The Arizona Coalition and The Compounders Group

Boesen & Snow Law firm is located in Scottsdale, AZ. Mark Boesen, Pharm.D., J.D. is one of the founding partners along with Allyson Snow, J.D. Prior to licensure as an attorney in 2013. Mark Boesen worked for the organization now known as Avella Specialty Pharmacies as a compounding pharmacist and administrator. Allyson Snow was also licensed as an attorney in 2013 and comes to the firm with considerable health care experience. Boesen & Snow was hired by a coalition of 19 independently owned pharmacies located in Arizona and The Compounders Group.

Boesen & Snow is one of three law firms who represent appellants concerned about the inflexible, arbitrary, and capricious proposed Beyond Use Date (BUD) requirements found in the 2019 proposed revisions to USP General Chapters <795> and <797>. The two other law firms representing the interests of other compounding pharmacies and compounding pharmacy stakeholders are Quinn Immanuel and Reed Smith. On January 21 and 22 the USP allowed each law firm to present its second round appeal to a panel of USP appointed individuals who are charged with determining whether the USP chapter revisions published in 2019 will become compendial, remanded to the Compounding Expert Committee for review and revision, or some other resolution. It is noteworthy that in the approximately 200-year history of the USP, a second round of appeals to any publication of a General Chapter has NEVER occurred.

Boesen & Snow presented its case on the morning of January 21, 2020. Mark Boesen, lead attorney for the Arizona/TCG Coalition presented along with coalition pharmacists Dr. Dana Reed-Kane of Reed's Compounding Pharmacy (Tucson, AZ), Dr. Tenille Davis of Civic Center Pharmacy (Scottsdale, AZ), and Dr. Richard Moon of Pharmacy Innovations (Jamestown, NY). Below is a summary of the information presented to the USP panel over a period of two and one-half hours, which includes a question and answer period.

Background

- **Professionalism and Trust:** For decades, pharmacists have been recognized as the most trusted professionals in the United States for honesty and ethical standards year after year. Pharmacists are licensed by the states to provide professional services, including the compounding of medications when there are no other reasonable options for our patients. The professional judgement of pharmacists must be respected by the USP. The practice of pharmacy is regulated by the states, and not by the USP or any other federal entity.
- **USP has No Authority to Regulate the Practice of Pharmacy:** The mere publication of General Chapters <795> and <797> that contain provisions with ZERO flexibility to accommodate for the professional judgment and experience of the pharmacist violates state and federal rules that generally prohibit the delegation of regulatory authority to an entity that has no legislative or regulatory authority under federal or states' laws.
- **Triad of Care:** Pharmacists operate in a "Triad of Care." This means that there are at least three people involved in decisions to treat with a compounded medication: the patient, the prescriber, and the pharmacist. Pharmacists are not acting in a vacuum. The revisions to BUD dating not only adversely affect the ability of pharmacists to practice within the scope of his or her license, but also limits prescribers from practicing within the scope of his or her license. Finally, the USP takes the power away from patients who wish to continue to participate (with informed consent) in their care by forcing those patients who are well controlled on safe and effective formulations to either receive different formulations that are new to the patient or pay more for their care by receiving medications more frequently.
- **USP Presented No Scientific Evidence Defend the BUDs.**
- **USP Did Not Present a Concern, Adverse Event, Sentinel Event, or Other Reason to Revise the BUDs.**

Unintended Consequences

- **Reduced Access:** The revisions to the assignment of BUDs will greatly reduce access to compounded products by forcing patients to pay more for medications and come to the pharmacy more often for refills.
- **Increased Cost:** The revisions to the assignment of BUDs will greatly increase the cost for compounded products for patients, pharmacies, third party payors and health care systems. Reasonable estimates of the cost of a standard stability indicating assay are $15,000.
- **Decreased Adherence:** The revisions to the assignment of BUDs will likely reduce adherence to compounded products. Patients will be less likely to refill in a timely fashion. The Triad will have less choice when it comes to their inactive ingredients (bases, for example), container or applicator which will ultimately reduce compliance.
- **Changes to Established Therapy:** Patients may be asked to unnecessarily change from a therapy that works well for their therapeutic outcome either by receiving a different formulation, delivery device, or reduced BUD. *WHEN PATIENTS ASK THE PHARMACIST WHY, PHARMACISTS WILL HAVE NO OTHER REASON TO OFFER OTHER THAN THE USP MADE CHANGES WITHOUT ANY SCIENTIFIC EXPLANATION.* Changes to therapy will most certainly result in adverse events such as changes in absorption, metabolism, therapeutic levels and therapeutic outcomes. The bottom line is that patients will suffer.
- **Reduced Adherence to BUDs:** Patients, prescribers and pharmacists already struggle with adhering to stringent BUDs. If shortened, the three participants in the Triad will be even less likely to comply.

- **Lack of Credibility:** USP risks losing more than 150 years of credibility as a standards setting organization. Numerous Boards of Pharmacy are rejecting adoption of certain USP standards that relate to the practice of pharmacy.
- **Disregard for Published and Unpublished Studies:** The new testing requirements will make the majority of studies performed in the past invalid despite the science behind those studies.
- **Less Testing:** Pharmacies cannot afford to do the testing required to extend BUDs on all of their products. Pharmacies will test their products less when they choose to assign default BUD's.
- **BUDs Do Not Kill People:** Medication errors kill people. The revisions are not based on science or adverse events.

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