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Mario P. Sindaco, M.S., MBA
Vice President, Science-Operations
Executive Secretariat to the Council of Experts
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Re: Appeal of New Standard for USP General Chapters <795> and <797>

Dear Mr. Sindaco:

I write on behalf of Alliance for Pharmacy Compounding[1], Innovation Compounding, and Wedgewood Village Pharmacy (collectively, "the Coalition") in response to your November 20, 2019 correspondence regarding the revised procedures and contemplated schedule for the Coalition's appeal of the United States Pharmacopeia's ("USP") proposed revisions to USP General Chapter <797> Pharmaceutical Compounding—Sterile Preparations and to USP General Chapter <795> Pharmaceutical Compounding—Nonsterile Preparations. Thank you for providing additional dates for the Appeals Hearing. The Coalition looks forward to presenting its appeal on January 22, 2020 and appreciates USP's agreement to provide additional time for the Coalition to present its case, as well as to broaden the scope of the hearing. At the same time, the Coalition is disappointed that USP will not be making its employees or agents available to testify, which we continue to believe would properly aid the Coalition's presentation and inform the Appeals Panel's evaluation of the merits of the Coalition's appeal. We respectfully urge USP to reconsider its position and we incorporate by reference the concerns we have raised about the absence of due process, while also respectfully reserving rights for the reasons we have previously stated.

That noted, one point requires further treatment. Specifically, the Coalition is perplexed by USP's refusal to disclose key information that would shine light on conflicts that may have afflicted members of the Compounding Expert Committee ("CEC") while those members developed, discussed, and considered the revisions to General Chapters <795> and <797>. We fail to understand why USP is declining the Coalition's request for basic information about these

[1] International Academy of Compounding Pharmacists changed its name to Alliance for Pharmacy Compounding in December 2019.

conflicted members or the nature of their conflicts, including (i) a list of all CEC members with conflicts of interests; (ii) the precise nature of those conflicts of interests; (iii) the date(s) upon which those conflicts of interests were disclosed to USP and/or the CEC; (iv) a full accounting of the conflicted members' involvement in the Coalition's appeal and/or their involvement in the creation of the new standards; (v) the dates on which their participation concluded; and (vi) all internal USP documents and communications concerning these conflicts of interests and the conflicted members.

Please understand that USP's refusal to provide this information to the Coalition is problematic and concerning. For one, this information is critical to assessing the legitimacy of the CEC's proposed revisions to Chapters <795> and <797> and the extent to which these revisions may have been propelled by undisclosed, improper influences. Separately, this information is essential to ensuring that the Coalition receives a full and fair hearing before a duly informed Appeals Panel. Indeed, absent this information, the Coalition as well as the Appeals Panel will be left in the dark as to whether and to what extent the revisions under appeal may have been tainted by conflicts at the Expert Committee stage, and as to how, when, and to what extent USP sought to mitigate or obviate the conflicts it ultimately acknowledged (albeit while withholding particulars). We cannot conceive of a legitimate reason why USP would keep secret basic information that stands to benefit all interested parties—including appellants, stakeholders, public observers, and the Appeals Panel itself—about identified conflicts of interest that may bear directly and profoundly upon the revisions proposed by the Expert Committee. For USP to persist in its stance is to say, in essence, that certain members of the Expert Committee *did* in fact face conflicts of interest while working and deliberating on the revisions, potentially right up until the point the revisions were put to a vote, but that USP is sworn to cover up those conflicts and its handling of same so as to thwart full and fair examination of these particulars on appeal. Needless to say, we are troubled by that stance and believe others should be too.

We recognize, of course, that USP is claiming basis for withholding the requested information. Specifically, USP cites Section 2 of the Rules and Procedures of the Council of Experts ("Rules") to justify its withholding of information about conflicted CEC members. By USP's account, Section 2 "requires [USP] to maintain confidentiality relating to the conflict-of-interest disclosures of its Expert Committee and Expert Panel members[.]" Ltr. from M. Sindaco to D. Shaffer, dated Nov. 20, 2019 at 2. But USP's reading defies common sense, as well as the actual terms of Section 2, at least by our reading. Far from limiting USP's ability to disclose information about identified conflicts of interest, Section 2 expressly calls for disclosure. Section 2.05 of the Rules, for example, expressly requires that all conflicts of interest be disclosed and recorded in CEC meeting minutes, which minutes are in turn subject to USP's Document Disclosure Policy. *See* Section 2.05 ("The minutes of any meeting at which a Conflict of Interest issue has been identified shall reflect disclosure and resolution of such issue, including any recusal of a CoE/EC Expert due to Conflict of Interest."). This disclosure requirement is part and parcel of other sections of the Rules, including Section 1.01, which emphasizes USP's goal to "promote transparency of USP's internal processes and procedures." Section 1.01.

Nor does Section 2 impose confidentiality obligations that would prevent the disclosure of identified conflicts of interest and handling of same by USP. The section contains two references

to confidentiality—neither of which bears on USP's ability to disclose information about how, when, and why conflicts of interests have been addressed. The first reference comes from Section 2.04, which requires USP to treat as confidential the mandatory "*Disclosure Statements*" that are completed by all expert committee members. So be it. For present purposes, we would understand and accept that USP has agreed to keep confidential certain personal information that its experts may entrust to USP (including, perhaps, research and employment terms that may be sensitive and be subject to conflict checks, without resulting in an identified conflict). As such, we would be content to go without the actual Disclosure Statements. But it by no means follows that USP should be *altogether withholding* any and all documents and information reflecting what *has* identified and acknowledged as a *conflict*, presumably as recorded in its *official minutes*. As to that, Section 2.04 expressly yields to Section 2.05: "Except as specified in Section 2.05 . . . ." If USP is nonetheless claiming the ability to shield from external scrutiny its official handling of an acknowledged conflict and its minutes reflecting same, then something is seriously amiss not only with USP's reading of Section 2, but with its overall approach to conflicts and/or transparency.

As for the second reference to confidentiality, that comes in Section 2.06, which addresses the general confidentiality obligations that constrain members of the Expert Committee themselves. Specifically, Section 2.06 states that Expert Committee members are required to "maintain the confidentiality of all information gained in the course of his or her activities as a[n] [Expert Committee member], and shall not use or disclose such information for any purpose, unless such information is already publicly available." Thus, by their terms, these confidentiality obligations pertain only to information specifically gleaned through an expert's participation on the relevant committee *i.e.* trade secret or proprietary information. Those obligations do not require that conflicts of interest remain confidential, much less that relevant minutes be scrubbed or withheld. In any event, the confidentiality obligations imposed by Section 2.06 expressly apply only to individual members of the Expert Committee, ***not*** to ***USP***.

In sum, nothing in USP's Rules (or Bylaws) disables, limits, or otherwise inhibits USP's disclosure of information about how it has addressed conflicts of interests among its Expert Committee. To the contrary, the Rules call for the disclosure of this information, and so does due process, basic fairness, and the ability of USP to claim public legitimacy as it makes pivotal judgments upon which industries, professions, and public health depend. We thank you for considering this one further submission and look forward to your prompt response. As always, we will be at your disposal if you wish to discuss.

Very truly yours,



Derek L. Shaffer