery to CMS is February 2008. USP is working with a project team from the International Pharmaceutical Federation to study culture/country-specific pictograms. USP plans to publish the findings of this research.

March 2008

Discussions continue with ASHP on a potential healthcare information collaboration. The collaboration is focused on oncology off-label indication approval utilizing USP's Oncology Expert Committee. The other Information Expert Committees would be involved as ad hoc or secondary reviewers of the information. ASHP will provide and manage all of the documentation and the workflow for this activity.

USP delivered the new Version 4.0 of the Model Guidelines and Formulary Key Drug Types and associated documents to CMS on February 4, 2008 as required in the cooperative agreement with CMS. USP will pursue an extension of the annual cooperative agreement with CMS to provide the annual Model Guidelines revision.

June 2008

CMS notified USP of its intent to move to triennial funding for revision of Model Guidelines Version 5.0. The work of the next cooperative agreement will begin March 2010. All Information Expert Committees were notified of this change, and the decision will be communicated to other USP volunteer groups shortly. USP is continuing to explore new opportunities for drug information and reengaging the Board Task Force.

Resolution #8 (continued)

September 2008

As USP continues to explore healthcare information opportunities, it is in discussions with the American College of Clinical Pharmacy regarding the potential for developing standards or guidelines for pharmacotherapy. Other areas under current exploration include academic detailing and development of clinical modules with the potential for USP to work collaboratively with other organizations to disseminate the modules on a national and/or international level.

December 2008

No activity to report.

Projected Resolution Completion Date

This resolution is expected to continue throughout the cycle.

Resolution #9: 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.

Status of Resolution Implementation

March 2006:

Staff is beginning to develop a prototype for a compendium of safe medication practices and to plan for focus groups that will provide feedback on the prototype. The Safe Medication Use (SMU) Expert Committee will convene in May to discuss defining the research, science and level of evidence needed for the compendium, as well as the criteria by which safe medication use practices are established. A stakeholder forum is tentatively planned for July/August 2006 to gather interested organizations to discuss whether such a compendium would serve the community and to determine each organization's willingness to contribute. In consideration of the feasibility and advisability of USP's involvement in the issue of safe disposal of pharmaceuticals in the environment, USP staff continues to monitor various activities associated with the issue to determine if/where USP could make a unique contribution.

September 2006

USP will hold a Patient Safety Stakeholder Forum in October to discuss with all interested parties the concept of a Compendium of Safe Medication Practices. Specifically, participants will discuss the feasibility and utility of creating such a Compendium and address specific issues through open forum and panel discussions. If appropriate, there will be a discussion of potential content areas that might be considered for inclusion and discuss possible roles and collaborative opportunities for USP and other organizations related to the proposed initiative.

USP continues to monitor the broad based discussions related to the disposal of pharmaceuticals. The USP Packaging and Storage Expert Committee also discussed the issue and a potential role for USP. In the last year, the American Medical Association, American Society of Health-System Pharmacists, and National Association of Boards of Pharmacy have adopted resolutions on the appropriate disposal of pharmaceuticals and there have been a number of efforts on the national level to address the issue. USP staff will brief CEO in October regarding these activities and discuss possible next steps for USP.

January 2007

Staff is reviewing the Stakeholder Forum's meeting summary and will prepare a recommendation for Board consideration. The Education and Training Subcommittee of the Safe Medication Use Expert Committee has been charged with developing educational programs to foster safe medication use practices for healthcare practitioners, students, consumers and others. To start, the Subcommittee is exploring development of interdisciplinary educational approaches based on actual medication errors from USP's medication error programs to include development of:

- Core curriculum or modular components for use within a curriculum that focus on safe medication management.
- Methodologies to build awareness of risk-prone processes and practices.
- Competencies in safe medication use and creation of mechanisms to document these competencies for health care facilities.

Resolution #9 (continued)

April 2007

Safe Medication Use: Nothing new to report.

June 2007

Results of the TALL Man lettering survey of practitioners were astounding, particularly from the state association constituents. Total responses were 1700, with 900 of those from the states. Of these, 840 (93%) are actively involved in patient medication activities. 777 (92%) of these 840 are aware of *Tall Man Lettering*, and 547 (70%) of the 777 say Tall Man Lettering is being used in their organizations. While data need to be analyzed more thoroughly, the tremendous response should give the Safe Medication Use Expert Committee an excellent set of data for their deliberations on standardizing tall man lettering.

Other SMU plans include: 1) development of a High Alert Medications List by Location — This is a web-based interactive tool that will assist healthcare practitioners with the required development of a “list” of high alert medications that they need to create for accreditation purposes. 2) Small Bore Tubing Connectivity — The SMU Standards Subcommittee has developed a position paper and recommendations that address what hospitals and other healthcare organizations can do to address issues where the availability of tubing and connectors for non-intravenous functions that are compatible with intravenous tubing are creating an unsafe, error risk, situations for patients in hospitals and other healthcare settings. 3) Completion of a USP General Chapter “Physical Environments that Promote Safe Medication Use.” 4) Identifying ways to strengthen the prohibition in the *USP-NF* of the use of apothecary units. Such use continues to create serious medication errors. 5) Recommendations for Standardized Concentrations of Parenterals, which could significantly improve patient safety particularly in critical care areas and pediatric settings.

USP and the Institute for Safe Medication Practices are delivering a joint educational workshop, *Using Data Effectively to Manage the Risks to Medication Safety*, in four locations in the US. The workshop was sponsored in part by Cardinal Health, which provided a \$25,000 unrestricted grant for the purpose.

December 2007

Two published articles based on MEDMARX data analysis, one authored by USP staff and the other by a USP resident fellow have received high acclaim and have been distributed broadly. One article has received almost 2 million media impressions. A third article written in collaboration with researchers at Johns Hopkins has received more than 800,000 media impressions.

USP’s Safe Medication Use (SMU) Expert Committee has proposed to the Chair of the CoE to establish an Advisory Panel to address the issues presented in the American College of Physician Foundation’s (ACPF) white paper on prescription labeling. The research was presented at the Institute of Medicine and USP’s CEO, who served on the editorial board for the paper, offered USP resources. If formed the Advisory Panel would look at inconsistent and confusing medication information and labeling; specifically addressing the format, content, dosage and use instructions, etc. on the dispensed container label.

The 2006 Annual MEDMARX Report will address the issue of drug nomenclature due to brand and/or generic names that look or sound alike and the potential for medication errors. A broad range of stakeholders will be briefed on the report prior to its release in late January 2008.



Resolution #9 (continued)

March 2008

The MEDMARX Data Summary was launched January 29, 2008. Analysis of more than 26,000 records with look-alike and/or sound-alike drug names indicates that the risk of a medication error increases with similar drug names. The report also includes a drug name pronunciation guide from the USP Dictionary of USAN and International Drug Names. Briefings were conducted with interested USP member organizations. Dr. Abernethy and Ms. Cousins briefed the media on the implications of the report on consumers and health professionals. Broad based press and media coverage resulted from the distribution of this year's report. An online program for searching drug name pairs involved in look-alike and/or sound-alike medication errors and their relating severity is in production and will be available in early Spring.

The final report on the USP conference on medication error reporting programs funded through a grant from the Agency for Healthcare Research and Quality was submitted in February. An article for publication is being prepared from the proceedings.

The Medication Errors Advisory Panel has completed a paper entitled *Bringing MEDMARX to the Point of Care: The Inclusion of a Case-based Component on High alert Medications in the Present MEDMARX System*. This paper is being reviewed in-house to determine appropriate journal submission. An online interactive tool that will assist healthcare practitioners with the required development of a "list" of high alert medications by location within the healthcare setting, that they need to create for accreditation purposes is in development and will be available in late spring.

The General Chapter on *Physical Environments that Promote Safe Medication Use* is in the "in-process revision" and will be ready for publishing in *Pharmacoepial Forum* prior to the SMU EC meeting schedule for May.

A survey for collecting Standardized Parenteral Concentrations (adult, pediatric, and neonatal) is being undertaken and will be e-mailed to more than 5000 Pharmacy Directors for their assistance in gathering this data.

June 2008

The Safe Medication Use Expert Committee is advancing a new General Chapter <1066> *Physical Environments that Promote Safe Medication Use* targeted for publication in the July-August *Pharmacoepial Forum* 34(4). USP is cosponsoring and hosting the **IV Safety Summit** with ASHP and 5 other national organizations for a day and a half meeting on July 14-15, 2008. The purpose of the Summit is to bring about changes that prevent further harm or death from intravenous medication errors. USP received more than 300 responses from Pharmacy Directors to its survey on Standardized Parenteral Concentrations. Results will be evaluated this summer by the Safe Medication Use Expert Committee. Finally, a Health Literacy and Prescription Container Labeling Advisory Panel was approved by the Chair of the Council of Experts, and the first meeting is being organized.

Resolution #9 (continued)

September 2008

USP was a co-convenor with the American Society of Health-System Pharmacists and 4 other national organizations to address IV safety at a summit held at USP headquarters on July 14-15. The summit called upon USP to create standardized drug libraries (to include standardized concentrations) for use in the implementation of technology in healthcare. The Safe Medication Use Expert Committee had identified the issue of non-standardized concentrations for IVs and conducted a survey of hospital pharmacy directors. More than 240 responses are being evaluated and the SMU aims to recommend such standards in the next year. A full comprehensive set of recommendations and best practices is forthcoming.

A Health Literacy and Prescription Container Labeling Advisory Panel has been formed. The Panel will be co-chaired by members of the Safe Medication Use Expert Committee, Dr. Joanne Schwartzberg (AMA) and Gerald McEvoy (ASHP). The first meeting is scheduled for December.

FDA held a public meeting on June 5-6, 2008 to discuss a Pilot Program to Evaluate Name Submissions. The pilot would enable pharmaceutical firms to evaluate proposed proprietary names and submit the data generated from those evaluations to FDA for review. The meeting discussed a concept paper that describes the logistics of the pilot program, proposed recommendations for carrying out a proprietary name review, and the way FDA intends to review submissions made under the pilot program. USP staff served on an expert panel to react to the proposal. The pilot includes a requirement for the industry to use databases of medication errors in order to assess the probability of name confusion. This could present an opportunity for USP's databases to become a source of such information. Staff continues to monitor.

For a second year, USP and the Institute for Safe Medication Practices are jointly conducting a series of educational workshops titled, *Using Data Effectively to Manage the Risks to Medication Safety*. Two of the 6 workshops scheduled in 2008 have already occurred. The workshops are sponsored in part by Cardinal Health, which provided a \$35,000 unrestricted grant for this purpose.

December 2008

The Safe Medication Use (SMU) Expert Committee published its first General Chapter <1066> Physical Environments that Promote Safe Medication Use in *PF 34(6)*. Targeted communications to practitioner organizations were sent out encouraging links to the chapter, which has been posted to USP's website to facilitate public review and comment.

Resolution #9 (continued)

Disposal: Since 2005, USP staff has closely monitored the many facets of this issue; participating in discussion groups and meetings to understand the environmental, regulatory, practice and industry implications of pharmaceutical waste and disposal. Current interest among stakeholders is high and the trend seems to be towards regulatory solutions, both at federal and state levels. There is an inter-agency task force of the US government involving EPA, DEA, FDA, and others. Recently, the President's Office of National Drug Control Policy (ONDCP) with the Department of Health and Human Services and the Environmental Protection Agency jointly issued new guidelines (*What Every American Can Do to Prevent Misuse of Prescription Drugs*), which are designed to reduce the diversion of prescription drugs, while also protecting the environment. The American Pharmacists Association recently did the same with its *Guidance on Proper Medication Disposal -- Use with Respect and Discard with Care*. A number of state governments seem to be considering bills to manage pharmaceutical waste and disposal, and DEA is reviewing its regulations within the context of take-back activities at the state level. Given these activities, USP has determined that a standards-setting approach to disposal would not contribute to any of the current solutions being undertaken. No further action on this element of Resolution 9 is planned in this cycle.

Projected Resolution Completion Date

This resolution is expected to continue throughout the cycle.

Resolution #10: 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.

Status of Resolution Implementation

March 2006:

Computerized Prescriber Order Entry (CPOE) is considered a long term project (3-5 years to complete) by the Safe Medication Use (SMU) Expert Committee. The SMU has established a nine-person CPOE subcommittee to gather pertinent information for subcommittee consideration and report to the SMU. Staff continues to work with Academy of Managed Care Pharmacy (AMCP) to develop recommendations on how the information from the drug-drug interaction project will be disseminated. USP's new Therapeutic Decision Making (TDM) Expert Committee will be consulted to determine if further projects are feasible/advisable.

September 2006

The Therapeutic Decision Making (TDM) Expert Committee will address this resolution when it meets. The EC will discuss potential relationships between this resolution and current medication therapy management (MTM) activity ongoing among national pharmacy associations and whether USP could make a unique contribution.

January 2007

USP's Safe Medication Use Expert Committee has a Subcommittee working on uniform information availability for e-prescribing and pharmacy computer systems with a focus on human factors consideration. The Subcommittee's initial work will be recommendations for the standardization of order set presentation. This may include items such as the fonts, line colors, column presentation, capitalization, abbreviations, decimals, dosage designation, and other ways in which information is presented.

The Subcommittee also plans to work with other Expert Committees to explore a 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. This would include prioritizing alert information to end users based upon these data's evidence and clinical importance.

April 2007

Nothing new to report.

June 2007

Nothing new to report.

Resolution #10 (Continued)

December 2007

The Safe Medication Use Expert Committee's Subcommittee assigned this topic continues to consider ways in which USP could make a contribution. They are focusing on an assessment of work already in process among other organizations so as not to duplicate efforts.

March 2008

The Safe Medication Use Expert Committee is currently identifying organizations and vendors for potential data and application standards within 3rd party CPOE software which reduce either the severity or frequency of medication errors generated while using CPOE systems. Analysis of MEDMARX data to identify actions taken in error reports involving CPOE is being undertaken. Research into existing data standards used by CPOE vendors (i.e., McKesson, Eclipse, Cerner, Cardinal Health, Epic) is also commencing.

June 2008

Nothing new to report at this time.

September 2008

USP, in a joint venture with the Brigham Center for Patient Safety Research and Practice, will provide MEDMARX data on CPOE errors for analysis in an effort to improve CPOE systems. The analysis will allow investigators to recreate selected CPOE error "scenarios" on various CPOE systems to determine whether the errors would be "possible" and how easily it could occur with the particular system. The research has the potential to offer USP's Safe Medication Use Expert Committee and the Expert Committee's Data Analysis Advisory Panel as many as six distinct opportunities for standards-setting and/or practice recommendations.

December 2008

Nothing new to report.

Projected Resolution Completion Date

This resolution is expected to continue throughout the cycle.

Resolution #11: 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.

Status of Resolution Implementation

March 2006:

President Abernethy appointed fifteen members to the Council of the Convention (COC) in September 2005. Two planning teleconferences and a first face-to-face meeting have been held thus far. The Council has developed a preliminary concept proposal, which will be formally presented to the Board of Trustees for approval in June. The members of the Council of the Convention are:

Darrell R. Abernethy, M.D., Ph.D., President, USP Convention and CoC Chair
Lloyd V. Allen Jr., Ph.D., University of Oklahoma School of Pharmacy
Lowell Anderson, R.Ph., D.Sc., Federation Internationale Pharmaceutique, Member at Large
Joseph W. Cranston, Ph.D., American Medical Association
Enrique Fefer, Ph.D., Honorary Member
Rita Munley Gallagher, Ph.D., R.N., American Nurses Association
Gordon Johnston, R.Ph., Generic Pharmaceutical Association
Marvin M. Lipman, M.D., Former Public Trustee, Member-at-Large
Lucinda Maine, Ph.D., American Association of Colleges of Pharmacy
Paul M. Schyve, M.D., Council Vice-Chair, Former Medical Science Trustee, Member-at-Large
Rebecca P. Snead, R.Ph., State Pharmacy Associations
Stephen P. Spielberg, M.D., Association of American Medical Colleges
Joseph G. Valentino, J.D., Honorary Member
Susan C. Winckler, R.Ph., Esq., American Pharmacists Association
Roger L. Williams, M.D., USP Executive Vice President–CEO

September 2006

The CoC presented for Board review on June 25, 2006, a framework concept for restructuring the Convention membership. The Board provided guidance on various aspects of the proposal and the CoC redrafted its proposal for Board review at its September 2006 meeting in Denver. Basically, the concept of sections was accepted by the Board, as long as member activity within the sections was focused on providing insight and developing creative approaches to strategic issues relevant to USP.

January 2007

The Council of the Convention (CoC) will meet via teleconference in January and receive the September comments of the Board. The CoC will discuss a potential pilot section activity in conjunction with the Annual Science Meeting in 2007, and mechanisms to communicate with the membership. Ms. Winckler resigned the CoC when she left APhA for a position at the FDA as Chief of Staff.

Resolution #11 (continued)

April 2007

The Council of the Convention (CoC) at its January teleconference formally endorsed a plan to roll out the sections concept. The roll out calls for milestone activities over the remainder of the 2005-2010 cycle focused on advancing the issues and concerns of USP stakeholders into concepts and ideas for Convention action and input at the 2010 meeting. As a first step, the CoC will expand to its full complement of 25 members. The following individuals have been appointed thus far and assigned to topic areas.

Christopher K. Allen, R.Ph., MPH, Centers for Disease Control and Prevention

Colleen E. Brennan, R.Ph., National Community Pharmacists Association

Thomas R. Clark, R.Ph., American Society of Consultant Pharmacists

Mary H. Hager, Ph.D., R.D., American Dietetic Association

Catherine M. Polley, B.S. Pharm., American Pharmacists Association

Frederick Razzaghi, Consumer Healthcare Products Association

Kathleen Weaver, M.D., Oregon Medical Association

These new appointees and current CoC members will convene at the Spring Governance Meeting with stakeholders in the respective topic areas.

June 2007

During the Spring Governance Meeting, CoC members received presentations about stakeholder forums and other related USP activities related to the five section topic areas approved by the CoC. The CoC will meet again June 28 to determine the scope of the section activities and the roles and responsibilities of the sections and the CoC. The CoC has been invited to participate at the Annual Science Meeting in September.

December 2007

Dr. Bravo has taken over leadership of the Council of the Convention (CoC) and has communicated personally with all of its members. There are five vacancies on the CoC and staff is working with CEO and Dr. Bravo to fill them. Two new members have been identified and will be presented for approval by the Board at its December meeting. Approximately half of the CoC membership attended the Annual Scientific Meeting in Tampa and held a business meeting there. At that meeting, the CoC finalized the Rules and Procedures for the Convention Sections which is also being presented for Board approval in December. Each section now has a volunteer chair and once the Rules are approved sections will begin to develop workplans and calendars for the new year.

March 2008

There remain only two vacancies on the Council of the Convention (CoC), and one of those has been allocated for the delegate from the American Pharmacists Association. During the Spring Governance Meeting the sections will attempt to finalize their workplans based on the Board's new draft strategic plan and the workplans of the Council of Experts. Additionally, the CoC will work on strategies for communicating USP's priorities to the various communities of interest within the Convention and consider potential activities that may be needed to further engage members in support of USP's work. It is anticipated that sections will hold separate meetings between the biannual meetings of the CoC.

Resolution #11 (continued)

June 2008

May 17-18, 2008, Council of the Convention Section Chairs, Drs. Bravo, Mauger, and Williams will attend the World Health Professions Alliance Conference on Regulation in Geneva on behalf of the USP Convention. During May and June, the CoC sections are holding individual teleconferences to finalize a communications campaign to Convention members, including selection of topics, mechanisms and a timeline.

September 2008

The Council of the Convention (CoC) Section teleconferences were held and based on discussions a communication matrix was created incorporating the priorities of each Section. The campaign was launched in July with a personal letter from Dr. Bravo. The CoC will meet by teleconference on August 27 to review the matrix and determine the next major campaign element (potentially the *Report to the Convention* being compiled by Corporate Communications), as well as subsequent vehicles through the end of the calendar year. The CoC will meet next at the Annual Scientific Meeting in Kansas City to determine the foci of Section white papers to be developed for deliberation at the 2010 Convention, Constitution and Bylaws amendments, and discuss next steps for the communications campaign..

December 2008

The *Mid-Cycle Report to the Convention* was mailed to all member organizations and individual delegates in October with constituent-specific cover letters signed by Drs. Bravo and Williams. The CoC also formed a subgroup, which Dr. Bravo appointed as the Constitution and Bylaws Committee for the 2010 Convention. Three CoC sections (Quality of Food Ingredients and Dietary Supplements, Quality of Compounded Medicines, and the Quality of Patient Care) will deliver communications in the next quarter. The following are white paper topics identified by the various sections for development and dissemination to the Convention as thought pieces for resolutions:

- Manufactured Medicines -- Counterfeits and Substandards
 - What can pharmacopeias do?
 - Research to support anti-counterfeiting initiatives
 - Global bioequivalence/pharmaceutical equivalence
- Compounded Medicines -- Standards and Conformity Assessment: A Practitioner- and Government-based Model System
- Food Ingredients and Dietary Supplements -- Food, Food Ingredients, Functional Foods, Dietary Supplements: A Landscape for Standards and Conformity Assessments
- Patient Care -- Medicines, Patient Care, and the Role of USP
- Global Public Health -- Food and Drug Information Needs in the Global Community

Projected Resolution Completion Date

This resolution is expected to continue throughout the cycle.

Resolution #12: 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.

Status of Resolution Implementation

March 2006:

In implementing this resolution staff also considered priorities as they relate to USP's international strategy. Staff has carefully restructured the approach to this cycle's Prescription/ Nonprescription Stakeholder Forum (P/NP SF) and established a P/NP SF-member planning committee that will function as a strategic planning body for the P/NP SF and also serve as a project team steering committee.

All project teams emanating from the P/NP SF will be formed in alignment with the workplans of the Council of Experts Expert Committees and grouped into four categories; Monographs, General Chapters, Biologics and Biotechnology, and Process (Project Team 19 – Compendial Process Improvement – has been reformed to provide input on this resolution). Plans are in place to hold Stakeholder Forums on Compounding, Patient Safety, and Biologics/Biotechnology. USP is considering Stakeholder Forums on Excipients, Veterinary Products and Information, and Dietary Supplements, as well as the possibility of establishing a consortium of quality and standards-setting organizations that would partner with USP to enhance the content of the *USP-NF*. Finally, USP has increased its efforts to reach out to and engage key stakeholders in the standards setting process, including observer invitations to Expert Committee meetings relevant to the stakeholders.

September 2006

USP has formed eight (possibly nine) Project Teams, including the following:

1. Compendial Process Improvement (formerly Project Team 19)
2. Inorganic Impurities/Heavy Metals
3. USP Monographs
4. Residual Solvents
5. Full-length Vaccine Monographs for *USP-NF*
6. Compendial Calculations
7. *USP-NF* General Notices
8. General Chapters
9. Compounding (considering)

USP hosted the Compounding Stakeholder Forum in June 2006, and will be hosting the Patient Safety Stakeholder Forum in October 2006. USP also is engaging stakeholders around the world:

1. India Stakeholder Forum and Annual Scientific Meeting (February 2006)
2. China Symposium (October 2006)
3. Latin America Scientific Meetings (Mexico, March 2007; Brazil, May 2006 and 2007)
4. Europe (December 2005 and 2006)
5. Middle East/Africa (Jordan (September 2006; Egypt September 2006)

USP is collaborating with B&B partner laboratories to develop horizontal and vertical standards.



Resolution #12 (Continued)

January 2007

In October 2006, USP cosponsored with the American Association of Veterinary Pharmacology and Therapeutics a workshop prior to the AAPS meeting on veterinary drug standards development. In November 2008 USP presented to the governing Board of the Animal Health Institute (AHI) on the value of collaborating with USP on drug standards. Also in November, AHI held a meeting where a USP Expert Committee volunteer presented on USP activities in the area of vaccines.

April 2007

In February 2007 the Council on Biologic and Therapeutic Agents (COBTA) of the American Veterinary Medical Association (AVMA) invited USP to present on three separate veterinary topics and participate in a panel discussion. The topics were: Compounding, USP Development of Veterinary Biopharmaceutics Classification System, and legal issues vis-à-vis veterinary compounding. In May, USP presented at the AAVPT meeting and also conducted outreach to the veterinary drug industry in Brazil. While in Brazil, staff also met with Brazilian regulatory authority on vet drugs.

June 2007

So far this year USP has convened stakeholders in India, Mexico, and Europe. USP also held the Food Additives Stakeholder Forum (first-ever) and the Dietary Supplements Stakeholder Forum (first for this cycle) in reaching out to new audiences. Plans are underway for the next stakeholder forum, which will be a Middle East Annual Scientific Meeting.

December 2007

An Annual Scientific Meeting (ASM) was held in Jordan and was well attended. An ASM is being planned for Hyderabad, India in February 2008.

March 2008

Staff again presented at the Council on Biologic and Therapeutic Agents (COBTA) of the American Veterinary Medical Association (AVMA) in February 2008. Also, staff has reached out to the Generic Animal Drug Association (GADA), which is quite small, has no paid staff, with most of its member companies located in the Midwest. GADA would like USP to speak to its Board about USP's standards setting activity and GADA has agreed to send out information about USP's upcoming Annual Scientific Meeting in Kansas City, at which USP will host several sessions on Veterinary Medicine. Kansas City is home to a number of veterinary drug manufacturers. In addition, USP is undertaking many activities in the biologics and biotechnology field through the efforts of new Chief Reference Materials Officer William Koch and Biologics and Biotechnology (B&B) Director Tina Morris. USP also held its Annual Scientific Meeting in India February 6-7, in Hyderabad, India, featuring a B&B track.

The only group covered by this resolution to which USP has not reached out is device manufacturers.

June 2008

USP continues to reach out to industry representatives throughout the five regions of the world through its Annual Scientific Meetings and Stakeholder Forums. Recently completed is the European Stakeholder Forum at which USP discussed compendial issues with members of the European industry. Topics included Heavy Metals, Genotoxic Impurities, Certification programs, and metrology. Plans are underway to co-host workshops with the Center for Biologics Evaluation and Review, the Institute for Pediatric Innovation, the American Association of Veterinary Pharmacology and Therapeutics and the Society of Nuclear Medicine.



Resolution #12 (Continued)

September 2008

USP is developing collaborative relationships with several organizations involved in veterinary healthcare, including the Society of Veterinary Hospital Pharmacists (for developing standards and information for compounded preparations), the Generic Animal Drug Alliance (for veterinary drug standards and related activities), the Veterinary Information Network (for veterinary drug information and related activities), and the American Association of Veterinary Medical Colleges (for related veterinary drug programs and related initiatives). USP will co-sponsor a workshop with the American Academy for Veterinary Pharmacology and Therapeutics in October 2008 on topic of antibiotics use in companion animals. In addition, the 2008 USP Annual Science Meeting will have a separate track on quality issues associated with veterinary drugs, which, it is hoped, will provide additional opportunities for USP to interact with the veterinary community.

USP held the first meeting of the Brazil Stakeholder Forum on August 19, 2008, at the new USP-Brazil facility. Approximately 20 attendees from the Brazilian pharmaceutical industry, food and dietary supplement industry, and academia attended. The hot topics that emerged included:

- Reference Standards
 - Importing, access
 - Material tracking
 - Metrologic traceability
- Training programs
 - Traditional USP information
 - Dietary supplements, herbal medicines
 - Available beyond Sao Paulo
- Increased communications, technical support, call center
- Certification programs (Imports and Brazil-manufactured)
- Compounding
 - Quality defined by process
 - USP monographs are used, reference materials are not
 - Compounding vs. manufacturing
- Procedures (what's acceptable, what's equivalent, what's better?)
- Tests (public, private, both for the ingredient and product)

December 2008

USP held its annual “week of meetings” in China, which included a meeting of the USP-China Advisory Panel and invited stakeholders, a Joint Symposium with the Chinese Pharmacopoeia (ChP), a series of meetings related to the MOU with ChP, and a meeting with the National Institute for the Control of Biological Products regarding a MOU with them to elaborate Reference Standards. USP also hosted a workshop of the American Academy for Veterinary Pharmacology and Therapeutics in October.

Projected Resolution Completion Date

This resolution is expected to continue throughout the cycle.

Resolution #13: 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.

Status of Resolution Implementation

March 2006:

USP continues to participate actively in the Pharmacy Compounding Accreditation Board and attends quarterly meetings of the Joint Commission of Pharmacy Practitioners in order to assess opportunities to collaborate. As the implementation of resolutions evolves, more opportunity for pharmacy and other health professional organization interaction is expected, particularly for Resolutions 4 (Compounding), 5 (Nomenclature and Labeling), 8 (Drug Information), and 9 (Safe Medication Use and Disposal). Continued assessment of content for the Pharmacists' Pharmacopeia and planned line extensions to the *USP-NF* offer other potential opportunities to engage health professions. Practitioner participation in the Prescription/Nonprescription Stakeholder Forum has been recommended by P/NP participants and USP will attempt to coordinate this for a future forum meeting.

September 2006

USP's Compounding Stakeholder Forum (held in June) was a successful conclusion to a very comprehensive campaign to engage pharmacy in providing comments on the proposed revision of Chapter <797>. Similar outreach to national practitioner organizations will occur in connection with the Patient Safety Stakeholder Forum scheduled for October 2006. Also, Staff met with American Society of Health-System Pharmacists and discussed a number of areas of synergy/collaboration. USP is in the process of recasting its Fellowship Program to provide opportunities for practitioners to work in more meaningful ways with USP. The thought is to use grants to help build relationships and at the same time advance USP's research and information agenda.

January 2007

USP contributed \$25,000 to the Joint Commission of Pharmacy Practitioners (JCPP) to fund implementation of JCPP's vision. Among JCPP's full and liaison membership are seven pharmacy organizations that USP has identified as strategically important (all of which are Convention member organizations.) USP has put into place a number of mechanisms to engage pharmacy and other healthcare professionals in its activities. With the reorganization that has created the Healthcare Quality and Information Department such interactions should become the norm.

April 2007

Relationships with the pharmacy practitioner community are well established through a number of individual organization and conclave activities. USP consistently reaches out at the right time to engage practitioners around USP initiatives and these organizations come to USP regularly for collaboration. As USP strategically considers its practitioner programs, the medical and nursing practitioner communities also should be engaged more fully. USP contributed \$30,000 to the Pharmaceutical Science World Congress 2007 which convenes under the aegis of the International Pharmaceutical Federation (FIP). This contribution categorized USP as a "sponsoring" organization garnering a large amount of visibility at this international conference.



Resolution #13 (continued)

June 2007

Both national and state pharmacy organizations are reaching out to USP on a regular basis as a result of USP's very strong and focused efforts to build relationships in the first half of this cycle. With the publication of revised Chapter <797> in early FY08, USP will once again launch a comprehensive outreach campaign to inform compounding professionals of the implications the new chapter may have on their practice. Additionally, staff in Pharmacopeial Education, Healthcare Quality and Information, Legal, and Member and Professional Relations are exploring the possibility of creating a PE course for practitioners on the application of the *USP-NF* to pharmacy practice.

In July for the first time, staff will attend the American Association of Medical Society Executives (AAMSE) Annual Meeting as a first step in exploring a strategy to engage the medical society community.

December 2007

USP continues to maintain its relationships with the pharmacy community through attendance at various national association meetings; e.g., USP presented at the recent National Alliance of State Pharmacy Associations meeting on the topic of counterfeiting. Materials provided by USP along with the presentation will be used for continuing education for pharmacists and pharmacy technicians. In addition, staff is focusing efforts on engaging the medical community. The Association of American Medical Colleges president, Dr. Darrell Kirch has agreed to reach out to US deans to encourage their participation in the USP Convention and staff is developing recruiting tools to use for follow up with the schools as well as contact with medical societies.

March 2008

A brochure was developed, *U.S. Pharmacopeial Convention and the Medical Community* and was delivered with Dr. Kirch's letter the week of February 18. Staff will conduct personal follow up with the deans to ensure appointment of their USP delegate. In addition, Association of American Medical Colleges' flagship newsletter, *The Report*, has invited an op-ed piece from Dr. Williams to highlight the value of USP to academic medicine and public health.

June 2008

Dr. Williams' article ran in *The Reporter*, and several deans have appointed delegates. Staff is planning an outreach event at the 2008 Association of American Medical Colleges, similar to those held in the pharmacy community, in an effort to speak directly to the medical community on the value of USP. American Medical Association CEO, Michael D. Maves, M.D., MBA, sent a letter on behalf of USP encouraging executives of all state medical associations to appoint their delegates promptly.

September 2008

Academic medicine appointments have risen 13% since March 2008 due to a concerted effort by USP staff, and overall appointments are at their highest level in this cycle. It is hoped that this emphasis on recruiting along with the Council of the Convention's communication campaign will help to engage previously nonresponsive constituencies. Emphasis will continue for the medical community, although a hoped-for event at the Association of American Medical Colleges annual meeting will not be possible this fiscal year. For FY09 initial outreach will begin in the foods community.

Resolution #13 (continued)

December 2008

USP has reached out through direct communication to the practitioner community to elicit comment on a recently published General Chapter <1066> *Physical Environments that Promote Safe Medication Use*. In order to facilitate input from pharmacy and other healthcare practitioner communities, the chapter is posted on the web page and online comment capability provided there.

Projected Resolution Completion Date

Because this resolution calls for regular and ongoing interaction, USP stall will continue throughout the cycle to look for opportunities to engage other healthcare professionals.