

**2020–2025 Council of the Convention (CoC)  
Meeting #10  
April 19, 2023  
Teleconference**

**Minutes**

**Goals and Anticipated Outcomes**

- Hear report on use of Bylaws this cycle
- Consider proposal for Voting Membership
- Hear update on USP supply chain efforts
- Hear Sector and Chapter updates
- Hear profile of Convention Member, Jordanian Association of Pharmaceutical Manufacturers

**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**

Shelley Whiddon noted that a quorum was present. Dennis E. Doherty, CoC Chair, welcomed everyone to the tenth meeting of the CoC for the 2020–2025 cycle. He convened the meeting at 9:00 a.m., and welcomed those attending from outside the U.S.

**a. Overview of Agenda and Meeting Goals**

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

**Motion:** Hanan Sboul moved to approve the meeting agenda. The motion was seconded and there was no discussion.

**Vote:** The motion was adopted by unanimous consent.

**b. Approval of Minutes from Previous Meeting**

The Chair asked attendees if there were any corrections to the minutes of the February 1, 2023, CoC Meeting. No edits were provided.

**Motion:** Hanan Sboul moved to approve the minutes of the February 1, 2023, CoC meeting. The motion was seconded and there was no discussion.

**Vote:** The motion was adopted by unanimous consent.

**Action Item**

- Shelley Whiddon will finalize the minutes of the February 1, 2023, CoC meeting.

**2. Launching the 2025–2030 Bylaws Amendments Process**

Deborah Biswas and Shelley Whiddon provided an overview of the CoC's responsibilities pertaining to the USP Bylaws amendment process, including oversight of the Open Hearings on Bylaws amendments and the timeline. Section 7.01 *Soliciting Input Prior to a Regular Membership Meeting* of the *Rules and Procedures of the 2020–2025 Council of the Convention* states the following: "At least two years prior to the Regular Membership Meeting, the CoC will consider input from staff on their experience with Bylaws provisions during the first three years of the cycle."



To fulfill this requirement, Deborah Biswas reviewed the following staff observations:

- Convention Membership Composition:
  - Better reflect USP's evolved stakeholder community by adjusting the requirement that a minimum of 60% combined of the Voting Members must be from categories 1 (Academic institutions) and 2 (Health practitioner professional and scientific associations and organizations that represent allopathic, osteopathic, and veterinary medicine, pharmacy, nursing, and other health and science-related fields).
- Convention Membership Removal
  - Reduce/adjust the threshold for removal. Currently, it can take up to 10 years to remove a Member.
  - Add a contingency for the Board to remove a Member for egregious acts.
- CoC Composition
  - To allow flexibility for selecting CoC members, consider adjusting requirements for composition. Consider lowering the requirement that there be at least two representatives from each category of Voting Member so that the CoC membership could more closely represent USP's work.
  - To streamline additions to the CoC each cycle, consider having the Board only approve the initial CoC roster. Subsequent additions could be approved by the President in consultation with the Secretary.
- Board of Trustees (BoT) Composition
  - To allow more flexibility to identify candidates best equipped to help lead USP in a continually evolving environment, add flexibility in the requirements for areas represented by Trustees.
- Conflict of Interest (Col)
  - Potentially update the Col definition to better reflect the goals of the language. For example, consider changing "conflict of interest" to "competing interest."
  - If this change were adopted by Convention Members, the *Rules and Procedures of the Council of Experts* would be revised to ensure alignment.

Shelley Whiddon noted that these were preliminary considerations to prompt thinking about possible Bylaws amendments. No decision was required at this meeting. The CoC will form a Bylaws Committee to advance this work and bring recommendations to the CoC for consideration. USP plans to announce the formation of the Committee by the end of August 2023.

## Discussion

CoC members noted the following: responses from USP staff are in sub-bullets:

- Could staff clarify the CoC composition proposal? This topic could be added to a future CoC meeting agenda.
  - Staff is asking the CoC to consider adding flexibility to the 60% threshold.
  - There will be more discussion about these proposals in the future. This was just an initial readout of some areas where there may be opportunities for Bylaws amendments.
  - The requirement for this preliminary discussion is in the current Bylaws. The Bylaws Committee could consider whether to retain or remove this requirement.
- Would "competing interest" be defined in the same way as Col is defined? The phrase "potential competing interest" could increase comfort in reporting.
  - "Competing interest" would acknowledge that Expert Volunteers are often engaged in the public health space. "Potential" could be added to the phrase.

- Regarding Convention Member removal, a Member's involvement in USP activities beyond attendance at the 5-year meeting could be considered (e.g., electronic voting before the meeting, virtual attendance).
  - The Member may also appoint an alternate delegate to attend the 5-year meeting.

The following CoC members volunteered to serve on the Bylaws Committee:

- Susan Cantrell
- Lynette Bradley-Baker
- Ilisa Bernstein

#### **Action Item**

- CoC members will email Shelley Whiddon if they are interested in joining the Bylaws Committee.

### **3. Deep Dive: USP's Impact Across the Supply Chain**

The Chair noted that USP recently had the honor to share its perspectives and expertise on drug shortages through the expert testimony of Vimala Raghavendran to the U.S. Senate Homeland Security and Governmental Affairs SC. Tony Lakavage shared a video clip of her testimony. This was an example of the success of USP's advocacy work in raising awareness of upstream supply chain issues. Another example was the inclusion of language in the Fiscal Year 2023 Omnibus Appropriations Bill urging the U.S. Department of Health and Human Services to invest resources in understanding upstream medicine supply chain vulnerabilities.

This topic will also be discussed when USP and FDA host the Asia-Pacific Economic Cooperation (APEC) Center of Excellence meeting. Tony Lakavage shared the agenda with the CoC. More than 200 leaders from 21 regulatory agencies have registered to attend in person and 300 additional attendees will attend virtually. He will share highlights at a future CoC meeting.

Ron Piervincenzi provided updates on USP's efforts to support and build a resilient supply chain. He noted the following:

- USP has taken a broader approach to this topic in this cycle, asking what it means to have a quality medicine supply chain and exploring many aspects that affect medicine supply. Resilience is built on a foundation of quality manufacturing systems, strong regulatory agencies, and public standards.
- In this cycle, USP prioritized the development of standards for products on the essential medicines list. Half of USP's COVID-19 work pertained to supply chain resilience and quality.
- Looking toward the future, faster technologies will be needed to increase access to medicine production in developing economies. The USP Advanced Manufacturing Technology Lab in Richmond, Virginia, is working in this area.
- Data from the 2023 USP Perception Monitor (a survey of users of USP standards) indicate that the perception of USP's role in strengthening global medicine supply has risen, especially among regulators. This tells us that our focus is on target.
- The Medicines Supply Map (MSM) is a relational database that links and relates dozens of large data sets from USP, FDA, partners, and commercial sources. The MSM identifies, characterizes, and quantifies risk in the upstream pharmaceutical supply chain so that stakeholders can prioritize investments in supply chain resilience and proactively prevent drug shortages through risk mitigation activities.
- Drivers of drug shortages include geographic concentration, complexity, and price.

#### **Discussion**

A CoC member noted that another key factor is the impact of drug shortages (e.g., Adderall, acetaminophen, amoxicillin) on community pharmacies. Ron Piervincenzi noted that there are different drivers that impact the whole system. When the only pharmacy in an area cannot provide a medicine, this has a significant impact on patients. If issues can be identified earlier in the supply chain, then the system can adjust before impacting patients. Problems that happen late in the pipeline have greater impacts.

#### **4. Proposed New Members**

Hanan Sboul, Membership Committee Chair, provided a summary of the Convention's current Voting Members and Membership criteria from CoC Rules. She presented the Membership Committee's recommendation to add the following organization as a new Voting Convention Member:

1. National Psoriasis Foundation

With the addition of this organization, the Membership count would still be consistent with the Bylaws requirements.

The Chair asked if there were any potential competing interests or conflicts of interest and none were declared.

There was no discussion. The Chair called for a motion to recommend that the BoT approve the new proposed Voting Member.

**Motion:** Sue Peschin moved 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 Item**

- Staff will forward the recommended new Voting Member of the USP Convention to the BoT for final approval.

#### **5. Convention Sector Updates**

##### **a. Joint Meeting of the Generic Medicines Sector and Excipients Sector**

Darcy Gentleman noted that the Excipients Sector, chaired by Erik Burns, was launched at a joint meeting with the Generic Medicines Sector on April 3, 2023. The meeting, titled "Gathering Perspectives on Nitrosamine Risks," featured a panel discussion on nitrosamines. Convention Members want targeted programming to address nitrosamines, impurities, and future threats. The Excipients Sector could be a collaborative venue to facilitate stakeholder input.

##### **b. Joint Meeting of the Biologics Sector and Healthcare Practice Sector**

Amy Sonderman noted that this was another example of bridging sectors based on common interests. Ilisa Bernstein, Chair of the Health Care Practice Sector noted that she co-chaired this meeting with Susan Cantrell, Chair of the Biologics Sector. Following up on the January 26, 2023 meeting on vaccine quality, a smaller group was invited to this joint meeting to discuss areas on which the two sectors could collaborate. Janet McCluskey represented the COVID-19 Vaccine Education and Equity Project. She discussed efforts to build trust in vaccines and the importance of consumer education. Susan Cantrell noted that joint sector meetings are very valuable when there are aligned interests.

Amy Sonderman noted that the Biologics Sector meeting on May 9, 2023, will feature a speaker on the regulatory research roadmap. USP staff will send an invitation to the meeting to CoC members.

#### **Action Item**

- USP staff will send an invitation to the May 9, 2023, Biologics Sector meeting to CoC members.

#### **c. Innovation Sector**

Darcy Gentleman shared that insights from the February 2023 Open Forum on the pharmaceutical environmental footprint were presented at the April 11, 2023, Innovation Sector meeting. Jane Weitzel spoke about identifying new processes for established methods and new tools for new methods. She discussed how USP General Chapter <1220> *Analytical Procedure Lifecycle* can be used to choose an analytical target and design a method. Attendees discussed how knowledge of system information can facilitate design changes, the need for complex monitoring of complex systems, the importance of packaging as a key aspect of the environmental footprint, and how digitalized infrastructure can help optimize processes. These topics will be discussed at future sector meetings.

#### **d. Europe Regional Chapter Launch**

Amy Sonderman noted that Catherine Duggan CEO of the International Pharmaceutical Federation, is interim Chair of this chapter. Zakiya Al-Kurdi noted that this chapter was launched at a hybrid meeting on March 21, 2023, in Basel, Switzerland. Sixteen organizations participated, including some that are prospective Convention members. They identified shared priorities including environmental sustainability, risk mitigation strategies for nitrosamines and other impurities, supply chain resiliency, biologics and biosimilars, and rapid microbiology testing. Members provided local insights and recommendations for compendial and noncompendial approaches (e.g., harmonization and exchange of expertise).

The Chair noted that Convention Sectors and Regions are doing great work. He thanked CoC members for bringing these activities to fruition during this cycle.

### **6. Member Organization: Profile and Priorities**

Hanan Sboul provided an overview of the Jordanian Association of Pharmaceutical Manufacturers (JAPM). She reviewed JAPM's membership, mission, and key focus areas.

#### **Action Items**

- USP staff will provide links to information on JFDA presented by Hanan Sboul.
- CoC members will email Shelley Whiddon if they are interested in sharing information about their organizations at a future CoC meeting.

### **7. What's Next**

Shelley Whiddon noted that USP is forming a Diversity, Equity, Inclusion, and Belonging (DEIB) Expert Panel to develop strategies and best practices to inform how USP recruits and selects volunteers for Expert Committees and Expert Panels and how diverse committees collaborate. Staff will include a link to the Call for Candidates in a follow-up email. She asked CoC members to share information about this opportunity with their colleagues and networks.

Shelley Whiddon also reminded CoC members to send their bios to her for the USP Leadership webpage.

### **Action Items**

- CoC members will email their bios to Shelley Whiddon for inclusion on the USP Leadership webpage.

### **8. Adjourn and Closing Remarks**

The Chair thanked CoC members for their attendance and commitment. He asked them to email ideas for future agenda topics and feedback on the meeting format to him.

### **Adjourn**

The meeting **adjourned at 11 am.**

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### **Action Items**

- Shelley Whiddon will finalize the minutes of the February 1, 2023, CoC meeting.
  - CoC members will email Shelley Whiddon if they are interested in joining the Bylaws Committee.
  - Staff will forward the recommended new Voting Member of the USP Convention to the BoT for final approval.
  - USP staff will send an invitation to the May 9, 2023, Biologics Sector meeting to CoC members.
  - USP staff will provide links to information on JFDA presented by Hanan Sboul.
  - CoC members will email Shelley Whiddon if they are interested in sharing information about their organizations at a future CoC meeting.
  - CoC members will email their bios to Shelley Whiddon for inclusion on the USP Leadership webpage.
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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
2. Lynette Bradley-Baker, Ph.D., R.Ph., CoC Vice Chair, Membership Committee Vice Chair, American Association of Colleges of Pharmacy

#### **USP Convention Sector Chairs**

3. Generics Sector Chair: David Gaugh, R.Ph., Association for Accessible Medicines
4. Dietary Supplements Sector Chair: Jay Sirois, Ph.D., Consumer Healthcare Products Association
5. Healthcare Practice Sector Chair: Ilisa BG Bernstein, PharmD, J.D., FAPhA, American Pharmacists Association
6. Biologics Sector Chair: Susan Cantrell, BS Pharm., Academy of Managed Care Pharmacy

#### **USP Convention Regional Chapter Chairs**

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

#### **At-Large Members**

10. Emmanuel Akala, R. Ph., Ph.D., DIM, Howard University College of Pharmacy
11. Barbara Exum, Pharm.D., Virginia Commonwealth University/Medical College of Virginia School 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
19. Otilia Koo, Ph.D., USP Complex Excipients Expert Committee

#### **Unable to Attend**

- Kanecia Zimmerman, M.D., American Academy of Pediatrics
- South Asia Region Chapter Chair: Bhojraj Suresh, M.Pharm., Ph.D., D.Sc. Indian Association of Colleges of Pharmacy (IACP)
- Greater China Region Chapter Chair: Mingzhe Xu, National Institutes for Food and Drug Control
- Excipients Sector Chair: Erik Burns, Ed.D., M.A., MBA, American Association of Pharmaceutical Scientists

#### **USP Staff**

Zakiya Al-Kurdi, Ph.D., Senior Manager, Public Policy Regulatory Affairs, EMEA  
 Deborah Biswas (Legal), Senior Counsel  
 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  
 Ronald Piervincenzi, Ph.D., Chief Executive Officer  
 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