NEWS

Michael Tucker Quoted in Wolters Kluwer Health Law Daily on Drug Compounding

Prior to a multistate fungal meningitis outbreak in 2012 that was traced to a drug compounding facility, three court decisions resulted in a lack of consensus on whether large-scale drug compounding without individual prescriptions being sold across state lines remains part of the practice of pharmacy, and thus subject to state oversight, or has become part of the drug manufacturing industry, giving the FDA authority to regulate these entities. To clarify the FDA's authority, Congress enacted the Compounding Quality Act (CQA) as Title I of the Drug Quality and Security Act. In this Wolters Kluwer article, Michael Tucker discusses the Compounding Quality Act.

Mr. Tucker notes that the CQA contains "two prominent sections, 503A and 503B. Sec. 503A governs traditional compounding, while 503B allows non-traditional or traditional compounders to be classified as outsourcing facilities. Together, they provide two separate exemptions to certain requirements of the FDC Act applicable to compounded drugs."

Read the Article