Response to Letter to the Editor on “Centralized Repackaging of Medications”

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We thank Mr. Timm for the thoughtful comments on our study and are pleased to respond to his inquiries.

One concern was noted regarding the compounding status of the Aurora Pharmacy Packaging Center (APPC). The APPC is indeed a 503a compounding pharmacy and does comply with all regulations of the Drug Quality and Security Act (DQSA), Food and Drug Administration (FDA) guidance recommendations, USP General Chapter <797> Pharmaceutical Compounding—Sterile Preparations guidelines, and other compounding best practices to provide products within its own health system.

The stipulation that a hospital pharmacy may only compound for its affiliates within a 1-mile radius, as cited by Mr. Timm, was a notion provided in an earlier FDA guidance draft but was removed in the final FDA guidance document.¹ The final guidance document states that a licensed pharmacist may engage in anticipatory compounding in limited quantities to fill medication orders it has not yet received for an individual patient, provided that there is a relationship with the provider and expectation of a written medication order. This guidance recommendation is indeed in accordance with the process described in our publication, which stated, “Standard procedure involved running weekly reports through EPIC health care software to determine the anticipated number of cataract surgery cases per week and then compounding the corresponding number of syringes.”

While the authors certainly recognize the risks associated with sterile compounding, we also maintain that compounding a preparation into its packaging for administration (a syringe) in a sterile compounding environment replete with specialized resources and expert practitioners is preferable to

the alternative of nonsterile preparation of intracameral injections in the operative suite. We believe this process maintains the principle goal of 503a: optimal communication and collaboration between the prescriber, pharmacist, and patient.

Declaration of Conflicting Interests

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Reference

1. US Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research. Pharmacy compounding of human drug products under section 503a of the Federal Food, Drug, and Cosmetic Act. Revision 2. <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469119.pdf>. Published June 2016. Accessed November 28, 2018.

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