FY 2017 Congressional Omnibus Legislation

Conference Report Language

Overview – Page 1
The House and Senate report language that is not changed by the explanatory statement is approved and indicates congressional intentions. The explanatory statement, while repeating some report language for emphasis, does not intend to negate the language referred to above unless expressly provided herein.

MOU – Page 31:
The agreement remains concerned with the draft MOU that the FDA proposed under Section 503A of the FDCA. Section 503A distinguishes between "distribution" and "dispensing" for the purposes of the MOU. In the DQSA, Congress only allowed the FDA to regulate "distribution." The MOU appears to exceed the authority granted in the statute by redefining "distribution" in a manner that includes dispensing. Congress did not intend to include dispensing of compounded drugs over state lines within the scope of the MOU. The MOU should not address dispensing of compounded drugs to a patient over state lines if all other requirements of 503A are met.

House Report 114-531 - AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS BILL, 2017

The Committee recommendation maintains fiscal year 2016 funding levels for the medical countermeasures initiative as well as recent funding increases for antimicrobial resistance, counterfeit drugs, food safety, foreign drug inspections, import safety, and pharmacy compounding. (p 65)

Drug Compounding.—The Committee believes patient access to the right drug at the right time is of utmost importance. In instances where a commercially manufactured drug is not appropriate for a patient for a specific reason, a compounded drug may be the difference between life and death. Since passage of the Drug Quality and Security Act (DQSA) of 2013, the Committee has had concerns that the FDA interpreted provisions of Section 503A of the FDCA in a manner that might jeopardize the availability of compounded medications for ''office use''. The practice of ''office use'' occurs when a compounder will compound a batch of drugs in anticipation of receiving patient-specific prescriptions at a later time. It may also be the case of a doctor in his or her office maintaining compounded drugs on site because it is unsafe or impractical to issue a traditional prescription. This practice is authorized in the vast majority of states and was intended to be allowable under DQSA. The Committee is aware that on April 15, 2016, FDA released a new Draft Guidance on the issue of ''office-use'' compounding. The Committee directs the FDA to issue a Final Guidance that provides for ''office-use'' compounding of drugs, in appropriate circumstances as well as including drugs compounded in anticipation of a prescription for an identified individual patient. Such ''anticipatory'' compounded drugs must be based on the history of previous valid compound prescription orders, and on an established history between the prescriber and the patient and the compounder. (p 68-69)

Drug Compounding Inspections.—The Committee understands that the FDA is interpreting provisions of Section 503A of the FDCA to inspect state-licensed compounding pharmacies under current Good Manufacturing Practices (cGMPs) instead of under the standards contained in the United States Pharmacopeial Convention (USP) for sterile and non-sterile pharmaceutical compounding or other applicable pharmacy inspection standards adopted by state law or regulation. The Committee reminds the FDA that compounding pharmacies are not drug manufacturers, but rather, are state licensed and regulated health care providers that are inspected by state boards of pharmacy pursuant to state laws and regulations that establish sterility and other standards for the pharmacies operating within their states. Compounding pharmacies are more appropriately inspected using USP standards or other pharmacy inspection standards adopted by state law or regulation in the state in which a pharmacy is licensed. (p. 69)

Pharmacy Compounding.—The Committee remains concerned with the draft MOU that the FDA proposed under Section 503A of the FDCA. Section 503A distinguishes between ''distribution'' and ''dispensing'' for the purposes of the MOU. In the DQSA, Congress only allowed the FDA to regulate ''distribution''. The MOU appears to exceed the authority granted in the statute by redefining ''distribution'' in a manner that includes dispensing. Congress did not intend to include dispensing of compounded drugs over state lines within the scope of the MOU. The MOU should not address dispensing of compounded drugs to a patient over state lines if all other requirements of 503A are met. (p. 76)

Animal Drug Compounding.—The Committee is concerned that the FDA has proposed draft guidance for industry (#230) for animal drug compounding that applies Sections 503A and 503B of the FDCA to animal health even though these provisions were written in regard to compounding of human drugs. The Committee is concerned that this will result in confusion in the industry and may result in a misallocation of the resources Congress makes available to the FDA to oversee compounding activities. The Committee expects that any final guidance on animal drug compounding will reference statutory provisions that specifically relate to veterinary practices. (p. 66)