

**2020-2025 Council of the Convention (CoC)
Meeting #3
Wednesday, May 12, 2021**

Minutes

Goals and anticipated outcomes

- Review activities from Convention Sectors and Regional Chapters
- Approve proposed changes to USP governance document
- Approve recommendations for new Convention Members

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 8:05 a.m. ET. Dr. Doherty welcomed everyone to the third meeting of the CoC for the 2020-2025 cycle.

Overview of Agenda and Meeting Goals

Scott Kuzner reviewed the meeting agenda, noting that the objectives of the meeting were to: 1) review new prospective Convention Members; 2) provide a final review of the proposed *Rules and Procedures of the Council of the Convention (CoC Rules)*; 3) receive updates from Convention Sector and Regional Chapter Chairs; and 4) hear from the first guest speaker of the cycle. Dr. Doherty then called on the CoC to approve the meeting's agenda.

Motion to Approve Agenda

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

David Gaugh 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. Convention Sector and Regional Chapter Updates

Shelley Whiddon introduced the Convention Sector and Regional Chapter updates portion of the meeting, noting that these activities are now part of a new engagement model for the USP Convention. Whiddon introduced each Sector and Chapter with a brief statement on how the group's recent activities have supported a USP priority or a Resolution: Generic Medicines Sector (Priority: strengthen supply chain resiliency); Healthcare Practice Sector and South Asia Regional Chapter (Priority: COVID-19 Vaccines and Treatments); Biologics (Resolution: Access to Biologics); Dietary Supplements Sector (Resolution: Coalition-Building); Latin America Regional Chapter (Resolution: Regulatory Systems Strengthening); and Greater China Regional Chapter (Resolution: Pharmacopeial Cooperation and Convergence).

Sector and Regional Chapter Chairs provided the following updates:

Generic Medicines Sector**Chair: David Gaugh (Association for Accessible Medicines)**

This Sector convened a panel discussion on supply chain resiliency, which featured representatives from the patient, payor, and manufacturer communities. The panel discussed the impact of COVID-19 on the global supply chain from each of their perspectives. Future Sector engagement may include gathering insights that would forecast risks as well as identifying practical solutions on strengthening resiliency within the global medicines supply chain.

Healthcare Practice Sector**Chair: Amy Cadwallader (American Medical Association)**

The first meeting of the Sector featured a presentation of the USP COVID-19 Vaccines Handling Toolkit which provides information to practitioners administering COVID-19 vaccines authorized in the U.S. During the meeting and in a subsequent follow-up communication, members were able to provide immediate and early feedback on the Toolkit. The meeting also hosted a discussion on disparities in vaccine access and administration.

Biologics Sector**Chair: Susan Cantrell (Academy of Managed Care Pharmacy)**

The second meeting of the Biologics Sector featured a panel discussion to explore possible solutions to help enable acceptance of the clinical utility and widespread use of genomic data and precision medicine through education and standardization. The panel discussion led to vigorous dialogue among Members about the challenges and best practices that can help enable widespread adoption and impact patient outcomes. Future Sector opportunities include: exploring approaches to standards for interpretations of genomic data and qualifications for clinical samples used in genomic research; and participating in the USP Ignite Challenge to provide input into possible standardization of data sequencing.

Dietary Supplements Sector**Chair: Jay Sirois (Consumer Healthcare Products Association)**

This Sector meeting featured a panel including representatives from industry, consumer advocacy, and a member of the Council of Experts to discuss label literacy and how quality standards influence how information flows from manufacturers to consumers. Following the panel, an open discussion explored ideas from Member organizations on possible regulatory reform in the areas of mandatory product listing, harmonization of retailers' standards, labeling to inform on possible drug interactions, efforts to define and educate on the meaning of quality. Future Sector opportunities for engagement include: a meeting on May 26 to consider available resources for practitioner education as possible Sector contributions (e.g., programming and a white paper); and further exploration of label literacy, given the onset of the online supplement marketplace since DSHEA passed in 1994.

South Asia Regional Chapter**Chair: Bhojraj Suresh (Pharmacy Council of India)**

This Chapter shared USP's strategic priorities in the South Asia region with Members for input. This included addressing the supply of quality medicines regionally and globally. The Chapter also discussed increasing capacity-building activities and information-exchange opportunities to support manufacturers and state governments. Future Chapter opportunities may include: increasing collaboration with manufacturers and regulators to provide technical assistance for API production and enabling increased manufacturing and supply of medicines domestically and globally; and sharing information and support for regulatory authorities and manufacturers to help strengthen pharmacovigilance networks in the development of COVID-19 treatments and vaccines in the South Asia region.

Latin America Regional Chapter**Chair: Caroline Weinstein (Chilean Pharmacopeia)**

This Chapter presented 2019 Regional Meeting survey results and proposed topics for the Chapter to collaborate on: COVID-19 response and supply chain resilience in the Latin America region. The Chapter reviewed the survey results of Convention Member priority areas, including medical use of cannabis, impurities and nitrosamines, post-market surveillance, and regulatory systems strengthening. The Chapter also presented select regulatory best practices. INVIMA from Colombia shared information on monitoring the healthcare supply chain and how drug shortages can be prevented. ANVISA from Brazil shared key strategies in their COVID-19 response. Future Chapter engagement opportunities may include: collecting country responses to COVID-19 to document best practices and lessons learned across the region; and hosting a short presentation series for knowledge exchange and dialogue based on Convention Member feedback.

Greater China Regional Chapter**Chair: Mingzhe Xu (National Institutes for Food and Drug Control)**

This Chapter's first meeting provided a platform to engage on USP's response to COVID-19, and NIFDC's post-market surveillance initiative. USP is working with regulators and industry on the convergence of approaches to assessment and control of nitrosamine and other genotoxic impurities. Regional Chapter Member priorities are aligned to support collaboration between the Chinese Pharmacopeia (ChP) and USP. Based on Convention Member feedback and overlapping priority areas, the Regional Chapter will organize four workshops in FY22 to support knowledge exchange. Future Chapter opportunities may include: a joint workshop and trainings to support knowledge sharing of USP's technical expertise, including, but not limited to biologics performance standards and qNMR; and a joint training with key stakeholders on medicine quality.

4. Membership**The Importance of Engaged Convention Membership**

Anthony Lakavage provided a brief overview of how engaged Convention Membership is essential to USP's new operating model for the Convention for the 2020-2025 cycle. This model focuses on engaging Convention Members throughout a five-year cycle via the newly established Convention Sectors and Regional Chapters. Lakavage emphasized that engaged Membership is important because it helps USP staff focus their time and resources on targeted activities for Sector and Regional interests rather than spending time managing and tracking down Member representatives no longer interested in

participation. Engaged Membership also helps maximize USP's impact through input perspective, and collaboration from across the Convention's breadth and depth and bolsters USP's accountability to the Convention. Further, engaged Membership supports informed decisions that impact the future direction of USP at the USP Convention Meeting, including the election of USP leadership and input on Resolutions and changes to USP's Bylaws.

Membership Committee Charge and Background

Scott Kuzner reviewed the charge of the newly formed CoC Membership Committee and reviewed the approval process and criteria for new Convention Members. The recommendations put forward to the CoC are a first wave of recommendations to address immediate needs of the Convention in the areas of Sector and Regional Chapter support; and underrepresented areas of the Convention (e.g., Membership category, international representation, under-represented population, or new priority growth areas for USP). The Membership Committee will conduct a larger evaluation at their next meeting to address the composition of the Convention as a whole, including potential Member removals and other rebalancing needs.

The charge of the Committee is threefold: 1) to review potential new Members and take recommendations to the full CoC; 2) to review organizations eligible for removal and take recommendations to the full CoC; and 3) to develop an outlook for Membership composition with USP staff and other key USP governing body members.

The following CoC Members are on the Membership Committee, following appointment from CoC Chair Dennis E. Doherty:

- Kanecia Zimmerman (American Academy of Pediatrics)
- Lynette Bradley-Baker (American Association of Colleges of Pharmacy)
- Sue Peschin (Alliance for Aging Research)
- Hanan Sboul (Jordanian Association of Pharmaceutical Manufacturers)
- Stephen Mullenix (National Council for Prescription Drug Programs)
- Caroline Weinstein (Chilean Pharmacopeia)

New Members Overview

Scott Kuzner presented the Membership Committee's recommendations for three types of new Members: seven Voting Members, four Associate Members (three organizations and one individual), and six Observer Organizations transitioning to the new Associate Membership category. Kuzner noted that the Observer Organization category was replaced with the Associate Member category in the 2020 revision to the USP Bylaws. Associate Members need only be approved by the CoC, while approved Voting Member recommendations will go to the USP Board of Trustees for final approval.

Voting Members

The Membership Committee recommended the following organizations for Voting Member status:

1. ALó ProCiencias
2. ANAMED - National Agency for Medicines in Chile
3. Chilean Institute of Public Health (ISP)
4. European Fine Chemicals Group (EFCG)
5. Hemophilia Federation of America

6. National Laboratory of Medicine Control, Tunisia (LNCM)
7. Patient Advocate Foundation

Dr. Kuzner noted that while ANAMED is a part of ISP, USP's Brazil site staff recommended both be included because USP will engage these two entities on different topics. In the past, ANAMED has represented ISP in interactions with USP. As noted in the briefing materials, since this organization is the agency in charge of registration and surveillance of medicines in Chile, USP anticipates closer contact with its activities on specific topics related to the quality of medicines. USP's Brazil site will engage with ISP in different matters. In addition, while for most instances USP prefers that only a parent or umbrella entity be included for representation in the USP Convention, there are some instances where both are permitted. A similar example can be seen in the U.S. where both the U.S. Department of Health and Human Services (HHS) and six FDA offices within HHS are represented in the USP Convention.

Associate Memberships

The Membership Committee recommended ten Associate Members. These included three organizations and one individual completely new to the USP Convention, and six Observer Organizations transitioning to Associate Membership status.

New Associate Member Organizations

1. Access Health India
2. Bangladesh Association of Pharmaceutical Industries (BAPI)
3. National Institute of Pharmaceutical Education and Research (NIPER) Hyderabad

Observer Organizations Transitioning to Associate Membership

1. A3P
2. Association of Biotech Led Enterprises (ABLE)
3. China National Pharmaceutical Packaging Association
4. China Pharmaceutical Association of Plant Engineering
5. Medicines Control Authority of Zimbabwe (MCAZ)
6. Pharmacy and Poisons Board of Kenya (PPB)

Discussion

The following topics were discussed after the presentation of new Members:

- **Individual Associate Members:** Several CoC members indicated that they preferred to put individual Associate Memberships on hold until the CoC's Membership Committee and the CoC have time to discuss the criteria for individuals and see a roadmap for the individual Associate Member experience. The group agreed to place the individual recommended for the first Associate Membership on hold and the Chair developed a call for a motion reflecting this.
- **Overall Convention Composition:** CoC Members asked if a larger plan for a comprehensive outlook on Membership will be developed, and USP staff confirmed that there is a plan in development that will be shared with the Membership Committee at their next meeting and later with the CoC. The recommendations at this meeting only address the immediate needs of Convention Membership.
- **Honorary Members:** A CoC Member inquired whether an Honorary Membership may be more appropriate for individuals than an Associate Membership. USP staff noted that USP only offers a few Honorary Memberships to individuals (staff or

volunteers) each cycle who have made significant contributions to USP. Associate Memberships are intended to be offered to accomplished, proactive individuals but not necessarily significant contributors to USP like a volunteer or retired staff member. Lastly, it is at the discretion of the Membership Committee and CoC to determine who to approve for Associate Membership. Associate Membership is a non-voting status that replaces the Observer Organization to help with the new five-year engagement model. While Observer Organizations were temporarily Members for the Convention Meeting itself, the Associate Member designation permits a Member to participate in Convention activities throughout a five-year cycle.

- **Associate Member List:** A CoC member asked whether USP will post a list of Associate Membership and USP staff confirmed that the organization will post a list of Associate Members on USP.org after their invitations are accepted.

Motion

The Chair called for a motion to approve the Membership Committee's recommendations for: 1) new Voting Members to be recommended to USP Board of Trustees for final approval; and 2) for new Associate Members (organizations only). Hanan Sboul moved to approve the motion, the motion was seconded, and then carried by a unanimous voice vote.

The Chair emphasized that the CoC will hold approving individual Associate Members until the Membership Committee and staff outline more specific information on the individual membership experience and related criteria.

Action Item

USP staff will develop more information on the Individual Associate Member experience and outlook on the Associate Membership as a whole for the Membership Committee to review prior to sharing with the full CoC.

5. CoC Rules

Scott Kuzner provided an overview of the proposed *Rules and Procedures of the Council of the Convention (CoC Rules)* recently approved by the CoC for sending to the Board of Trustees for final approval. The revised *CoC Rules* were first shared with the CoC at their January 28, 2021 meeting. At that meeting, the CoC approved posting the proposed *CoC Rules* for comment from Convention Membership for a period of 90 days. Following the comment period, USP staff updated the *CoC Rules* to reflect changes necessitated by these comments. Kuzner's presentation covered a summary of noteworthy changes to the *CoC Rules* and USP's responses to the comments submitted. In total, USP received comments from three Convention Members.

Nearly all comments were incorporated into the *CoC Rules* except two related to engagement and communications. One of those was to add Sectors and Regional Chapters to Section 5 as an example of engagement approaches as well as some related details. Staff explained that this section is not intended to be an exhaustive list of engagement opportunities. The content in this section maintains flexibility as USP implements this new engagement structure of Sectors and Regional Chapters. USP will re-evaluate where to best formalize the Convention Sectors and Regional Chapters (i.e., the *USP Bylaws* and/or the *CoC Rules*) as it gains further insights into this type of

engagement. The second comment not incorporated requested separating engagement and communication in Section 5.01 and creating a new separate “regular reporting” section. Staff explained that the first sentence of the paragraph expressly addresses both engaging and communicating, so reporting is not distinct from the rest of the paragraph. Also, it is preferable to keep engagement and communication together in the same paragraph since activities related to engagement and communication often overlap. Lastly, additional, extensive changes could be made to this section if updated in the future to account for the Convention Sectors and Regional Chapters.

Discussion

There were no comments or questions on this topic.

Motion

Bhojraj Suresh moved to approve sending the proposed *CoC Rules* to the full Board for final evaluation and approval at the May Board meeting. The motion was seconded and then carried by a unanimous voice vote.

6. Medicine Supply Chain

The Chair introduced the guest speaker by noting that the topic of the medicines supply chain was chosen because it is an issue that all Convention Members and their constituencies are addressing or impacted by in some way. The medicine supply chain also has been addressed in the meetings of Convention Sectors and Regional Chapters. Lastly, this topic is likely to emerge for the CoC later this cycle when the CoC opens the Call for Resolutions and receives stakeholder submissions and develops the Resolutions that will be put forward to the full Convention for consideration.

Mike Levy, Senior Vice President of USP’s Digital and Innovation Division provided a brief overview of USP’s efforts related to the medicine supply chain before introducing the guest speaker Stephen W. Schondelmeyer, PharmD, MPubAdm, Ph.D., FAPhA. Dr. Schondelmeyer is the Co-Principal Investigator for CIDRAP’s Resilient Drug Supply Project at the University of Minnesota’s College of Pharmacy. CIDRAP is the Center for Infectious Disease Research Policy.

Schondelmeyer’s presentation touched on a number of topics related to the medicines supply chain, including the history of drug shortages in the U.S., the definition of a resilient drug supply in the U.S., USP’s medicines supply map, critical acute drugs, critical drugs for treating COVID-19, critical chronic drugs, contextual factors related to shortages, and the impact of COVID-19 pandemic on drug supply.

7. What’s Next

Scott Kuzner briefly reviewed post-meeting activities and what’s on the horizon for the CoC, noting that CoC members will soon see a poll for their quarterly meeting in the summer. The fall quarterly meeting will take place sometime between October 26-28 which is also when the Volunteer Leadership Meeting takes place – this is an event where the leadership from all three of USP’s governing bodies (CoC, Council of Experts, and Board of Trustees) will gather to hold their respective meetings and observe portions of the meetings of other governing bodies. The event also will feature plenary sessions for governing bodies to attend. Kuzner also noted that Voting Member recommendations and proposed *CoC Rules* going to Board of Trustees for approval (May 20-21, 2021). Finally,

all CoC members will soon see an online invitation to attend two special portions of USP's Science Week activities the following week: keynote speaker Rear Admiral Denise Hinton, Chief Scientist for the FDA and a fireside chat between Dr. Michael Osterholm Director, Center for Infectious Disease Research and Policy at the University of Minnesota and Dr. Jaap Venema, USP's Chief Science Officer and Chair of the USP Council of Experts.

8. Closing Remarks and Adjourn

The Chair adjourned the meeting at 10:00 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

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. Barbara Exum, PharmD, Virginia Commonwealth University/Medical College of Virginia School of Pharmacy
14. Stephen Mullenix, BS Pharm., R.Ph., National Council for Prescription Drug Programs
15. Pallavi Nithyanandan, Ph.D., FDA Center for Drug Evaluation and Research
16. Sue Peschin, *M.H.S., Alliance for Aging Research*
17. Hanan Sboul, M.B.A., B. Pharm, CAE, Jordanian Association of Pharmaceutical Manufacturers
18. Kanecia Zimmerman, M.D., American Academy of Pediatrics

Council of Experts Representatives

19. Martin Coffey, Ph.D., USP General Chapters—Dosage Forms Expert Committee
20. Stephanie Crawford, M.P.H., Ph.D., USP Nomenclature and Labeling Expert Committee
21. Kim Huynh-Ba, M.S., B.Sc., USP Small Molecules 4 Expert Committee

Unable to Attend

- Keysha Brooks-Coley, M.A., American Cancer Society/Cancer Action Network (unable to attend)
- Xiaorong He, MBA, Ph.D., M.S., B.S., USP General Chapters– Physical Analytical Methods Expert Committee (unable to attend)

USP Staff

1. Anthony Lakavage, J.D., Convention and Board Secretary and Senior Vice President, Global External Affairs
2. Deborah Biswas, J.D., Senior Counsel
3. Darcy Gentleman, Ph.D., Senior Stakeholder Engagement Manager
4. Scott Kuzner, Ph.D., Director, Board and Convention Operations
5. Mike Levy, M.B.A., Senior Vice President of Digital and Innovation Division
6. Amy Sonderman, Director, Convention and Stakeholder Engagement
7. Joy Titus-Young, Senior Stakeholder Engagement Manager
8. Shelley Whiddon, M.A., Senior Director, Operations, Convention and Stakeholder Engagement
9. Emily Yu, Stakeholder Engagement Manager

Guest Speaker

1. Stephen W. Schondelmeyer, PharmD, MPubAdm, Ph.D., FAPhA, Co-Principal Investigator for CIDRAP's Resilient Drug Supply Project at the University of Minnesota's College of Pharmacy