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8 January 2021

Dr. Jaap Venema
U.S. Pharmacopeia
12601 Twinbrook Pkwy
Rockville MD 20852

Re: Rules and Procedures of the Council of Experts

Dear Dr. Venema,

First, PDA congratulates USP on a successful anniversary year and launch to the 2020-2025 USP cycle. While we would have liked to celebrate your 200th anniversary with you in person, we applaud your successful virtual collaboration and celebration this year.

As a member of the USP Convention, PDA appreciates the opportunity to continue to provide input into USP's strategic direction through the proposed revisions to the Rules and Procedures of the Council of Experts for the 2020-2025 cycle. Our detailed comments are attached.

While PDA generally supports several of the changes, we offer suggestions and comments about others. In particular, PDA is concerned about the new language that would exclude Government Liaisons from final discussions of matters. Close collaboration between USP and governmental authorities is critical to the ongoing utility of *USP-NF* standards. The relationship between USP and the US FDA is of special significance due to FDA's role in enforcing the *USP-NF* in its home market. PDA believes that the benefits of governmental input throughout the standards-setting process, including during final discussions, outweighs the benefits that could come from excluding Government Liaisons from those discussions.

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. Our comments have been prepared by PDA members with expertise in pharmaceutical, biopharmaceutical, and combination products manufacturing and compendial topics on behalf of PDA's Regulatory Affairs and Quality Advisory Board and Board of Directors.

If you have any questions, please do not hesitate to contact me via email at johnson@pda.org.

Sincerely,

Richard Johnson
President and CEO

cc: Glenn Wright, PDA; Ruth Miller, PDA

U.S. Pharmacopeia
Rules and Procedures of the Council of Experts 2020-2025
Jan. 8, 2021

Section No.	Current Text	Comment / Proposed Change	Rationale
5.01	An Expert Body may engage one or more individuals to provide additional expertise and assist in the development of a standard by participating in Expert Body discussions and/or reviewing documents. Such participating individual shall be deemed an Expert Advisor and shall not be deemed a member of the Expert Body or vote on any Expert Body matter.	Clarify aspects as further discussed in the Rationale column.	PDA strongly encourages USP to seek and obtain broad and diverse stakeholder input. Many compendial topics benefit from thoughtful discussion among an array of potentially impacted parties. PDA understands that, in certain circumstances, it may be useful to obtain input from one or more additional experts. PDA does not object to formally documenting the mechanism for doing so but suggests that it may be useful to include additional clarity in this section. Specifically: • PDA understands that Expert Advisors may have conflicts of interest that would otherwise prevent them from serving on an Expert Committee or Expert Panel. Is there a mechanism by which the committee or panel will ensure that its conclusion will not be inappropriately swayed by the input of the conflicted Expert Advisor? • PDA suggests defining procedures to assure fair and unbiased selection of Expert Advisors. Procedures for the selection of Expert Advisors should require evidence of their commitment to rigorous scientific inquiry. This would help the Expert Committee or Expert Panel feel confident in accepting the final input of the Expert Advisor. It also would help prevent the inadvertent selection of Expert Advisors with a predetermined outcome in mind.
6.02	GLs are not permitted to attend official meetings, or portions thereof, during which experts share or discuss confidential information related to their specific conflicts	Omit this new sentence.	Close collaboration between USP and governmental authorities is critical to the ongoing utility of *USP-NF* standards. The relationship between USP and the US FDA is of particular importance. As USP's Council of the Convention accurately noted, FDA's liaisons "have a critical function to provide FDA perspectives, contributing to the

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	of interest, and during final discussions, as defined in section 12.01(d) below.		development of standards by providing expert input and regulatory context." Report of the Council of the Convention on Resolutions, Proposed Resolution 2, at 2 (2020). PDA believes that the benefits of governmental input throughout the standards-setting process, including during final discussions, outweighs the benefits that could come from excluding government liaisons from those discussions.
8.04	USP may engage in additional forms of stakeholder outreach or engagement to solicit input in furtherance of public standard-setting goals. These include, but are not limited to, hosting workshops, convening roundtables, working groups or advisory groups, publishing *Stimuli* articles, developing key issue web pages, and pre-publishing drafts of standards prior to publication in *Pharmacopeial Forum* as described below.	None.	PDA applauds USP's codification of the multiple opportunities for early communication and outreach. PDA encourages USP to involve a broad range of stakeholders in these activities, and to integrate feedback received in the further development and revision of draft standards. PDA also recognizes the centrality of the Pharmacopeial Forum (PF) and encourages USP to continue to build global stakeholder awareness and engagement with the PF platform.
9.05(c)	All comments submitted to USP in response to proposals or *Stimuli* articles published in PF, as well as the identities of commenters, are considered public information unless clearly and specifically designated as confidential. USP may publish or otherwise disclose comments in furtherance of standard-setting goals.	PDA urges USP to continue to use caution in publicly releasing comments.	The continued development of meaningful and workable monographs requires that stakeholders have high confidence that data submitted confidentially will remain confidential. If industry were to begin to perceive that USP might inadvertently release confidential information, companies might become less willing to submit this necessary data. In order to maintain a high level of confidence among stakeholders, USP may wish to check with the commenter before

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			making public any comment on a monograph, any comment containing data, and any comment on which there is any question about whether the content was intended by the commenter to be confidential.
9.05(c)	In accordance with USP's Document Disclosure Policy, information contained in comments that is designated as confidential is not subject to publication or public disclosure.	~~In accordance with USP's Document Disclosure Policy,~~ Information contained in comments that is designated as confidential is not subject to publication or public disclosure.	These Rules and Procedures of the Council of Experts are a governing document defined in Art. 7, Section 6, of the USP Bylaws. As such, PDA understands that internal USP policies, including USP's Document Disclosure Policy, are subordinate to these Rules and Procedures. As drafted, this statement appeared to suggest the contrary – that these Rules and Procedures are subordinate to internal USP policy. Striking the initial clause would reduce confusion.
11.02 – 11.07	Conflict of Interest	PDA encourages USP to continue to emphasize conflict of interest principles with volunteer experts.	PDA appreciates USP's ongoing commitment to preventing individuals with conflicts of interest from participating in final discussions and votes on relevant matters. As USP is aware, identification of conflicts of interests usually relies on the impacted individual. Thus, a culture of integrity is essential to meaningfully implementing the language in the Rules and Procedures. PDA encourages USP to continue active communications to sustain a culture of integrity among its volunteers.
11.06	As provided for in Section VII above, Expert Committee members, Expert Panel members and Expert Advisors may choose to collaborate across groups in pursuit of mutually beneficial standard setting goals. In	None.	PDA supports USP's inclusion of this clear and specific language. Collaboration between expert groups within USP is beneficial and should be encouraged. By requiring clarity around conflicts of interest, PDA is hopeful that this language will encourage trust and facilitate collaboration.

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	all cases where Experts convene with others not on their Committee(s) or Panel(s), the disclosure and management of Conflicts of Interest must be executed in accordance with Section 11.07 below.		