July 19, 2017

Ms. Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd, Suite N 219
Sacramento, CA 95834

Dear Ms. Herold,

The International Academy of Compounding Pharmacists (IACP) would like to provide the California Board of Pharmacy (the "Board") with information relevant to the Board's upcoming July 25, 2017 meeting. Specifically, within Part 2 of Agenda Item VI, the California Board of Pharmacy, Enforcement & Compounding Committee (the "Committee") will be providing the Board with proposed recommendations to CCR Sections 1735 – 1735.8 as a result of the Committee's June 2, 2017 and July 12, 2017 meetings. While IACP commends the Committee for collaborating with the compounding community in developing these proposed amendments, an area of major concerns that remains open is the Committee's perspective on the type of information a compounding pharmacist is permitted to use when assigning a Beyond-Use Date (BUD) to a sterile compound.

The Committee's proposed amendments to CCR Section 1735.2(i) includes changes to clarify the requirements for the assignment of a BUD to a non-sterile compound (CCR Section 1735.2(i)(1)). However, the Committee's proposal does not include amending or removing the requirement for a stability study to be performed on a compounded sterile preparation (CCR Section 1735.2(i)(3)(C)) in order for a compounding pharmacist to assign a BUD greater than 14 days for a non-frozen sterile preparation. The Committee, with support from Board staff, has expressed their intention to retain this stability study requirement and, in addition, has deferred to a single outside expert to establish the type of stability study they expect a compounded sterile preparation to undergo. IACP has great concern that the Committee's position on these stability studies, if upheld by the Board, will dramatically reduce the number of compounded sterile preparations available to California patients, leaving many without access to much needed medication.

Historically, compounding pharmacists have relied upon their education, experience, and a variety of other scientific factors to determine the BUD for sterile preparations. In fact, the Committee itself recognizes this in its proposed revisions to CCR 1735.2(i)(1) regarding non-sterile compounds. However, for reasons that remain unclear, the Committee has concluded that the factors acceptable for pharmacists to determine the stability of non-sterile compounds are unacceptable for determining the stability of sterile compounds, and instead must be replaced with stability studies. And while there are a number of different tests to demonstrate the stability of a compounded sterile preparation, the only method the Committee and Board staff are willing to accept is a stability study performed according to a validated test method incorporating forced degradation. These tests are extremely expensive and, as a result, would either greatly reduce the number of sterile compounds that pharmacies would be willing to test, or drastically increase the price of sterile compounded preparations, or both. In all scenarios, the

number of compounded sterile preparations available to California patients would be significantly reduced, leaving many patients in need of these medications untreated.

IACP feels this potential reduction in patient access to sterile compounded medication can be completely avoided without compromising the quality of sterile compounds. The type of stability study being recommended to the Committee is typically utilized by drug manufacturers to establish the shelf life of a new drug. In those situations, the drug being studied often contains a newly-created active pharmaceutical ingredient (API) that has never been used in any dosage form. In addition, the drug manufacturer likely desires to establish a shelf life of many years. Either of these two factors would justify the need to conduct the type of stability study described to the Committee. However, for a pharmacist who is utilizing an existing API with known stability characteristics in a sterile compound that is going to be assigned a BUD of only three to six months, a stability study performed according to a validated test method incorporating forced degradation is completely unnecessary. This type of stability study is not required by any other state board of pharmacy or compounding accreditation body. This point was expressed during the June 2nd and July 12th Committee meetings by many in the pharmacy community, some of whom offered scientifically sound alternative testing methods that would provide extremely reliable stability information at a cost that would be economically feasible for pharmacies. Unfortunately, there has been no indication from the Committee or Board staff that these alternatives are being considered.

IACP respectfully asks the Board to carefully weigh the overall impact on patient safety when hearing the Committee's recommendations related to extending the BUDs on compounded sterile preparations. IACP supports practice standards that require the highest level of quality for compounded medications to ensure patient safety. However, when those practice standards are not applicable to compounding pharmacies and restrict patient access to compounded medications with little to no effect on the quality of those compounds, the end result is patient safety that is compromised due to a lack of treatment.

IACP appreciates the opportunity to present its perspective to the Board and is available to answer any questions the Board may have. IACP looks forward to any opportunity to work with the Committee or the Board regarding this or any other matter to achieve the mutual goal of protecting and promoting the health and safety of Californians through continued access to high quality compounded medication.

Sincerely,

Baylor Rice, RPh, FIACP
IACP President