PDA Global Headquarters
Bethesda Towers,
Suite 600
4350 East West Highway
Bethesda, MD 20814 USA
TEL: +1 (301) 656-5900
FAX: +1 (301) 986-0296

PDA Europe gGmbH
Am Borsigturm 60
13507 Berlin
Germany

27 August 2019

Anthony Lakavage, J.D.
Secretary, United States Pharmacopeial Convention
12601 Twinbrook Parkway
Rockville MD 20852
membership@usp.org

via e-mail

Dear Mr. Lakavage –

PDA appreciates the opportunity to provide input into the development of the Resolutions for the 2020-2025 Revision Cycle by the USP Council of the Convention (CoC) as described in Article IX, Section 1d of the 2015-2020 USP Bylaws.

I attach PDA's Resolution proposals for the CoC's consideration. Due to web formatting constraints we were unfortunately unable to enter the information on each Resolution proposal through the USP Resolutions Portal.

We took note of and reviewed the Resolution Concepts that USP published on July 29th, 2019, with the request for endorsement by August 31st. While we understand that USP may wish to proactively start a directional dialog around specific themes, we are concerned that this approach may unduly limit the CoC's and member's conversation. Because the CoC is tasked with developing resolutions *"based on input from the Membership, the Board, and … the Council of Experts,"* it would be unfortunate if USP's publication of Resolution Concepts preemptively focused the conversation on topics other than those of greatest importance to USP's 458 member organizations. Because of these concerns, PDA declines to endorse any of the Resolution Concepts at this time and looks forward to the Resolutions discussion at the USP Convention.

After reviewing the proposed 2020 Resolution Concepts, PDA offers these additional recommendations:

1. Recognizing the role of the Resolutions in the USP Governance Process as high level strategic and directional goals against which the organization is expected to report progress over five years, we encourage the CoC to develop resolutions that can be measured in a meaningful way and to incorporate clearly measurable and achievable objectives in each resolution.

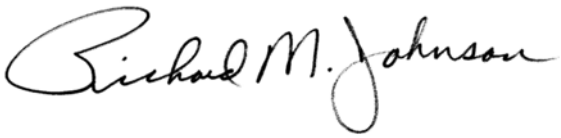
2. We encourage the CoC to carefully review and prioritize the concepts not only for alignment with USP's current mission and vision themes of *Standards, Capability Building, and Advocacy*, but also to link them back to USP's legal mandate as the official compendium of the United States.

3. We encourage the CoC to evaluate all resolutions, including those in the Resolution Concepts relating to regulatory systems strengthening and policy shaping, to assure that they would not create conflicting overlap with the roles of domestic and international regulatory agencies or the World Health Organization (WHO).

PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological, and device manufacturing and quality, and is an ANSI-accredited standards development organization. Our input has been prepared by a committee of experts in regulatory affairs and standards-setting on behalf of our Regulatory Affairs and Quality Advisory Board and Board of Directors.

If you have any questions, please do not hesitate to contact PDA's delegate to the USP Convention, Dr. Tina Morris via email at tmorris@pda.org.

Sincerely,



Richard Johnson
President and CEO

cc: Tina Morris, PDA; Ruth Miller, PDA

Resolution Proposal 1

Resolution Summary

Title – Globally Harmonized Standards

> **Summary –** USP will expand its commitment to harmonization of compendial standards by working with pharmacopoeias, the World Health Organization, and other stakeholders to determine optimal ways to advance and sustain globally harmonized standards.

1. Harmonization process improvement - USP will continue to champion a leaner and nimbler harmonization process, and will promote the fundamental reform of historically established harmonization work plans to be more reflective of issues that are critical and current to stakeholders rather than working through legacy items
2. Harmonization scope - USP will encourage broader harmonization dialog that fosters alignment of the pharmacopeias from relevant emerging markets and mirrors the growing circle of ICH engagement. USP also will encourage greater convergence and dialog between ICH and WHO to narrow gaps and reduce disagreement in requirements between ICH and non-ICH countries

Statement of the Challenge: What issue is this Resolution intended to address?

Current harmonization mechanisms are not capable of supporting a global supply chain of increasing complexity and rapidly accelerating development pace.

Desired Outcome: What is the desired outcome from this Resolution?

Establish and maintain mechanisms to create modern, globally relevant standards

Resolution Alignment

How does the proposal align with USP's mission and vision?

USP's core mandate is to create standards that support global public health. This resolution proposal is a re-commitment to Resolution III from the 2015 Convention – Globally Harmonized Standards

Which of the three essential components of "Standards", "Advocacy" and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why.

Standards and advocacy. This proposed resolution maps to the 2020 Resolution Concept "Harmonization"

Resolution Proposal 2

Resolution Summary

Title – Sustainability, Relevance, and Reach

Summary –

1. USP commits to protecting the organization's future by strengthening revenue sources beyond the required reference standard model, as future medicines are expected to rely less and less on broadly applicable physical reference materials

2. USP commits to making physical reference standards available at special pricing in the context of public health emergencies and to non-profit NGOs engaged in the manufacture of products for the treatment of communicable diseases intended for use in underserved regions or populations.

3. USP will expand its outreach and collaboration into academia to build a stakeholder base in the most innovative scientific and medical fields that will support USP's innovation and relevance moving forward

Statement of the Challenge: What issue is this Resolution intended to address? Protecting the organization's future in an environment that requires less and less broadly applicable reference standard materials

Desired Outcome: What is the desired outcome from this Resolution?

Establish and maintain scientific, regulatory, and operational sustainability models for new types of standards concepts

Resolution Alignment

How does the proposal align with USP's mission and vision?

USP's core mandate is to create standards that support global public health. This resolution proposal is a re-commitment to Resolution V from the 2015 Convention that speaks to Research and Innovation. It expands upon this by including reach and impact expansion, as well as the commitment to a sustainability model not primarily grounded in physical reference materials

Which of the three essential components of "Standards", "Advocacy" and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why.

Standards and capability building. This proposed resolution maps to the 2020 Resolution Concept "Impact Expansion"

Resolution Proposal 3

Resolution Summary

Title – USP Standards Quality

Summary –

USP will continue strengthening its quality systems to ensure the timely and accurate delivery of public standards. USP will maintain and strengthen its commitment to implementing a fully integrated, global approach to quality and will monitor its progress against clearly specified metrics and objectives to achieve continuous improvement as measured by USP performance.

1. Council of Experts and associated groups: USP commits to fostering more cross-functional collaboration for greater consistency across expert body deliberations to improve the management of chapter/monograph dependencies and avoid conflicting requirements

2. Revision process and standards quality:

a. High impact revisions: USP commits to timelier stakeholder dialog and to expanding its communication and outreach about proposed changes beyond the PF route

b. Early and throughout the standards development process, USP will consider implementation challenges that industry will face, and will consider flexible timing for the introduction of new or significantly changed requirements

c. Revision process: USP will assure that the quality of the commentary is consistently reflective of the revision input received

Statement of the Challenge: What issue is this Resolution intended to address? Despite improvements in the 2015-2020 Revision Cycle, there is a continuing need for USP to improve and adapt its processes and quality systems to stay abreast of stakeholder needs

Desired Outcome: What is the desired outcome from this Resolution?

Ensure the timely and accurate delivery of public standards

Resolution Alignment

How does the proposal align with USP's mission and vision?

USP's core mandate is to create standards that support global public health. This resolution proposal is a re-commitment to Resolution IV from the 2015 Convention that speaks to USP's Quality Systems. It expands upon this by including a more proactive and more generally interactive stakeholder dialog during the standards development process

Which of the three essential components of "Standards", "Advocacy" and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why.

Standards and capability building. This proposed resolution maps to the 2020 Resolution Concept "Culture of Quality"

Resolution Proposal 4

Resolution Summary

Title – Modern Standards

Summary –

USP will meet the needs of the US Food and Drug Administration (FDA), industry, and other stakeholders for modern quality standards. USP will work with industry and FDA to explore new strategies for developing and sharing analytical approaches needed to create and maintain modern, relevant standards.

Compendial and Scientific Focus areas:

1. To improve the applicability and relevance of key tests, USP will invest in the development and validation of multi-source or universal procedures to replace methods that favor specific reagents or were provided by a single manufacturer.

2. USP will continue the systematic modernization of key standards that align with FDA's and other stakeholders' needs

3. USP will explore where USP public standards represent or provide a clear link to patient safety and clinical relevance. USP will further aim to articulate the clinical relevance and applicability of those standards as appropriate

Reference standard quality and science:

1. USP will invest in the quality and relevance of the USP reference standard portfolio by improving scientific and quality oversight of reference standards development, value assignment, and release

2. USP will continue to advance reference standard science by utilizing modern measurement and metrology approaches to the development of reference materials whenever possible

Statement of the Challenge: What issue is this Resolution intended to address?

Ensure the creation of modern and relevant standards that are at pace with the development of modern medicines and fulfill the needs of all stakeholders

Desired Outcome: What is the desired outcome from this Resolution?

Ensure the continued relevance and sound science for USP standards

Resolution Alignment

How does the proposal align with USP's mission and vision?

USP's core mandate is to create standards that support global public health. This resolution is a re-commitment and update to Resolution II of the 2015 Convention – USP-NF Monograph Modernization.

It expands beyond monograph modernization to a more comprehensive and cross-cutting look at modernizing standardization approaches and science.

Which of the three essential components of "Standards", "Advocacy" and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why.

Standards and capability building. This proposed resolution maps to the 2020 Resolution Concept "Quality Standards"

Resolution Proposal 5

Resolution Summary

Title – Working with US FDA

Summary –

USP commits to a substantial and meaningful dialog with the FDA that strengthens the complementary roles of both organizations to improve access to high quality medicines.

Key focus areas for this dialog will include:

a. Modernization of standards for high priority generic medicines

b. Modernization of key general tests to modern expectations (e.g. rapid microbial testing)

c. USP's role and contribution to standardization for biological medicines and the applicability of those standards

d. Gap analysis and identification of overlap or redundancy, particularly as it relates to biological medicines

Statement of the Challenge: What issue is this Resolution intended to address?

Ensure a more seamless and collaborative working relationship between the organizations that recognizes and leverages their respective complementary roles in the overall safety net for medicines quality

Desired Outcome: What is the desired outcome from this Resolution?

Increased efficiency in the delivery of standards and guidance that support medicines quality and patient safety

Resolution Alignment

How does the proposal align with USP's mission and vision?

USP's legal mandate is to create the official compendium for the United States. This resolution is a re-commitment and update to Resolution I of the 2015 Convention - Collaboration with the U.S. Food and Drug Administration.

Which of the three essential components of "Standards", "Advocacy" and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why.

Standards and Advocacy. This proposed resolution maps to the 2020 Resolution Concept "US FDA"

Resolution Proposal 6

Resolution Summary

Title – Global Health Impact

Summary –

USP will work with regulators around the world to combat counterfeit, falsified, and substandard medicines to secure the global supply chain of life-saving medicines.

Statement of the Challenge: What issue is this Resolution intended to address?

To effectively combat global public health issues, USP has to effectively work with regulators, industry, and other pharmacopeias around the world to advance innovative solutions to unmet medicines quality needs.

Desired Outcome: What is the desired outcome from this Resolution?

Increased medicines quality and availability in the global supply chain

Resolution Alignment

How does the proposal align with USP's mission and vision?

USP's core mandate is to create standards that support global public health. This resolution is a re-commitment and update to Resolution XI of the 2015 Convention – Global Health Impact. It sharpens the focus on combating counterfeit, falsified, and substandard medicines, an area where compendial standards can most effectively support the global stakeholder community.

Which of the three essential components of "Standards", "Advocacy" and "Capability Building" does the proposed Resolution support? Use language from the 2025 Strategy regarding these three areas to explain why.

Standards and Advocacy. This proposed resolution maps to the 2020 Resolution Concept "Regulatory Systems Strengthening"