

September 18, 2019

Jaap Venema, Ph.D.
Chief Science Officer & Chair, Council of Experts
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1792

Dear Dr. Venema:

On behalf of the undersigned pharmacy associations, whose members include compounding pharmacists and technicians, we are writing in regard to our concerns with the recent decision by the United States Pharmacopeia Convention's (USP) Compounding Expert Committee to reject multiple requests to not move forward with proposed revisions to USP General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations and USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations. Of particular concern, and our primary reason for writing, are the proposed revisions that severely limit beyond-use dates (BUDs). We respectfully request that USP instruct the Expert Committee to engage compounding pharmacists to develop alternative BUDs that will ensure continued patient access to compounded medications.

We believe the proposed revisions severely limiting the BUDs are not supported by sufficient scientific evidence to outweigh the negative impact the restrictions will have on patients. The severely shortened BUDs, especially those specified for sterile compounds, will not only reduce the useable life of compounded medication, it will also limit pharmacists' ability to prepare sufficient quantities of compounded medication to serve their patients. An inadequate supply of short-dated compounded medication will result in delays in initiating patients' therapy, disruptions to ongoing medical treatment and continuity of care, and an overall lack of access to medications that have proven effective for many patients. Since compounded medications obtained from traditional compounding pharmacies are prescribed when no other available medications are effective for treating patients, severely limiting the availability of these "last resort" medications will leave a large population of patients with no place to turn for treatment.

It appears that the USP Compounding Expert Committee has not taken a balanced approach in creating and upholding the restrictive BUDs proposed in the revised General Chapters <795> and <797>. Compounding pharmacists have presented the negative impacts of the proposed BUDs on patient treatment to the Compounding Expert Committee on multiple occasions since 2016, but at no time has the Compounding Expert Committee acknowledged these as valid concerns worthy of revising the proposed BUDs. Nor has the Compounding Expert Committee provided any indication to the pharmacy compounding community that it would be receptive to discussing alternative BUDs prior to implementation of the revised General Chapters <795> and <797>. From our perspective, the Compounding Expert Committee has taken an uncharacteristically unbalanced approach to working with all stakeholders to find an appropriate solution to the patient access problem that these proposed BUDs will create. That's why we strongly urge USP to direct the Compounding Expert Committee to engage compounding pharmacists in developing balanced alternative BUDs prior to implementation of the revised General Chapters <795> and <797>.

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The proposed revisions regarding shortened BUDs will disrupt the sound, established therapeutic regimens of patients and will impede a health care providers' ability to effectively treat patients.

We strongly encourage USP to heed the concerns of a growing coalition of affected compounding pharmacists, prescribers, patients, and boards of pharmacy, and revisit the BUD restrictions contained in revised <795> and <797> before the effective date of the chapters.

Please contact IACP's Scott Brunner, CAE, at scott@iacprx.org if you wish to discuss.

Sincerely,

Alabama Pharmacy Association
Arizona Pharmacy Association
California Pharmacists Association
Colorado Pharmacist Society
Florida Pharmacy Association
Georgia Pharmacy Association
Idaho State Pharmacy Association
Indiana Pharmacists Association
Illinois Pharmacist Association
International Academy of Compounding Pharmacists
Iowa Pharmacy Association
Kansas Pharmacists Association
Kentucky Pharmacists Association
Maryland Pharmacists Association
Michigan Pharmacists Association
Montana Pharmacy Association
National Alliance of State Pharmacy Associations
National Community Pharmacists Association
Nebraska Pharmacists Association
New Jersey Pharmacists Association
New Mexico Pharmacists Association
North Carolina Association of Pharmacists
North Dakota Pharmacists Association
Ohio Pharmacists Association
Oklahoma Pharmacists Association
Pennsylvania Pharmacists Association
Rhode Island Pharmacists Association
Tennessee Pharmacists Association
Texas Pharmacy Association
South Carolina Pharmacy Association
Utah Pharmacy Association
Virginia Pharmacists Association
Washington State Pharmacy Association
West Virginia Pharmacists Association