American Society for Pharmacy Law

COMPOUNDING

Senate HELP Committee reports out the Pharmaceutical Compounding Quality and Accountability Act

On May 23, the Senate Committee on Health, Education, Labor and Pensions passed out a substitute bill (S.959) amending the FDCA through revisions to §503A – "Human and Animal Drug Compounding." In addition to defining a "compounded human drug" and a "compounded animal drug," the bill creates a new category of "compounding manufacturers" which would be regulated by FDA. Such entities would qualify if it is a facility at one geographic location or address that compounds a sterile drug product without receiving a prescription prior to beginning compounding, and distributes or offers to sell such a produce in interstate commerce. Alternatively, such an entity qualify if it repackages any preservative-free sterile drug product or pools any sterile drug products, subject to certain exceptions. The bill defines "traditional compounders" to include entities in which a product is compounded by a licensed pharmacist, other pharmacy personnel allowed by state law, in a state-licensed or federal facility, as well as a licensed physician or veterinarian as permitted by state law. The bill allows traditional compounding (1) pursuant to an individual prescription for an individual patient, (2) which may be compounded in limited quantities prior to dispensing as permitted by state law based on a history of receiving such prescriptions, (3) subject to a prescriber – patient/animal caregiver – pharmacist relationship, and (4) not meeting the definition of a compounding manufacturer. Hospital pharmacies would generally be considered traditional compounders.

Traditional compounders and compounded human or animal drugs produced thereby are exempted from requirements for GMPs (§501(a)(2)(b)), adequate directions for use (§502(f)(1), or approved NDAs (§505 – for human drugs; §512 – for animal drugs; or PHSA §351 – for biological products). Drugs compounded by compounding manufacturers are exempt from adequate directions or NDAs, but are subject to cGMPs.

Exceptions that were previously in §503A are generally retained, including drugs with demonstrable difficulties in compounding, copies of marketed drugs generally, and drugs removed from the market for lack of safety and efficacy. Prior §503A restrictions on sources of drugs are retained, and exemptions from inspections of pharmacies' records continue.

Compounding manufacturers would need to be overseen by a licensed pharmacist, annually register with FDA, report to FDA in June and December the drugs that were compounded during the prior 6 months, track and report adverse events, adhere to more strict labeling requirements, and pay inspection and reinspection fees established by FDA starting in 2015. [S.959, 113th Congress; http://1.usa.gov/13Xul4E]