

2020-2025 Council of the Convention (CoC) Meeting #6 Wednesday, April 20, 2022

Minutes – Final

Goals and Anticipated Outcomes

- Hear updates on Resolution 13: Coalition Building
- Provide input on USP's Resolution 13 activities and share perspectives and best practices from Member Organizations to help inform future efforts
- Receive update on recent Supply Chain Series activities
- Receive a preview of key governance activities and milestones for the remainder of the cycle

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 9:05 a.m. ET. Dr. Doherty welcomed everyone to the sixth meeting of the CoC for the 2020–2025 cycle.

Overview of Agenda and Meeting Goals

The Chair reviewed the meeting agenda and then called on the CoC to approve the meeting's agenda.

Motion to Approve Agenda

Susan Cantrell 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

Stephen Mullenix 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. Deep Dive: Coalition Building

Shelley Whiddon reviewed Resolution 13: Coalition Building and provided an overview of the purpose of and value in creating coalitions to advance the work of USP. Whiddon emphasized the importance of building and supporting a diversity of coalitions to achieve myriad goals, from supporting broad, information-sharing activities to achieving targeted, consensus-driven actions.

USP staff shared highlights and outcomes from the following coalitions and strategic engagement opportunities:

- Dietary Supplements Quality Collaborative
- Access to Generic Medicines
- Fight the Fakes Alliance
- Supply Chain Resiliency

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- Advanced Manufacturing Technologies
- Antimicrobial Resistance

Anthony Lakavage provided additional context around USP's supply chain resiliency initiatives. USP will collate the feedback and outcomes from its national, regional, and global supply chain initiatives and develop a global supply chain resiliency report. Lakavage emphasized the global focus of USP's supply chain work and the importance of Members' ongoing engagement and leadership to the success of these efforts.

Discussion

Members shared the following challenges and best practices for advocacy and coalition building:

- Best practices
 - o Appreciating the complexity of working with many different stakeholders.
 - Engaging with coalition members directly to increase participation and gather feedback.
 - Drafting sign-on letters, which can be more powerful than position statements from large coalitions.
 - Including a diversity of stakeholders and continually asking for input.
 - o Leveraging patient advocacy groups to strengthen engagement with policymakers.
- Challenges
 - Building consensus on a path forward.
 - Working with diverse stakeholders.
 - Educating policymakers who are not well versed in basic science.

Lakavage emphasized the importance of focusing coalition work on using evidence, data, and best practices to help inform better policy. A key focus is not to lobby but to approach advocacy from the perspective of a non-profit institution that has the convening power to create dialog, assemble groups, amplify voices, and inform policymakers.

4. Governance Timeline to 2025

Anthony Lakavage provided an overview of USP's Governing Bodies, including the roles of the CoC, Council of Experts, and Board of Trustees. As USP moves forward in the current cycle, staff will seek additional input on where the organization can have the greatest impact in the next cycle.

Mario Sindaco summarized some of the key workstreams as we prepare for the next cycle, including those for revising the USP Bylaws and defining the 2025 Resolutions. He reviewed the cycle transition timeline as well as the responsibilities of the CoC leading up to the Convention Meeting.

Discussion

Sindaco clarified that USP's Bylaws do not mandate that the CoE Nominating Committee (NC) include a CoC representative. The CoE NC, however, typically includes representation from the CoC. CoC Members also may nominate individuals from their respective organizations to help ensure a broad diversity of expertise on the NC. Lakavage emphasized the importance of increasing the diversity of USP's Governing

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Bodies and Volunteer Bodies. Staff will work with NC Members to develop a framework to help achieve greater diversity.

5. What's Next

Mario Sindaco noted that USP has a number of Sector and Chapter meetings scheduled throughout the spring and summer. The next CoC meeting will be planned for this summer. A face-to-face Volunteer Leadership Meeting is being planned for the fall.

Action Items

- USP will clarify how advocacy groups are supporting monograph development.
- USP will share the outcomes of the April 19, 2022, Dietary Supplements Sector meeting.

6. Adjourn and Closing Remarks

The Chair adjourned the meeting at 10:32 a.m.

ADDENDUM

<u>Attendees</u>

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. Biologics Sector Chair: Susan Cantrell, BS Pharm., Academy of Managed Care Pharmacy
- 4. Dietary Supplements Sector Chair: Jay Sirois, Ph.D., Consumer Healthcare Products Association

USP Convention Regional Chapter Chairs

- 5. Latin America Region Chapter Chair: Caroline Weinstein, Ph.D., Chilean Pharmacopeia
- 6. Asia Pacific Region Chapter Chair: John Chien-Wei Lim, M.D., M.S., Centre of Regulatory Excellence, Duke-NUS Medical School
- 7. 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

- 8. Emmanuel Akala, R. Ph., Ph.D., DIM, Howard University College of Pharmacy
- 9. Lynette Bradley-Baker, Ph.D., R.Ph., Membership Committee Vice Chair, American Association of Colleges of Pharmacy
- 10. Barbara Exum, Pharm.D, Virginia Commonwealth University/Medical College of Virginia School of Pharmacy
- 11. Stephen Mullenix, BS Pharm., R.Ph., National Council for Prescription Drug Programs
- 12. Pallavi Nithyanandan, Ph.D., FDA Center for Drug Evaluation and Research
- 13. Sue Peschin, M.H.S., Alliance for Aging Research

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- 14. Pam Traxel, American Cancer Society/Cancer Action Network
- 15. Kanecia Zimmerman, M.D., American Academy of Pediatrics

Council of Experts Representatives

- 16. Martin Coffey, Ph.D., USP General Chapters—Dosage Forms Expert Committee
- 17. Stephanie Crawford, M.P.H., Ph.D., USP Nomenclature and Labeling Expert Committee
- 18. 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. Joe Hill, M.A., United States Government Affairs Director
- 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. Michael Schmitz, Director, International Advocacy
- 8. Kavitha Nallathambi, M.Sc., M.P.H., Senior Global Public Policy Manager
- 9. Mario Sindaco, M.S., M.B.A., Senior Board and Convention Operations Director
- 10. Nicholas Healy, M.S., Technical Writer II, Publications
- 11. Peter Suh, Manager, Meetings Technology & Operations