NOTES AND COMMENTS

Update: Federal Legislative Response to the Controversy over Drug Compounding

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ABSTRACT: In the October 2012 issue of the Journal of Health & Life Sciences Law, a Comment entitled “The NECC Fungal Meningitis Outbreak Revives the Controversy over the Regulation of Drug Compounding” detailed the historical regulatory environment in which compounding pharmacists often exceeded the bounds of traditional pharmacy compounding, entering into the practice of pharmacy manufacturing. The Comment concluded with the authors’ prediction of possible regulatory responses to the New England Compounding Center (NECC) fungal meningitis outbreak. In this update, they examine the initial federal legislative response, the November 2013 Drug Quality and Security Act.

KEYWORDS: Pharmacy Compounding, Pharmacy Manufacturing, Food and Drug Administration, FDA, Drug Quality and Security Act


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In the interest of full disclosure, the authors would inform the readers that they currently represent NECC’s lead pharmacist.
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