**House Report 114-205 - AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS BILL, 2016**

***Pharmacy Compounding.--***The Committee is very concerned with the draft MOU that the FDA has proposed under Section 503A of the FDCA. The proposed MOU would complicate patient and prescriber access to compounded medications, and may have a deleterious effect on small pharmacies. Under the draft MOU, the FDA attempts to describe `distribution' as occurring when `a compounded human drug product has left the facility in which the drug was compounded.' In the DQSA, Congress only allowed the FDA to regulate `distribution.' But the MOU appears to exceed the authority granted in the statue by redefining `distribution' in a manner that includes dispensing--something unprecedented. This overreach could generate exactly the kind of costly and confusing litigation that Congress intended to avoid when it amended and reinstated Section 503A. The Committee expects that, when a final MOU is proposed as a model agreement for the states to consider, that distribution and dispensing are treated as the different and separate activities that they actually are. (P. 71-72)

***Drug Compounding.--***The Committee is concerned that, since passage of the Drug Quality and Security Act (DQSA) of 2013, the FDA has interpreted provisions of Section 503A of the FDCA in a manner inconsistent with its legislative intent and with the agency's own previous positions. Specifically, the FDA has taken the position that under 503A, a pharmacist may not compound medications prior to receipt of a prescription and transfer the drugs to a requesting physician or other authorized agent of the prescriber for administration to his or her patients without a patient-specific prescription accompanying the medication. This practice, which is often referred to as `office-use' compounding, is authorized in the vast majority of states and was intended to be allowable under DQSA. The Committee is aware that in 2012, prior to passage of the DQSA, FDA was working on a draft compliance policy guide for 503A of the FDCA that provided guidance on how `office-use' compounding could be done consistent with the provisions of 503A. The Committee understands the intent of the DQSA was not to prohibit compounding pharmacists from operation under existing 503A exemptions; therefore, the Committee directs the FDA to issue a guidance document on how compounding pharmacists can continue to engage in `office-use' compounding before the receipt of a patient-specific prescription consistent with the provisions of 503A within 90 days after the enactment of this Act. (P.67)

***Active Pharmaceutical Ingredients*.—**The Committee is concerned that the FDA has not yet approved a list of Active Pharmaceutical Ingredients (APIs) for use by compounding pharmacists pursuant to the Drug Quality and Security Act (Public Law 112–43, 127 Stat. 587) and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a et seq.). Within 90 days of enactment of this Act, the FDA shall report to Congress on when its review of proposed APIs pursuant to § 503A(1)(a)(iii) will be completed. (P.64)