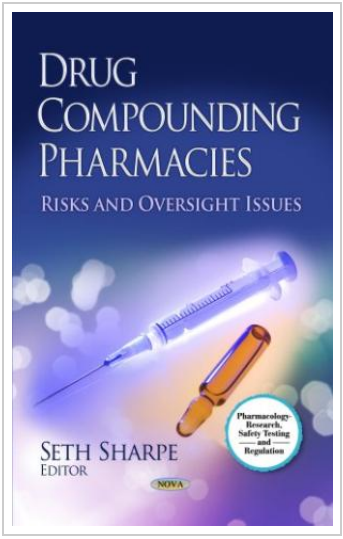

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Drug Compounding Pharmacies: Risks Oversight Issues (Hardback)

By Seth Sharpe

Nova Science Publishers Inc, United States, 2013. Hardback. Condition: New. UK ed.. Language: English . Brand New Book. In light of the 2012 fungal meningitis outbreak, believed to have been caused by a contaminated compounded steroid injection, the regulation of human drug compounding has received significant attention. Drug compounding in its traditional form is the process of combining, mixing, or altering ingredients in order to create a medication for a particular patient. However, as illustrated by the entity that created the steroid medication linked with the meningitis outbreak, concerns have been raised about compounding pharmacies producing drugs on a larger scale. While drug compounding has historically been the focus of state governments through their regulation of pharmacies, questions have arisen regarding the extent the federal government can regulate the practice of compounding through the Food, Drug, and Cosmetic Act (FDCA). This book examines the FDA s regulation of drug compounding and discusses relevant legal authorities, and the potential limits to the FDA s authority to regulate human drug compounding.

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