



June 6, 2016

NHIA Testifies on Compounding Memorandum of Understanding at FDA Listening Session

On June 6, 2016, Kendall Van Pool, NHIA Vice President for Legislative Affairs and Tom Brown, NHIA Board Vice Chair, Thomas Jefferson University Hospitals, Home Infusion Services testified at a listening session held by the FDA to discuss issues regarding implementation of the Drug Quality and Security Act. This listening session was one of several listening sessions held by the FDA over the past few days.

NHIA's testimony focused on the still outstanding Memorandum of Understanding (MOU) which seeks serve as a template to establish agreements between states and FDA about interstate distribution of compounded drug products. NHIA has been concerned with the text of the draft MOU since its release in February of 2015. NHIA commented on the MOU in July of 2015.

During this listening session NHIA reiterated its concerns with regard to the draft MOU including dispensing over state lines within its definition of distributing over state lines; the arbitrary nature of the 30% cap on interstate dispensing and/or distribution of compounded product; and the lack of a definition for a unit of compounded product.

Please read NHIA's Testimony here.

<http://www.nhia.org/resource/legislative/documents/FDAListingSessionTestimony662016FINAL.pdf>

Please visit NHIA's Compounding Advocacy Center here.

<http://www.nhia.org/resource/legislative/CompoundingActionCenter.cfm>