

USP Appeals Panel Decision on General Chapters <795> and <797>

March 12, 2020

This correspondence sets forth the USP Appeals Panel's decision and rationale in response to your clients' request for further review of appeals originally submitted in July 2019 under Article VII, Section 7 of USP's Bylaws. In recognition of the coordinated nature of the appeals to General Chapters <795> and <797>, the Appeals Panel is providing a unified response to the issues presented.

The Appeals Panel acknowledges the critical roles and substantial efforts of the Compounding Expert Committee, along with its Government Liaisons and Expert Consultants, with respect to the development and publication of revisions to General Chapters <795> and <797>. We also acknowledge the numerous stakeholders and commenters who provided input and who contributed to the development of these standards during several provided opportunities. It is evident from our review that the Expert Committee was deliberate and conscientious in its approach to the numerous challenges that arise in the practice of pharmacy compounding. These Chapters reflect the Committee's sincere commitment to public health, and to improving product quality and safety.

As USP previously has indicated, the Appeals Panel was charged with considering the sufficiency of the process used by the responsible Expert Committee to develop and approve the Chapters under appeal. Consistent with that mandate, we considered whether opportunity for public comment was provided, how the Expert Committee considered the input received from all stakeholders, and whether the basis for the resolution of such comments was communicated publicly. We make no determination with respect to the scientific content of the Chapters under appeal.

During the course of this appeal, which included hearings on January 21 and 22, 2020, you provided the Appeals Panel with information and perspectives concerning the beyond-use-date (BUD) provisions of General Chapters <795> and <797>, addressing the process, scientific aspects, and the potential for unintended consequences that you believe could affect patient access. You also expressed a desire to engage directly with the Expert Committee on these issues. While recognizing that the process to date provided opportunities for comment, we conclude that further engagement with stakeholders is merited. The Appeals Panel does not intend to convey or conclude that the Chapters require modification; rather, our view is that their finalization warrants additional dialogue about, and consideration of, issues raised in the appeals. It is the purview of the Expert Committee to determine the appropriateness of future modifications, if any.

For the foregoing reasons, this Appeals Panel grants your appeals and remands General Chapters <795> and <797> to the Compounding Expert Committee with the recommendation for further engagement with regards to the issues you have raised. We note that most aspects of the Chapters have broad support and that the intent of the Chapters is to protect public health and patient safety. In this spirit, we will encourage USP and the Compounding Expert Committee to move forward in an open, transparent, and balanced manner as soon as practicable to enable the

Chapters to be finalized and implemented in a timely manner, thus realizing the public health benefits these standards are intended to address.

Finally, we acknowledge that the USP appeals process does not provide for a hearing at the first level of appeal; in our view, the Expert Committee could have benefited from a fuller record on which to decide on your appeals. We thus will further recommend that USP evaluate its appeals process to provide potential appellants greater opportunity for substantive engagement on both scientific and non-scientific issues in connection with any request for reconsideration of a standard, balanced by the needs for process efficiency and timeliness.

We thank you for your commitment to the standards-setting process and for bringing these issues to USP's attention for full consideration.

Should you have any questions about the above, please direct them to Mario Sindaco, Executive Secretariat (mys@usp.org or (301) 816-8246).

Jesse Goodman

President of the USP Convention and Chair of USP Appeals Panel

