

**2020-2025 Council of the Convention (CoC)
Meeting #4
Wednesday, October 27, 2021**

Minutes – Final

Goals and anticipated outcomes

- Approve recommendations for Member removals and new Convention Members
- Review year-one Resolutions progress
- Discuss Convention engagement progress and ongoing growth

Attendees: See addendum for a list of CoC and USP staff attendees.

1. Welcome, Opening Remarks, Confirmation of Quorum and Agenda Approval

Welcome

Council of the Convention (CoC) Chair Dr. Dennis E. Doherty confirmed that a quorum was present and opened the meeting at 7:03 a.m. ET. Dr. Doherty welcomed everyone to the fourth meeting of the CoC for the 2020-2025 cycle. Dr. Doherty acknowledged Lynette Bradley Baker for agreeing to serve as Vice Chair and welcomed new member Pam Traxel from American Cancer Society Friends of Cancer Research.

Overview of Agenda and Meeting Goals

Shelley Whiddon reviewed the meeting agenda, noting that the objectives of the meeting were to: 1) approve recommendations from the Membership Committee for Member removals and new Convention Members, 2) hear updates on resolutions VI & VIII from USP staff, and 3) discuss Convention engagement progress and ongoing growth through a panel with two Sector Chairs and two Regional Chapter Chairs. Dr. Doherty then called on the CoC to approve the meeting's agenda.

Motion to Approve Agenda

Hanan Sboul moved to approve the agenda, and the motion was seconded. The motion carried by unanimous consent, and the agenda was approved.

2. Approval of Minutes from Previous Meeting

Bhojraj Suresh moved to approve the minutes from the previous meeting, and the motion was seconded. The motion carried by unanimous consent, and the minutes were approved.

3. Membership

The Value of Engaged Convention Membership

Anthony Lakavage affirmed the success of the new model for engaging with Convention Members on substantive topics critical to public health. Lakavage emphasized that to continue with effective engagement, it was important to have Convention Members that are active and engaged. USP staff and volunteer time is most effective when focusing on organizations that want to actively participate in the Convention. Additionally, the future state of the Convention should create a membership that is more representative of USP's evolving work and the communities it serves.

Lakavage thanked the CoC Membership Committee for reviewing potential new members and organizations eligible for removal, thanked everyone for supporting this model, and turned it over to Membership Committee Chair, Hanan Sboul.

Member Removals & New Members Overview

Hanan Sboul reminded everyone that the CoC Membership Committee is responsible for reviewing and recommending new members and member removals to the CoC. Sboul stressed that all members on the removal list were eligible for removal based on USP Bylaws and that USP staff had attempted to reach all of these members in the year leading up to the 2020 Convention Meeting.

Recommendations for Member Removals

Sboul presented the Membership Committee's recommendations for fifty-five member removals.

Discussion

The following topics were discussed after the presentation of Member removals:

- **Conflict with pandemic:** A CoC Member pointed out the inability to reach Members may have been due to their conflicting priorities during the pandemic. Staff noted that the initial outreach was done in 2019 and even over previous cycles.
- **Reapplying for Membership:** It was confirmed that Members could seek Membership again should they choose based on changes in priorities, leadership, etc. Furthermore, each Member proposed for removal will receive a final letter from USP inviting them to contact USP if they think the removal is in error or they wish to remain an active Member of the Convention.
- **Outreach to right individuals:** Some CoC members expressed concern if the right individuals had been contacted and would receive the final letter. Whiddon confirmed that the initial outreach was done to both Delegates and Executives via email as well as other means as needed. Lakavage further reiterated that over the last couple of years, USP staff had made significant efforts to ensure the accuracy of the list of Delegates and Executives for Convention Members. Sboul added that the team would make every effort to ensure the final letter was sent to the right individuals at the decision-making level.
- **Concern over large number of removals and implications.** Sboul noted that this is not a concern since there were also several new Member recommendations as part of an ongoing effort to realize a membership that is more representative of USP's work and the communities served. Lakavage further added that having Members that did not participate could pose the challenge of meeting quorum requirements in terms of governance responsibilities.

Action Item

USP staff will proceed with sending removal letters via email. If no response is received, staff will follow up with phone calls and additional email outreach to other leadership.

Motion

The Chair called for a motion to approve the Membership Committee's recommendations for the Member removals. Stephen Mullenix moved to approve the motion, the motion was seconded, and then carried by a unanimous voice vote.

Recommendations for New Members

Sboul presented the Membership Committee's recommendations for six new voting Members and one Associate Member.

Voting Members:

1. China Society for Drug Regulation
2. South African Health Products Regulatory Authority (SAHPRA)
3. National Pharmaceutical University of Ukraine
4. Indian Pharmaceutical Association
5. National Rural Health Association (NRHA)
6. Pharmaceutical Security Institute

Associate Members:

1. Rita Munley Gallagher

Associate Membership

Sboul stated that the CoC considers organizations for Associate Membership status by reviewing established criteria, noting that some organizations are prohibited from joining or do not currently meet the criteria to become voting Members. Sboul reviewed the criteria for individuals to become Associate Members and how they will participate in Convention activities. Dr. Doherty reemphasized that the Associate Member is a non-voting position. Whiddon also clarified that while voting members and removals went to the board for approval, the Associate Members receive the final recommendation from the CoC.

Motion

The Chair called for a motion to approve or amend the CoC Membership Committee's recommendations for Voting Members and Associate Members. Mary Kirchhoff moved to approve the motion and the motion was seconded.

David Gaugh amended the motion to hold the nomination of the China Society for Drug Regulation until the next meeting to resolve some questions. The motion was seconded and then passed by unanimous voice vote.

Action Item

At the next meeting, USP staff to provide more information on the China Society for Drug Regulation and provide the list of other Voting Members that might be part of the Chinese regulatory bodies.

4. 2020-2025 Resolution updates

Lakavage first took a moment to introduce Mario Sindaco, as he will now be leading Board and Convention Operations.

USP made significant progress on all 15 resolutions adopted by the Convention, despite a significant pandemic response.

Jude Nwokike, Vice President, PQM+, provided a progress update on Resolution 8: Regulatory Systems Strengthening, and Steven Emrick, Director, Translational Informatics, provided an update on Resolution 6: Digital Transformation of Standards.

5. Convention Sector and Chapter Chair Panel

Shelley Whiddon facilitated a panel discussion on Convention engagement progress and ongoing growth with two Sector Chairs - Susan Cantrell, Biologics Sector Chair and Jay Sirois, Dietary Supplements Sector Chair, and two Chapter Chairs - Caroline Weinstein, Latin America Regional Chapter Chair and Bhojraj Suresh, South Asia Regional Chapter Chair.

Discussion

Recommendations and approaches to continue to sustain and grow engagement

The panel discussed focusing on areas of shared priority with Members. They also addressed the importance of taking the time to build engagement through Member-driven dialogue, engaging members through a feedback mechanism, and finding opportunities for collaboration with other Sectors to help advance dialogue.

Supporting a connected invested Convention Membership

The panel highlighted a sustained connection with USP's Council of Experts outside of commenting opportunities, active participation with a broad coalition of stakeholders, and Sector/Chapter meetings being a platform for government officials, industry, regulators, and other stakeholders to come together to improve public health and lead to successful outcomes.

Insights from Convention meetings that were taken back to their own work

The panel agreed that discussions during these meetings were useful, and helped to inform and advance their work. Furthermore, engagement with a diverse set of stakeholders brought different perspectives they wouldn't have otherwise had access to.

6. What's Next

Shelley Whiddon briefly reviewed post-meeting activities and upcoming Sector and Regional Chapter meetings. Whiddon also noted that Member Removals and New Voting Member recommendations going to Board of Trustees for approval (February 2, 2022). The USP team was evaluating when the Volunteer Leadership Meeting could take place and whether it would be in-person or hybrid. Lastly, Dr. Doherty announced that Ron Piervincenzi, USP's Chief Executive Officer, would be joining the next CoC meeting.

7. Closing Remarks and Adjourn

The Chair adjourned the meeting at 8:58 a.m.

ADDENDUM

Attendees

CoC Members

CoC Chair and President of the Convention

1. Dennis E. Doherty, M.D., Convention President and CoC Chair

USP Convention Sector Chairs

2. Generics Sector Chair: David Gaugh, R.Ph., Association for Accessible Medicines
3. Healthcare Practice Sector Chair: Amy Cadwallader, Ph.D., American Medical Association
4. Biologics Sector Chair: Susan Cantrell, BS Pharm., Academy of Managed Care Pharmacy
5. Excipients Sector Chair: Mary Kirchhoff, Ph.D., American Chemical Society
6. Dietary Supplements Sector Chair: Jay Sirois, Ph.D., Consumer Healthcare Products Association

USP Convention Regional Chapter Chairs

7. South Asia Region Chapter Chair: Bhojraj Suresh, M.Pharm., Ph.D., D.Sc. Pharmacy Council of India
8. Latin America Region Chapter Chair: Caroline Weinstein, Ph.D., Chilean Pharmacopeia
9. Greater China Region Chapter Chair: Mingzhe Xu, National Institutes for Food and Drug Control
10. Asia Pacific Region Chapter Chair: John Chien-Wei Lim, M.D., M.S., Centre of Regulatory Excellence, Duke-NUS Medical School
11. Middle East and North Africa Region Chapter Chair and Membership Committee Chair: Hanan Sboul, M.B.A., B. Pharm, CAE, Jordanian Association of Pharmaceutical Manufacturers

At-Large Members

12. Emmanuel Akala, R. Ph., Ph.D., DIM, Howard University College of Pharmacy
13. Lynette Bradley-Baker, Ph.D., R.Ph., Membership Committee Vice Chair, American Association of Colleges of Pharmacy
14. Barbara Exum, Pharm.D, Virginia Commonwealth University/Medical College of Virginia School of Pharmacy
15. Stephen Mullenix, BS Pharm., R.Ph., National Council for Prescription Drug Programs
16. Pallavi Nithyanandan, Ph.D., FDA Center for Drug Evaluation and Research
17. Sue Peschin, M.H.S., Alliance for Aging Research
18. Pam Traxel, American Cancer Society/Cancer Action Network
19. Kanecia Zimmerman, M.D., American Academy of Pediatrics

Council of Experts Representatives

20. Martin Coffey, Ph.D., USP General Chapters—Dosage Forms Expert Committee
21. Stephanie Crawford, M.P.H., Ph.D., USP Nomenclature and Labeling Expert Committee
22. Xiaorong He, MBA, Ph.D., M.S., B.S., USP General Chapters– Physical Analytical Methods Expert Committee
23. Kim Huynh-Ba, M.S., B.Sc., USP Small Molecules 4 Expert Committee

USP Staff

1. Anthony Lakavage, J.D., Convention and Board Secretary and Senior Vice President, Global External Affairs
2. Darcy Gentleman, Ph.D., Senior Stakeholder Engagement Manager



3. Amy Sonderman, Director, Convention and Stakeholder Engagement
4. Joy Titus-Young, Senior Stakeholder Engagement Manager
5. Shelley Whiddon, M.A., Senior Director, Operations, Convention and Stakeholder Engagement
6. Mario Sindaco, Senior Board and Convention Operations Director
7. Raliza De Souza, M.B.A., Note Taker
8. Peter Suh, Manager, Meetings Technology & Ops

Guest Speakers

1. Steven Emrick, Director, Translational Informatics
2. Jude Nwokike, Vice President, PQM Plus