SUMMARY

Animal Compounding

“Animal Drug Compounding.—The Committee has been concerned that the FDA’s proposed draft Guidance for Industry (GFI) for animal drug compounding (#230) would apply certain human drug compounding requirements to animal drug compounding. There also is concern that some state regulatory agencies are implementing the guidance even though it is not finalized. The Committee appreciates that in the FY 2018 budget request FDA stated, ‘‘In the draft guidance, FDA is not proposing to apply sections 503A or 503B of the FDCA to the compounding of animal drugs from bulk drug substances.’’ FDA further explains how some of the concepts may be appropriate for animal drugs as well as human drugs. Within 30 days of enactment of this Act, the Committee directs FDA to communicate to state regulatory agencies that the guidance is still in draft form. The Committee expects that any final guidance on animal drug compounding will only reference statutory provisions that specifically relate to veterinary practices and will not exceed statutory authority. (page 63).

Office-use Compounding

Human Drug Compounding—Permissible ‘‘Office Use’’.—The Committee continues to believe that 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 compounding 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 directed 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 is based on the history of previous valid compound prescription orders, and on an established history between prescriber, patient and compounder. Despite clear directives in previous reports accompanying FDA’s appropriations bills for the agency to finalize guidance that authorizes office-use compounding, in December of 2016, the FDA finalized a Guidance for Industry (GFI) entitled “Prescription Requirement Under Section 503A of the FDCA,” which expressly prohibits office-use compounding. The Committee directs the FDA to rescind this GFI and issue a proposed rule, subject to the notice and comment provisions in the Administrative Procedure Act. The proposed rule should be consistent with Congressional intent as stated in both Appropriations Reports and the DQSA, and that also allows for office-use compounding as authorized by state law. In the proposed rule, FDA should lay out the means by which office use is permissible while addressing such critical safety matters, such as maintaining controls on quantity and safety issues such as those related to office stock shelf life. Lastly, FDA’s clarification on the line between traditional compounding and outsourced compounding will support state regulators, outsourcing facilities, and traditional compounders in their efforts to ensure that patients have access to safe compounded drugs while reducing the risks associated with sterile drugs produced in bulk. (page 67)

Memorandum of Understanding

Human Drug Compounding—Draft MOU.—The Committee is also very concerned with the draft MOU issued February 13, 2015, entitled “Draft Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the State of ( ) and the Food and Drug Administration” as it applied to 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 statute 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. (pages 67-68)

Pharmacy Compounding Advisory Committee

Human Drug Compounding—Compound Pharmacist on Pharmacy Compounding Advisory Committee.—The Committee is concerned that the Pharmacy Compounding Advisory Committee (PCAC) established under the DQSA does not adequately represent the interests and needs of providers and patients who use and depend on compounded medications. The Committee expects that, at the earliest possible date, whether filling open positions or replacing existing members, the FDA shall appoint voting members with recent, actual, and diverse experience in the preparation, prescribing, and use of compounded medications. (page 68)