

**2020-2025 Council of the Convention (CoC)
Meeting #1
Monday, October 5, 2020**

Minutes - Final

Goals and anticipated outcomes

- Provide a foundational understanding of USP and its governance system as well as the CoC role
- Establish the CoC's role in helping guide Convention member engagement
- Approve provisionally-approved *CoE Rules* for Convention-member input
- Approve organization for recommendation for membership in the USP Convention

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

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

Welcome from CoC Chair

Council of the Convention (CoC) Chair and Convention President Dr. Dennis E. Doherty confirmed that a quorum was present and **opened the meeting at 10:00 a.m. ET**. Dr. Doherty welcomed everyone to the first meeting of the CoC for the 2020-2025 cycle, noting that the CoC represents and guides the USP Convention's nearly 500 Member Organizations. He also noted that with attendees joining from multiple time zones, the CoC will rotate the start time throughout the year and 5-year cycle to be as inclusive and accommodating as possible; this is very important to USP. He thanked everyone for their flexibility to join the meeting. Every CoC member was in attendance.

Dr. Doherty asked CoC members to refrain from recording this meeting. USP staff will produce minutes for all CoC meetings, and the minutes will be shared with CoC members.

Lastly, Dr. Doherty announced that this cycle's CoC contains both returning Convention committee members and new members. In the last cycle there were two Convention committees – the Council of the Convention and the Convention Governance Committee. Following amendments to USP Bylaws passed at the 2020 Convention Meeting, the CoC absorbed the responsibilities of the Convention Governance Committee. The returning members on this cycle's CoC include members from both of these committees.

Opening Remarks from Convention Secretary

Convention Secretary Anthony Lakavage thanked CoC members for accepting USP's invitation to serve on the CoC. He noted that many members of the CoC are new, and several members are coming from across the globe, representing the continuum of healthcare-related professions and industries impacted by quality medicines. As USP delivers on its public health mission, USP's work, relationships, and partnerships around the globe have never been more critical. Convention Members in other regions of the world provide valuable perspectives, experiences, and expertise. USP is happy to have this range of representation on the CoC.

CoC members have a special role, as each member represents the Convention's membership categories and sectors and regions. To be fully representative of the

membership, USP not only needs this presence on the CoC, but also their voice and participation since CoC members will be looked at to represent their constituencies and stakeholders.

Sectors and regional chapters are new and something the previous CoC helped to shape, as did USP's Board of Trustees. Both endorsed this new model. Over the next five years, CoC members will be making decisions that impact USP's governance structure, the Convention's Membership, and Resolutions which contribute to USP's strategic direction every five years.

Overview of Agenda and Meeting Goals

Dr. Scott Kuzner reviewed the meeting agenda and objectives, noting that the agenda starts with big picture topics covering background on USP's five-year strategy and governance structure before turning to the Convention governing body, CoC member responsibilities, and how the CoC will carry out its work over the next five years. With that foundation and context in place, the CoC will discuss two brief items of business for the CoC.

Motion to Approve Agenda

Ms. Kim Huynh-Ba moved to approve the agenda, and the motion was seconded. The motion carried by unanimous consent, and the agenda was approved.

2. Introductions

CoC members and USP staff introduced themselves. CoC members shared the name of the Convention Member Organization they represent; their current position and role with their organization, and any previous engagement they or their organization has had with USP. USP staff shared their position at USP and role with the CoC and Convention.

3. USP 2025 Strategy

Dr. Doherty opened this topic by noting that prior to the meeting, CoC members were provided a link to watch a video from the 2020 Convention Meeting that outlined the 2025 strategy.

To set the stage for USP's CEO Dr. Ron Piervincenzi's presentation on the 2025 strategy, Mr. Lakavage briefly explained the connection between the 2025 strategy and the role of the CoC with the Convention's Call for Resolutions process. During this process, submitters of proposed Resolutions were asked to describe how their submission aligns with the strategy approved by USP's Board of Trustees. It is the role of the CoC to evaluate how proposed Resolutions align with this strategy and other considerations. The CoC also can develop with USP staff proposed Resolutions on their own that align with the strategy.

Dr. Piervincenzi's presentation on USP's 2025 strategy first touched on USP's mission and how the three pillars of the strategy – standards, advocacy, and capability-building – are designed to help fulfill USP's mission statement to "improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods." His presentation then connected how USP's governing bodies, USP staff and lab capabilities, and breadth of standards contribute to this mission and strategy.

4. USP Governance and Convention Overview

Dr. Kuzner provided an overview of USP's governance structure, USP Convention Membership, where the CoC fits within this structure, and how the CoC carries out its work. This overview covered the three branches of USP's governance system (Board of Trustees; the Council of Experts and Expert Committees; and the CoC and the Convention) and the underlying governing documents that support this system. Dr. Kuzner's presentation also covered the composition and categories of the USP Convention, responsibilities of Voting Member Organizations and Delegates, CoC responsibilities, the Resolutions process, and the impact Delegates make at the Convention Meeting held every five years.

5. Convention Sectors and Regional Chapters

Ms. Shelley Whiddon shared a new model for Convention Membership designed to build sustained Convention Member engagement throughout the five-year cycle. This new model consists of Convention "sectors" and "regional chapters" that aim to harness the full breadth and depth of perspectives of the USP Convention around priority issues. USP held proof-of-concept regional Convention meetings in late 2019 and early 2020 and is now scaling these models to other regions of the world and for topical sectors within the U.S. Each sector and chapter is led by a Chair who also has a seat on the CoC. USP plans to assign Voting Member Organizations to sectors and regions for initial assignments; however, organizations will be free to move to other sectors or join additional sectors.

This new model will launch with six sectors (Generic Medicines, Healthcare Practice, Biologics, Excipients, Innovation, and Dietary Supplements) and four regional chapters (Latin America, South Asia, Greater China, and Asia Pacific). There are plans to launch four additional regional chapters later (Europe, Middle East and North Africa, Russia and Newly Independent States, and Sub-Saharan Africa).

Sectors and regions will be supported by both USP staff and a working group. Sample activities for sectors and regional chapters include: annual meetings, quarterly teleconference, roundtables and panel discussions; guest speakers; and co-created content. USP hopes to begin initial sector and chapter meetings in late 2020 and into 2021; these will be virtual events.

6. CoC Business

a. CoE Overview and CoE Rules

Dr. Doherty noted that at the beginning of each cycle, the CoC approves sending one of USP's key governing documents to Convention Membership for comment – *The Rules and Procedures of the Council of Experts (CoE Rules)*. The CoC does not approve the changes to the *CoE Rules*, but reviews them to offer feedback and approve sending them to the full Convention Membership for a 90-day comment period. Those comments are sent to the CoE for responses. The CoC will review comments from Convention Members plus the CoE response to comments before sending both (the comments and responses) along with the *CoE Rules* to the Board of Trustees who ultimately will approve the changes after all of this has taken place.

Dr. Doherty explained that the authority of the *CoE Rules* comes from USP's Bylaws – USP's primary governing document. The *CoE Rules* define the standards-setting activities that are the responsibility of USP's CoE, a volunteer governing body. The *CoE Rules* govern the activities of the CoE and their Expert Committees, Expert Panels, Joint Standard-Setting Subcommittees, Stakeholder Forums, and Project Teams. The proposed revisions to the *CoE Rules* were made by the CoE in conjunction with USP staff.

Mr. Mario Sindaco and Ms. Deborah Biswas then provided an overview of the CoE and a summary of the recent revisions to the *CoE Rules* which was also provided in the briefing materials for review. Mr. Sindaco provided an overview of the CoE and its Expert Committees, what the *CoE Rules* cover, and the adoption process of the *CoE Rules*. Ms. Biswas outlined particular proposed changes to the *CoE Rules*.

Discussion

- CoC members asked for clarification on what the term “final discussion” means for Government Liaisons. USP staff clarified that this is the portion of the meeting after the presentation and discussion have taken place where anyone that is conflicted or is not a voting member is asked to leave the room before an Expert Committee or Joint Standards-setting Subcommittee votes and provides any final comments before voting. According to section 12.01(d) of the provisional *CoE Rules*, final discussions must occur before an item is advanced for final balloting by an Expert Committee or a Joint Standard-Setting Subcommittee. Final discussions are intended to promote full and frank deliberation and are closed to the public and limited only to nonconflicted voting members.
- CoC member Pallavi Nithyanandan who is the Delegate for the FDA Center for Drug Evaluation and Research noted for the record that FDA opposes the revised final discussion portion of the *CoE Rules*. Ms. Nithyanandan also added that FDA sent a letter to USP indicating this position.

Motion

David Gaugh moved to approve the provisionally-approved *CoE Rules* to go forward to the full Convention Membership for a 90-day comment period. The motion was seconded and then carried by unanimous consent.

b. Membership Approval: CoRE – Duke-NUS

Dr. John Chien-Wei Lim, a provisionally-approved member of the CoC, recused himself from this part of the meeting since his organization would be discussed. Dr. Doherty noted that after being admitted to membership, Dr. Lim will be called on to lead the Convention's Asia Pacific Regional Chapter. Dr. Doherty also noted that approving new members will be a task the CoC evaluates throughout the cycle as the CoC looks to ensure the Convention's Membership reflects the stakeholders impacted by USP's standards.

Dr. Kuzner presented an overview of an organization for the CoC's consideration as a new Convention Voting Member Organization. Per USP's Bylaws, recommendations for membership are approved by the CoC before they are sent to the full Board for final approval. The organization presented for membership was the Centre of Regulatory

Excellence (CoRE), Duke—NUS. The organization's member profile was included in the briefing materials. CoRE's compatibility, contribution, and alignment with Convention Membership includes:

- CoRE supports the strengthening of health product regulatory systems in the Asia Pacific region.
- The organization is a well-known and neutral, academic convener and has an established global network of regulators in the Asia Pacific region, the U.S., and Europe.
- CoRE's admission to membership helps expand non-U.S. membership and aligns with two Convention Resolutions: Regulatory Systems Strengthening; and Impact Expansion.
- An MOU partnership between CoRE and USP will help expedite CoRE's understanding of USP and the Convention.

Motion

Martin Coffey moved to approve recommending CoRE to the USP Board of Trustees for membership approval. The motion was seconded and then carried by unanimous consent.

7. Meeting Frequency and What's Next

Dr. Kuzner noted there are three main activities coming up next for the CoC: Meeting minutes will be distributed to CoC members; Convention Sectors and Regional Chapters will begin activities in late 2020 and into 2021; and the next major item of business for the CoC will be reviewing proposed changes to the *Rules and Procedures of the Council of the Convention* at their next meeting which likely will be held in January; a meeting poll is soon to follow for upcoming quarterly meetings.

8. Adjourn and Closing Remarks

Dr. Doherty thanked CoC members for sitting through a long, online meeting, noting that the CoC covered a lot of topics and activities – foundational information on USP and the Convention and the completion of two items of business. The CoC approved the *CoE Rules* to go forward to the full Convention Membership for a 90-day comment period and approved the recommendation of a new member for Convention Membership that will now go to USP's Board of Trustees in early November for final approval. He concluded by noting that this is just the start of the group's work, and everyone at USP is looking forward to working with the CoC.

The Chair adjourned the meeting at 1:30 p.m. ET.

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*

At-Large Members

11. Emmanuel Akala, R. Ph., Ph.D., DIM, Howard University College of Pharmacy
12. Lynette Bradley-Baker, Ph.D., R.Ph., American Association of Colleges of Pharmacy
13. Keysha Brooks-Coley, M.A., American Cancer Society/Cancer Action Network
14. Barbara Exum, PharmD, 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. Hanan Sboul, M.B.A., B. Pharm, CAE, Jordanian Association of Pharmaceutical Manufacturers
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. Kim Huynh-Ba, M.S., B.Sc., USP Small Molecules 4 Expert Committee
23. Xiaorong He, MBA, Ph.D., M.S., B.S., USP General Chapters—Physical Analytical Methods Expert Committee

* *Provisionally-approved member*

USP staff

1. Ron Piervincenzi, Ph.D., USP Chief Executive Officer,
2. Anthony Lakavage, J.D., Convention and Board Secretary and Senior Vice President,
3. Global External Affairs
4. Amanda Cowley, J.D., General Counsel and Senior Vice President, Legal, Strategy and People
5. Shelley Whiddon, M.A., Senior Director, Operations, Convention and Stakeholder Engagement

6. Scott Kuzner, Ph.D., Director, Board and Convention Operations
7. Amy Sonderman, Director, USP Convention and Stakeholder Engagement
8. Mario Sindaco, M.S., M.B.A., Vice President, Volunteer and Compendial Operations
9. Deborah Biswas, J.D., Senior Counsel