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To United States Pharmacopeia (USP) Expert Committee,

During a regularly scheduled meeting on January 5, 2016, the members of the Massachusetts Board of Registration in Pharmacy ("Board") voted to authorize William E. Frisch, Jr., RPh, Director of Pharmacy Compliance and Kelly Ann Barnes, JD, RPh, Director of Pharmacy Quality Assurance to review proposed USP <797> and submit feedback to United States Pharmacopeia ("USP") expert committee.

On behalf of the Board, we would like to thank you for accepting feedback on the proposed USP chapter, as you continue to work on revisions. We acknowledge that USP <797> and companion chapters provide scientifically based standards for the delivery of quality compounded sterile preparations. We hope to assist the committee in its efforts to revise the current sterile compounding chapter by adding feedback based on our training and experiences gained while enforcing the current standards.

As the committee considers comments of the many stakeholders, we ask that the committee especially consider the regulatory enforcement point of view. Since the catastrophic events in 2012, Pharmacy Boards across the country have incorporated USP standards into state regulations. Moreover, as you review the Board's feedback, we ask you to be mindful that the recommendations are drawn from experience gained through current enforcement efforts, which include the development of compliance standards and inspection audit tools as well as the interpretation of standards contained in current USP <797> and companion chapters with our registrants.

Following the tragic events in 2012, the Massachusetts Legislature passed sweeping pharmacy reform legislation to ensure the safety of compounded medications for the citizens of the Commonwealth of Massachusetts, Chapter 159 of the Acts of 2014 ("Chapter 159"). Of the many requirements of the pharmacy reform legislation, the requirement for adherence to all current chapters of the USP and promulgation of supplementary regulations for the practice of sterile compounding in all pharmacy practice settings are incorporated into our feedback. Since the enactment of Chapter 159, the Board and its staff have been working diligently promulgating pharmacy compounding regulations, 247 CMR 17 and enforcing USP compliance among our registrants. Conducting on-site inspections of pharmacy sterile compounding practices has been a

main tool for enforcement efforts over the past 2 ½ years. Board staff have gained experience through our many observations during our enforcement efforts. One underlying theme exists, enforcement of a guidance document has its challenges.

While USP <797> and its companion chapters is developed by experts and attempts to set consistent practice standards for sterile compounding, the chapters are written as guidance documents combining requirements with best practices that are not necessarily required (i.e. should vs. shall) and in some areas contain vague language. This has led to differences in interpretation by sterile compounders and makes it challenging to enforce the standards consistently across pharmacy practice settings.

For example, the chapter requires immediate remediation of an above action level environmental monitoring result; however without guidance of clear standards for the required steps of remediation, inconsistencies in remediation processes exist which adds to the enforcement challenges. Sterile compounders and Boards of Pharmacy across the country need clear requirements to prevent varying interpretation and inconsistent application of the standards that are now incorporated into state law in many jurisdictions.

In closing, the Board is charged by the Massachusetts Legislature to raise the bar in pharmacy practice and we support the committee's efforts to revise the current sterile compounding chapter and its desire to implement consistent standards across sterile compounding practices. However, in order for the Board to meet this charge, it is clear that the Board needs to eliminate areas subject to interpretation and provide clarity pertaining to compliance with the standards. We ask the committee to consider our feedback in that specific light and when moving forward with the revisions also consider careful drafting of the language so the revisions do not inadvertently prohibit standards being drafted by the Board.

Thank you again for the opportunity to provide feedback on USP <797> proposed revisions. If the committee needs more information, would like to discuss any of our feedback or our proposed regulations, 247 CMR 17, please feel free to contact us.

Respectfully submitted,

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