



## Report of the Executive Vice President and Chief Executive Officer

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This report provides USP Convention Members—core stakeholders of the organization—an overview of the 2000–2005 cycle. It is divided into six parts: I–Overview; II–USP Volunteers; III–USP Staff; IV–USP Products and Services; V–USP Processes; and VI–the Future. The report focuses on the Who, the What, and the How of USP. The standards-setting activities of the Council of Experts—the core work of USP—are provided in a separate report. A further group of USP volunteers was established in the 2000–2005 cycle. These are individuals participating in Stakeholder Forums and Quality Communication Groups. The activities of these groups are also summarized in the report of the Council of Experts.

### **I. Overview: State of the Pharmacopeia—2000-2005**

Since its inception in 1820, with publication of the first volume of the *Pharmacopeia of the United States of America (USP)*, the United States Pharmacopeial Convention, Incorporated (USP), periodically has undergone transformative changes.<sup>1</sup> USP's ability to evolve over time and adapt to the changing demands of its environment are key strengths of the organization. Examples include: 1) the rise of USP as a national pharmacopeia, based on the dedication of early volunteers; 2) the need for better control of the US marketplace for food and drugs, embodied in the 1848 Drug Import Act, which recognized the USP and other pharmacopeias<sup>2</sup>; 3) the transition from process (preparation recipes) to product standards (tests, procedures, acceptance criteria) in USP, led by Charles Rice in the latter part of the 19<sup>th</sup> century<sup>3</sup>; 4) the 1906 Pure Food and Drug Act, which named USP as an authoritative standard against which drugs were to be tested for adulteration; 5) the passage of the Federal Food Drug and Cosmetic Act (FDCA) in 1938, which names *USP* and *NF* as official compendia of the United States and specifies what aspects of *USP* FDA can enforce; 6) USP's role in drug information, which began in 1975 and concluded in 2004—and may begin again through the Model Guidelines provisions of the Medicare Modernization Act; 7) the subsequent amendments to the FDCA, especially the 1984 Drug Price Competition and Patent Term Restoration amendments (Hatch–Waxman); 8) advances in analytical capability, with an emphasis on instrumental techniques (chromatography) that rely on comparator chemicals (official USP Reference Standards); 9) the rise in modern manufacturing and globalization of the pharmaceutical industry, coupled with transnational harmonization efforts in the International Conference on Harmonization and the Pharmacopeial Discussion Group, and the emergence of the intergovernmental European Pharmacopeia; 10) the rise in FDA's power and authority, with attendant rules protecting confidential commercial and trade secret information; 11) the continuing debate between innovation and access, with strong

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<sup>1</sup> As a 501(c) corporation working in the public interest, USP's formal name is the United States Pharmacopeial Convention, Incorporated, abbreviated without italics as USP. USP's primary products are the *United States Pharmacopeia* and *National Formulary*, abbreviated with italics as *USP–NF*. The formal name of *USP* is also the *Pharmacopeia of the United States of America* (see the USP Constitution, Article I, Sections 1 and 2).

<sup>2</sup> Heath WJ. America's first drug regulation regime: the rise and fall of the import drug act of 1848. *Food Drug Law J.* 2004;59:169–199.

<sup>3</sup> Wolfe HG. Charles Rice (1841–1901), an immigrant in pharmacy. Paper presented at: Joint meeting of American Pharmaceutical Association and American Institute of the History of Pharmacy; April 1949; Jacksonville, FL; available in Convention Member Notebook.



support at times for intellectual property protection as a means of promoting access to new medicines. These national and transnational trends, and many others, both challenge and create opportunities for USP. They emphasize that, although USP operates independently, it nonetheless is closely allied, as a national pharmacopeia, with pharmaceutical and dietary supplement manufacturers, compounding professionals, and FDA.

All cycles of USP are necessarily transformative, but the events of the 1995–2000 cycle and the current cycle—the topic of this report—seem especially so. The 1995 cycle brought several management challenges to light, primarily through the McKinsey report.<sup>4</sup> The current cycle—a turbulent one—brought understanding about how the McKinsey challenges might be solved. The continuing challenge and opportunity for USP in the 2005 to 2010 cycle will be to build on these emerging solutions. Given the subtle and sometimes not-so-subtle transformations regarding the availability of therapeutic products in the U.S., USP now confronts perhaps its greatest challenge, which is how to better serve the international community of practitioners and patients while remaining committed to practitioners and patients in the U.S.—to the extent these U.S. practitioners desire and support this commitment. This challenge is expressed thoughtfully in a *Stimuli* article prepared by the USP Council of Experts and staff, which is available in the Miscellaneous section of the Convention Member Notebook, together with a summary of public comments and USP's responses.<sup>5</sup> It promotes the idea that USP can create a separate compendium to serve international practitioners in providing good pharmaceutical care. Should USP pursue this possibility, with the approval of the USP Board of Trustees, it is likely to be one of USP's most transformative changes.

And underlying this possible change is an even deeper challenge, which is the public availability of quality information. Quality information in this context refers specifically to the stipulations of a *USP–NF* monograph, which undergirds the safety and efficacy information that appears in approved product labeling. Although USP strongly believes this triad of quality, safety, and efficacy information needs to be in the public domain, with frequent updating, the U.S. has to some extent turned away from the public availability of quality information, which are the product standards espoused by Charles Rice in the nineteenth century. As this report will show, *USP–NF* is missing many monographs and, of those that exist, many need updating. The reasons for this relate to the complex transformations cited in the first paragraph of this report. They reflect reduced interest on the part of pharmaceutical manufacturers in submitting voluntary information in a Request for Revision. Yet USP believes—and is founded on the notion—that public monographs—and corresponding official USP Reference Standards, developed through USP's independent collaborative testing process, when needed—are critical for the public trust. The challenge for Convention Members is clear: If Members do not value these public standards—both documentary (monographs) and physical (official USP Reference Standards)—USP's task becomes more difficult and perhaps, ultimately, impossible.<sup>6</sup>

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<sup>4</sup> McKinsey & Company. Redefining the Strategy and Organization for Accomplishing USP's Mission: Final Progress Review. Rockville, MD: US Pharmacopeia; September 30, 1997.

<sup>5</sup> Council of Experts Executive Committee, Ad Hoc Council of Experts Committee, and USP Staff. Development of a new official compendium, separate from *USP–NF*, for articles not legally marketed in the U.S. *Pharm Forum*. 2004;30(5):1877–1894; Meeting Notes. Meeting on *USP–International* and India Site. USP Headquarters. 10 December 2004; de Mars S, Schuber S, Singh E, Williams RL. *USP International—Responses to Comments on Stimuli Article*. *Pharm Forum*. In press.

<sup>6</sup> Bhattacharyya L, Cecil T, Dabbah, R, et al. The value of USP public standards for therapeutic products. *Pharm Res*. 2004;21(10):1725–1731.



*USP–NF* and official USP Reference Standards—and associated products and services—provide independent support and thus enhance the public trust of therapeutic articles legally marketed in the U.S. Under a name, the monograph contains information, labeling instructions, and a specification (tests, procedures, acceptance criteria) that allow first (manufacturers), second (purchasers), or third (independent bodies/others) parties to evaluate the quality of a therapeutic article.<sup>7</sup> The evaluation usually assesses the strength or potency of the active ingredient in the drug, biologic, or dietary supplement substance in terms of mass or units. One can also assess a corresponding pharmaceutical dosage form or dietary supplement product in the same way and further, using the USP Performance test (e.g., dissolution or disintegration), determine whether the active ingredient is properly leaving the dosage form or product. Many pharmacopeial tests also control other components in a therapeutic article, including undesirable ones such as impurities. These are at heart simple yet powerful concepts. If the article when tested meets the stipulations of the monograph then it documents unequivocally that the article is what it purports to be, is fit for this purpose, and is so named. The approach directly corresponds to the enduring mission of USP, as stated in the preface of the first pharmacopeia of 1820 (*USP 0*), which states:

It is the object of a Pharmacopoeia to select from among substances which possess medicinal power, those, the utility of which is most fully established and best understood; and to form from them preparations and compositions in which their powers may be exerted to the greatest advantage. It should likewise distinguish those articles by convenient and definite names, such as may prevent trouble or uncertainty in the intercourse of physicians and apothecaries.

As the McKinsey report noted, USP’s primary work is the elaboration of *USP–NF* and the provision of official USP Reference Standards. Throughout the cycle, USP has worked to both focus and amplify products and services that relate to this core activity. The overall effort results in USP’s products and services, produced through tactical programs that operate according to the Board of Trustees’ five strategic objectives. These include: 1) official text in *USP–NF* and associated authorized text by the Council of Experts, including the new *USP Pharmacists’ Pharmacopeia*<sup>8</sup>; 2) official USP Reference Standards developed through independent testing with multiple laboratories and subject to final endorsement by the Reference Standards Committee of the Council of Experts; 3) USP’s verification programs, which now focus on dietary supplements ingredients and products, with planned extension to other articles; 4) USP’s information programs; and 5) and USP’s patient safety programs.

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<sup>7</sup> National Institute of Standards and Technology. *Federal Register*. 10 August 2000;65(155):48894–48902.

<sup>8</sup> USP distinguishes between official and authorized text. The latter accounts for informational text “prepared in accordance with the rules and procedures adopted by the Council of Experts, or otherwise by direction of the Board of Trustees” (USP Constitution, Article 1, Section 2; cf. Appendix III, Glossary of Terms, “Authorized Publication” and “Official Compendium,” the latter comprising *USP–NF*, *Supplements*, *Interim Revision Announcements*, etc.).



## II. USP Volunteers

### *The USP Convention: Delegates/Members*

USP's Convention Members are divided into the following nine categories: 1) U.S. colleges of pharmacy and medicine; 2) state medical and pharmacy associations; 3) national professional and scientific organizations; 4) governmental bodies; 5) foreign organizations and pharmacopeias; 6) consumer organizations; 7) manufacturers, trade, and affiliated organizations; 8) members at large; and 9) honorary members. Key Convention Committees number four: the Nominating Committee for Officers and Trustees, the Nominating Committee for the USP Council of Experts, the Resolutions Committee, and the Constitution and By-Laws Committees. Reports of the four committees are provided separately in Convention Member Notebooks. In this cycle, USP focused on ways to better include core constituencies in the operations of USP. These begin with a series of meetings at USP that focus on the following topics (dates): 1) Information exchange between practitioner/consumer organizations and USP (September 2001); 2) Preparing for the biotech pipeline explosion: key issues and impacts/Impact of IT on life sciences and health: global and local (December 2001); 3) The Health Insurance Portability and Accountability Act (April 2003) 4) Patient safety (December 2002). Out of these meetings arose the idea that a Council of the Convention might better involve USP's core constituencies—and all Convention delegates—in the activities of USP in the intervening years of a cycle. The idea became a means of addressing Resolution 18 from the 2000 Convention (see Convention Member Notebook) and was developed through the work of an ad hoc Convention Resolution 18 Committee. A background document for the work of this Committee is provided in the Background section of the Convention Member Notebook. At the 2005 Convention, Convention Members will be asked to vote on Constitution and By-Laws changes that allow the creation of a Council of the Convention.

### *The USP Board of Trustees*

The Board met 21 times during this cycle; its first meeting convened in April 2000. It began with four standing committees (the Audit, Compensation & Continuity, Executive, and Investment Committees) and added a fifth (Governance). The resolutions of the 2000–2005 Board numbered 95. The Board concluded a 2003–2005 Strategic Framework, which is provided in the Convention Member Notebook. During this Convention, the Chair of the Board of Trustees will provide a summary presentation about the work of the board.

### *The USP Council of Experts*

A report of the accomplishments of the Council of Experts in the 2000–2005 cycle is provided separately to Convention Members in the report of the Chair of the Council of Experts.

### *Stakeholder Forums and Quality Communications Groups*

A report of the accomplishments of these new volunteer groups during the 2000–2005 cycle is provided separately to Convention Members in the report of the Chair of the Council of Experts.

### III. USP Staff

Approximately 55 years ago, USP was an all-volunteer organization with no staff. USP’s first staff member was Dr. Lloyd Miller (1950 to 1970). USP staff has grown substantially, especially during the past 15 years, as USP’s opportunities and responsibilities have increased. Organization of staff at USP undergoes frequent change, reflecting USP’s growth and expansion/focus of the organization’s public health organization opportunities. The final organization chart for the cycle (Figure 1) indicates the chief officers for science, business, legal, and finance/accounting, a possibility that arises as a result of a proposed Constitution and Bylaws change that Members are asked to endorse at this Convention.

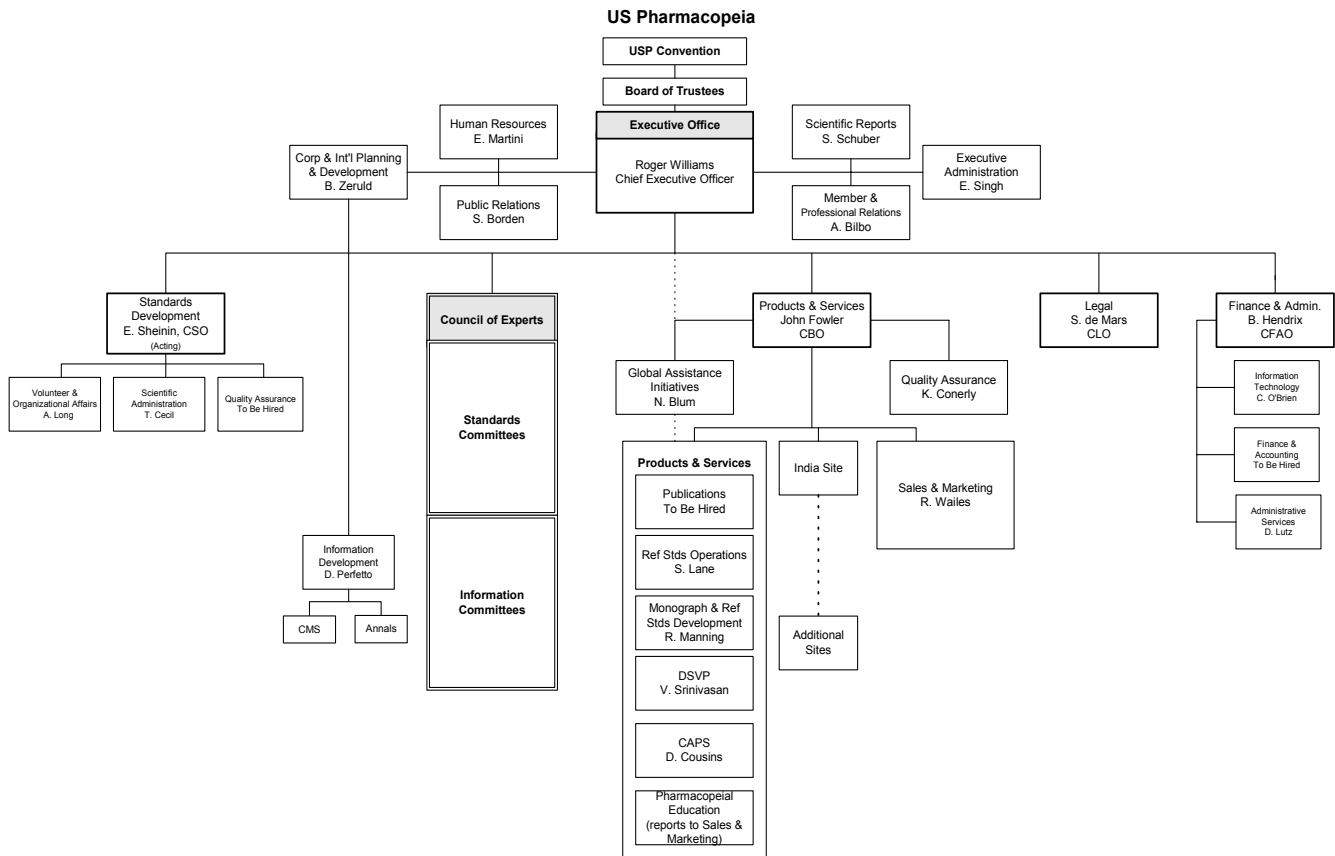


Figure 1

Figure 1 depicts a developmental part of the organization—the Department of Standards Development and Department of Information Development—to the ‘left’ of the Council of Experts. The Council of Experts’ activities are located in the center, acknowledging that USP’s core activity is standards-setting. Interestingly, the American Society for Testing and Materials has pointed out that the U.S. is unique in having two broadly defined types of standards: mandatory and voluntary, the former typically set by government and the latter involving voluntary participation by stakeholders who have an interest in the use and applications of the



standard.<sup>9</sup> To the ‘right’ are departments that develop, plan, implement, market, and sell USP’s products and services that arise in connection with USP’s standards-setting activities. Even farther right are business units—legal, finance, accounting, information technology—that undergird all of USP’s activities. The segment of this report that follows reviews this structure, covering first units that support all of USP’s activities, followed by those that support the Council of Experts, those that support USP’s products and services, and finally those that represent the business units of USP: legal, finance, accounting, and information technology.

### Departmental Units in Support of All USP Activities

*Corporate and International Planning and Development:* As a 501(c)(3) organization, incorporated in the laws of the District of Columbia, USP operates as a non-profit body working to promote the public health. Its primary activity is to elaborate the *USP-NF* and to develop and maintain, where needed, official USP Reference Standards. With income from the sale of these products, USP offers additional products and services to the healthcare community as a means of promoting the public health. These offerings are tactical programs that evolve according to the 2003-2005 Strategic Plan of the USP Board of Trustees. Based on the efforts begun by the McKinsey evaluation and with strong Board of Trustees oversight and interest, USP developed a comprehensive approach to planning and budgeting. A critical aspect to this approach was establishing the Corporate Planning and Development group in December 2001 to manage USP's business planning process. The planning and budgeting process begins with detailed situation analyses and environmental scans in the mid part of USP’s annual fiscal year (July 1 to June 30). Thereafter, an interactive process between staff and Board of Trustees results in identification of specific activities and creation of a final budget concluded by the end of the fiscal year. Working with the Department of Finance, Corporate Planning and Development staff execute a continuous activity throughout the year that monitors and assists implementation of tactical programs and develops new programs as well. Development of new tactical programs involves information gathering (research through surveys, reports, web and other searches) and analysis as a means of building business plans for a new tactical program or in support of evolution of an existing one. These plans undergo review and resource allocation by USP’s Department of Finance, USP's Senior Management Group, and then by USP’s Board of Trustees. As the organization has evolved these last few years, so too has the role for this department. Now entitled Corporate and International Planning and Development (CIPD), this department has been expanded to include new product development, corporate market research, and international business and corporate development. In addition, this department has directed USP's efforts relative to the Model Guidelines for the Medicare Prescription Drug Benefit. As USP's reach expands to new areas (whether they be new domains of science or new geographic regions), CIPD works to build the relationships, develop the plans, and support the execution of these plans to help USP have optimal public health impact.

*Human Resources:* The Human Resources staff is responsible for a number of activities relating to USP staff employment. The total number of USP employees increased by 36.3%, rising from 286 at the beginning to 390 at the close of the cycle. Several initiatives from the USP Human Resource staff covered organizational development, employee satisfaction, and employee

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<sup>9</sup> *The Handbook of Standardization: A Guide to Understanding Standards Development Today.* West Conshohocken, PA: ASTM International. n.d. Available at <http://www.astm.org/NEWS/handbook02/images/Handbook02.pdf>. Accessed 23 February 2005.



development and helped to prepare and guide employees through this period of intensive growth. An annual employee opinion survey was introduced in 2000 to gain a better understanding of employee opinions about USP as a place to work. The survey results for 2004 indicate that USP remains stable in morale, climate, and retention indices, with overall results above US normative data and high-performance normative data. Several human resources programs and initiatives that follow were developed as a result of feedback from the annual surveys. Leadership development training was expanded in 2003 to include a series of eight programs for managers and supervisors. One hundred five employees initially participated. In 2004, these were further expanded to include all USP employees, along with introduction of additional programs and training for administrative, customer service, and other support staff. USP's ability to compete in the workforce marketplace is key to attracting and retaining highly qualified staff. To ensure that the organization remains competitive, USP's compensation and benefit programs are reviewed annually and benchmarked against local and national survey data. An organization scoreboard (the USP Scoreboard) and opportunities to meet with senior managers were introduced in 2002. A new mid-year and annual performance management program, which emphasizes goals and metrics with results tied to performance, was developed and implemented in 2004. To amplify staff feedback and suggestions, an ad hoc committee process was introduced in 2004. These committees consider a specific topic and, when their deliberations are concluded, are disbanded. A standing Benefits Committee works with the Compensation and Continuity Committee of the USP Board of Trustees to oversee USP's health care, retirement, and other benefits.

*Public Relations:* USP created a public relations staff in 2001 to help establish and promote USP's media presence. Staff began work by creating a public relations infrastructure for USP, establishing relationships with the media, and identifying news opportunities and issues. These activities educate the media about USP, help establish USP's credibility and leadership, and promote USP's public health mission. In the ensuing years of the cycle, USP received increasing coverage by print and broadcast media, both from trade and consumer press. USP has been featured in every leading newspaper across the country, as well as all the major television networks. Beyond this public relations campaign, staff is responsible for specific written and electronic presentations. These include two newsletters: *Inside DSVP* and *USP Press*. *Inside DSVP* was issued from March 2002 through March 2003 to provide public information about USP's verification program for dietary supplements. *USP Press* began in July 2003 and continues to be published on a quarterly basis. It provides USP news and information of interest to the organization's members and stakeholders. The public relations staff is also responsible for USP's Annual Report.

*Professional Affairs:* This staff function supports USP's outreach to professional associations with which USP maintains important relationships. These include major medical, pharmacy, nursing, manufacturer, and compounding professional groups, as well as many others. The function also is responsible for Convention planning and execution. Should Members at the 2005 Convention endorse the concept of a Council of the Convention, support for that body will come from the professional affairs staff.

*Scientific Reports:* This staff function supports the publication of scientific reports in the biomedical literature and in *Stimuli* articles in *Pharmacopeial Forum*. As needed, staff also assists in the preparation of miscellaneous technical reports and documents for internal use.

*Executive Administration:* The executive administration function was created in summer 2004 to coordinate the activities of USP’s Executive Office and senior USP staff. This function also lends support to the Board of Trustees, working closely with the Secretary to the Board. During the 2005 fiscal year, the Executive Office reinstated a professional development series for USP staff and is also assessing organizational needs for a corporate records management program.

Departmental Units in Support of the Council of Experts

*Department of Standards Development:* This department supports the work of the Council of Experts in the continuous evolution of USP–NF. Given the many demands on the volunteers in the Council of Experts and the complexity of the compendia vis-à-vis the work of manufacturers, compounding professionals, and conformity assessment bodies such as FDA, the work and impact of the department are expected to increase. USP is a science-based organization, and a dominant part of USP’s science arises as result of staff work in this department.

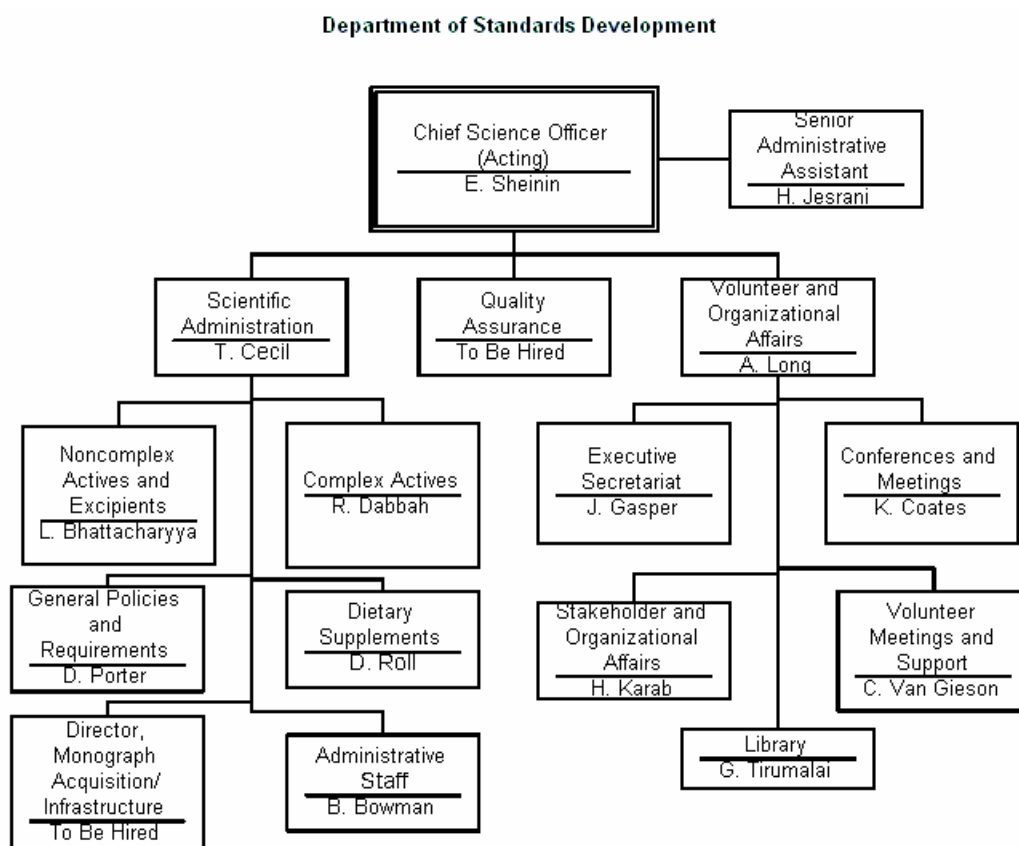


Figure 2

The department is advancing under a new structure and leadership team endorsed by the Board of Trustees (Figure 2). The Scientific Administration group is responsible for obtaining and evaluating accurate, up-to-date, and complete scientific information in Requests for Revision advancing to the standards Expert Committees of the Council of Experts. This group also provides extensive and continuous user support. There are four scientific programs within the group for non-complex actives and excipients, complex actives, general policies and



requirements, and dietary supplements topics. The Volunteer and Organizational Affairs group is responsible for a coordinated approach that supports the work of USP volunteers and stakeholders. This is accomplished by creating an open and communicative environment in which volunteers, stakeholders, and staff feel valued and confident in contributing their time, expertise, and ideas to USP. Major programs within the group cover executive secretariat, conference and meetings services, library administration, and stakeholder and organizational affairs activities.

The monographs in *USP* and *NF* evolve, subject to the standards-setting decisions of the Council of Experts, through receipt of information from interested parties. This information for the most part comes voluntarily from Sponsors in Requests for Revision. Sponsors are usually manufacturers of pharmaceutical or dietary supplement articles legally marketed in the U.S. To assist Sponsors, and working in this cycle with project teams under the Prescription/Nonprescription Stakeholder Forum, the department finalized a *Guideline for Submitting Requests for Revision to USP–NF* ([www.usp.org/standards/revisionguideline/index.html](http://www.usp.org/standards/revisionguideline/index.html)) The *Guideline* provides separate chapters for non-complex active drug substances and products, complex active drug substances and products, excipients, and vaccines. Additional chapters on blood and blood products and dietary supplements are in development.

The cohort of monographs in *USP–NF* is about 4000. Of these, approximately 1200 require updating. With sufficient information a further cohort of approximately 2000 could be developed. As part of the effort to gain information to support Requests for Revision to either create a new or update a current monograph, the department developed the following approaches:

- Updating USP's infrastructure to provide accurate data regarding outstanding monographs for drug substances, drug products, and excipients (about 2000 in total)
- Identifying and communicating with potential Sponsors for these missing monographs
- Scientific outreach in which department scientific liaisons visit a company and assist in the creation of monographs
- Obtaining required information from alternative sources
- Support for company visits by account managers in USP's Department of Marketing and Sales, at times accompanied by DSD scientific liaisons
- Periodic Sponsor telephone contact by scientific liaisons
- Updating activity by USP's Research and Development Laboratory.

In addition to monographs, the elaboration of *USP–NF* also includes Requests for Revision for USP's General Chapters. There are approximately 250 General Chapters in USP that provide official text on a broad variety of techniques and procedures. General Chapters also cover process standards, e.g., General Chapters <1978> *Good Manufacturing Practices for Bulk Pharmaceutical Excipients* and <2750> *Manufacturing Practices for Dietary Supplements*. Articles recognized in *USP* and *NF* must comply with the official standards and tests, procedures, and acceptance criteria in the General Notices to *USP–NF*, relevant monographs, and General Chapters numbered below 1000. General Chapters numbered above 1000 are considered interpretive and are intended to provide information on, give definition to, or describe a particular subject. They contain no official standards, tests, procedures, acceptance criteria, or



other mandatory requirements applicable to any pharmacopeial article unless specifically referenced in a monograph or elsewhere in the pharmacopeia.

During the 2000–2005 cycle, the department developed many opportunities for stakeholders to work with USP and the Council of Experts. Some manifestations of this work were the following USP Open Conferences:

1. Excipients – December 11–14, 2001, Sanibel Harbor, Florida
2. Microbiology – May 19–22, 2002, Sanibel Harbor, Florida
3. Analytical Methods and General USP Issues – June 1–4, 2003, Philadelphia, Pennsylvania
4. Packaging, Storage, and Distribution – October 12–15, 2003, Washington, District of Columbia
5. Biologics and Biotechnology – November 17–21, 2003, Crystal City, Virginia

In addition, departmental scientific staff participated in numerous national and international scientific conferences by invitation and as participants and also by serving on planning committees for some of these meetings.

USP held a scientific meeting, termed the First Annual Scientific Meeting, in September 2004 in Iselin, New Jersey. This meeting was designed to cover eight tracks that might previously been considered in separate open conferences.<sup>10</sup> Departmental staff supported and participated in on the overall planning committee and on planning committees for the eight tracks. These planning committees included members of the Council of Experts and representatives from key stakeholder forums. Departmental staff made several presentations and served as session moderators. The number of attendees at this meeting totaled 350, including both attendees and speakers. The second annual scientific meeting is planned for September 28–30, 2005, in San Diego, with the expectation that these will occur annually throughout the U.S. and Canada in the next cycle. They are expected generally to replace open conferences.

Departmental staff provide support for implementing work on the following USP's products and services: 1) Spanish translation of *USP–NF*; 2) Pharmacopeial Education course development and instruction; 3) the planned *USP Pharmacists' Pharmacopeia*; 3) USP's Dietary Supplement Verification Program.

Department staff executes the USP internship program under which college students in pharmacy and related fields work at USP in the summer in areas that support the elaboration of *USP–NF* and related projects.

Departmental staff also executes the USP fellowship program. Under this program six postgraduate students are awarded one-year fellowships of \$20,000 each to work on research projects related to the mission of USP to promote the public health. Originally this program was intended to reward academic volunteers participating in USP's standards-setting process. Over the years, graduate students of other faculty members have received fellowships.

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<sup>10</sup> USP's first open conference occurred in 1986 to cover the topic of impurities in pharmaceutical articles. In the 2000–2005 cycle, 5 open conferences were held.



DSD also has initiated a pharmacy internship program with several Colleges of Pharmacy. During this program students spend two months helping to develop monographs for compounded preparations.

*Department of Information Development:* Although USP sold all rights to *USP DI Volume I: Drug Information for the Health Care Professional* and *USP DI Volume II: Advice for the Patient* to Thomson Publishing Company in 1998, USP retained editorial control of and continued to create value-added content, including off-label use information, for these volumes in the early years of the 2000–2005 cycle.<sup>11</sup> In the first years of the cycle, departmental staff thus worked with 28 Information Expert Committees to provide value-added information for these two *USP-DI* publications. In May 2004, USP adjusted its agreements with Thomson Healthcare, a division of Thomson Publishing Company, to terminate USP's editorial control and creation of content for *USP DI Volumes I and II*. Content for these publications became solely the responsibility of Thomson Healthcare. Thomson may edit, create content, and publish these texts under the *USP DI* name through publication of the 2007 edition. Thomson Healthcare also may institute a name change at any time. *USP DI Volume III* will continue to be published under its current title and is owned in its entirety by USP. It will be published and distributed by Thomson Healthcare under an agreement that is renewed annually. Under the new arrangements with Thomson, USP is prohibited from engaging in the manufacture, publication, sale, license, distribution, or promotion of any drug information products until January 1, 2007. Exceptions include the compilation of articles for the *Annals of Internal Medicine* and USP's work in connection with the Medicare Model Guidelines. The department will also continue creating and editing content for *USP-DI Volume III*. With these changes, the sole remaining publishers of medically accepted indications for purposes of reimbursement under the Omnibus Budget Reconciliation Act of 1993 legislation are the American Society of Health-System Pharmacists (*AHFS DI*), and Thomson Healthcare, a division of Thomson Publishing Company (*DRUGDEX*).

The *Annals of Internal Medicine* is a biweekly publication of the American College of Physicians. Via a memorandum of understanding, the *Annals* editorial staff and USP have agreed to develop drug information articles for consideration by the journal. These articles will focus on advances in drug therapy utilizing new drugs or treatments. The articles will be developed by USP's Information Expert Committees.

In 2001, USP's Therapeutic Decision Making Committee Expert Committee began participation in a drug–drug interaction project with the Academy of Managed Care Pharmacy, the American Pharmacists Association, the American Society for Automation in Pharmacy, the National Association of Chain Drug Stores, the National Community Pharmacists Association, and the Pharmaceutical Care Management Association. Funding for this effort is supplied in part by USP and in part by a grant from Janssen Pharmaceutica. The purpose of the project is to assess evidence review methodology developed by the Expert Committee by applying it to a selected list of drug–drug interactions. In addition, the Expert Committee will develop and test a protocol for forming evidence-based recommendations. The Expert Committee will finalize a protocol for forming recommendations based on systematic reviews of available evidence at the completion of this project. Further testing and implementation of the protocol may be part of the

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<sup>11</sup> Although the sale included rights to *AMA-Drug Evaluations*, purchased from AMA by USP in 1995, very little of that publication was included in *USP-DI Volumes I and II*.



ongoing work of the 2005–2010 Expert Committees based upon resources and future collaboration. The department will continue the work of the Expert Committee through the beginning of the 2005–2010 cycle with potential project extension.

USP was named in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Section 1860D-4(b)(3)(C)(ii) of the law states:

*Model Guidelines.* The Secretary shall request the United States Pharmacopeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered part D drugs and additions of new covered part D drugs.

In response to the Secretary's request, USP and the Centers for Medicare and Medicaid Services entered a cooperative agreement to support the implementation of the Medicare prescription drug benefit. The cooperative agreement required USP to: 1) develop the Model Guidelines; 2) conduct public outreach; 3) provide a comprehensive listing of all drugs in each category and class; and 4) provide a proposed plan for revision of the Model Guidelines over time. These activities were completed during the period of performance outlined in the agreement: May 1, 2004–December 31, 2004, with extensive departmental staff support.

#### Departmental Units in Support of USP's Products and Services

USP's products and services are produced in six departments (Figure 1). USP's chief business officer is responsible for these departments. This officer is also responsible for USP's physical sites in other countries, e.g., USP's planned site in India, and the Department of Marketing and Sales. The overall activity results in a series of products and services that are developed and offered to USP's direct and primary customers throughout the world. USP's Quality Assurance staff reports to the chief business officer. USP's Global Assistance Initiatives are located in this administrative group as a means of fostering links to activities arising in association with presentation of USP's primary products and services. The work of the Global Assistance Initiatives also links to the work of the Executive Vice President/Chief Executive Officer and, through that position, to Corporate and International Planning and Development staff.

*Global Assistance Initiatives (GAI):* Staff in Global Assistance Initiatives work in many countries and regions throughout the world, primarily through the USP Drug Quality Implementation (USP DQI) program supported by the U.S. Agency for International Development (USAID) in country missions, regional bureaus, and funding streams for infectious diseases, maternal health, and child survival. GAI work overseas and in the U.S. has also been funded by WHO, Drug Information Association, and the Department of Commerce. In December 2004, USAID informed USP that the USP DQI program would be extended for another five years until September 30, 2010.<sup>12</sup> These resources will support continued and

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<sup>12</sup>In 1992 the first agreement was awarded to USP for the Rational Pharmaceutical Management Program funded for ~\$3 million. This agreement ended in 2000. In 1994, another agreement was awarded for \$1.1 million exclusively for Russia and the Newly Independent States (NIS). This was completed in 1999. In 2000 a new award was made for five years for \$7.5 million for the USP DQI



expanded international activities to improve drug quality assurance in developing countries and increase dissemination of unbiased drug information.

GAI activities—such as in-country laboratory training, marketplace surveillance, proficiency testing of staff in official medicines control laboratories, and facilitation of regional networks to reduce substandard and counterfeit drugs—have increased the availability of USP’s products and services throughout the world. GAI also provides technical assistance to USAID strategic teams, UNICEF, World Health Organization (WHO), and other organizations that must make decisions about what medicines to buy and how to ensure that medicines purchased are of good quality. At this global level, GAI is able to raise awareness of USP standards, products, and services among leadership in the international health community. Examples of staff activities during the 2000–2005 cycle based on USAID support include the following:

In October 2004 USP DQI co-sponsored a conference in Hanoi with faculty and staff from the Hanoi University of Pharmacy and faculty and staff from the University of California, San Francisco (Department of Pharmacy, Global Health Sciences, and AIDS Research Institute). Conference attendees focused on expanding the role of pharmacists in the prevention and treatment of HIV/AIDS. As a result, faculty and staff from the University of California, San Francisco, will pursue collaborative activities with both the Hanoi University of Pharmacy and USP DQI in curriculum development and retraining of pharmacists to identify symptoms of HIV/AIDS and to appropriately select, purchase, and dispense medicines for HIV/AIDS and opportunistic infections. USP DQI will provide curriculum development and training about aspects of drug quality assurance that are within the control of pharmacists. Funding for these activities will be pursued through proposals to USAID and Atlantic Philanthropies.

In October 2004, USP DQI staff participated in a World Health Organization Southeast Asian Regional Office (SEARO) meeting in Bangkok that focused on meeting producers of artemisinin combination products for malaria. Key discussion points included a review of good manufacturing practices essentials that producers must meet in order to be prequalified by WHO as a reliable source of a specific anti-malarial product. Currently, there is a worldwide shortage of artemisinin combination products, and WHO estimates they will have only about 50% of the supply needed to treat malaria patients next year.

In 2004, USP DQI technical staff provided training to Ghana’s Food & Drug Board laboratory staff about the proper use of USP monographs to test drugs, various testing methods, and the importance of following Good Laboratory Practices. A consultant from KMI-PAREXEL accompanied USP staff to Ghana and inspected two factories in Accra for adherence to good manufacturing practices. Both manufacturers produce antimalarial drugs. The inspection found they were not compliant with generally accepted good manufacturing practices. Recommendations were provided to the manufacturers, the Food & Drug Board, and USAID for improving the operations.

USP DQI staff participated in a 2004 biregional World Health Organization/Western Pacific Regional meeting with SEARO in Hanoi to look at three aspects of efforts to slow the

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program. In 2004, USP requested a five-year extension until Sept.30, 2010 and an additional \$15 million. Verbal approval for this work has been received, although USP has not yet received the agreement extension paperwork from USAID.



development of resistance to malaria drugs in South and Southeast Asia. The World Health Organization and USAID are supporting a three-pronged approach addressing drug quality, drug use practices, and surveillance of resistance patterns. USP DQI is implementing the drug quality monitoring component. Also in 2004, USP DQI participated in a two-day retreat organized by USAID to review and revise work plans for the South American Infectious Diseases Initiative (SAIDI). USP DQI will join RPM Plus, the Pan American Health Organization and the US Centers for Disease Control and Prevention (CDC) in efforts to monitor and curb the development of antimicrobial resistance in Peru, Bolivia, and Paraguay.

In 2001, USP DQI co-sponsored with the Drug Information Association a regional meeting in Nepal that was attended by more than 200 manufacturers, pharmacists, and regulators to identify and discuss drug quality issues in the region. One year later, the two organizations joined with WHO/SEARO in Hyderabad. Drug Regulators from nine countries participated in a discussion of availability and quality assurance for antiretroviral drugs for HIV/AIDS. Also in 2002, USP DQI conducted an assessment of drug quality control in five Mekong region countries; this led to the Mekong Malaria drug quality assurance initiative in which USP DQI has trained official medicines control labs in Vietnam, Cambodia, Thailand, China, and Laos to perform basic tests, provided lab equipment, and helped to set up a regional surveillance network using portable minilabs in remote areas to screen malaria drugs for identity. In 2004, all five countries actively removed from the market poor quality products identified by this initiative. In 2003, USP DQI partner Smolensk Medical Academy developed and implemented the first internet-based distance learning course for physicians and pharmacists in Russia. The course focused on the proper use of antimicrobial drugs and was certified by the government of Russia to provide continuing education credits.

In the current cycle, USP's GAI staff has increased its focus on drug quality initiatives, and—in line with elimination of support for *USP-DI Volumes I and II*,—diminished its activities in the area of drug information. Increasing attention by the international health community to the problem of substandard and counterfeit medicines, especially in developing countries, provides an opportunity for USP to take a leadership role in focusing the discussion on issues that are both significant and can be effectively addressed. Such issues include acceptance of appropriate standards, building local capacity to effectively use standards, overcoming a dearth of reliable manufacturers of drugs for serious diseases such as malaria, tuberculosis, and HIV/AIDS that mostly affect poorer nations, and defeating the relatively high tolerance for the existence of counterfeits. In recognition of these challenges, the GAI staff executed two key accomplishments in the 2000–2005 cycle: 1) Web site and 2) report.

With suitable support, USP DQI activities can increase annual allocation of funds from USAID. Barriers to success in this context arise from: a small number of GAI staff who can travel and provide the type of assistance most in demand; changing priorities within USAID; travel restrictions for security reasons; and local partners who sometimes change timeframes of activities unexpectedly or fail to complete their part of the work plan. For these reasons, in the 2005–2010 cycle, the activities of the GAI program will be more strongly allied with senior management at USP (see Figure 1). The increasingly international focus of USP should synergize well with GAI and USP DQI.

*Quality Assurance:* USP's Quality Assurance staff was created in the 2000–2005 cycle to establish and maintain a quality management system. Key elements of this system include



standard operating procedure (SOP) document management and control, training, tracking, corrective and preventative actions, deviations, validation, and an audit program. Since the installation of the quality management system, there have been two significant milestones. First, the corporate and departmental system was externally audited in March 2004 by BSI, Inc. and certified against ISO 9001:2000 requirements for quality management systems. This ISO standard specifies requirements for a quality management system according to which an organization demonstrates its ability to provide consistently product(s) that meets customer and applicable regulatory requirements and aims to enhance customer satisfaction. Then, in December 2004, USP was externally audited by ACLASS and accredited against ISO 17025:1999 requirements (General Requirements for the Competence of Testing and Calibration Laboratories). The Quality Assurance staff now works to help USP continually improve on its quality management system, using internal and external audits to proactively identify opportunities for improvement. Staff also engage in USP staff training and implementation of key corporate and staff SOPs. The end result is that USP is a customer-focused organization, centered on meeting and exceeding the needs of both direct and primary customers.

*Publications Department:* As a result of the most recent staff reorganization, this function, which had been managed by Information Technology staff, will become its own department at USP. A Vice President, Publications, is currently being recruited. The primary responsibilities of the publications department are for the production of USP's publications and for its publication services, including USP's primary publications (e.g., *USP-NF*), line extensions thereof, and other official emanations from the Council of Experts. In addition, the publications department will assume responsibility for all domestic and international publishing activities and all production, editorial, authoring alliances/partnerships, and publications contractors.

*Monograph and Reference Standards Development and Reference Standards Operations (MRSD and RSO):* In March 2000, the departments now known as Monograph and Reference Standards Development and Reference Standards Operations were organized under the Division of Actives and Excipients. That division consisted of 4 departments: Reference Standards Laboratory, Research and Development Laboratory, Non-Complex Actives, and Excipients. Two of the departments were laboratories and two were primarily scientific liaison-based, directly supporting the Council of Experts. At that time other liaison groups (General Chapters, Dietary Supplements, and Complex Actives), as well as an Executive Secretariat (administration, portions of publications production, and editing) reported directly to USP's Chief Executive Officer. Other operational departments such as Reference Standards Operations (which included Reference Standards Procurement, Reference Standards Production, and Reference Standards Evaluation) and the Information Technology portion of publications production report to the Chief Operating Officer (now Chief Business Officer).

In February 2001 a reorganization grouped all the compendial (*USP-NF* and *PF* content and Expert Committee coordination) departments into a single division, the Department of Standards Development. A second grouping combined Research and Development Laboratory, Reference Standards Laboratory, Reference Standards Evaluation, Reference Standards Production, and Reference Standards Procurement into Standards Operations. The IT department was expanded to include publication activities formerly handled by the Executive Secretariat. In July 2004 Standards Operations was divided into two departments, Monograph and Reference Standards Development and a new Reference Standards Operations. Monograph and Reference Standards Development partners with the Department of Standards Development in scientific activities



such as revising monographs, developing new types of Reference Standards, and implementing Council of Experts initiatives (including day-to-day interactions with the Reference Standards Committee). Reference Standards Operations duties include scheduling, handling, evaluating, packaging, and labeling Reference Standards.

*Dietary Supplement Verification Program (DSVP):* In October 2000, USP's DSVP started with Board approval of a Quality Demonstration Program and funding authorization. The demonstration program involved four dietary supplement manufacturers (Pharmavite LLC, Leiner Health Products LLC, Perrigo Company of South Carolina Inc., and Rexall Sundown Inc.) and was conducted between July and October 2001. Based on the success of this program, USP launched its Dietary Supplement Verification Program (DSVP) and the implementing department in November 2001. In April 2004, USP expanded the scope of its verification programs by adding an Ingredient Verification Program for Dietary Supplements.

*Center for the Advancement of Patient Safety:* In 2000, USP ceased operation of the Drug Product Problem Reporting Program, a quality-oriented program operated for more than 30 years, in order to concentrate resources on its medication error reporting programs. In 2003, USP discontinued the Veterinary Practitioners' Reporting Program. For 10 years the program operated with USP funding, and reports were shared with three regulatory agencies: FDA, EPA, and USDA and the practice organization, the American Veterinary Medical Association. When neither outside sponsorship nor a funding source was available to continue the program, USP ceased operations associated with the program altogether in April 2003.

Two years later, USP's Patient Safety Public Health Program was divided into two parts: 1) the Patient Safety Product Group responsible for MEDMARX<sup>®</sup> development and client support; and 2) the Center for the Advancement of Patient Safety (CAPS) responsible for the analysis and dissemination of information developed from reports to MEDMARX, and to the USP Medication Errors Reporting Program, housed in CAPS. Under the leadership of its vice president and with 5 nurses and pharmacists and one administrative assistant, the Center for the Advancement of Patient Safety set forth to encourage medication error reporting, conduct data analysis and research, develop educational programs, and propose standards, recommendations, and guidelines that ultimately improve the safety and quality of patient care.

*Pharmacopeial Education:* This USP program was created in 2001 as a result of a resolution from the 2000 Convention.<sup>13</sup> It functioned initially as a stand-alone activity but for the last three years has been a staff activity in the Department of Sales and Marketing (Figure 1). The program has provided opportunities to demonstrate the value of USP standards to direct customers (and thus increase sales of publications and reference standards), and as a result it was moved into the Sales and Marketing department. At the close of the cycle, the account managers, who have science backgrounds, teach most of the classes themselves. Assistance on some courses is provided by three scientists from the Department of Standards Development. This gives account managers an opportunity to demonstrate to customers the depth of their knowledge of both USP and of the problems their students face in their jobs in laboratories.

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<sup>13</sup> Resolution 13 – Education & Training Programs (Establish education and training programs to support the appropriate use of *US Pharmacopeia* and *National Formulary* standards and compendial methods).



*India Site:* At the close of the cycle, the USP Board of Trustees approved staff plans to establish a site for USP's operations in India. Among the key objectives in alignment with USP's mission are promoting the global availability of good-quality therapeutic products. Obviously, having a physical presence in India will facilitate monograph acquisition—but only for products legally approved for sale as generics in the U.S. In addition, USP staff will strive to obtain candidate bulk reference standard materials and candidate impurity standards. The India site also will offer opportunities for USP collaborative testing and collaboration with Indian national laboratories. Naturally the site will increase the availability of USP's pharmacopeial products and services and will be a convenient venue from which to promote USP's pharmacopeial education programs. Having a physical presence in the region will make it much easier to enlist regional pharmaceutical scientists in the Council of Experts and will facilitate information exchange. In practical terms, the site will enhance USP's financial viability and stability and will enable USP to act as its own distributor and move closer to key customers. Site selection is focusing on Hyderabad, and opening of the site is planned for the end of calendar year 2005. Additional sites may be developed subject to Board concurrence.

*Sales and Marketing:* The Sales and Marketing Department today numbers 54 people, including 19 devoted to customer account management or product management of publications, education, and reference standards; 9 in marketing communications; 10 in patient safety; 3 in sales analysis, and 13 in customer service. Among the notable changes in this cycle has been the hiring of sales staff with degrees in chemistry. These account managers meet regularly with customers to understand their needs and promote satisfaction. The department also took on the patient safety sales, customer support, and education functions that had been part of the Center for the Advancement of Patient Safety.

### USP Business Units

*Legal Department and General Counsel:* In addition to its core functions of providing ongoing legal support for USP's new and existing activities and establishing and interpreting the organization's internal governance policies, the department established early in this cycle a government relations function to allow USP to monitor and become involved in legislative and regulatory matters that affect USP operations. Through both internal and external resources, this function allowed USP to become aware of and participate in legislative and regulatory discussions of issues such as patient safety, dietary supplements, importation, counterfeits, and biologics. The department interacted frequently with regulatory agencies including FDA, CMS and the Agency for Healthcare Research and Quality (AHRQ), and with members of Congress and their staff from key Senate and House committees with jurisdiction over issues of interest to USP. The department also monitored and responded to key developments on relevant issues at the State level. Major areas for which the department provided legal analysis and advice as well as government relations support to the organization included USP's work on the Medicare Model Guidelines, for which the department conducted periodic briefings for Congressional staff, and pharmacy compounding, where in addition to writing articles on the regulation of compounding the department also worked extensively with Congress, FDA, and various pharmacy groups to advance quality standards for compounding by the development of monographs and establishment of a voluntary accreditation program. The department also provided significant legal support for USP's international activities, working on issues such as international trademark and copyright protection, legal structure, governance issues for USP's India site, and international intellectual property issues. Legal staff also analyzed and provided advice to the



organization about major federal legislation such as Sarbanes-Oxley and the Health Insurance Portability and Accountability Act (HIPAA), and the implications of such legislation on USP's activities. Late in the cycle, the department underwent a transition in leadership with the retirement of Dr. Joseph Valentino, a thirty-five year USP employee. The functions of the legal department have now been reorganized under its new General Counsel.

*Finance & Administration:* During the 2000–2005 cycle, the Department of Finance & Administration was formed from functions that previously had resided within other USP departments. During this period, the Department developed a platform for strong financial management and high-quality management reporting, value-added financial analysis for operations, and an efficient warehousing and shipping platform to serve customers. The implementation of the Oracle Enterprise Resource Planning (ERP) system<sup>14</sup> and an electronic timekeeping system facilitated the development of accurate and detailed financial reports for use in managing the public health programs and the organization as a whole. It also facilitated efficiency gains and reduced cycle time in order fulfillment and improved inventory-management capabilities. The Department also developed strong customer-focused credit management processes, thus reducing credit risk for USP. USP's external financial audit became more successful during the cycle with fewer auditor comments. Additionally, USP implemented several best practices from Sarbanes-Oxley,<sup>15</sup> including management signoff on audited financial statements. External audiences recognized the strength of USP when Moody's gave USP an investment-grade bond rating of A2. This rating allowed USP to issue bonds to fund the new building construction for laboratory and office expansion that is in progress. Finally, USP engaged the services of Smith Barney Consulting Group to revise the Investment Policy Guidelines and to provide active oversight of the investment portfolio. These financial and administrative activities establish a strong platform for the next cycle.

*Information Technology:* The past five years have brought about many changes and expansion in the Information Technology Department at USP. Working with DSD Department staff, the Department's *developmental group* released new electronic products for *USP-NF*, *Pharmacopeial Forum*, and *USAN*, including CD, Internet, and Intranet products. The *applications group* implemented a new ERP system using an Oracle platform to replace an antiquated business system termed FACTS. The new system provides USP with numerous benefits, including consolidated views of the financials, reporting capabilities, and a manufacturing planning system that allows more effective planning by the laboratory groups. The MEDMARX system has also seen major development. The system was converted to a JAVA-based system, with multiple new modules released. The group also has implemented well over a hundred user enhancements. The Web team has launched four new Web sites in the past five years and does almost daily content updates to keep information on the Web current. The *operations group* implemented many changes during the cycle, including a stable and secure infrastructure that allows maximum performance from USP's information technology systems while protecting security, identity, and intellectual property.

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<sup>14</sup> Oracle is a seamless, companywide integrated systems platform with components for accounting, order entry, inventory, manufacturing, purchasing, shipping, and receiving—among other components.

<sup>15</sup> The Sarbanes-Oxley Act of 2002 was passed to restore shareholder confidence in publicly traded securities following highly publicized scandals. Goals include greater transparency in financial reporting, greater accountability by making Board members and staff personally accountable for financial statements, and greater emphasis on fraud detection and prevention. This Act is mandated for publicly traded companies only, but USP has adopted many of the best practices included in the Act.



*New Building Project:* USP currently owns and occupies approximately 110,000 square feet of space in three buildings located at the corner of Twinbrook Parkway and Fishers Lane in Rockville, Maryland. USP leases an additional 22,000 square feet of space in a building on Wilkins Avenue and 2,800 square feet of space in a building on Nebel Street in Rockville. Altogether, these buildings house USP's current operations, which include offices, laboratory and laboratory support facilities, and packaging and warehouse facilities. In 2002 USP staff determined an increasing need for new space. This need was presented to the USP Board of Trustees, who agreed and in response established a Real Estate Committee to oversee the extensive staff activities needed for the project. An internal management team (Real Estate Executive Committee) was created to manage the project on behalf of the Board of Trustees. The intent of the project is to create facilities that support USP's growth to 2012. To begin, USP evaluated combinations of new and existing sites versus consolidation and expansion of operations at the existing Twinbrook site. USP chose to remain at the existing Twinbrook site. After site selection, the Board itself performed an extensive number of activities related to architect selection, project management selection, financing, design, legal considerations, county approvals, and other activities necessary for construction of a building to serve complex needs in a busy and congested suburban area.<sup>16</sup>

At the close of the 2000–2005 cycle, this is the status of USP's new building project: With completion of the general design phase, the schematic design proposed to USP by HOK has been completed, presented, and approved by the Real Estate Executive Committee. In conjunction with the Orr Company, a pricing consultant completed a budget verification exercise for the facilities. This exercise will be repeated at the end of Construction Documents phase of the project. USP has sent out requests for proposals and bids to candidate general contractors for the project. Selection of a general contractor will occur by March 2005. The demolition of the old facilities will begin in spring 2005, and completion of the new facilities is scheduled for October, 2006.

#### **IV. USP's Products and Services**

*Publications:* USP's publishing department produced the last 5-year *USP–NF* in 2000. This frequency of publication was associated with ten *Supplements*. Publication of the two compendia in 2000 occurred using traditional cut-and-paste methods. The publishing department prepared approximately thirty separate publications based on the *USP–NF* database in 2000. Beginning in 2002 (*USP 25–NF 20*) USP advanced the publication frequency of the two compendia to annually with two *Supplements*. The database for *USP–NF* was converted into XML (eXtensible Markup Language). This allows the *USP–NF* database to yield more than 50 scheduled print electronic books and journals annually. These and other moves to electronic publishing now allow:

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<sup>16</sup> Orr Partners is a Development, Construction and Project Management firm founded in 1988 in Falls Church, Virginia that coordinates every aspect of the building process for its clients. Hellmuth, Obata + Kassabaum, Inc. (HOK) is a global provider of design and project delivery services that manages the planning, design, and construction process for all types of clients and facilities in every part of the world. They have offices in North America, Latin America, Europe, and Asia.



- *USP–NF* and related *Supplements* in print, CD, and online formats;
- *Pharmacopeia Forum* in print and online with PDF highlights;
- The *United States Adopted Names Dictionary* in print and online;
- *USP-DI Volume III* in print with monthly updates in Hypertext Markup Language (HTML);
- USP Catalog in print and Acrobat PDF.

The number of monographs in *USP 24–NF 19*, published in 2000, was 3777, with 164 General Chapters and 2569 pages. *USP 28–NF 23*, published in 2005, contains approximately 4000 monographs, with 184 General Chapters and 3187 pages. USP’s publications department will assume responsibility for all print and electronic media presentations of official and authorized text emanating from the Council of Experts (e.g., the *USP Pharmacists’ Pharmacopeia* and translations). They will also be responsible for producing additional informational text drawn from staff and other bodies beyond the work of the Council of Experts. In this effort they will work closely with the Department of Marketing and Sales to understand primary and direct customer interests and needs and also with staff in the Departments of Standards Development.

*Reference Standards:* A summary of results during the 2000–2005 cycle include the following: Approximately 500 new official USP Reference Standards were introduced into the catalog, increasing the number of items from about 1200 to more than 1700. At the same time, order availability rate increased to 99.5%, and out-of-stock situations were terminated, leading to improved overall availability and timely delivery of official USP Reference Standards to customers. USP also maintained a cooperative research agreement with FDA in which USP provided resources in support of FDA’s participation in collaborative evaluation and qualification of candidate reference standards. Beyond this cooperative research agreement, USP developed a new cooperative research agreement with Health Canada by which they are a partner in the collaborative evaluation and qualification of candidate reference standards. As a result of these activities and other factors as well--ending backorders, creating more impurity reference standards, improving customer service and order fulfillment, investing in quality and achieving ISO certifications, and adding a sales force—sales of official USP Reference Standards increased 94% in the 2000-2005 cycle.

*Dietary Supplement Verification Program (DSVP):* Following extensive staff development work and Board debate, USP engaged in a voluntary program to verify dietary supplements products (DSVP) and, in the later years of the cycle, dietary ingredients (IVP). The general approach was an expansion of USP’s core activities, moving from standards setting from dietary supplements to assessments for conformity to these and other standards, e.g., GMPs.<sup>17</sup> While input from scientists on the Council of Experts was welcomed as the program evolved, care was also taken to separate the standards-setting for dietary supplement and conformity assessment activities for dietary supplement manufacturers. Pharmavite Corporation was the first company to join DSVP, two months prior to the end of FY ’02; verification sales were 0% of plan year. In FY ’03, Leiner Health Products, Inverness Medical Nutritionals Group, Nutramax Laboratories Inc., Weider Nutrition International Inc., and Tishcon Corporation entered DSVP; verification program sales were 59.3% of plan year. In FY ’04, Inter Farma SA, Ocean Nutrition Canada Ltd. and Cargill Health & Food Technologies Inc. entered IVP; verification program sales were

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<sup>17</sup> Pending finalization of FDA’s dietary supplement GMPs, the program relies on General Chapter <2750> *Manufacturing Practices for Dietary Supplements* in the Dietary Supplement section of *USP*.



89.5% of plan year. In FY '05, Parry Nutraceuticals Ltd. and Sigma Tau Health Science Inc. entered IVP; through the period ending January 2005, verification program sales were 76.6% of plan year.

Working with these dietary supplement manufacturers—who have come to the program as a means of demonstrating with USP a commitment to offer good-quality dietary supplement products to the consumer—DSVP has had demonstrable impact on improving the manufacturing and quality control systems to the benefit of dietary supplement consumers. It has helped companies to establish a consistent standard of good manufacturing practices, including improvements to their document management systems, incoming material and product release control systems, process equipment controls, process verification programs, deviation control program, supplier approval programs, laboratory controls and method validation procedures, and programs for evaluating the shelf life of marketed products. DSVP and IVP have ensured that verified products contain the declared ingredients in the declared amount on the product label; that they meet acceptable limits for contaminants, and have the appropriate performance characteristics. At the close of the cycle, DSVP/IVP has verified more than 750 vitamins, minerals, botanicals, and other supplements and has placed the USP Verified mark on approximately 50 million bottles or packs. The USP verification processes have led to more than 100 changes to products, formulations, and labels. DSVP has enhanced understanding on the part of dietary supplement manufacturers for USP dietary supplement monographs, resulting in increased monograph submissions from supplement manufacturers worldwide. Market research conducted by the Natural Marketing Institute in September 2004 established that the USP verified mark on dietary supplements has gained increasing recognition and acceptance among consumers, with 33 million U.S. citizens now cognizant of the USP verification program for dietary supplements legally marketed in the U.S.<sup>18</sup>

*Patient Safety:* The principal work in Patient Safety lies in analyzing data from USP's two reporting programs—the Medication Error Reporting Program and MEDMARX.<sup>®</sup> At the close of the cycle, MEDMARX celebrated five years as a successful proof-of-concept, supporting the Institute of Medicine's recommendations for a national medication errors reporting program. During the cycle, the number of MEDMARX subscribers grew from 173 to more than 600. In turn, the number of medication error records in the MEDMARX national database grew from 54,128 records in FY '00 to nearly 900,000 records at the close of the cycle. The annual MEDMARX summaries are employed by institutions as guidelines to assist them in formulating procedures and designing processes aimed at enhancing the quality of patient care. The department also provides data on pediatric errors to the University of North Carolina Center for Education and Research on Therapeutics program, which is focused on adverse events in the pediatric population. Key publications based on the MEDMARX data during the cycle include: MEDMARX 5<sup>th</sup> Anniversary Data Report. A Chartbook of Findings and Trends, 1999 – 2003, Translating Research into Practice: Voluntary Reporting of Medication Errors in Critical Access Hospitals, Unfractionated heparin: Focus on a high-alert drug, Selected medication-error data from USP's MEDMARX program for 2002, Medication Errors in Post Anesthesia Care Unit: A Secondary Analysis of MEDMARX findings, Summary of information submitted to MEDMARX in the year 2002. The quest for quality, Medication errors: Experience of the United States Pharmacopeia (USP) MEDMARX reporting system, Medication errors in day surgery – A secondary analysis of MEDMARX, Medication errors in the OR – A secondary

<sup>18</sup>HealthBeat Interactive June 2002 and September 2004 Surveys.



analysis of MEDMARX and Medication errors: Experience of the United States Pharmacopeia (USP).

During the cycle, data from USP's two reporting programs were reviewed and analyzed by USP's Safe Medication Use Expert Committee. The work of this Expert Committee contributes to both standards and information development. Seven proposals were submitted for USP labeling and packaging standards to address medication errors. The Safe Medication Use Expert Committee also makes recommendations to the National Coordinating Council for Medication Error Reporting and Prevention, a conclave of 25 national organizations and agencies that works to promote the reporting, understanding, and prevention of medication errors. USP was a founding member of the Council in 1995 and serves as its secretariat.

The department has developed an array of educational resources (Web, print, CD, workshops) derived from the USP medication error databases to convey findings and provide shared learning to promote patient safety. It published *Advancing Patient Safety in U.S. Hospitals: Basic Strategies for Success* and *USP Medication Errors Safety Pocket Reference* to influence safe medication practices in U.S. hospitals. At the American Society of Health-System Pharmacists (ASHP) 2002 Mid-Year meeting USP CAPS was awarded ISMP's 5<sup>th</sup> Annual Cheers Award for its outstanding work in the patient safety field by setting a "superlative standard of excellence for others to follow in the prevention of medication errors." The department provides support for and participates in a Medication Errors Databases Research Advisory Panel. This panel will help the department focus its research activities on the health care environment with a view to identifying unmet needs. At the close of the cycle and with approval from USP's Board of Trustees, the department entered into a research agreement with Johns Hopkins University's Bloomberg School of Public Health to make the medication errors databases accessible to researchers in the field by the acquisition of grants and/or contracts. This relationship will help support the department's research agenda and co-publish in primary literature.

During the 2000–2005 cycle, the department responded frequently to subscriber requests and added a number of products that now account for 20% of total Patient Safety Program revenue. The MEDMARX Multi-Facility Module was introduced in FY '03 and enables hospital systems to view the medication errors of its participating hospitals. The MEDMARX Data Interface was introduced in FY '04 and allows subscribers to easily upload risk management data into MEDMARX. The introduction of the Adverse Drug Reaction Module in FY '05 provided USP with a complete adverse event reporting program. This has resulted in an improvement in the subscription renewal rate from 68% in FY '00 to 87% YTD FY '05. In FY '04, USP signed a 5-year contract with the Department of Defense for the use of USP's patient safety products and services.

*Pharmacopeial Education:* During this cycle, the program realized approximately \$1.6 million in revenue from courses and provided courses to approximately 4,000 students. Seven courses were developed: Fundamentals of USP, Advanced USP, Dissolution, Titration, Analytical Method Validation, Statistics, and Microbiology. In addition, courses have been offered internationally in eight countries. They include Spain, Germany, United Kingdom, Ireland, Switzerland, Mexico, Italy, and Turkey.



## **V. USP Processes**

USP staff and volunteers are governed by its Constitution, its Bylaws, and a number of internal rules and procedures that have developed over time and must be periodically revised to meet USP's changing needs and demands. USP is additionally confronted with the challenge of maintaining and enhancing interactions of a highly committed group of volunteers and staff. At the direction of the Board chair in this cycle, USP engaged the services of Cone Resource Group (CRG). Working under an annual consulting agreement, staff from this firm, Dr. Harles Cone, was encouraged to interact with all volunteer and staff groups of USP. This effort has resulted in a series of changes to USP's procedures, which is expected to continue in the next cycle. The start of these procedural changes will occur with the Convention's adjustment of the USP Constitution and Bylaws—see Convention Member Notebook. Additional management consulting activities are in progress, working with CRG and other management consultants.

## **VI. THE FUTURE**

During its almost 185-year history, USP has been privileged to make public health contributions at critical junctures for the nation and the world. The capability arises out of USP's unique heritage as a volunteer-driven, science-based organization working in the public interest. Its volunteer base and nongovernmental character preserve its independence. Although USP is independent, it remains accountable—to Convention Members attending this Convention and to the public at large. USP's activities are built on voluntary donation of services, information, and materials that are transformed, through the hard work of its volunteers and a dedicated staff, into products and services. These products and services work at many points within national and international health care systems to help patients and practitioners maintain health and treat disease. USP future work lies in four areas—national quality, international quality, drug information, and patient safety. USP has developed a strong foundation for this work, which will be carried forward through USP's strategic plan and its objectives, as developed by the USP Board of Trustees for the 2005–2010 cycle. Based on this plan, staff will execute tactical programs in support of primary and direct customers—as it has done since 1820.

The past five years have seen dramatic growth in USP to fulfill its public health mission throughout the world. USP is now at a juncture where the volunteers, staff, constituencies, and stakeholders must address the challenges of the next cycle and allow USP to fulfill its public health mission in a fiscally responsible manner that will help provide quality medicines worldwide.