

**2020–2025 Council of the Convention (CoC)
Meeting #9
February 2, 2023
Teleconference**

Minutes – Final

Goals and Anticipated Outcomes

- Receive updates on Sector meetings and Supply Chain work
- Hear profile of Convention Member, Academy of Managed Care Pharmacy
- Approve recommendations for Member removals
- Consider candidates for Associate and Voting Membership

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

1. Welcome, Opening Remarks, Confirmation of Quorum, and Approval of Agenda and Previous Meeting's Minutes

Ms. Shelley Whiddon confirmed that a quorum was present. Mr. Anthony Lakavage noted that he would serve as Chair *pro tem* for this meeting because Dr. Dennis E. Doherty, CoC Chair, was recovering from a medical procedure and the Vice Chair, Dr. Lynette Bradley-Baker, was unable to attend. The Chair *pro tem* noted that Dr. Bradley-Baker agreed to serve as CoC Vice Chair for another year. The Chair *pro tem* welcomed everyone to the ninth meeting of the CoC for the 2020–2025 cycle. He convened the meeting at 8:00 a.m.

a. Overview of Agenda and Meeting Goals

The Chair *pro tem* reviewed the meeting agenda. CoC members provided no edits.

Unanimous Consent: The agenda was approved by unanimous consent without objection.

b. Approval of Minutes from Previous Meeting

The Chair *pro tem* asked attendees if there were any corrections to the minutes of the October 11, 2022, CoC Meeting. No edits were provided.

Motion: Dr. Steven Mullinex moved to approve the minutes of the October 11, 2022, CoC meeting. The motion was seconded and there was no discussion.

Vote: The motion was adopted by unanimous consent.

Action Item

- Ms. Whiddon will finalize the minutes of the October 11, 2022, CoC meeting.

2. Protecting Patients from Adulterated Medicines – USP Tools and Support

The Chair *pro tem* noted that the following presentation would focus on the adulteration of cough syrup in several countries and how USP is addressing raw materials and excipients challenges.

Dr. Chaitanya Kumar Koduri explained that the global supply chain of raw materials used in medicines is complex. Quality is at risk at different points in the supply chain. Excipients and reagents are being procured from different places and transported, increasing the risk to these components. Manufacturers and regulators need risk-based approaches to address these issues, and USP tools and standards can help.

Dr. Koduri noted that the diethylene glycol (DEG) contamination of medicines led to the formation of the modern U.S. FDA 90 years ago, and it is still a significant public health problem today. Stakeholders need to come together and act to address these issues. The World Health Organization (WHO) recently issued a Call to Action that reinforces the collective responsibilities of manufacturers, regulators, and pharmacopeias across the supply chain.

Dr. Koduri noted that USP's PQM+ program is helping to strengthen regulatory capabilities in developing economies. USP has also created free a DEG Toolkit with documentary standards and detailed educational videos. USP continues its engagement with Fight the Fakes and USP is hosting the Asia-Pacific Economic Cooperation (APEC) Center of Excellence meeting in April 2023. Dr. Koduri encouraged CoC members to help disseminate the DEG Toolkit and other information on this topic.

The Chair *pro tem* noted that this is a global challenge. The upstream supply chain has multiple points of failure, including the original excipient manufacturer, the lack of ingredient testing by the finished drug manufacturer, and the lack of export and import monitoring by regulators in exporting and importing countries. A small number of excipients are in 80% of our drug supply. USP is lending its voice to this discussion and prioritizing this important topic. USP will present the DEG Toolkit and discuss these issues at a WHO event in May 2023. The Chair *pro tem* asked CoC members to consider other platforms where they could talk about these issues. Ms. Whiddon noted that some Convention Chapters could address these topics.

Discussion

CoC members expressed appreciation for USP's work in this area. They noted the following; responses from USP staff are in sub-bullets:

- Prevention depends on the strength of regulatory systems in exporting and importing countries. USP is doing important work in this area.
- Could information on the sources of excipients and APIs be included in drug packaging?
 - Stakeholders have asked for information on the source countries for excipients, but this information is difficult to obtain. No single regulator has full visibility on the sources of drug ingredients.
- The U.S. FDA requires API and excipient vendors to file with FDA. Drug manufacturers must refer to these files when submitting their dossiers. How can USP help other countries embrace this model?
 - This will be a key topic for regulators participating in the APEC Center of Excellence meeting. USP is doing what it can to raise awareness and share tools through APEC and PQM+.
- Excipient regulation is complex. In China, authorities found that it was impossible to trace and track excipient sources because of the complexity of the supply chain. USP has played a leading role by updating monographs to address specific contaminants.
- Regulators may not have enough resources to track and trace every drug component. USP could raise the awareness in other levels of government about the need to provide appropriate resources to regulators. This could be discussed at the April APEC meeting.
 - Resourcing regulators is a key part of the solution to this issue.

Action Item

- USP staff will share the Convention Exchange Series report "Ensuring a Resilient Supply Chain: A Shared Imperative," and the Association for Accessible Medicine's (AAM's) "The U.S. Generic & Biosimilar Medicines Savings Report," with CoC members.

3. Proposed New Members and Removals

Ms. Hanan Sboul, Membership Committee Chair, provided a summary of the Convention's current Voting Members and Associate Members. She also reviewed the rationale and USP Bylaws provisions pertaining to Convention Member removals and USP's attempts to communicate with these organizations.

a. Proposed Removals

Ms. Sboul presented the Membership Committee's recommendation to remove the following Convention Members:

- 1) Southern Illinois University School of Medicine
- 2) Albany College of Pharmacy and Health Sciences
- 3) Wilkes University Nesbitt School of Pharmacy
- 4) Washington University School of Medicine in St. Louis
- 5) University of Chicago Pritzker School of Medicine
- 6) New York University School of Medicine
- 7) Emory University School of Medicine
- 8) Case Western Reserve University School of Medicine
- 9) University of Alabama at Birmingham School of Medicine
- 10) International Council of Nurses
- 11) Association of the European Self Medication

The Chair *pro tem* called for a motion to approve the list of 11 organizations recommended for removal from USP Convention Membership.

Motion: Ms. Susan Cantrell moved to approve the list of 11 organizations recommended for removal from Convention Membership. The motion was seconded. No conflicts were declared and there was no discussion.

Vote: The motion was adopted unanimously.

Action Item

- Ms. Whiddon will forward the list of 11 organizations recommended for removal from Convention Membership to the Board of Trustees (BoT).

b. Proposed New Members

Ms. Sboul reviewed the Membership criteria from the CoC Rules. She presented the Membership Committee's recommendation to add the following organizations as new Convention Members:

- Proposed New Voting Members
 1. Pharmaceutical Manufacturers Association of Turkey (IEIS)
- Proposed New Associate Members
 1. Federation of African Pharmaceutical Manufacturers Associations (FAPMA)
 2. Mexican Association of Pharmaceutical Laboratories (AMELAF)

The Chair *pro tem* asked if there were any questions.

Discussion

A CoC member asked the Membership Committee to consider providing a more fully defined definition of "underrepresented" Members. Ms. Sboul noted that the Membership Committee reviews the percentage of Members in each Membership category, and some of these percentages are very low. The Chair *pro tem* thanked the CoC member for their comment.

USP could be more precise when talking about what “underrepresented” means in this context.

The Chair *pro tem* called for a motion to approve the proposed new Associate Members and recommend that the BoT approve the new proposed Voting Member.

Motion: Mr. David Gaugh moved to approve the two organizations as new Associate Members, and to recommend one organization as a new Voting Member to the BoT for final approval. The motion was seconded. No conflicts were declared and there was no discussion.

Vote: The motion was unanimously adopted.

Action Items

- Ms. Whiddon will forward the recommended new Voting Member of the USP Convention to the BoT for final approval.
- USP staff will work with the Membership Committee to consider ways to talk about underrepresentation in the context of Convention Membership.

4. Convention Sector Updates

Ms. Amy Sonderman noted that Convention Sectors and Chapters can deliver important content to stakeholders. She asked CoC members to provide input on potential topics, directions, collaborations, or deliverables for Sectors and Chapters.

a. Dietary Supplements Sector

Dr. Jay Sirosis reported that this Sector is compiling a resource to support healthcare practitioners as they guide consumers and patients in choosing quality dietary supplements. The December 12, 2022, Sector meeting featured a presentation by Dr. Adam Kuszak of the National Institutes of Health (NIH) Office of Dietary Supplements (ODS). Dr. Kuszak values USP as a convenor of a range of stakeholders, and he had an active, engaged audience. An ODS practicum to be held in May 2023 will include extensive information for practitioners and consumers. USP is hosting a [Dietary Supplements and Herbal Medicines Stakeholder Forum](#) on February 16, 2023.

b. Healthcare Practice Sector

Dr. Ilsa Bernstein reported on the recent joint meeting of the Biologics and Healthcare Practice Sectors, co-chaired by Dr. Bernstein and Dr. Cantrell. Subject matter experts contributed to robust discussion, focusing on three areas:

- Developing guidelines and resources to support vaccines quality
- Providing tools for the preparation, handling, and storage of vaccines for use by frontline healthcare practitioners
- Facilitating access to quality vaccines in low- and middle-income countries

Dr. Cantrell noted that she was surprised by the high level of discussion about how stakeholders use the tools and what else is needed. The collaboration with another Sector led to richer dialog and the sharing of perspectives. It was effective and could be replicated for other cross-cutting topics. Ms. Sonderman noted that USP plans to bring together smaller groups to discuss vaccine topics to maintain the momentum. More multi-Sector meetings will be planned.

Dr. Doherty noted that there has been increased participation by Delegates and colleagues leading to robust discussion across Convention Sector and Region meetings. He thanked CoC members for making those discussions so successful.

c. Supply Chain Updates

The Chair *pro tem* noted that USP has conducted advocacy work on Capitol Hill over many years. The 2023 Omnibus Appropriations bill included language that encourages the U.S. Department of Health and Human Services to provide resources to understand challenges in the upstream medicine supply chain. USP's communications campaign on supply chain resilience includes an [article by USP CEO Dr. Ron Piervincenzi](#) published in *Chain Drug Review* and an article on the [Omnibus spending law](#) published USP's *Quality Matters*. "Ensuring a Resilient Supply Chain: A Shared Imperative," a report on the three-part series USP Convention Exchange meetings, will be published soon. Ms. Sonderman noted in 2022, AAM published "The U.S. Generic & Biosimilar Medicines Savings Report." The Chair *pro tem* congratulated Dr. Gaugh for his contributions as Interim Chair of AAM.

Action Item

- USP staff will share "Ensuring a Resilient Supply Chain: A Shared Imperative" and "The U.S. Generic & Biosimilar Medicines Savings Report" with CoC members.

5. Member Organization: Profile and Priorities

Ms. Susan Cantrell provided an overview of the Academy of Managed Care Pharmacy (AMCP), including AMCP's mission and Membership. AMCP members work behind the scenes to manage pharmacy benefits. They use clinical and economic evidence that drives decision making on the appropriate use of medicines, and they help implement clinical programs to improve patient adherence. AMCP's policy priorities include biosimilars, prescription digital therapeutics, manufacturer-payer communications, drug pricing negotiations, and the availability and quality of affordable medicines.

Discussion

- USP staff asked about a grant pertaining to user fees that was mentioned at a Sector meeting. Ms. Cantrell noted that AMCP received the grant from FDA as part of the Biosimilars Reauthorization Act. They are applying real world evidence and evaluating the extent that studies on biosimilars can inform regulatory decision making. One such study by the Biologics and Biosimilars Collective Consortium will be published soon.
- A CoC member noted that drug shortages are still significant issues. The involvement of pharmacy benefit managers (PBMs) in the practice of medicine needs to be discussed.

6. What's Next

Ms. Whiddon noted that USP is revising the leadership section of USP.org to include updated bios of the Executive Team, BoT, Council of Experts, and CoC. USP staff will send a bio template and guidance on how to create a headshot photo to CoC members. She asked CoC members to provide their bios and headshots by February 22, 2023.

Action Item

- CoC members will send their bios and headshots to Ms. Whiddon by February 22, 2023.

7. Adjourn and Closing Remarks

The Chair *pro tem* thanked CoC members for their attendance and commitment.

Adjourn

The meeting adjourned at 9:45 a.m.

Action Items

- Ms. Whiddon will finalize the minutes of the October 11, 2022, CoC meeting.
 - USP staff will share the Convention Exchange Series report “Ensuring a Resilient Supply Chain: A Shared Imperative,” and the Association for Accessible Medicine’s (AAM’s) “The U.S. Generic & Biosimilar Medicines Savings Report,” with CoC members.
 - Ms. Whiddon will forward the list of 11 organizations recommended for removal from Convention Membership to the Board of Trustees (BoT).
 - Ms. Whiddon will forward the recommended new Voting Member of the USP Convention to the BoT for final approval.
 - USP staff will work with the Membership Committee to consider ways to talk about underrepresentation in the context of Convention Membership.
 - USP staff will share “Ensuring a Resilient Supply Chain: A Shared Imperative” and “The U.S. Generic & Biosimilar Medicines Savings Report” with CoC members.
 - CoC members will send their bios and headshots to Ms. Whiddon by February 22, 2023.
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Addendum

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. Dietary Supplements Sector Chair: Jay Sirois, Ph.D., Consumer Healthcare Products Association
4. Healthcare Practice Sector Chair: Ilisa BG Bernstein, PharmD, J.D., FAPhA, American Pharmacists Association
5. Excipients Sector Chair: Erik Burns, Ed.D., M.A., MBA, American Association of Pharmaceutical Scientists
6. Biologics Sector Chair: Susan Cantrell, BS Pharm., Academy of Managed Care Pharmacy

USP Convention Regional Chapter Chairs

7. Asia-Pacific Region Chapter Chair: John Chien-Wei Lim, M.D., M.S., Centre of Regulatory Excellence, Duke-NUS Medical School
8. Greater China Region Chapter Chair: Mingzhe Xu, National Institutes for Food and Drug Control
9. 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
10. Latin America Region Chapter Chair: Caroline Weinstein, Ph.D., Chilean Pharmacopeia

At-Large Members

11. Emmanuel Akala, R. Ph., Ph.D., DIM, Howard University College of Pharmacy
12. Stephen Mullenix, BS Pharm., R.Ph., National Council for Prescription Drug Programs

13. Pallavi Nithyanandan, Ph.D., FDA Center for Drug Evaluation and Research
14. Sue Peschin, M.H.S., Alliance for Aging Research
15. Pam Traxel, American Cancer Society/Cancer Action Network

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

Unable to Attend

- Lynette Bradley-Baker, Ph.D., R.Ph., CoC Vice Chair, Membership Committee Vice Chair, American Association of Colleges of Pharmacy
- Barbara Exum, Pharm.D., Virginia Commonwealth University/Medical College of Virginia School of Pharmacy
- Bhojraj Suresh, M.Pharm., Ph.D., D.Sc. Indian Association of Colleges of Pharmacy (IACP), South Asia Region Chapter Chair
- Kanecia Zimmerman, M.D., American Academy of Pediatrics

USP Staff

Raliza De Souza, M.B.A., Project Manager, Global Stakeholder Engagement
Darcy Gentleman, Ph.D., Senior Stakeholder Engagement Manager
Chaitanya Kumar Koduri, International Government & Regulatory Engagement Director
Anthony Lakavage, J.D., Convention and Board Secretary and Senior Vice President, Global External Affairs
Diana Newhart, M.P.H., Senior Advocacy & Stakeholder Engagement Manager
Elana Pate, Project Coordinator, Global Stakeholder Engagement
Max Saffell, MBA, Senior Manager, Stakeholder Engagement
Amy Sonderman, Director, Convention and Stakeholder Engagement
Marie Temple, Technical Writer III, Publications
Shelley Whiddon, M.A., Senior Director, Operations, Convention and Stakeholder Engagement