



REPORT OF THE COUNCIL OF THE CONVENTION

January 25, 2010

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ADVANCING HEALTH THROUGH PUBLIC STANDARDS

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PART I

INTRODUCTION

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

PART I. INTRODUCTION

At the 2005 meeting of the USP membership, delegates formally established and defined the activities of the Council of the Convention (CoC) through approval of a Constitutional amendment (which established the CoC and defined its composition) and adoption of an accompanying resolution (which outlined the CoC's scope of activities). The excerpt from the 2005 Constitution and Bylaws pertaining to the Council of the Convention and full text of Resolution 11 are attached (Attachments A and B).

During the 2000-2005 cycle, the ad hoc Committee on Resolution 18 had recommended the creation of the Council to the Board of Trustees in answer to concerns that member organizations did not fully understand the importance or relevance of Convention activities and thus were not adequately engaged. Resolution 18, adopted at the 2000 Convention, posited that more frequent meetings were a possible solution to this lack of engagement. The ad hoc Committee concluded that the frequency of member meetings was less important than the strategic question relating to the purpose, role and composition of the USP Convention membership and whether it provided a value for the organization. The ad hoc Committee further concluded that a separate, standing Convention committee (Council of the Convention) should deal with this larger issue in the succeeding cycle.

The Council of the Convention is chaired by **René H. Bravo, M.D., F.A.A.P.**, President, USP Convention.

Committee members include:

Paul M. Schyve, M.D., CoC Vice-Chair, Member-at-Large

Christopher K. Allen, R.Ph., M.P.H., Chair, CoC Section on Global Public Health; Member-at-Large

Loyd V. Allen, Jr., Ph.D., Chair, CoC Section on the Quality of Compounded Medicines; Member, University of Oklahoma College of Pharmacy

Lowell J. Anderson, R.Ph., D.Sc., Member-at-Large

Dawn M. Boothe, D.V.M., Ph.D., Member-at-Large

E. James Bradford, Ph.D., Member, AOAC-International

Thomas R. Clark, R.Ph., M.H.S., Member, American Society of Consultant Pharmacists

Enrique Fefer, Ph.D., Honorary Member

Barbara J. Ferguson, Member, New Jersey Pharmaceutical Quality Control Association

Rita Munley Gallagher, Ph.D., R.N., Chair, CoC Section on the Quality of Patient Care; Member, American Nurses Association

Mary H. Hager, Ph.D., R.D., F.A.D.A., Chair, CoC Section on the Quality of Food Ingredients and Dietary Supplements; Member, American Dietetic Association

Gordon R. Johnston, R.Ph., Chair, CoC Section on the Quality of Manufactured Medicines; Member, Generic Pharmaceutical Association

Marvin M. Lipman, M.D., Former Trustee, Member-at-Large

Charles W. Maas, M.D., M.P.H., Member, California Medical Association

Lucinda L. Maine, Ph.D., Member, American Association of Colleges of Pharmacy

Lyn O. Nabors, Member, International Food Additives Council



N. Lee Rucker, M.S.P.H., Member, AARP

Rebecca P. Snead, R.Ph., Member, National Alliance of State Pharmacy Associations

Stephen P. Spielberg, M.D., Member, Association of American Medical Colleges

Joseph G. Valentino, J.D., Honorary Member

Liaisons to the CoC include:

Vasilios Bill H. Frankos, Ph.D., Food and Drug Administration (FDA) Liaison to the CoC;
Member, FDA CFSAN

Thomas R. Temple, R.Ph., M.S., Membership Committee Liaison to the CoC; Chair, Membership
Committee; Member, Iowa Pharmacy Association

Respectfully submitted,

René H. Bravo, M.D., F.A.A.P.
President, USP Convention
Chair, Council of the Convention





PART II

2005 TO 2007

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

PART II. 2005 TO 2007

1. DEVELOPMENT OF CHARGE

Following the 2005 Convention a charge for the CoC was developed and approved by the President, as follows:

Based on the recommendations of the ad hoc Committee on Resolution 18, which served in the 2000-2005 cycle and Resolution 11 passed at the 2005 Convention, the following constitutes the charge of the Council of the Convention:

- As an ongoing responsibility, the Council shall review the purpose, role, and composition of the Convention membership. Components of this include:
 - The “Who”: Given USP’s mission, activities and opportunities, what constituencies should be represented in the Convention membership?
 - The “What”: What should the role and responsibilities of the Convention membership be, and how do these interface with the functions and duties of other parts of the organization (e.g. Board of Trustees, Council of Experts, Stakeholder Forums, and Staff)?
 - The “How”: What is the most efficient and effective way for the Convention membership to fulfill its role and responsibilities within USP? This includes, but certainly would not be limited to, the task assigned by Resolution 11: to examine and evaluate the voting procedures used during the Convention and make recommendations for improvement.
- The Council shall serve as a communications conduit to and from the Convention membership, providing updates to and soliciting input from the Convention membership on USP programs and activities, with the goal of keeping Convention members informed and engaged between Convention meetings. For example, the Council could:
 - Receive periodic briefings from the Board, Council of Experts, Stakeholder Forums, and Staff in areas such as the status of resolutions adopted at the previous Convention, and provide these to Convention members.
 - Employ environmental scans, surveys and other means to determine Convention members’ and other constituents’ perspectives on important USP issues and activities, and share these perspectives with the organization.

2. MEMBERSHIP

As provided by the Constitution, President Darrell R. Abernethy, M.D., Ph.D., in consultation with CEO Roger L. Williams, M.D., and with the advice and consent of the Board, appointed the members of the CoC. A core group of 14 members (Dr. Abernethy served as chair) comprised the CoC at the outset, which fulfilled the composition provisions of the Constitution, and left the President with the ability to add members he might need to complement the expertise of the core members. By April 2007, President Abernethy had appointed an additional seven delegates to the CoC, bringing the total to 21 members.

3. ISSUE PAPER

One of the first actions the CoC took, beginning in early 2006, was to work with staff to draft an issue paper about the Convention membership. The CoC felt that in order to provide guidance on strategic questions related to the purpose and value of the USP Convention, CoC members needed to understand how the Convention membership had evolved over time to its current state. As part of the research, the CoC requested an historical analysis of the roles and responsibilities of the Convention membership in order to consider whether there was a more efficient and effective way for the Convention to fulfill its current/future



role and responsibilities. The paper, *A Discussion of Issues Relating to the USP Convention Membership* (Attachment C), identified key points about the various constituencies within the USP membership. It also analyzed the functions the membership had performed over time and what its current functions were within USP's governance structure that serve to chart and direct USP's public health activities.

4. INITIAL SECTIONS CONCEPT

As the paper developed, the information suggested to the CoC a possible framework for restructuring the Convention membership into sections, or communities of interest. The CoC's initial sections proposal to the Board, suggested shifting several governance responsibilities from the membership-at-large to a smaller "steering group" (leaders of the various sections). The concept was to empower a smaller, engaged group of the membership that represented USP's various constituencies to perform Convention governance functions rather than rely on the membership-at-large. The thought was that this would result in more informed and efficient decision-making by the Convention membership. After reviewing the CoC proposal at its June 2006 meeting, the Board endorsed the concept of sections within the Convention, but directed that all governance authority remain with the entire membership.

5. REVISED SECTIONS CONCEPT AND GLOBALIZATION

The issue paper was finalized in March 2007, and with the prior direction from the Board, formed the basis for a revised sections concept. The full description of the concept is attached (Attachment D). The CoC's revised proposal did not suggest any major changes to the composition of the membership, but recommended organizing the membership into smaller groups focused on topics of common interest in order to facilitate more targeted communication and help to engage USP's diverse constituencies. The new proposal also contemplated ultimately *globalizing* the Convention by involving organizations from other parts of the world that might subsequently be considered for Convention membership.

The sections identified by the CoC in March 2007 essentially have remained the same through the cycle:

- Quality of Manufactured Medicines (Human/Veterinary, including Biologics)
- Quality of Compounded Medicines
- Quality of Food Ingredients and Dietary Supplements
- Quality of Care (now Quality of Patient Care)
- International Health–Non-Manufacturing (now Global Public Health)

In April 2007, the CoC attended the Spring Governance Meeting and were briefed on USP's activities related to each of the section topics and interactions with key stakeholders of the topic. These discussions added to the CoC's understanding of the challenges and opportunities USP was encountering within each area and defined the perspectives of the related stakeholders. The sections generally aligned with USP's Stakeholder Forums (SF), which operate under the authority of and are advisory to the Council of Experts, USP's scientific body. It was thought that connecting the stakeholder forums with the proposed sections would create the opportunity for the CoC, and ultimately the Convention membership, to begin to translate the issues and concerns of USP stakeholders into concepts and ideas for Convention action and input at the 2010 meeting.

René H. Bravo, M.D., became President of the USP Convention in mid-2007 following the resignation of Dr. Abernethy to take a USP staff position, and the CoC's work continued under Dr. Bravo's leadership.

6. RULES AND PROCEDURES OF THE COUNCIL OF THE CONVENTION

For the remainder of 2007, the CoC worked on developing its rules and procedures, which formalized the sections and laid the groundwork for the CoC to fulfill its charge of serving as a “communications conduit” for the Convention utilizing the section topic areas. In December 2007, the CoC finalized the *Rules and Procedures for USP Convention Membership Sections* (Attachment E). The *Rules* provided that the initial membership of the sections would consist of the CoC only. To accomplish this, the CoC divided itself into sections (as noted above), with a planned configuration of 5 members for each section. Placement in a section was based on the constituency the CoC member represented, his/her interests, and expertise. Each section had a volunteer chair. The *Rules* allowed the CoC later in the cycle to invite members from the Convention at-large to join a section to accomplish the work of the CoC. The *Rules* encouraged the CoC sections to attend relevant Stakeholder Forum meetings and any Expert Committee meetings that might be useful in gaining a better understanding of USP’s challenges and opportunities. The *Rules* also encouraged education and communication to the Convention membership.



PART III

2008

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

1. SECTION CHARTERS, WORKPLANS, AND IMPLEMENTATION

In the early part of 2008, each section of the CoC finalized its individual charter and workplan for the cycle, based on the Board's new strategic plan and the workplans of the Council of Experts. The CoC also worked on strategies for communicating USP's priorities to the various communities of interest within the Convention and to tie such communication strategies to the section workplans. It was decided that full implementation of Convention sections and roll out to the entire membership was not feasible in the 2005-2010 cycle and that the CoC would form a steering committee to pilot the section concept and plan for future implementation. The notion of globalizing the Convention membership remained an important additional focus of the CoC and an opportunity presented itself in May 2008 for the chair of each section to attend the World Health Professions Alliance Conference on Regulation held in Geneva. Section chairs were able to interact with their counterparts at the international level.

2. COMMUNICATIONS CAMPAIGN IS LAUNCHED

In May and June of 2008, all of the CoC sections held individual teleconferences to develop a list of priority topics for an overall communications campaign from the CoC. A topic matrix was developed and the CoC launched its campaign in July 2008 with a personal letter from President Bravo to each Convention member organization executive and delegate. Dr. Bravo's letter was followed by:

- Mid-Cycle Report to the Convention
- Article on Food Ingredient Standards as part of our safety net against tainted foods - 2008

3. WHITE PAPERS AS A PROJECT FOR THE CoC

Also in 2008, Dr. Williams proposed that the CoC consider developing a series of white papers (~one from each section) for dissemination to the Convention membership. The thought was that the white papers could provide the context

for USP's future challenges and opportunities. With this background, Convention members would be better informed and potentially motivated to propose a resolution for consideration at the 2010 Convention. The CoC agreed and the sections worked in the next several months to come up with the topic(s) for their white papers.

4. CONSTITUTION AND BYLAWS COMMITTEE

At the September 2008 meeting of the CoC, President Bravo explained that he wanted a subgroup of the CoC to form the Constitution and Bylaws (C&B) Committee for the 2010 meeting. He explained that the CoC's prior work reflected in the Issue Paper and members' deep understanding of USP's strategic direction and priorities were important for the C&B Committee. Six CoC members volunteered and Dr. Bravo charged them to undertake a comprehensive review of the current USP Constitution and Bylaws and, working with USP staff, to propose any amendments or changes to the documents deemed necessary to update and/or improve their usefulness to the organization. He emphasized the Convention's composition and globalization of the membership as important considerations. The C&B Committee (subgroup of the CoC) completed its review and presented *Amended and Restated Bylaws* in early 2009. The C&B Committee sought broad member feedback on the proposed amendments and incorporated that feedback into their final proposal to the Board and Convention.





PART IV

2009 TO 2010

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

PART IV. 2009 TO 2010

1. COMMUNICATION CAMPAIGN CONTINUES

Additional topics were identified for further communications from the CoC to the membership in 2009 through to the Convention in 2010, including:

- Drug Error Finder (planned for January 2009, but cancelled because of USP's transition of its error reporting programs)
- Resources for the Compounding Professional (April 2009)
- USP Drug Quality and Information cooperative program with USAID (September 2009)
- Dietary Supplement Tip Sheets (planned February 2010)
- Value of Public Standards (planned April 2010)

2. WHITE PAPERS DEVELOPED AND DISSEMINATED

In May of 2009, based on the CoC's prior discussions, staff began to draft seven white papers targeted for dissemination to the Convention membership as a means of stimulating resolutions for the 2010 meeting. In consultation with the CoC and after several redrafts, the papers were completed and made available for the first time at the September 2009 Annual Scientific Meeting in Toronto. The documents are a rich source of information about USP not only for the Convention membership, but for anyone interested in understanding USP and its activities. The USP home page hosted a link to the papers and members and other interested parties were notified separately through a Member Alert and News Release. For Convention members, the announcement of the white papers was accompanied by a Call for Resolutions. The white papers are available on USP's website and will be provided in hard copy at the Convention.

3. INFORMATION EXCHANGE AT THE 2010 USP CONVENTION

At its last face-to-face meeting (September 2009), eager to advance the sections concept further, the CoC approved an activity for the 2010 Convention meeting, where the concept could be explored with the larger membership group. The interaction will occur at lunch on Friday, April 24 and will be an information exchange among delegates, observers, CoC section members and staff around the seven white paper topics. USP Staff will be available to provide insight regarding current projects and planned activities for the new cycle, and the discussion will be moderated by CoC members. When registering for the meeting, each attendee will be required to select a topic. In this way, all participants can judge the value of the experience and how the concept might translate to membership activities in the next cycle.





PART V

FINAL PERSPECTIVES

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

PART V. FINAL PERSPECTIVES

The issues paper prepared by the CoC early in its tenure provided valuable insight into the role of USP's Convention membership over time and the difficulty of engaging members who interacted with USP only infrequently and did not always see the relevance of USP's activities to their own priorities. The concept of communities of interest, or sections, evolved from the notion that member organizations and delegates could be better engaged between the five-year meetings if they were more aware of USP programs that were of specific interest to them and their particular constituencies. The sections concept was implemented within the CoC as a pilot, and this pilot was successful in that it generated white papers and other targeted communications which delved into particular areas of interest and spoke more directly to USP constituencies.

The white papers were intended to stimulate resolutions and, through the involvement of the CoC in their development, incorporate the perspectives of various Convention constituencies. The "flow through" to resolutions is apparent in the proposals that the Resolutions Committee will present at the meeting. If the concept of sections advances and expands in the new cycle, sections could focus on the new resolutions. With this approach, a new pattern of sections could emerge at the beginning of each new cycle linked to adopted resolutions.

It is worth noting that if the Bylaws amendments are adopted, the CoC's functions will change significantly, in that the CoC will assume the duties currently performed by the Membership Committee and Resolutions Committee. In its new capacity, the 2010-2015 CoC will have further opportunity to consider whether thinking of the Convention membership in terms of "communities of interest" will better engage USP's diverse stakeholders and advance the mission of USP in the greater community.





CONVENTION

2010

PART VI

APPENDICES

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

**APPENDIX A. EXCERPT FROM THE
2005-2010 USP CONSTITUTION AND BYLAWS**

ARTICLE V—THE COUNCIL OF THE CONVENTION

There is hereby created a Council of the Convention. The President of the Pharmacopeial Convention shall be the Chairperson of the Council. The Council of the Convention shall be appointed by the President and Executive Vice President-CEO with the advice and consent of the Board of Trustees.

The Council shall be composed of not more than 25 members of the Pharmacopeial Convention, with at least one member representing the institutions named in Article II, Sections 1(a), (b), (c), (d), (e), (f) and (i).



APPENDIX B. 2005 RESOLUTION 11 – 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.

1. EXECUTIVE SUMMARY

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

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

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

2. BACKGROUND

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

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

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

Specifically, the recommendation was that the CoC would be advisory to the governing bodies of the organization, i.e., Council of Experts and Board of Trustees. Thus, an amendment to the Constitution and Bylaws is being proposed that creates the Council of the Convention. During its deliberations, the ad hoc Committee on Resolution 18 also acknowledged the need for an in-depth evaluation of the purpose, role, and



composition of the Convention and recommended that such a study be undertaken in the next cycle. It was thought that the CoC, if established through the proposed Constitutional amendment, could conduct the assessment.

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

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

3. RESOURCES

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

APPENDIX C. DISCUSSION OF ISSUES RELATING TO THE USP CONVENTION MEMBERSHIP

1. OVERVIEW

The purpose of this paper is to assist the Council of the Convention in its deliberations regarding the roles, responsibilities and composition of the USP Convention. The paper provides background on the evolution of the Convention and attempts to describe the issues associated with the current model. In particular, it attempts to identify key points regarding the *who* and the *what* of the Convention – that is, *who* are the members of the Convention, and *what* is their function and role within USP’s governance structure in charting and directing USP’s public health activities.

2. BACKGROUND — MILESTONES IN THE EVOLUTION OF MEMBERSHIP

a. 1820

At its earliest beginnings, the concept of a national pharmacopeia was rooted in representation, both geographically and by profession. The 11 physicians who began the pharmacopeia in 1820 were representatives of the four major regions of the U.S. at that time, and for many years, Convention members were responsible for the production of the pharmacopeia. The *USP* became the official text of the professions not because of law, but by its voluntary adoption and utilization by the health professions.

Prior to 1900, the USP functioned as an unincorporated association. Delegates (three each) representing the various medical and pharmacy institutions of the time (primarily colleges and state associations) met at ten-year intervals to authorize publication of the national pharmacopeia, the *United States Pharmacopeia*,¹ to which they would subscribe. These delegates elected a publication committee (now the Council of Experts, formerly the Committee of Revision) and entrusted it with the task of preparing the text. Delegates also provided "principles of revision" to guide the committee in its work over the decade.

From 1820 through the present, the membership of the Convention has consisted of delegates, or representatives, of organizations which by virtue of being named in the Constitution (or later by invitation) are entitled to appoint a member. The exception to this is the category for members-at-large, which was created to allow individual members to be appointed for their specific expertise.

b. 1900

The incorporation of USP resulted in a subtle but important change in the relationship between delegates and the work of USP. Prior to incorporation, the delegates who met were themselves the Convention responsible for the text of the United States Pharmacopeia. Following incorporation, and the creation of “The United States Pharmacopeial Convention” as a separate legal entity, the meetings became simply a meeting of members of this organization. In some sense, this resulted in a loss of identity for delegates and lessened the connection they felt with the work of USP.²

¹ The National Formulary (NF) was added in 1974.

² The incorporation of USP under the name of “The United States Pharmacopeial Convention,” and the use of the term “Pharmacopeial Convention” throughout USP’s Constitution and Bylaws, also created some confusion in terminology which continues to exist. While USP’s corporate name establishes the corporation as the “Convention,” the term “Convention” is also frequently used to refer to the membership of USP, and also sometimes used to refer to the meetings themselves. For purposes of clarity, the term “USP” is used in this document to refer to the corporate entity, while the term “Convention” is used to denote the collective membership of the organization.

c. 1950's

In 1950, Convention delegates changed the Constitution and Bylaws to limit Convention members to one delegate and an alternate (who could represent the institution if the delegate could not attend). Each delegate or alternate had to be a member or employee of the institution. The Constitution and Bylaws also were changed to allow the Convention President to call special meetings. This decade also placed the *USP* on a five-year revision cycle so that each Convention meeting, which took place at ten year intervals, authorized publication of two compendia. (In 2000, USP advanced to yearly publication of *USP-NF* so that Convention meeting cycles are now associated with five annual compendia publications.)

d. 1970's

In 1970, the concept of continuous representation was introduced whereby a member organization could appoint a delegate to serve throughout the period between Convention meetings. At this time, the frequency of Convention meetings was increased from ten to five years (thus, members were appointed and credentialed at the meeting and served for the ensuing five years). Provision also was made in the Bylaws for a Resolutions Committee, which became responsible for drafting resolutions that reflected the approved policies of the Convention.

In 1973, at a special meeting, Convention delegates debated the limits of their authority. A legal opinion was obtained. The opinion re-emphasized that the basic control and management of the affairs of the USP rest with the Board of Trustees. The Convention may provide policy direction, but may not pass binding resolutions. Rather, resolutions adopted by the Convention are always subject to the Board's overall responsibility to appropriately manage and control the affairs, funds and property of the organization. The Board of Directors, as well as the Committee of Revision, are ultimately held accountable to the Convention by virtue of the fact that they are elected by Convention members. As stated in the legal opinion:

Although a nonprofit corporation such as the Convention differs in many respects from a typical business corporation, the relationship between the Convention and its members is not unlike the relationship between a typical corporation and its stockholders. In other words, the basic control and management of the affairs and problems of the organization are in the Board of Trustees. The intent behind the Constitution and Bylaws was that the Convention, at its stated meetings, was to set policy while the Board of Directors and Committee of Revision are to run the organization and prepare a Pharmacopeia during the five-or previously ten-year period between meetings.

e. 1980's

In 1980, the Convention voted to increase by 5 the number of delegates who could be selected by the Board of Trustees as members-at-large, bringing to 25 the number of members-at-large appointed for the scientific or administrative needs of the Convention. The Board received the added authority to appoint 10 additional delegates – 5 at-large public members and 5 at-large members from other nations that recognize *USP-NF* standards.

As time went on, USP's publication of the *USP DI* began to reinvigorate some interest from the medical practitioner community, which had gradually lost its strong connection to USP as the manufacturing, prescribing and dispensing of pharmaceuticals evolved over the 1900s. Practitioners recognized it as an authoritative source of drug information, and many patient organizations used the *USP DI* to help patients understand and use their medicines. *USP-NF*, for the most part, was still being used in academic pharmacy and was a required text in pharmacies in many states.



f. 1990's

In 1990, the Convention adopted changes to the Constitution that broadened the Board of Trustees' appointment authority to include ten members-at-large from international bodies and foreign pharmacopeias. *USP DI* gained stature through legal recognition in OBRA 90 and 93, which provided that uses recognized in the *USP DI* would be considered medically accepted indications reimbursable under Medicare and Medicaid. By the 90's, USP also had gained experience in operating error and defect reporting programs, which provided data pertinent to USP's standards-setting activities. USP's reporting programs and the emergence of *USP DI* strengthened USP's link with practitioners. In 1994, USP purchased the *AMA-DE* from the American Medical Association with the intention of merging it with the *DI*.

USP staff leadership sought to capitalize on the opportunity to reengage the professions around the *USP-DI*, *AMA-DE* and USP's patient safety activities. Despite plans for *AMA-DE*, opportunities to advance content from this publication into *USP-DI* did not occur. At the same time, the use of *USP-NF* — the primary manifestation of USP's standards-setting activity — had begun to decline in pharmacy schools, and many states were no longer requiring the compendia in pharmacies.

g. 1995-2000 Cycle

The most significant change to the Convention size and composition was set forth by Constitutional amendment and accompanying resolution at the 1995 meeting. The outcome was that:

- Membership was expanded to include an “invited” component to complement organizations named in the Constitution. With this change, the Convention could include as many as 525+ organizations;
- The Board was authorized to extend all invitations;
- Categories were defined and the numbers of each were limited (the “big four” academic pharmacy and medicine/state pharmacy and medical associations remained the majority, with the next largest category being national associations – mostly practitioner-based);
- Desired constituencies were identified; and
- The membership term of delegates was “reversed” so that the Convention meeting in which a delegate participated was at the end of his or term instead of the beginning.³

The rationale for the expansion in membership was that the Convention should include all organizations that were affected by USP standards and programs, and in turn could affect those same standards and programs. Also, the ability to re-cast a portion of the membership through invitation to support the changing needs of the organization was thought to provide USP with a certain amount of “nimbleness,” which was perceived as lacking.

In order to implement the 1995 resolution which expanded the USP membership, the Board of Trustees appointed an ad hoc Membership Committee. This committee included a number of members from the 1995-2000 Credentials Committee, plus other individuals appointed for their knowledge of the broader healthcare community. The ad hoc Committee was charged by the Board with determining which organizations in the healthcare community would be appropriate for the Board to consider for Convention membership. The ad hoc Committee established general criteria by which to judge organizations and a systematic process for gathering and reviewing relevant information on candidate organizations. The Convention had provided parameters for the expansion by amending the membership provisions of the Constitution so as to limit the number of organizations within each

³ Prior to this time, delegates were “approved” prior to the meeting by a Credentials Committee (predecessor to the Membership Committee). Doubtful or disputed credentials were voted upon by the Convention. After approval, a delegate served as a member of the Convention until the next stated meeting when a new delegate would be appointed and the credentialing process would occur again.

category that could be invited to membership. The Credentials Committee continued to approve the individuals appointed by the various member organizations.

As the membership expansion rolled out in 1995 and additional organizations were identified and invited to appoint representatives to the Convention, USP discovered that national and academic pharmacy, specialty medicine, and pharmaceutical manufacturers' organizations were relatively eager to establish a formal relationship with USP, but the academic medical community and consumer organizations were not.

During the 1995-2000 cycle (1998), USP sold the *USP DI* database to Thomson Healthcare and licensed the *USP DI* name to Thomson. The decision to allow Thomson to take over the *USP DI* was based on the fact that the publication was not self-sustaining financially and required increasing subsidies for USP to maintain. As part of the agreement with Thomson, USP retained the right to approve all value added information beyond FDA approved labeling used in the publication, allowing USP to continue its role as an independent, non-commercial body in authorizing content. Even this constrained role for USP's work was difficult to maintain, given dramatic declines in sales of *USP-DI* after the sale to Thomson. Based on the fact that revenues from the *USP DI* were insufficient to support the work required of USP, the USP Board of Trustees altered the agreement with Thomson in several ways, the most important of which was that USP via its volunteer committees would no longer create content for Volumes I and II of the *DI* series. The *USP-DI* name would no longer be used as of January 2007, and USP could re-engage in the independent development of drug information after that time. The loss of the *DI* removed one of the links USP had with practitioners and in particular with medicine.

h. 2000-2005 Cycle

Three of the 19 resolutions adopted at the 2000 Convention meeting focused on Convention membership and attempted to engage the members in more meaningful activities. Resolution 17 called for an increase in representation from the biotechnology industry, pharmaceutical manufacturers and consumers. It called on the Membership Committee to revisit the named and invited model and to consider establishing policies and criteria for removal of organizations that are invited but that do not respond. This resolution seemed to be a reaction to the expansion resolution from 1995, which had favored practitioner/professional organizations. Organizations that wanted to participate in the Convention (industry organizations) were limited in terms of Convention impact because of their small numbers, while entitled organizations such as schools of medicine and state medical societies, which were numerous, were generally not interested in participating. Resolution 18 called for a feasibility/advisability study of increasing the frequency of Convention meetings, and Resolution 19 took a step closer to engaging the Convention more meaningfully in the strategic planning process of the organization.

During the 2000-2005 cycle, the USP Board of Trustees formed an ad hoc Committee to address Resolution 18. The rationale for suggesting more frequent meetings was articulated in the resolution with the following statement. *"Events over the past decade have shown that the health care system, the industries developing and marketing products of health care technologies (pharmaceuticals, biologics, biotechnology, gene and cell therapies, etc.), and the information age of computers, (informatics and the world wide web) are evolving at an exponential rate. USP must be capable of acting and responding rapidly to new challenges to its standards, information and experience programs. USP must have greater certainty that its leadership is contemporaneous with the scientific and policy issues of the time and must have greater support and participation of its members."* With this rationale in mind and after significant deliberations, the Committee concluded that the issue was not simply the frequency of meetings but something broader: namely, that the current composition, role, and responsibilities of the Convention membership might need to be re-evaluated to ensure that the Convention could vigorously support and engage in the organization and its activities.

With Board approval to refocus their inquiry, the Committee continued their deliberations with a final recommendation for the establishment of a Council of the Convention as a new Convention standing committee. The purpose of the new Council, as advocated by the ad hoc Committee, would be



to 1) engage Convention members in providing environmental scanning and their respective constituents' perspectives, 2) obtain and disseminate updates from their constituencies, and 3) act as an advisory body that could recommend and/or comment on advocacy, action, Convention meeting planning and support for other Convention Committees.

The Board approved this recommendation from the ad hoc Committee and directed staff to develop an implementation plan for the Board to review. Board members further recommended that the Council also might address two key issues: 1) What is the purpose of the Convention; and 2) How does the Council of the Convention facilitate that purpose.

Based on the deliberations of the ad hoc Committee and recommendations from the Board, the Resolutions Committee of the Convention proposed, and members of the 2005 Convention adopted the following:

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.

3. CONVENTION RESPONSIBILITIES

Currently, the responsibilities of the membership are carried out primarily at Convention meetings.⁴ These responsibilities consist of the following:

a. Election of the Council of Experts

The membership votes to elect the Council of Experts, who serve as the chairs of USP's Expert Committees, from a ballot that includes two candidates for each position. For the most part, members do not know the candidates for the Council of Experts and must depend on the short bios provided by USP to determine qualifications. Candidates that are better known tend to be those who have served on the Council previously, which can make it difficult for new candidates to get elected. The Convention's Nominating Committee for the Council of Experts, therefore, is critically important and staff also plays an integral role in finding the best possible candidates. USP works to avoid loss of talent in the electoral process by encouraging 'non-winners' to remain as members of an Expert Committee, perhaps in the role of vice-chair. Continuity also is promoted by allowing the prior chair the opportunity to continue to serve on an Expert Committee. If an election is required outside the meeting, it can be done by mail, but the information about the candidates is the same as that provided at the Convention meeting, and fewer members are likely to participate in the election. The Convention's election of Council of Expert members is final, and the Convention must also elect replacements required in between Convention meetings to fill vacancies resulting from resignation, removal, etc. However, authority to remove a member of the Council of Experts is vested in the Board, and must be based on a recommendation from the EVP-CEO or the Executive Committee of the Council of Experts.

⁴ It should be noted that beginning in 1995, USP has paid the expenses for members to attend Convention meetings in order to obtain broad representation and participation and eliminate any financial barrier that would prevent a member organization from being represented. It was determined that schools and associations of pharmacy and medicine were "forgetting" to budget the expense to send a representative to the USP meeting because of the five year interval between meetings. This was perceived as less of an issue with national professional and industry organizations. Despite this inducement, the overall attendance remained low: 1995-303; 2000-331; and 2005-255. Attendance remains particularly low in some categories, as reflected in the chart attached as Exhibit "A," which reflects the attendance at these Convention meetings for each category of membership. The extent to which certain constituencies participate speaks to core issues—who are USP's stakeholders and what are the barriers to their participation.

b. Election of the Board of Trustees

The entire Board of Trustees also is elected by the membership at each Convention meeting, with two candidates for each of the following ten positions: president, treasurer, 2 in pharmaceutical sciences, 2 in medical sciences, 1 public member, and 3 at-large. The past-president sits ex-officio and is not elected. The EVP-CEO also serves as an ex-officio, but non-voting, member of the Board. The members are provided with short bios and perhaps a brief opportunity to meet candidates. The Convention's Officers and Trustees Nominating Committee and staff play an important role in identifying and recruiting the candidates, and those candidates who have previously served on the Council of Experts, Convention Committees, or the Board often have an advantage in the election. Unlike the more positive situation that exists with the Council of Experts, USP is challenged to maintain links to 'non-winners' in the Board electoral process, although staff works to maintain interest and participation. The Convention's election of the members of the Board is final. However, the Convention has no ability to remove a Board member in between Convention meetings, and if vacancies occur between Convention meetings the vacancy is filled by the Board and not by the Convention.

c. Amending the Constitution and Bylaws

At each Convention meeting, the Convention also votes on proposed amendments to USP's Constitution and Bylaws (C&B). These are proposed to the Convention membership primarily through a procedure authorized in the C&B which requires that:

- The proposed amendment be submitted in writing by five members to the Board no later than 120 days before the meeting;
- The Board reviews and sends the proposed amendment(s) to the membership with its recommendation no later than 60 days before the meeting.

In practice, this primarily is a staff-driven process. Even though amendments theoretically can be proposed by members, members usually do not submit them. Instead, staff recommends changes based on experience during the cycle and presents these to a C&B Committee composed of five Convention members. The C&B Committee (which is not specified in the Bylaws but instead is informally created) is established to ensure appropriate consideration and because of the five-member requirement noted above. The report of the C&B Committee containing all of the proposed amendments is sent to the Board as required above and then to the Convention. At the meeting, amendments proposed in this fashion need a three-fourths vote for approval. While there may be limited debate and discussion over the amendments proposed by the C&B Committee, these are generally adopted by the Convention without significant changes.

Amendments to the Constitution and Bylaws also may be proposed from the floor of the Convention meeting by ten or more members. Such a proposal is then submitted to the Board for consideration/recommendation. Following Board consideration, the Chair of the Board presents the amendment to the Convention membership with a Board recommendation. A seven-eighths vote is required for approval of a floor-proposed amendment. In practice, amendments are infrequently presented in this manner, and even more rarely are they adopted by the membership.⁵

Proposals to amend the Constitution and Bylaws outside of a Convention meeting may be sent to the membership by mail ballot, at the discretion of the Board. However, this process again requires a seven-eighths vote for approval and a minimum of 130 votes cast. Again, amendments through this process rarely occur.

⁵ At the 2000 and 2005 Convention meetings, this procedure was used by organizations wanting to amend the Bylaws to name themselves in the Constitution as permanent members of the Convention. At both meetings, the Board recommended that the proposed amendment be submitted instead to the Membership Committee, in order to comply with the usual process for naming members and this recommendation was adopted by the Convention.

Amendments approved by the Convention are final and binding. As described above, however, Convention members' ability to propose amendments is limited, and exists only in connection with a Convention meeting.

d. Resolution Consideration and Adoption

The membership also considers and votes on proposed resolutions presented by the Resolutions Committee. The Resolutions Committee is appointed by the President to review ideas for resolutions submitted to it by eligible organizations or individual Convention members. A call for resolutions is sent out with the criteria for submissions and deadlines. For resolutions submitted by the specified deadline (30 days in advance of the Convention meeting) the Resolutions Committee:

- Confers with the submitter to understand intent and drafts the final language of the resolution to conform to the official policy of USP.
- Presents resolutions to the Board and Council of Experts for a needs or resources assessment.
- Presents resolutions to the Convention for consideration.

Unwritten in the Bylaws is that the Resolutions Committee may combine resolutions and/or reject submissions if the organization already has plans to implement the idea. When there are suggestions that relate to the scientific work of the Council of Experts, the ideas are forwarded to that body, rather than to the Convention. Staff is a strong contributor to resolutions and uses resolutions to garner support for the work of the organization.

Prior to the Convention meeting, members are provided with a *preliminary* Resolutions Committee report (first official report occurs at the meeting itself, following the Open Hearing), which contains each proposed resolution, accompanied by a background statement providing the rationale for the resolution and the needs assessment. Resolutions can be hotly debated on the floor and can be amended substantially prior to their adoption. This can create a problem when practitioner-members who are not engaged during the cycle (and who may only attend the Convention because USP pays their way) or do not understand the implications of the language changes for USP, or special interest groups, dominate the debate and are successful in swaying members who again may not understand the full ramifications of the change for USP.

In addition to the resolutions proposed by the Resolutions Committee, resolutions may also be introduced by members at the Convention meeting if permitted by a two-thirds vote of the members present and voting.

Resolutions approved by the Convention are final, but binding only to the extent previously discussed given the Board's fiduciary role.

The chart attached as Exhibit "B" reflects the Convention's role and responsibility with respect to each of the primary functions described above as compared to the role of the Board of Trustees and the Council of Experts with respect to these functions.

4. KEY POINTS TO CONSIDER WITH REGARD TO MEMBERSHIP CONSTITUENCIES

a. General Considerations

- (1) The respective interest levels of Convention constituencies have varied over time, as demonstrated throughout USP's history. This has occurred primarily because of changes in the practice of medicine and in the development, manufacture, dispensing and regulation of pharmaceuticals over time. Changes in USP programs have also affected the interest levels of its constituencies. Today, attempting to maintain a strong link to all of USP's diverse constituencies requires USP to engage in an extremely broad spectrum of activities.



- (2) One of the most significant evolutions within USP currently is its increasing focus of resources and energy on international sites and programs. Certainly, USP has had an international presence for a long time, for many reasons: the recognition of its standards by other countries; the demand for its products and services by foreign manufacturers wanting to import their drugs into the U.S. market; and the leadership role USP has occupied in working collaboratively with other pharmacopeias, regulators and other organizations on international health issues. However, in recent years there has been even more emphasis placed on international activities, in part due to the rise of India and China as sources of pharmaceutical ingredients and all regions as sources of dosage forms for the U.S. market, coupled with an increasingly dangerous rise in counterfeit and substandard medicines. This international expansion has had an effect on several membership constituencies, as noted below.
- (3) USP's authority, independence, and credibility must be maintained at all times. There must be no perceived conflicts in the structure and execution of programs or processes.

b. Practitioners (Schools of Medicine and Pharmacy, State Medical Societies and Pharmacy Associations, Professional Associations)

- (1) It still is predominantly physicians who diagnose conditions and prescribe medications, and pharmacists who oversee the accuracy of prescribing, manage medication therapy, do most of the dispensing, and maintain the nation's drug inventory. Beginning with the physicians who founded the USP, these two professions historically have provided the foundation for USP and constituted the majority of the Convention.
- (2) USP's reputation as an independent and credible standards-setting organization, as well as its ability to play the role of a neutral convener, has elevated USP's status to some extent among practitioners.
- (3) Because of their general support and regard for USP, practitioners may be valuable in providing USP's political base. However, they have only a limited interest in and understanding of USP's core pharmacopeial activities: the creation of documentary and physical reference standards that enable manufacturers, regulators and purchasers to perform conformity assessments to ensure the quality of pharmaceuticals.
- (4) As noted above, the exit from *USP-DI* further weakened USP's connection with practitioners, especially physicians.
- (5) If practitioners have an interest in USP today, it probably is primarily through patient safety and compounding activities. International practitioners also are interested in USP's compounding and global assistance initiatives.
- (6) While USP's activities in the patient safety arena traditionally have provided a link with practitioners, USP has struggled to develop a financially viable, self-sustaining program or clearly define its distinct and unique public health role in this area.
- (7) USP's involvement in the Medicare Model Guidelines is relevant to and has an impact on practitioners as well as consumers, pharmaceutical manufacturers, and health plans. While the activity has created and strengthened USP's connection with health plans, it has not necessarily had the same effect on USP's relationship with practitioners, who may not see themselves as benefiting from USP's work in this area.

- (8) There is an increasing dichotomy between academia and the practitioner community, so that Convention delegates from medical schools and pharmacy schools may not represent the interests or concerns of the practitioner community.
- (9) Academic pharmacy is increasingly focused on graduating clinicians and with few exceptions does not use *USP–NF*. Instead schools rely on primary literature on large clinical studies and books such as Dr. Koda-Kimble’s *Applied Therapeutics: The Clinical Use of Drugs* or *Pharmacotherapy* by Joseph DiPiro. The *Pharmacists’ Pharmacopeia* holds little hope of reinvigorating interest in USP except perhaps in the compounding community.
- (10) National practitioner associations are struggling to establish new models for improving patient care—both the quality and safety thereof, and USP is creating few if any programs that will help them. A resolution adopted at the 2005 Convention meeting encourages USP to develop a compendium of safe medication use practices.

c. Manufacturers (Domestic, Foreign and International Manufacturers Trade Associations)

- (1) USP has changed significantly in the last 20 years. Most of USP’s products and services now are focused towards pharmaceutical manufacturers, and yet manufacturers have only minimal representation in the Convention. In addition, while manufacturers are USP’s most direct customers, USP standards essentially create a regulatory burden for manufacturers, and may be perceived as potentially threatening innovator manufacturers’ intellectual property. Thus, innovator manufacturers are not necessarily willing to work with USP to strengthen the USP-NF by developing missing monographs, and frequently are unsupportive of USP’s growth and expansion. USP believes that multisource, OTC, and ingredient manufacturers are more supportive of USP’s creation of ‘safe harbors’ for end product testing.
- (2) The move to strengthen USP’s international presence has created friction with multinational pharmaceutical manufacturers who believe USP should confine its activities to the U.S. and focus on harmonization efforts that will eventually result in a single set of global standards and requirements. USP has not been able to develop a convincing argument that its international work, which can help reduce counterfeit and substandard medicines, is as much in the interest of multinationals as it is in the interest of public health.

d. FDA, CMS and Department of Commerce (Government Bodies)

- (1) Despite USP attempts throughout the 2000-2005 cycle to establish closer relations with FDA, at the Commissioner and Center level, the two organizations met only sporadically. At the 2005 Convention, FDA’s position on several important issues were not aligned with those of the larger practitioner segment of the Convention. This positioning was also evident during debate of the resolutions. It is unclear if FDA’s response to these important issues affects member perceptions of USP’s authority.
- (2) While not voicing strong opposition, FDA was not necessarily supportive of USP’s initiative to set standards for articles outside the U.S. and cautions that such standards could create confusion for manufacturers. However, USP’s limited implementation of this initiative has attempted to address FDA concerns by clearly distinguishing between the USP-NF and monographs for articles legally marketed outside of the U.S.
- (3) FDA has not supported USP in the area of dissolution, and currently is promoting the use of mechanical calibration as opposed to a periodic performance verification test with the use of chemical standards, which USP requires. FDA’s broader involvement in process analytical



technology and “quality by design” does not necessarily synergize with USP’s interests in supporting end product testing as a means of promoting the public health.

- (4) FDA’s implementation of provisions of the Hatch-Waxman Act potentially could create a conflict between FDA and USP. Non-binding FDA guidance documents currently allow manufacturers to change product standards immediately to comply with USP monographs, provided that FDA is informed of the changes annually. FDA could change its interpretation to require FDA approval before certain of these changes can be made. This interpretation would weaken USP’s ability to upgrade standards and methods unilaterally and would diminish USP’s position as the preeminent pharmacopeia.
- (5) USP has been able to strengthen its working relationship with FDA in certain areas through cooperative research and development agreements that provide for collaboration on testing of reference standards, assistance in creation of national database, etc. USP has renewed efforts to re-establish a closer relationship with the Agency at higher levels, and these efforts seem to be having a positive effect on USP’s interaction with the agency.
- (6) USP’s role in developing the Medicare Model Guidelines has resulted in increased interaction with another Department of Health and Human Services agency that is a Convention member, the Centers for Medicare and Medicaid Services (CMS). Although CMS has not provided the level of financial support USP has desired for the Model Guidelines, the relationship is generally positive.

e. Consumer Organizations

- (1) USP traditionally has struggled to obtain and maintain the interest of consumer groups. Currently, there are only six members in this category, although the Bylaws permit up to twenty-five.
- (2) Although the Medicare Model Guidelines work would seem to be an opportunity to enhance USP’s relationship with this constituency, it has not had a significant effect in this regard.

5. QUESTIONS

Although questions are posed separately below for the Convention’s “responsibilities” and “composition,” it is important to note that they are integrally related, especially given that the Council is charged with re-examining both. For example, one could start by considering what the composition of the Convention should be, given the responsibilities that it has under USP’s Constitution and Bylaws. Conversely, the inquiry could begin by considering what the responsibilities of the Convention should be, given its composition as defined by USP’s Constitution and Bylaws. In reality, given the Council’s charge, neither the “responsibilities” nor the “composition” should be assumed to be fixed. However, it is also true that a meaningful change in either the “composition” or the “responsibilities” of the Convention will require a change to USP’s Constitution and Bylaws – a reality that also needs to be taken into account.

a. Responsibilities

- (1) Should the Convention set policy and/or strategic direction for the organization, or is it only important that the Convention support the policy/strategic direction set by the Board? What is the relation between the Convention and the Board with respect to setting policy? If resolutions are non-binding, to what extent must the Board ensure that they are carried out? Does the Board act for the Convention in setting policy? Can the Board change policy decisions set by the Convention in between meetings if needed, e.g., changes in laws, resource constraints, etc.?



- (2) Is the resolutions process truly meaningful or valuable given that resolutions rarely originate from members as opposed to staff, that resolutions proposed by the Resolutions Committee often simply are adopted as recommended, and that to the extent changes are made on the Convention meeting floor, these changes are often proposed and/or supported by special interests or uninformed members who do not really understand their ramifications? How could the resolutions process be improved?
- (3) How could the membership's election of the Board of Trustees be improved? What is the impact of having a new Board every five years as opposed to staggered terms, and how could staggered terms be implemented (e.g., mail elections, more frequent Convention meetings) without creating other negative consequences?
- (4) Should the Council of Experts continue to be elected by the membership, given that the membership may not be in the best position to evaluate candidates for this scientific (as opposed to policy-making) body? If so, how could the election process for the Council of Experts be improved?
- (5) What are the disadvantages of identifying and recruiting two candidates for each position on the Board and Council of Experts, when one candidate must inevitably lose the election? How could this process be improved while still maintaining a meaningful election?
- (6) How could USP better engage the Convention in between Convention meetings, given that the Convention's responsibilities are largely fulfilled at Convention meetings?

b. Composition

- (1) Should the Convention include a broad array of practitioner, industry, international, governmental and consumer organizations, or only segments of these constituencies that have a clear and direct connection to USP's current activities? What purpose do constituencies without such a connection serve in the Convention? What are the effects of non-participation or disinterest by Convention members on USP?
- (2) If a broad array of organizations makes up the Convention, is it reasonable to expect each organization to understand and care about all of USP's programs, products, and services? What is the impact on USP of continually attempting to engage in activities that will "speak" to each of its membership constituencies, when such activities may not be central to USP's mission and current strategy?
- (3) Could a smaller representative group provide the political base, electorate, and authority USP needs to conduct its work and ensure credibility?
- (4) Given USP's increasing international presence, are international organizations appropriately represented within the Convention? Do the letters U.S. in the organization's name contribute to a perception on the part of both domestic and international constituencies that USP is not – or should not be – an international organization?
- (5) What are the practical challenges to changing the composition of the Convention, given that the composition is prescribed by the Constitution and Bylaws and any changes to these documents must be approved by the current membership?

**APPENDIX D. COUNCIL OF THE CONVENTION—
CONCEPT TO CREATE USP MEMBERSHIP SECTIONS (MARCH 2007)**

1. COMPOSITION AND RESPONSIBILITIES OF THE PHARMACOPEIAL CONVENTION MEMBERSHIP (CONVENTION)

- a. The Convention will remain primarily “organization-based,” with broad and diverse representation across the healthcare community, nationally and internationally.
- b. A Constitutionally-named and invited approach for membership will be retained to continue to provide continuity/flexibility. The Board of Trustees (BoT) will retain the authority to invite additional organizations, as well as individual members-at-large, to join the Convention in order to reflect the changing activities of USP.
- c. Each eligible organization, named and invited, will continue to appoint one representative as its delegate to the Convention. Such organizations are referred to in this document as “Convention member organizations,” and their delegates are referred to as “Convention members.”
- d. The Convention members will continue to meet every five years to:
 - Elect Officers and Trustees.
 - Elect the Council of Experts (CoE).
 - Adopt resolutions.
 - Amend the USP Constitution and Bylaws.

2. DIVISION OF CONVENTION INTO SECTIONS

- a. The intent behind creating sections is to organize Convention member associations into smaller groups that will focus on USP’s current and possible initiatives that are of interest to them and their constituencies. In that sense, the sections may also be thought of as “communities of interest.” The goals of creating sections are to:
 - Engage Convention member organizations in USP’s activities on a more continuous, ongoing basis between Convention meetings;
 - Create more frequent opportunities for exchanges of ideas and perspectives between/among Convention member organizations, USP staff, and potentially other bodies within USP’s governance;
 - Build a better understanding within USP’s Convention member organizations of USP’s mission and vision and the intent and scope of activities, programs, and services;
 - Build closer relationships with Convention member organizations, tap into their knowledge base and seek their input on healthcare issues of the day;
 - Better fulfill USP’s role as an unbiased convenor, allowing it to more effectively reach out to and interact with organizations that are affected by USP standards and information and who in turn can affect USP’s work; and
 - Allow Convention member organizations to exercise their governance responsibilities in a more informed way.
- b. The BoT approves the number and type of sections to be created, based on recommendations from staff and the CoC. This is similar to the process utilized for the Expert Committees to be created each cycle. Sections may be added or changed upon recommendation of staff and the CoC with the approval of the BoT.



- c. The sections generally will be organized around topics of common interest to USP member organizations. To promote community input, in addition to existing members a section may include representatives from observer associations who might subsequently be considered for Convention membership. Given USP's role in standards-setting, section membership and observers are expected to include direct users of USP's standards, conformity assessment bodies, and ultimate beneficiaries of USP standards when used by the direct users. The initial sections include:
- Quality of Manufactured Medicines (Human/Veterinary)
 - Quality of Compounded Medicines
 - Quality of Foods, Food Additives and Dietary Supplements
 - Quality of Care (Evidence Based Care; Patient Safety, Other)
 - International Health (Non-Manufacturing)

These sections and their titles will need to be further defined and clarified so that Convention member organizations and individual members can clearly identify what sections are relevant to them and will be motivated to become involved in the section. For additional clarity and to encourage participation, an initial charge should be developed for each section describing the scope of its activities and those topics on which USP is seeking member input and engagement. To ensure that sections are being created that collectively may engage all USP member constituencies, the proposed sections should be evaluated against the various USP membership categories. Over time, sections are expected to align with current stakeholder forums.

- d. With oversight from the CoC, as discussed below, Convention member organizations self-select the sections in which they participate and may appoint additional individuals to various sections depending on interest and expertise (further discussion may need to occur about the right number of additional section members any organization may have so as to address the issues of balance and size). As stated above, however, only the official member from each Convention member organization is eligible to participate in Convention governance activities. All other appointees to sections from the organization are considered section members, which carries no governance authority.
- e. Each section may adopt its own procedures for participation in section activities, within approved parameters and subject to CoC and BoT oversight and approval, as discussed below.
- f. The sections will be encouraged to propose nominees for the CoE and Officers and Trustees, which will be considered by the Nominating Committees. The sections also will be encouraged to submit proposals for resolutions, which will be considered by the Resolutions Committee.
- g. USP should consider funding section meetings at least in the start-up phase in order to foster development of and broad participation in the sections.

3. ROLE OF THE COUNCIL OF THE CONVENTION (COC)

- a. As currently provided for in the Constitution, the CoC shall continue to be appointed by the President and Executive Vice President-CEO with the advice and consent of the Board of Trustees, and will continue to consist of up to 25 members representing various USP membership categories.
- b. The CoC and staff will make recommendations to the BoT regarding the number and type of sections to be created, based on input it solicits from the Convention. The CoC will also work with staff to develop the initial charge and topics for consideration by each section, and recommend these to the BoT for approval.



- c. The CoC will work with staff to develop standard procedures for the operation of sections, including parameters within which a section may vary certain aspects of these procedures, and will recommend these to the BoT for its approval. Sections may modify the procedures within the approved parameters with approval of the CoC; modifications that exceed the parameters will require BoT approval.
- d. To provide oversight of section membership and activities and ensure that all constituencies within a section are being heard, the CoC will appoint the chair of each section, and will also appoint a liaison to each section from the CoC.
- e. The CoC periodically shall report to the BoT and the Convention on the activities conducted by each section, which might include (but not be limited to): environmental scanning and development of recommendations relating to section topics; new resolution development; recommendations for candidates for the CoE and CoC; monitoring of and recommendations for activities relating to existing resolutions; and interactions with USP stakeholders and constituencies. The CoC periodically also shall report to the BoT on the success of the section concept, as measured against the goals set forth in Paragraph 5 above, and if appropriate make recommendations to modify the section concept to better achieve such goals.

APPENDIX E. RULES AND PROCEDURES FOR USP CONVENTION MEMBERSHIP SECTIONS

1. PURPOSE AND GOALS

The Convention membership shall be organized into “communities of interest” (Sections) to achieve the following goals:

- a. Engage Convention member organizations on a more continuous, ongoing basis between Convention meetings;
- b. Build a better understanding within USP’s Convention member organizations of USP’s mission and vision and the intent and scope of activities, programs and services, and the impact and benefit of such activities, programs and services to Convention members;
- c. Build closer relationships with Convention member organizations, tap into their expertise on current and developing healthcare issues and seek their input on USP’s current activities and future direction;
- d. Create more frequent opportunities for exchanges of ideas and perspectives on USP’s opportunities and challenges between/among Convention member organizations, USP staff, and other USP governing and advisory bodies such as Stakeholder Forums, the Council of Experts and Expert Committees, and the Board of Trustees (BoT);
- e. Better fulfill USP’s role as an unbiased convener, allowing it to more effectively reach out to and interact with organizations that are affected by USP standards and who in turn can affect USP’s work;
- f. Help identify and recruit organizations and individuals as potential USP Convention members and observers; and
- g. Enable Convention member organizations to exercise their USP governance responsibilities in a more informed and active way.

2. SECTIONS

The initial Sections to be created shall include the following:

- a. Quality of Manufactured Medicines – Human and Veterinary (including Biologics/Biotechnology);
- b. Quality of Compounded Medicines;
- c. Quality of Food Ingredients and Dietary Supplements;
- d. Quality of Patient Care (drug information, patient safety, other); and
- e. Global Public Health (focused on pharmaceutical and food-related public health needs and issues in developing countries).

These Sections may be modified and/or new Sections may be created over time as recommended by the Council of the Convention (CoC) with approval of the BoT.

3. MEMBERSHIP

a. Initial Membership

Prior to the 2010 Convention Meeting, the membership of the Sections shall be drawn from the members of the CoC. CoC members shall become members of the Section that best reflects their professional interests and the constituencies they represent. In 2008, the Sections may begin to invite additional Convention members to participate in Section activities, with the goal of expanding Section membership as needed to accomplish the work of the Sections. Such additional members shall be chosen by the CoC Section members with input from USP staff based on their willingness to participate in the Section meetings and activities described in Paragraphs 4 and 5 below and their anticipated value and contribution to the Section.

b. 2010 Selection and Participation by Convention Members

At the 2010 Convention meeting, all Convention members shall be invited to join Sections and to participate in one or more Section meetings subject to the limitations in this Paragraph. Subject to oversight by the CoC as provided in Paragraph 7c below, Convention member organizations shall be allowed to select the Sections in which they desire to participate and in addition to their designated Convention member may appoint individuals with interest and expertise to participate in Section activities. However, only the designated Convention member from each organization shall be eligible to vote in matters considered at Section meetings as described in Paragraph 5a below, and have the right to exercise the governance responsibilities reserved to Convention members under USP's Constitution and Bylaws.

4. SCOPE OF WORK

Each Section's scope of work shall be set forth generally in a charge (Charge) to be developed by the Section at the beginning of each cycle, and more specifically, in an annual workplan (Annual Workplan) to be developed by the Section as described in Paragraph 5a below. However, the scope of work for each Section is expected to include the following:

a. Participation in USP Activities

- (1) Stakeholder Forums. Section representatives shall participate in meetings of the Stakeholder Forum or Forums that correspond to such Section, as identified by USP staff.
- (2) Annual Science Meeting. Section representatives shall participate in USP's Annual Science Meeting, attending those sessions relevant to the Section.
- (3) Other. Working with USP staff, each Section shall seek to identify and designate representatives to participate in other USP meetings and events of interest to the Section, including Council of Experts and Expert Committee meetings, workshops, symposia, etc.

b. Education, Communications and Outreach

- (1) Education and Communication to Section Members. Working with USP staff, each Section shall seek opportunities to inform and communicate with current and potential Section members regarding USP activities, programs and services, in furtherance of the goals described in Paragraph 1 above. Such efforts may include the development of impact statements, which explain the impact of USP's standard-setting and other activities on Section constituencies, and other communications materials that convey the value and importance of USP's work in a manner tailored to the specific Section audience. All impact statements and other educational and communications materials to be sent to Section members or other audiences must be

reviewed and approved by USP staff prior to distribution. Such materials shall be owned by USP, who shall have the right to determine their usage.

- (2) Surveys and Other Input from Section Members. Working with USP staff, each Section may also consider conducting surveys of Section members or identifying other opportunities to seek input and feedback from Section members regarding USP's activities, programs and services. USP staff or USP volunteer bodies such as the CoC, BoT, or an Expert Committee may request that the Section seek input from its members on topics from time to time.
- (3) Outreach Activities. Working with USP staff, each Section shall also seek opportunities to advance USP's efforts to identify and establish contacts with new constituencies that are relevant to USP's activities, for the purpose of educating such constituencies about USP, developing relationships, and encouraging such constituencies to seek Convention observer or member status where appropriate. Such constituencies may include global practitioner and other health care organizations.

c. Governance-Related Activities

As USP's Convention meeting approaches, each Section shall develop ideas and recommendations that will enhance the fulfillment of Convention membership governance responsibilities. Specifically, each Section shall consider and relay to the CoC recommendations regarding (i) nominations for USP officers, trustees, and members of the CoE; (ii) proposed Resolutions for the coming cycle; and (iii) proposed changes to USP's Constitution and Bylaws. In addition, during the ensuing cycle, each Section shall assist in monitoring and considering ways to advance Resolutions adopted at the prior Convention meeting that relate to such Section.

d. Reporting

Each year, working with USP staff, each Section shall prepare and deliver to the CoC an Annual Report of its work and activities for the prior year. The Annual Report shall be delivered to the CoC prior to the Spring Governance Meeting. Beginning in 2010, and in those years in which a Convention meeting is held, the Section shall prepare and deliver to the CoC not less than ninety (90) days prior to the Convention meeting a report of its work and activities for the cycle as a whole (Cycle Report). Such Cycle Reports shall be consolidated by the CoC and delivered to the BoT and Convention membership as described in Paragraph 7b below.

e. Funding

Funding for Section activities shall be provided only as approved in writing in advance by USP staff. Unless otherwise approved in advance on a case-by-case basis, travel expenses to Section meetings and other activities shall be paid by USP only for CoC members.

5. SECTION MEETINGS

a. Annual Meetings

Each Section shall annually (a) approve and deliver to the CoC the annual report (Annual Report) of Section activities for the previous year, as described in Paragraph 4d above, and (b) with input from the CoC and USP staff, develop an Annual Workplan for the coming year, which shall include a calendar of anticipated Section meetings and activities for the year. The Annual Workplan shall be approved by the CoC and the BoT as described in Paragraph 7a below. Such actions may occur at a meeting or through such other mechanism and venue for accomplishing these responsibilities as is deemed appropriate by each Section.



b. Convention Meetings

Beginning in 2010, each Section shall meet in person at USP's Convention meeting every five years. At such meeting, the Section shall develop a Charge and proposed activities for the Section which shall be approved by the CoC and the BoT as described in Paragraph 7a below. Minutes shall be taken of such meetings and a summary thereof shall be posted on USP's website.

c. Informal Meetings and Teleconferences

Each Section may hold other informal meetings and teleconferences as the Chair deems appropriate, provided that prior notification thereof is given to the CoC and USP staff. Such meetings may occur at USP's Annual Science Meeting, at meetings held by other organizations, or at such other times and places as may be convenient and advantageous for the Section.

6. SECTION CHAIRS

a. Selection of Chair.

The initial Chair of each Section shall be a volunteer from among the members of the CoC, and shall serve for the remainder of the 2005-2010 cycle. Following the 2010 Convention meeting, and each ensuing Convention meeting thereafter, the Section shall elect a Chair for the coming cycle from among the CoC members appointed for such cycle by the President.

b. Responsibilities of Chair.

The Chair of each Section shall serve as the Section's primary liaison with USP staff and with the CoC. With assistance and support from USP staff, the Chair shall be responsible for the following:

- (1) Organizing each of the Section meetings described in Paragraph 5 above, chairing such meetings, and ensuring that a summary of the minutes of such meetings is posted on USP's website when required under such Paragraph;
- (2) Ensuring Section participation at the USP meetings and activities described in Paragraph 4a above, by designating one or more Section members who will attend each such meeting or activity;
- (3) Obtaining approval of Section educational and communications materials described in Paragraph 4b above;
- (4) Ensuring the preparation and delivery to the CoC of the Annual Reports and Cycle Report described in Paragraph 4c above; and
- (5) Providing to USP staff and obtaining approval for any requests for USP funding of Section activities as described in Paragraph 4d above.
- (6) Identifying with input from USP staff, potential section members to assist in advancing Section activities.

7. OVERSIGHT BY COC

The CoC shall be responsible for providing oversight of the Sections as follows:

a. Approval of Charge and Workplan

The CoC shall review and approve the Charge and Annual Workplan of each Section to ensure consistency with these Rules and Procedures. Following review and approval by the CoC, such items



shall be provided to the BoT for their review and approval. Any changes requested by the CoC or BoT as a condition of approval shall be incorporated by the Section into the final Charge or Annual Workplan.

b. Consolidation and Communication of Reports and Recommendations

- (1) Annual Report. As described in 4d above, the CoC shall collect the Annual Reports provided by the Sections and combine them into a consolidated report, which shall be provided by the CoC to the Convention and to the BoT.
- (2) Convention Report. Prior to each Convention meeting, the CoC shall collect the Cycle Reports provided by the Sections and combine them into a consolidated report which shall be delivered by the Convention President as part of his report at the Convention meeting.
- (3) Reporting to Convention Committees. The CoC shall review and consolidate those recommendations from Sections developed under Paragraph 4c above related to Convention membership governance functions, and provide them via USP staff to the relevant Convention Committee (e.g., Nominating, Resolutions, Constitution and Bylaws, Membership, etc.)

c. Monitoring of Section Development and Work

As the Sections are established and expanded the CoC shall continuously monitor and evaluate all aspects of their development and operation, including their membership, progress under their Annual Workplans, and fulfillment of their other functions under these Rules and Procedures. The CoC shall work with the Section Chair to address any questions or issues it has concerning the development or work of a Section. On an ongoing basis, the CoC shall provide reports to the BoT regarding the status of the development of Convention Sections as provided herein, including recommendations on any modifications to these Rules and Procedures or any other aspect of the Section concept.

d. Communication Between Sections

The CoC shall seek to identify and cultivate opportunities to enhance communication and interaction among and between Sections where appropriate given commonalities of interests and issues.

e. Approval and Amendment of these Rules and Procedures

These Rules and Procedures shall be effective when approved by the CoC and BoT, and may be amended from time to time as recommended by the CoC and approved by the BoT.