

**2020–2025 Council of the Convention  
Meeting #11  
Wednesday, July 19, 2023**

**Webex**

**Minutes – Final**

**Goals and Anticipated Outcomes**

- Hear update on APEC Medical Product Supply Chain Dialogue
- Decide on proposed new Voting Convention Members
- Learn CoC Resolutions Committee responsibilities
- Hear Sector and Chapter updates
- Hear profile of Convention Member, American Cancer Society Cancer Action Network

**Attendees:** See addendum for a list of Council of the Convention (CoC) and USP staff attendees.

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

Anthony Lakavage noted that a quorum was present. Dennis E. Doherty, CoC Chair, welcomed everyone to the eleventh meeting of the CoC for the 2020–2025 cycle and convened the meeting at 8:02 a.m. The Chair introduced Catherine Duggan as the newest CoC Member and newly appointed chair of the Europe Regional Chapter.

**a. Overview of Agenda**

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

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

**Vote:** The motion carried by unanimous consent.

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

The Chair asked attendees if there were any corrections to the minutes of the April 19, 2023, CoC Meeting. CoC Members provided no edits.

**Motion:** Stephen Mullenix moved to approve the minutes of the April 19, 2023, CoC meeting. The motion was seconded and there was no discussion.

**Vote:** The motion carried by unanimous consent.

**2. Deep Dive: Asia-Pacific Economic Cooperation (APEC) Medical Product Supply Chain Dialogue**

Anthony Lakavage provided an overview of the USP-APEC Center of Excellence, the APEC Supply Chain Security Toolkit, and the APEC Medical Product Supply Chain Dialogue event co-hosted by FDA and USP at USP–Rockville, MD, on April 25–26, 2023. He summarized the key themes of the keynote address and APEC panel discussions. John Lim noted the value of regional collaboration among regulators and stakeholders at the Asia Pacific (APAC) Regional Chapter meeting held April 27, 2023, at USP–Rockville in support of supply chain resilience and regulatory lessons for pandemic preparedness. Carrie Harney noted the public health benefits and risks of online pharmacies and that communication,



collaboration, and compliance with the APEC Toolkit can help overcome these challenges. Anthony Lakavage noted that USP welcomes ideas from CoC Members on promoting the APEC Toolkit and that CoC Members are welcome to link to the APEC Supply Chain Toolkit on their websites.

### **Discussion**

A CoC Member noted that USP staff should include general practitioners as recipients of the toolkit. Another CoC Member suggested that discussions on stockpiles might result in recommendations for reducing drug shortages. USP staff replied that USP has made recommendations to the U.S. Department of Health & Human Services' Administration for Strategic Preparedness & Response. A CoC Member noted that USP's Medicine Supply Map makes drug shortages more transparent and may help avoid unnecessary stockpiling.

### **Action Items**

- USP staff will provide CoC Members with a link to the APEC Supply Chain Security Toolkit that is posted on USP.org.
- CoC Members who are interested can link to the APEC Supply Chain Toolkit.
- USP staff will include general practitioners as recipients of the toolkit.

### **3. Convention Sector and Chapter Updates**

The Chair called on Amy Sonderman for an introduction of the Sector and Chapter speakers. John Lim summarized the key takeaways from the APAC Regional Chapter meeting. Jay Sirois provided updates on the Dietary Supplements and Healthcare Practice Sectors Joint Meeting held on June 22, 2023, and the launch of the "Choosing for Quality: Dietary Supplements" resource. He noted that CoC Members who have contacts or colleagues who might benefit from USP's dietary supplements resource can contact Darcy Gentleman. Ilisa Bernstein provided updates on the May 23, 2023, Healthcare Practice Sector luncheon meeting. She provided an update on pictograms for fall 2023. Susan Cantrell described the success of the Infographic on Biosimilars Quality, which rolled out in 2022, and provided updates on the Biosimilar User Fee Act III regulatory research roadmap discussion with FDA.

### **Action Items**

- CoC Members interested in sharing recommendations for distributing the "Choosing for Quality: Dietary Supplements" resource can contact Darcy Gentleman.

### **4. New Convention Member Approvals**

CoC Membership Committee Chair Hanan Sboul reviewed the proposed new Voting Members recommended by the Committee for CoC consideration:

- California Life Sciences
- Brazilian Association of the Pharmaceutical Ingredients Industry
- Pharmaceutical Sciences Academy of Brazil / National Pharmacy Academy

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

### **Discussion**

A CoC Member commented that they support all three proposed new Voting Members and that members of the Pharmaceutical Sciences Academy of Brazil have shown a notable commitment to USP and smaller pharmacopeias.

The Chair called for a motion to recommend to the BoT approval of the new proposed Voting Members.

**Motion:** David Gaugh moved to recommend to the Board of Trustees approval of the three organizations as new Voting Members of the USP Convention. The motion was seconded. No conflicts were declared and there was no discussion.

**Vote:** The motion was unanimously adopted.

#### **Action Item**

- USP staff will forward to the Board of Trustees their recommendation for the approval of new Voting Members to the USP Convention.

### **5. Launching the 2025–2030 Resolutions Process**

Shelley Whiddon provided an overview of the CoC's responsibilities related to the 2025–2030 Resolutions process and summarized the CoC's related responsibilities.

#### **Discussion**

USP staff noted that there is a concurrent process in which the Board of Trustees works with USP staff to develop a proposed strategy in tandem with the Resolutions development process, which will be shared with attendees of the upcoming Volunteer Leadership Meeting (VLM). A CoC Member commented that the number of Resolutions proposed for the 2025–2030 cycle should be discussed. In response to questions from a CoC Member, USP staff clarified the process for developing and approving the Resolutions and noted that they will share the dates of the Spring 2025 Convention Meeting with CoC Members when the information is finalized.

#### **Action Items**

- USP staff will share the dates of the Spring 2025 Convention Meeting with CoC Members.

### **6. CoC Bylaws Committee Update**

Shelley Whiddon provided an update on the Bylaws Committee's composition and next steps.

#### **Discussion**

A CoC Member asked whether the Bylaws Committee was accepting additional volunteers and noted that it might need an additional industry-related representative. USP staff replied that they would respond after consulting with the Chair and others.

#### **Action Item**

- Shelley Whiddon will inform the requesting CoC Member whether the CoC Bylaws Committee can accept an additional volunteer.

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

Pam Traxel provided an overview of the American Cancer Society Cancer Action Network, its organizational priorities, and activities. USP staff noted that CoC Members who are interested in providing an update to the CoC about their organization can contact Shelley Whiddon.

#### **Action Item**

- CoC Members who are interested in providing an update to the CoC about their organization can contact Shelley Whiddon.

## 8. What's Next

Shelley Whiddon recapped the action items from the meeting. She noted the following upcoming meetings:

- Middle East and North Africa Regional Chapter, September 27, 2023
- Hybrid VLM, October 11–13, 2023

Shelley Whiddon summarized the schedule and objectives of the VLM and encouraged all CoC Members who will attend in person to stay at the InterContinental at the Wharf in Washington, DC, to facilitate their participation in the VLM activities. She provided information on travel arrangements and guidance on expense reporting.

## 9. Adjourn and Closing Remarks

The Chair congratulated CoC Members for their accomplishments. The Chair adjourned the meeting at 10:00 a.m.

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## Action Items

- USP staff will update CoC Members when the APEC Supply Chain Security Toolkit is posted on USP.org.
- CoC Members who are interested can link to the APEC Supply Chain Toolkit.
- USP staff will include general practitioners as potential recipients of the toolkit.
- CoC Members interested in sharing recommendations for distributing the “Choosing for Quality: Dietary Supplements” resource can contact Darcy Gentleman.
- USP staff will forward to the Board of Trustees the recommended proposed new Voting Members of the USP Convention.
- USP staff will share the dates of the Spring 2025 Convention Meeting with CoC Members.
- Shelley Whiddon will inform the requesting CoC Member whether the CoC Bylaws Committee can accept an additional volunteer.
- CoC Members who are interested in providing an update to the CoC about their organization can contact Shelley Whiddon.

## 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. Healthcare Practice Sector Chair: Ilisa BG Bernstein, PharmD, J.D., FAPhA, American Pharmacists Association
5. Biologics Sector Chair: Susan Cantrell, BS Pharm., Academy of Managed Care Pharmacy

6. Excipients Sector Chair: Erik Burns, Ed.D., M.A., MBA, American Association of Pharmaceutical Scientists
7. Dietary Supplements Sector Chair: Jay Sirois, Ph.D., Consumer Healthcare Products Association

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

8. Europe Region Chapter Chair: Catherine Duggan, Ph.D., FRPharmS, Honorary Professor
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
11. Asia-Pacific Region Chapter Chair: John Chien-Wei Lim, M.D., M.S., Centre of Regulatory Excellence, Duke-NUS Medical School
12. South Asia Region Chapter Chair: Bhojraj Suresh, M.Pharm., Ph.D., D.Sc. Indian Association of Colleges of Pharmacy (IACP)

### **At-Large Members**

13. Emmanuel Akala, R. Ph., Ph.D., DIM, Howard University College of Pharmacy
14. Barbara Exum, Pharm.D., 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. Pam Traxel, American Cancer Society/Cancer Action Network

### **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
22. Otilia Koo, Ph.D., USP Complex Excipients Expert Committee

### **Unable to Attend**

- Kanecia Zimmerman, M.D., American Academy of Pediatrics  
Mingzhe Xu, Greater China Region Chapter Chair, National Institutes for Food and Drug Control

### **USP Staff**

- Raliza De Souza, M.B.A., Project Manager, Global Stakeholder Engagement  
Darcy Gentleman, Ph.D., Senior Stakeholder Engagement Manager  
Carrie Harney, Vice President, US Government and Regulatory Affairs  
Chaitanya Kumar Koduri, International Government & Regulatory Engagement Director  
Anthony Lakavage, J.D., Convention and Board Secretary and Senior Vice President, Global External Affairs  
Elana Pate, Project Coordinator, Global Stakeholder Engagement  
Doug Podolsky, Technical Writer IV, Publications  
Max Saffell, MBA, Senior Manager, Stakeholder Engagement  
Diego Salazar, M.S., Senior Board & Convention Operations Manager, Global Stakeholder Engagement  
Amy Sonderman, Director, Convention and Stakeholder Engagement  
Shelley Whiddon, M.A., Senior Director, Operations, Convention and Stakeholder Engagement