



REPORT OF THE 2005–2010 MEMBERSHIP COMMITTEE

April 15, 2010

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ADVANCING HEALTH THROUGH PUBLIC STANDARDS

CONTENTS

PART I	MEMORANDUM FROM THE MEMBERSHIP COMMITTEE	4
PART II	2005 TO 2006.....	7
PART III	2007	10
PART IV	2008	13
PART V	2009 TO 2010.....	15
PART VI	APPENDICES.....	16





PART I

MEMORANDUM FROM THE 2005–2010 MEMBERSHIP COMMITTEE

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

PART I.

MEMORANDUM FROM THE 2005–2010 USP MEMBERSHIP COMMITTEE

The following pages describe the work of the Membership Committee (MC) during the 2005-2010 cycle. The MC appreciates the opportunity to provide this brief summary and for the privilege of serving the USP.

On August 18, 2005, then USP Convention President Darrell R. Abernethy, M.D., Ph.D., appointed ten members of the USP Convention to serve on the MC for the five year cycle, 2005 to 2010. The composition of the MC is prescribed in the USP Bylaws (see Appendix A). The MC was chaired by Thomas R. Temple, R.Ph., M.S., Iowa Pharmacy Association and included:

- Christopher K. Allen, R.Ph., M.P.H., Member-at-Large
- Dennis E. Doherty, M.D., F.C.C.P., University of Kentucky College of Medicine
- Greg S. Johnson, Pharmaceutical Care Management Association
- Donald C. Singer, M.S., American Society for Quality
- Peter J. Tyczkowski, M.B.A., R.Ph., University of Connecticut School of Pharmacy
- Diane E. Dorman, National Organization for Rare Disorders
- Raimar Löbenberg, Ph.D., Association of Faculties of Pharmacy of Canada
- C. Edwin Webb, Pharm.D., American College of Clinical Pharmacy

The Bylaws also define the authority of the MC, which is to:

- Identify and recommend for Board of Trustees consideration organizations eligible to appoint a delegate according to the provisions of the USP Constitution (Appendix A);
- Adopt procedures and criteria sufficient to ensure the fair and orderly consideration in the identification and recommendation of such organizations (requires Board approval);
- Report at least annually to the Board on the committee's work and composition of the Convention;
- Review and approve the credentials of delegates proposed as members to the Convention;
- Report to the Convention on the committee's work and the composition of the Convention; and
- Provide to the Resolutions Committee guidelines for the types of institutions and bodies that should be invited to appoint a delegate for the following stated meeting.

A resolution adopted in 2005 called on the newly-formed Council of the Convention (CoC) to evaluate the composition of the USP membership. To ensure close coordination and communication between the CoC and MC, the MC Chair, Mr. Temple, served as the liaison from the MC to the CoC. In this way, as the MC identified appropriate organizations for membership, it took into account the evolving deliberations of the CoC.

From 2005 to the present, the MC held four face-to-face meetings and six teleconferences. Several discussions regarding specific organizations occurred through e-mail as did monthly approvals of credentials for all delegate appointments.



Starting with a base of 361 organizations—those named in the USP Constitution—the MC vetted and recommended another 97 organizations to the Board for membership. These included both new and previously invited members; because under the Bylaws, the term of all invited member organizations ends six months after the membership meeting, the MC had to review all previously invited organizations to determine if re-invitation in the 2005-2010 cycle was appropriate. All 97 organizations were approved by the Board. It also should be noted that at the end of this cycle, 90% of all Convention organizations had appointed a delegate. This is an unprecedented accomplishment, as appointments in previous cycles stayed below the 75% level.

The MC also dealt with several policy issues during the cycle of importance to the Convention. The lack of participation by medical schools and societies was concerning to the MC, particularly because these organizations are named in USP's Constitution and, like all named organizations, retain membership regardless of the level of participation. This is unlike invited organizations, where lack of a response may lead to an invitation being withdrawn or an organization not being invited in the next cycle. For this reason, the MC supports the proposed amendments to the Bylaws, which will provide the same status to all member organizations and allow all to continue their membership as long as they remain engaged with USP.

A major accomplishment in the cycle was the MC's development and implementation of the Official Observer category. To date, the MC has invited 86 organizations to be Official Observers to the USP Convention. Many have named representatives and nearly half of them will be present at the 2010 Membership Meeting.

The report provides additional details about the MC's work throughout the cycle. For each period of time, you will see a brief summary of activities, followed by details of how the MC completed its work.

Respectfully Submitted,

Thomas R. Temple, R.Ph., M.S.
Chair, 2005–2010 Membership Committee





PART II

2005 TO 2006

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

PART II. 2005 TO 2006

In 2005 and 2006, the MC determined the process and criteria for considering and inviting organizations to membership. At each meeting from 2005 to the present, the MC evaluated organizations it was considering for membership against its established criteria. During the meetings the MC also discussed the response of invited organizations, and reviewed the level of delegate appointments in each membership category. During the period 2005-2006, the MC recommended that 51 organizations be re-invited and 14 additional organizations be invited to membership. The committee also began discussions about the possibility of implementing a new Official Observer status.

A. Motions from the 2005 Convention

At the 2005 membership meeting, two Constitutional amendments pertaining to membership were proposed from the floor. The delegate representing the American Herbal Products Association (AHPA) proposed an amendment to USP's Constitution to add AHPA as a Constitutionally-named member. In addition, the delegate representing the American Veterinary Medical Association requested that "Colleges of Veterinary Medicine Accredited by the Council on Education of the American Veterinary Medical Association" be added to the list of accredited colleges and schools named in USP's Constitution.

As directed by the USP Bylaws, the Board of Trustees provided its recommendations regarding the two amendments, which was to refer them for further consideration to the 2005-2010 Membership Committee. The Convention membership agreed and these proposals came before the MC. The MC considered the addition of Constitutionally-named Convention member organizations and sought additional guidance from the Board. The MC recommended that the Constitution not be amended to add to the list of Constitutionally-named members. AHPA and AVMA were informed of the MC's decision, which was supported by the Board, and instead both organizations were re-invited to membership.

B. Considering and Inviting Organizations to Membership

As noted in the memo preceding this report, when the MC met for the first time in November 2005, the Convention membership was composed only of Constitutionally-named organizations. The term of the 92 organizations invited to membership in the 2000-2005 cycle had ended September 15, 2005.

The MC first established a *Process for Considering and Inviting Organizations for Membership in the USP Convention*. Once an invitation has been extended, it is incumbent on the invited organization to respond by naming a delegate. The MC expanded the process used in the previous cycle by including parameters for rescinding invitations for non-response. (Appendix C).

Based on its new process, the MC recommended to the Board that 51 member organizations from the previous cycle be re-invited to membership. The Board approved the list and formal invitations were sent to the organizations. Letters also were sent to organizations that were not re-invited. A few of these organizations petitioned to be considered for membership, and their petitions were assessed following the MC's new process. By the close of 2006, the Board had approved an additional 17 new member organizations. USP had 479 Convention member organizations, 74% of which had appointed delegates.



C. Representation by Multiple Delegates

The MC also considered the prior cycle practice where some organizations, which were named in the Constitution, were also given a second invited membership. A 1995 Resolution had set the stage for this by specifying that the Pharmaceutical Manufacturer's Association (PhRMA) be allowed an additional delegate to capture perspectives from the biological and technical committees of PhRMA. The MC discussed the changing nature of USP's activities and direction over time and noted the need to continually re-evaluate how to best obtain a range of industry perspectives. There was a general consensus that the principle of one organization-one vote was an important one given USP's governance structure. The MC recommended to the Board that additional invitations to already named organizations not be extended.

D. Impact of Acquisition of Food Chemicals Codex

In 2006, USP acquired the *Food Chemicals Codex* and formed the Food Ingredients Expert Committee. In response to this expansion of USP's activities, the MC began to consider organizations that could bring a *foods* perspective to the Convention.

E. Official Observer Status

During the course of looking at potential member organizations, the MC became aware of situations where, due to internal reasons (e.g., organizational procedures or bylaws), an organization could not accept membership in the USP Convention. Declining USP's invitation, even under these circumstances, essentially ended the dialog about establishing a "Convention" relationship. This situation led the MC to begin exploring other ways of engaging such constituencies, and the possibility of creating a new Official Observer status began to emerge. It was hoped that such status would:

1. Provide a mechanism to formally engage organizations that may not otherwise be able to participate in USP Convention deliberations; and
2. Create a "first step" for organizations that USP may wish to consider for membership, to allow them to become acquainted with USP and vice versa.

This approach was also attractive because a Constitutional amendment would not be required to create an observer status, as no governance responsibilities would be involved. The MC presented its ideas to the Board who responded favorably and vested the authority to extend Observer invitations with the Membership Committee.





PART III

2007

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

PART III. 2007

In 2007, the MC increasingly focused on evolving the USP membership to reflect USP's international expansion and focus. The Committee was challenged by its chair, Mr. Temple, to consider a future Convention structure that could take USP's domestic-based membership to an international platform while retaining the unique practitioner nature of the Convention.

The MC continued to debate the implications of organizations being named in the USP Constitution versus inviting organizations. These discussions were precipitated by another request from an organization to be named in the USP Constitution.

During 2007, the MC recommended 8 new organizations to the Board, among them a strong contingent of foods organizations to reflect USP's new standards activity in this area. At that point in the cycle, the percentage of organizations that named delegates rose slightly to 75%.

A. Two Types of Membership

In response to another request from an invited member asking for Constitutionally-named status, the Board asked the MC to develop a process and criteria by which an invited organization with a good track record of participation might be named in the USP Constitution. Again, the MC confronted the two-tiers of Convention membership. The Committee reviewed the participation history of all the invited organizations, but also discussed ways in which USP could engage not just invited organizations, but all Convention members, whether named or invited. The MC ultimately recommended to the Board that the Convention membership be redefined in the Constitution and Bylaws (C&B) in a way that provided an appropriate and balanced structure, retained the general representation of certain constituencies, and eliminated the need to name organizations within the Constitution. The Board's Governance Committee and full Board agreed with the concept and asked the Council of the Convention to assist in developing the relevant amendments to the C&B.

B. Official Observer Status

Monitoring the MC's process towards an Official Observer status, the Board of Trustees encouraged the MC to develop criteria for the status. It agreed that this status could also be used to introduce a new organization to USP, gain experience with that organization, and assess its level of interest in the USP Convention before inviting the organization to become a member. The MC developed a process and criteria for considering organizations or individuals for Official Observer status. The MC also defined observer's privileges (receipt of Member Memoranda, invitation to membership meetings), and clarified that Observers would have no voting rights (reserved for Convention members). The Board approved the final Official Observer Status Process and Criteria (Appendix D) and set the maximum number of Official Observers at 100.

C. Multiple Seats for Member Organizations

The MC continued to support the idea of one vote for each organization in the USP Convention. The MC noted that many obstacles had existed to an ongoing exchange of ideas and perspectives from industry but that these had been eliminated in the 2005-2010 cycle through a robust system of Stakeholder Forums. The MC determined that multiple delegate representation would discriminate against organizations with only one delegate. The MC ultimately established a one delegate, one vote principle and determined that Official Observer status could be used for trade associations and other organizations to ensure a broader exchange of ideas. While not granting a second vote to the organization, this approach would provide a recognized status and eliminate any perception of bias or inequality.



D. Convention Member Responsibilities Document

During this period, the MC focused its attention on developing a document that listed the responsibilities of Convention member representatives. A key role of Convention delegates is to act as communications conduits between USP and their organizations. The MC's discussions focused on how to best create and facilitate this two-way communication, creating member messages that communicate the benefits that USP offers to each of its member constituencies.





PART IV

2008

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

PART IV. 2008

In 2008, the MC recommended to the Board that four organizations be invited to Convention membership. The MC increased recruiting efforts and the percentage of organizations that named delegates rose to 80%. The MC also discussed proposed changes to the C&B and considered a long term strategy for globalizing the Convention membership.

A. Engaging Convention Members

The MC continued to explore ways to engage Convention members and considered the levels of participation and communication required in light of USP's new Strategic Plan. The idea of illustrating "What USP Does for You" was discussed. Based on these and previous discussions, the MC finalized *USP Convention Member Organization and Delegate Responsibilities* (Appendix E).

Acknowledging the continued difficulty of engaging physicians domestically and internationally, the MC began a delegate recruitment campaign. On behalf of USP, Dr. Darrell Kirch, CEO of the Association of American Medical Colleges sent a letter to the deans of all fully accredited medical colleges in the US (Constitutionally-named Convention members), encouraging them to appoint representatives. Although overall Convention member participation increased, medical colleges remained one of the constituencies with the lowest participation rate.

B. Proposed Changes to USP Constitution and Bylaws

The Constitution and Bylaws Committee sought MC feedback on changes it intended to propose in amendments relating to the composition of the Convention membership. The changes included the following:

- Eliminating the concept of Constitutionally-named and invited membership categories (all organizations would be invited);
- Automatically inviting organizations that are currently Constitutionally-named (to provide continuity) but establishing criteria for removal for non-participation.
- Broadening category descriptions to be more inclusive of the constituencies with which USP interacts;
- Eliminating the caps for each category in exchange for an overall limit on the total number of Convention members; and

The MC also recommended clearly defining the roles of each Convention Committee to eliminate overlap, which had occurred between the MC and the Council of the Convention. The MC also emphasized the need to introduce the proposed changes to delegates and obtain their feedback early in the C&B amendment process.

C. Globalizing the Convention Membership

As a mechanism for considering long-term strategies for globalizing the Convention, the MC examined the current Convention membership using the more general membership categories proposed in the proposed Bylaws over a matrix of global regions. In this way, the MC identified gaps that could be filled by potential member or Official Observer organizations.





PART V

2009 TO 2010

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

PART V. 2009 TO 2010

In 2009, the MC recommended 12 organizations for Convention membership, including standards setting organizations in countries where USP has a presence. The MC also encouraged USP staff to more actively recruit delegates. By the end of 2009, 87% of eligible member organizations had named delegates and by March 2010, 90% of all organizations had named their delegates. Also in this period, the MC issued over 85 invitations to organizations around the world to become Official Observers of the USP Convention. The MC made some general recommendations on ways to engage delegates at the 2010 Convention. Finally, the MC reviewed and updated all of its process documents for the new Committee and suggested ways to improve the delegate experience for the 2010-2015 cycle.

A. Official Observers

In identifying the organizations that would be invited to participate as Official Observers of the USP Convention, the MC paid particular attention to maintaining a balance among industry, regulatory, and practitioner constituencies. A list of Official Observer Organizations is available in the Delegate materials for the 2010 Convention and is also posted on the USP Web site.

B. Preparing for the 2010 Membership Meeting

The MC discussed the following strategies to engage delegates at the Convention.

- All delegates will be encouraged to attend the Delegate Orientation;
- Delegates will adopt rules for the open hearing that will ensure that all have an equal opportunity to voice their perspectives; and
- Delegates will be asked to register for a specific topic for the Information Exchange Luncheon, which will give delegates an opportunity to learn about and provide feedback on topics related to USP's future.

C. Transition to the Next Cycle

Looking toward the 2010-2015 cycle, the MC suggested the following to further engage Member organizations:

- Reframe Member Responsibilities into Member Opportunities: How can USP help an organization achieve its goals?
- Broaden the Convention's food and international constituencies.
- Welcome new members with a phone call from USP staff or an existing convention member to talk about how they could get involved in USP activities.
- Find out how delegates interact with their organizations with respect to USP.

D. Conclusion

The MC endeavored in this cycle to provide the USP Convention with the breadth of constituents and perspectives needed to perform its work and fulfill its mission. The new composition of the Convention membership that is proposed in the Amended and Restated Bylaws will allow USP to evolve its membership globally in a measured fashion while maintaining its practitioner traditions.





CONVENTION

2010

PART VI

APPENDICES

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

**APPENDIX A. 2005–2010 USP CONSTITUTION AND BYLAWS
PROVISIONS PERTAINING TO MEMBERSHIP**

CONSTITUTION

Article II—Membership

Section 1

The members of the Pharmacopeial Convention shall consist of: accredited delegates representing the following educational institutions, professional and scientific organizations, and designated divisions of the federal government, hereafter designated as eligible organizations, and others as herein provided.

In this Constitution and Bylaws “state” or “United States” includes each of the several states, the District of Columbia, the Commonwealth of Puerto Rico, and all territorial possessions of the United States of America.

- (a) Colleges and schools of medicine in the United States with programs accredited by the Liaison Committee on Medical Education sponsored by the Association of American Medical Colleges and by the Council on Medical Education of the American Medical Association; colleges and schools of pharmacy in the United States with programs accredited by the Accreditation Council on Pharmacy Education; state medical associations or state medical societies, which are constituents of the American Medical Association; and state pharmaceutical associations or state pharmaceutical societies, which are entitled to voting delegates in the House of Delegates of the American Pharmacists Association.
- (b) Not more than seventy-five national and state professional and scientific organizations or sections thereof, designated by the Board of Trustees as eligible to appoint a delegate. The following national and state professional and scientific organizations shall be so designated: The American Association of Pharmaceutical Scientists; the American Chemical Society; the American Dental Association; the American Medical Association; the American Nurses Association; the American Pharmacists Association; the American Society for Clinical Pharmacology and Therapeutics; the American Society for Pharmacology and Experimental Therapeutics; the American Society for Quality; the American Society of Consultant Pharmacists; the American Society of Health-System Pharmacists; the American Veterinary Medical Association; the AOAC International; the Association of Food and Drug Officials; the Drug Information Association; the National Association of Boards of Pharmacy; the National Community Pharmacists Association; the Parenteral Drug Association; or the successors thereto.
- (c) Not more than twenty governmental bodies or divisions thereof, designated by the Board of Trustees as eligible to appoint a delegate. The following governmental bodies shall be so designated: The Centers for Medicare & Medicaid Services; the Department of Veterans Affairs Veterans Health Administration; the Food and Drug Administration; the National Institute of Standards and Technology; the Office of the Surgeon General, the Bureau of Medicine and Surgery, United States Navy; the Office of the Surgeon General, United States Air Force; the Office of the Surgeon General, United States Army; the Office of the Surgeon General, United States Public Health Service; and, the Office of the Secretary of the Department of Health and Human Services; or the successors thereto.
- (d) Not more than five governmental bodies designated by the Board of Trustees as eligible to appoint a delegate to represent nations, other than the United States, that give official recognition to the standards of the USP or the NF.



- (e) Not more than twenty-five organizations designated by the Board of Trustees as eligible to appoint a delegate to represent organizations representing the health sciences in other nations, international health, scientific, or professional organizations or other pharmacopeial bodies.
- (f) Not more than twenty-five domestic or international consumer organizations designated as eligible to appoint a delegate or individuals representing the public interest designated by the Board of Trustees to serve as public members also shall be members of the Pharmacopeial Convention.
- (g) The President, the Past President, the Treasurer, the Board of Trustees, the Executive Vice President-CEO, and the Chairpersons of Committees directed to report at a stated meeting, serving by authority of the preceding stated Pharmacopeial Convention or the Constitution and Bylaws, also shall be members, ex officio, of the Pharmacopeial Convention.
- (h) Not more than twenty-five members-at-large, selected by the Board of Trustees for their special competence in relation to the administrative or scientific needs of the Pharmacopeial Convention.
- (i) Not more than twenty-five organizations or divisions thereof, either domestic, international, or from other nations, designated by the Board of Trustees as eligible to appoint a delegate to represent manufacturers, trade, and affiliated associations. The following organizations shall be so designated: the Advanced Medical Technology Association, the American Hospital Association; American Chemistry Council; the Animal Health Institute; Consumer Healthcare Products Association; Cosmetic, Toiletry and Fragrance Association; Council for Responsible Nutrition; Generic Pharmaceutical Association; Healthcare Distribution Management Association; National Association of Chain Drug Stores; the Pharmaceutical Research and Manufacturers of America.
- (j) Nominees for elective offices, selected in accordance with Chapter IX, Sections 2 and 3, of the Bylaws, shall be members of the Pharmacopeial Convention for the stated meeting when their names are presented as nominees in accordance with Chapter IV, Section 1(g), of the Bylaws, whether present or not.

Section 2

In designating those organizations or governmental bodies or divisions or sections thereof as eligible to appoint a delegate to the USP Convention, the Board of Trustees shall consider the membership guidelines provided by the Convention at the previous stated meeting, as well as recommendations made by the Membership Committee. The Board shall at least annually review the composition of the Convention and designate any additional organizations, governmental bodies, or divisions or sections thereof as deemed necessary.

Section 3

Each eligible organization entitled to representation in the Pharmacopeial Convention, as provided for in Article II, Section 1, of this Constitution shall elect or appoint in such manner as it may determine, one delegate who shall be approved as a member of the Pharmacopeial Convention, as provided in the Bylaws.

Section 4

Once approved by the Membership Committee, members appointed by organizations named in the Constitution shall continue to serve as members of the Convention until replaced by their appointing organizations, unless disqualified under the provisions of Article II, Section 6. The term of members appointed by organizations designated by the Board of Trustees shall end six months following the stated meeting.



Section 5

Six months prior to a stated meeting, each eligible organization shall be requested to elect or appoint in such manner as it may determine, one alternate delegate, who shall be approved as an alternate member of the Convention as provided in the Bylaws. The alternate delegate shall represent the appointing organization only if the member is unable to attend the stated meeting. The alternate delegate's term ends at the adjournment of the stated meeting.

Section 6

Each delegate and alternate delegate, at the time of his or her election or appointment, and each member of the Convention, during his or her membership, except those individuals named by the Board under Article II, Sections 1 (f), (g), and (h), shall be an officer or a member of the academic staff of the educational institution; an officer, active member, or employee of the organization; or an employee of the division of the federal government that he or she represents.

Section 7

By unanimous vote the Board of Trustees may elect honorary members to the Convention in recognition of their distinguished contribution to drug standardization, drug information, the sciences of medicine and pharmacy, the public health, or other special contribution to the USP. Each honorary member shall have the rights, privileges, and duties prescribed by the Constitution and Bylaws and defined by the Board of Trustees except the right to vote, to hold office, or to otherwise determine the policy and administration of the Convention.

BYLAWS

Chapter XI—The Membership Committee

Section 1

The Membership Committee shall consist of not less than seven and not more than ten members and shall be appointed by the President. Six members shall represent the organizational membership categories as defined in Article II of the Constitution and additional members shall be appointed without regard to their affiliation. The President shall appoint the Committee and name the chairperson, not later than sixty days after the stated meeting of the Pharmacopeial Convention. The Chairperson of the Board of Trustees, the President, and the Executive Vice President-CEO shall be members, *ex officio*, of the Membership Committee. The Secretary of the Pharmacopeial Convention shall serve as the secretary. Members of the Membership Committee shall retain their Pharmacopeial Convention membership until their successors are appointed.

Section 2

The Membership Committee shall identify and recommend organizations eligible to appoint a delegate for the Board of Trustees' consideration. Such recommendations shall take into account any guidelines provided by the Convention at the previous stated meetings. The Membership Committee shall adopt such procedures and criteria as are sufficient to ensure the fair and orderly consideration in the identification and recommendation of organizations eligible to appoint a delegate. The Board of Trustees shall approve such procedures. The Membership Committee shall report to the Board of Trustees at least annually on the composition of the Pharmacopeial Convention and the work of the committee since its last report.

Section 3

The Membership Committee shall also examine carefully the credentials of all delegates or alternate delegates in the absence of delegates. Credentials issued in blank, with the names of the delegates and alternate delegates to be inserted subsequently by other than the regularly constituted officers of the appointing eligible organization shall not be accepted. Credential forms presented for the first time at a meeting shall be independently verified before acceptance. Immediately prior to the opening of the stated meeting of the Pharmacopeial Convention, the Committee shall furnish to the Secretary of the Pharmacopeial Convention a



list of delegates whose credentials have been approved by the Committee and a list of alternate delegates whom it has approved in lieu of delegates who are absent.

Section 4

The Membership Committee shall make a report to the Pharmacopeial Convention concerning all credentials that have not been approved. A majority vote of the members of the Pharmacopeial Convention shall be required to overrule a decision approving or disapproving the credentials of any person by the Membership Committee.

Section 5

The Membership Committee shall make a report to the Pharmacopeial Convention regarding the composition of the Convention and the work of the committee since the last stated meeting. The Membership Committee shall also provide to the Resolutions Committee guidelines for the types of institutions and bodies that should be invited to appoint a delegate for the following stated meeting.



APPENDIX B. PROCESS FOR CONSIDERING AND INVITING ORGANIZATIONS FOR MEMBERSHIP IN THE USP CONVENTION

Approved November 2005 by the 2005-2010 Membership Committee

1. Recommendations for potential members may come through the Membership Committee or USP family (members, Council of Experts, Expert Committees, Board and staff). Additionally, organizations may contact USP directly to be considered for membership.
2. If identified as an *organization of interest* by the MC, Staff will prepare an organization “dossier” for MC consideration/discussion to ensure that the organization meets criteria established by the MC. Additional information will be provided as needed.
3. If approved by the MC, a formal recommendation will be presented to the Board by the MC with the rationale for inviting the organization to become a USP Member.
4. Upon Board approval, a letter will be sent to the organization executive officer extending an invitation to USP Membership (copying any other individuals within the organization that might facilitate the process). The letter will be organization-specific and explain that there are no dues associated with USP membership. The letter will explain how USP perceives the two organizations working together, relevance to one another, citing compatible missions, specific resolutions, strategic directions, and/or other initiatives.
5. *Actions for No Response: An organization has six (6) months to respond to an invitation from USP to become a member. If a response is not received within six months, a member of the USP family will attempt to contact the organization to confirm their receipt of the invitation and ask for a response within 30 days, or to identify an alternate person in the organization whom to resend an invitation.

A “not interested” response at any time will cause no further action to be taken by USP.

If an alternate person within the organization is identified, an additional three-month time period will be given for a potential response to USP’s invitation. No response after three months will be interpreted as a 'not interested' response, and no further action will be taken.
6. *Rescinding Invitations: In order to maximize participation from each constituency, invitation to USP membership will be rescinded if no response is received after 18 months (provided all of the actions described in No. 5 above have been fulfilled). The organization will be informed by letter that the invitation has been rescinded and that the organization may contact USP if it wishes to be considered for membership.
7. If an organization contacts USP requesting membership consideration and is not approved by the Membership Committee, the Board will be informed of the Membership Committee’s decision and rationale for the decision.

** Time adjustments will be made to these provisions as we near the Convention.*



APPENDIX C. OFFICIAL OBSERVER STATUS PROCESS AND CRITERIA FOR CONSIDERATION

The Membership Committee (MC) has established an Official Observer Status within the USP Convention for the purpose of allowing participation and representation within the Convention by organizations and individuals that collaborate and assist USP in its public health mission. Designated Observers will receive Member Memoranda and other member communications, have access to USP's Member Page, and will be invited to attend (unfunded by USP) the 5-year meetings of the Convention. Observers will not have any of the voting rights reserved to members under the Constitution and Bylaws, and thus will not have the right to vote at or between Convention meetings on amendments to the Constitution and Bylaws, Resolutions, or in elections of Officers, Trustees or the Council of Experts.

The MC has the authority to grant Official Observer Status to an organization or individual according to the criteria and process below. If an organization is recognized for Official Observer Status, it will be asked to identify an individual to represent it in the USP Convention.

1. An organization or individual may be recommended for observer status by staff, Board, MC, Council of the Convention, Council of Experts, or may request observer status.
2. Organizations that may be considered could include:
 - Organizations that are current members, where additional representation would be desired by USP or requested by the organization
 - Organizations that are invited to membership, but cannot accept due to internal procedures/restrictions
 - Organizations that are desirable to have in the Convention, but that do not completely meet member criteria
 - Organizations that meet all member criteria, but for number limits in their category cannot be invited to membership
 - Organizations that collaborate with USP in advancing its mission
 - Other
3. Individuals that may be considered could include:
 - Executive officers of member organizations that are not the delegate
 - Council of Experts and Expert Committee members
 - Advisory panelists, international and domestic stakeholders
 - Individuals that collaborate with USP in advancing its mission
 - Other



4. Organizations or individuals identified for or requesting Official Observer Status shall be vetted by the Membership Committee and judged on:
 - Value to USP
 - Unique perspective on issues relevant to USP's programs and activities
 - If organization — ability to meet basic criteria used for member consideration (would not need to meet all criteria)
 - If individual — existing or potential contribution to USP programs/initiatives
5. The maximum number of official observers shall be 100.



APPENDIX D. USP CONVENTION MEMBER ORGANIZATION AND DELEGATE RESPONSIBILITIES

Understand USP's purpose and value to the public health. — Your foremost responsibility as a USP member is to fully understand USP's mission, vision, and Strategic Plan, and to become familiar with the programs and activities that support our mission. USP will provide opportunities for you to learn about its work through member memoranda, newsletters, and reports. It is incumbent upon you to stay updated through these communications.

Make a connection with your organization's work. — Related to developing an understanding of USP, you should seek to identify areas and programs where your organization and USP share a common purpose or interests, such as quality product standards (medicines, dietary supplements, and foods), practice standards, patient safety, and global public health initiatives. Then, as these programs develop, keep USP informed of ways in which our organizations might collaborate or complement each other's work.

Inform the constituency you represent. — You are also expected to endeavor to educate your organizational leadership and constituents about USP, and to keep colleagues updated on the various and relevant programs and services USP provides and the work it is doing.

Provide your viewpoint. — When USP requests feedback on its initiatives, standards, and/or processes, members should make every effort to provide their organizational viewpoint and respond in a timely fashion.

Serve when asked. — Occasionally, members may be asked to serve on a USP Convention committee. Although it can sometimes be difficult to predict the time commitment needed for each such request, USP will attempt to estimate it. To the extent possible, delegates or other representatives from the member organization should agree to participate when asked.

Be prepared to execute your governance responsibility. — As the five-year meeting of the USP Convention approaches, delegates receive important communications intended to prepare them to execute their critical governance responsibilities. Among these are proposed amendments to the USP Constitution and Bylaws; a call for resolutions and subsequent resolutions proposals; and nominee information for election of the Council of Experts, Convention Officers, and Trustees. You should review/understand the material and be prepared to vote at the meeting. Additionally, delegates should select alternates to act on behalf of the organization if the delegate is absent.

March 2009

