

**2020-2025 Council of the Convention (CoC)
Meeting #5
Thursday, January 20, 2022**

Minutes – Final

Goals and anticipated outcomes

- Receive update on outreach to Members approved for removal
- Approve recommendations for new Convention Members
- Discuss Convention Sector and Regional Chapter engagement activities
- Engage with USP CEO Ron Piervincenzi on USP's evolution in support of innovation and access

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 8:02 a.m. ET. Dr. Doherty welcomed everyone to the fifth meeting of the CoC for the 2020-2025 cycle.

Overview of Agenda and Meeting Goals

USP staff reviewed the meeting agenda, noting that the objectives of the meeting were to: 1) review results of additional outreach on Member removals and approve retaining a portion of those proposed removals, and approve recommendations from the Membership Committee for new Convention Members; 2) hear updates on two Regional Chapters, two Sectors, and planned speakers' series; and 3) hear reflections and updates from CEO Ron Piervincenzi. Dr. Doherty then called on the CoC to approve the meeting's agenda.

Motion to Approve Agenda

Dr. Emmanuel Akala 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

Susan Cantrell 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 emphasized that given the need to achieve quorum for governance actions as well as the limited resources available to allocate to support of Convention outreach, it was vital to ensure that Convention Members were engaged and wanted to be part of the dialogue. In proposing changes to Membership, USP would continue to follow the provisions of the Bylaws that outline the composition of member organizations in each category. Lakavage thanked the CoC Membership Committee for their work.

Member Removals & New Members Overview

Mario Sindaco explained that further outreach was done to all fifty-five Members that were proposed for removal at the previous CoC Meeting. The outcome was that fifteen Members wanted to retain Membership, eleven agreed to being removed, twenty-eight were unreachable by email or phone, and one requested more time to evaluate.

Recommendations for Member Removals

Sindaco presented the Membership Committee's recommendations for the removal of thirty-nine Members:

Academic Institutions – Medicine (22)

1. Chicago Medical School at Rosalind Franklin University of Medicine and Science
2. Florida State University College of Medicine
3. Geisel School of Medicine at Dartmouth
4. Medical University of South Carolina College of Medicine
5. Northeast Ohio Medical University College of Medicine
6. Ponce School of Medicine
7. Rutgers, the State University of New Jersey - New Jersey Medical School
8. Rutgers, the State University of New Jersey Robert Wood Johnson Medical School
9. San Juan Bautista School of Medicine
10. SUNY Upstate Medical University
11. Temple University School of Medicine
12. The Warren Alpert Medical School of Brown University
13. Tulane University School of Medicine
14. Universidad Central del Caribe School of Medicine
15. University of Kansas School of Medicine
16. University of Nevada School of Medicine
17. University of New Mexico Health Sciences Center School of Medicine
18. University of Puerto Rico School of Medicine
19. University of South Alabama College of Medicine
20. University of Tennessee, Memphis College of Medicine
21. University of Utah School of Medicine
22. West Virginia University School of Medicine

Academic Institutions – Pharmacy (4)

1. Lake Erie College of Osteopathic Medicine School of Pharmacy
2. Texas Tech University Health Sciences Center School of Pharmacy
3. Touro University California College of Pharmacy
4. University of Mississippi School of Pharmacy

Health Practitioner Professional and Scientific Associations (10)

1. American Society for Microbiology
2. Connecticut State Medical Society
3. Kansas Medical Society
4. Maine Medical Association
5. Massachusetts Medical Society
6. Medical Association of the State of Alabama
7. Minnesota Medical Association
8. South Carolina Medical Association

9. Colegio de Farmaceuticos de Puerto Rico
10. Utah Medical Association

Manufacturer, Trade, and Affiliated Associations (1)

1. Grocery Manufacturers Association (now called "Consumer Brands Association")

Consumer Organizations and Individuals Representing Public Interests (2)

1. Center for Science in the Public Interest
2. The Clinton Foundation

Discussion

The following topic was discussed after the presentation of Member removals:

- Questions on two Members proposed for removal: Shelley Whiddon and Amy Sonderman confirmed that the 'Clinton Foundation' and 'Center for Science in the Public Interest' were non-responsive to repeated USP outreach. Ron Piervincenzi further added that the Clinton Foundation no longer had the same agenda that had been overlapping with USP's in public health.

Motion

The Chair called for a motion to approve the Membership Committee's recommendations for thirty-nine Member removals. Susan Cantrell made the motion, the motion was seconded, and then carried by a unanimous voice vote.

Sindaco further added that USP would reengage with retained Members. They would be oriented like new Members and would be monitored at least over the course of the next year for purposes of tracking participation, having check-ins with Delegates and Executives, and finding opportunities to collaborate. Sindaco then turned it over to Membership Committee Chair, Hanan Sboul.

Recommendations for New Members

Sboul reminded everyone of the rationales for proposed new Members and the membership attributes sought in new Voting and Associate Members. In response to the request at the previous CoC Meeting, the Membership Committee reviewed all Convention Members based in China and noted affiliations with the Chinese government. Sboul presented the Membership Committee's recommendations for two new voting Members and one Associate Member.

Voting Members:

1. China Society for Drug Regulation
2. Indian Association of Colleges of Pharmacy (IACP)

Associate Members:

1. Nevada Pharmacy Alliance

Motion

The Chair called for a motion to approve the China Society for Drug Regulation. Susan Cantrell moved to approve the motion and the motion was seconded, and then carried by a unanimous voice vote.

The Chair called for a motion to approve the Nevada Pharmacy Alliance as an Associate Member. Stephen Mullenix moved to approve the motion and the motion was seconded, and then carried by a unanimous voice vote.

Dr. B. Suresh recused himself from the meeting during the vote on the Indian Association of Colleges of Pharmacy (IACP) due to conflict of interest.

The Chair called for a motion to approve the IACP. David Gaugh moved to approve the motion and the motion was seconded, and then carried by a unanimous voice vote.

Membership Composition

Hanan Sboul provided an update on the new composition of Membership, noting its continued alignment with Bylaws requirements and evolution towards a composition that we believe will be more engaged with USP's work.

4. Regional Chapter and Sector Updates

Shelley Whiddon provided a brief overview of how the Convention Sectors and Regional Chapters have formed a foundational structure for deepening engagement across Convention Members. They have provided forums for both rich discussion and co-creation of impactful content and resources.

Chairs provided updates on several Sectors and Chapters, as follows: Hanan Sboul on the MENA Regional Chapter, Caroline Weinstein on the LATAM Regional Chapter, Susan Cantrell on the Biologics Sector, and Jay Sirois on the Dietary Supplements Sector.

Action Item

Jay Sirois, Darcy Gentleman, and Sue Peschin to discuss opportunities within Medicare for the older adult population and consider area agencies on aging as a venue for distribution of information.

Whiddon informed the Members that USP would be launching a three-part Convention Exchange series on resiliency in the supply chain for pharmaceuticals. The first event is planned for February on Advanced Manufacturing and Technology with focus on ideas and strategies to help reduce barriers to adoption.

5. CEO Update

Dr. Doherty invited USP CEO Ron Piervincenzi to provide an overview of USP's progress in the current cycle and some of the future work being undertaken. Piervincenzi described some of the key factors in public health that USP has been working to understand and address, including complexity in the supply chain, new medicine modalities, and new analytical technologies. The COVID-19 pandemic emerged as an enormous challenge and influenced how USP works and what we work on. Responding to COVID-19 has joined supply chain resiliency, supporting advances in biomedical science, cannabis quality, and improving regulatory capacity as USP's primary challenges. He described key USP work in each area.

Piervincenzi noted that public trust in the health care sector, and medicines in particular, has been challenged in recent years, yet it remains fundamental to public health. USP promotes a set of principles intended to ensure that we build trust through consistency and

competence. Several of those principles are reinforced by the work of the CoC and the input of Convention Members, that helps us focus our work, consider broad stakeholder viewpoints, and respond to stakeholder needs. He indicated that he hoped to hear from CoC Members about the contributions of Chapter and Sector meetings and the issues to which CoC Members' organizations are paying the most attention.

Discussion

Perspectives that are rising in Chapter and Sector meetings

Cantrell pointed out that in the three Biologics Sector meetings, they were able to bring forward the perspectives of health care delivery, patients, and manufacturers under the umbrella of quality and position USP as a resource to address the issues related to quality. It will be important that we continue to bring forward disruptive topics to these venues.

Alignment on top priorities in Regions given limited resources

Sboul highlighted the challenge of addressing different topics and expectations at the Regional Meetings given limited resources and asked how we could achieve alignment and get the best results. Piervincenzi suggested that we rise to the occasion when urgent matters arise, but the long-lead issues remain and need to be addressed as we are able. Good dialogue in advance of meetings helps identify those priorities.

Institutional collaboration

John Lim emphasized the importance of institutions in reducing barriers to trust and noted that it varies by region. Piervincenzi acknowledged that in some ways it is not the easiest time to push for international collaboration, making collaborations like APEC even more important.

6. What's Next

Mario Sindaco noted that Member Removals and New Voting Member recommendations would go to Board of Trustees for approval (February 2, 2022). [Post-meeting note: these recommendations were approved by the Board of Trustees with gratitude to the CoC for their efforts.] The next CoC Meeting is planned for April or May. A Volunteer Leadership Meeting has been proposed for this Fall.

7. Closing Remarks and Adjourn

The Chair adjourned the meeting at 9:59 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. Ronald T. Piervincenzi, Ph.D., Chief Executive Officer
2. Anthony Lakavage, J.D., Convention and Board Secretary and Senior Vice President, Global External Affairs
3. Darcy Gentleman, Ph.D., Senior Stakeholder Engagement Manager
4. Amy Sonderman, Director, Convention and Stakeholder Engagement
5. Joy Titus-Young, Senior Stakeholder Engagement Manager
6. Shelley Whiddon, M.A., Senior Director, Operations, Convention and Stakeholder Engagement
7. Mario Sindaco, M.S., MBA, Senior Board and Convention Operations Director
8. Raliza De Souza, MBA, Note Taker
9. Peter Suh, Manager, Meetings Technology & Operations