Compounding Pharmacy Report Language Included In FY 2017 Continuing Resolution

As part of the recently passed FY 2017 continuing resolution (CR) Congress included "report language" regarding compounding pharmacy regulation under the Drug, Quality and Security Act (DQSA). The report language included in the FY 2017 CR was very similar to report language included in the FY 2016 and FY 2015 appropriations bills.

Report language is a tool that Congress uses to direct the federal agencies in how Congress expects for them to operate under the appropriations provided by the underlying legislation. Report language does not carry the weight of law and by pure legal interpretation sunsets at the end of the appropriation contained within the legislation, in this case FY 2017. However, in many cases report language is a signal from Congress on how they expect certain laws to be implemented over a longer period of time.

NHIA has been advocating inclusion of report language on several compounding regulation issues in the FY 2017 CR report. We are pleased that in the most recent CR's, passed on May 4th, accompanying report included several sections regarding compounding pharmacy and the DQSA. Most notably NHIA actively lobbied for the inclusion of language regarding the compounding Memorandum of Understanding (MOU) and Food and Drug Administration (FDA) inspection authority.

While the report language does not carry the weight of law it does send a clear signal to the FDA that Congress is watching how the FDA is implementing the DQSA. This establishes "Congressional intent" which if the FDA dramatically overstepped their bounds could be used in a court of law. Below is the report language that was included in the FY 2017 CR is below.

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)

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)

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)

Drug Compounding of Allergen Extracts.—The Committee is concerned that proposed changes to general chapter 797 of the USP contradicts the legislative intent of Section 503A of DQSA regarding the practice of ''office-use'' compounding of allergen extracts. The FDA recognizes USP general chapter 797 as federal policy on the practice of drug compounding. The Committee is concerned that the proposed changes to USP general chapter 797 would be inconsistent
with its legislative intent of Section 503A and with the agency's own previous positions on the practice of office-use compounding of allergen extracts. It is the sense of the committee that the practice of office-use compounding of allergen extracts by physicians is proven to be both safe and effective for the diagnosis
and treatment of allergic conditions. The Committee suggests that the USP work with organizations from the physician and patient communities that represent physicians who regularly engage in office-use compounding of allergen extracts or patients who benefit from such compounding of allergen extracts, to ensure that any changes to USP general chapter 797 regarding office-use compounding of allergen extracts are reflective of the clear legislative intent of Section 503A of the DQSA. (p. 69)

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)

Biological Products.—The Committee commends the FDA for issuing draft guidance to address the mixing, diluting, or repackaging of biological products outside the scope of an approved biologics license application. The Committee urges the FDA to finalize the guidance without delay following the public comment period and continues to emphasize the need for close FDA inspection and supervision of large-

scale compounding and repackaging of sterile injectable drugs and biological products, particularly products that are administered into areas of the human body where there is tempered immunity, such as the eye or spinal column, to ensure that they are processed in keeping with current good manufacturing practice for sterile products, in particular 21 CFR 200.50 regarding ophthalmic preparations. (p. 67)

ADDITIONAL VIEWS OF THE HONORABLE ROSA L. DELAURO

In 2012, after 753 people were sickened, and 63 died, from contaminated compounded drugs, Congress passed the Drug Quality and Security Act. I was concerned that this law was weak to begin with—in that it set up a voluntary regulatory regime for compounding pharmacies and failed to require a prescription for all compounded drugs. However, this bill contains numerous provisions that further weaken the law by lowering the standards for compounding facility inspections and ''office use'' compounding. Given that the meningitis outbreak caused by poorly compounded medicines was less than 4 years ago, now is not the time to lower the standards we hold compounding pharmacies to. In addition, the committee adopted an amendment that will exempt already marketed e-cigarettes, nicotine vapor, and other tobacco products from FDA's tobacco deeming rule. We must protect the nation's youth from the dangers of tobacco use. It is now almost seven years since Congress passed the Family Smoking Prevention and Tobacco Control Act. Yet there are still many kinds of tobacco products that remain unregulated, and youth are using those products at disturbing rates. The Centers for Disease Control and Prevention recently released data showing an alarming increase in use of electronic cigarettes among youth continues—almost a tenfold increase in use over the past 4 years. The report also found that approximately 4.7 million children and teenagers who use tobacco, and that tobacco use and addiction mostly began during youth and young adulthood. More must be done to drive these rates down, and sadly this new rider will do just the opposite. The issues with the bill are not just limited to provisions regarding the FDA. The bill includes a study to explore allowing the purchase of vitamins by WIC recipients. Vitamins are an unregulated industry with no guarantee of safety or effectiveness. Additionally, this committee adopted an amendment to block USDA rules to protect farmers from unfair and abusive practices that are all too common.

During markup in the full committee, I offered a series of amendments would have stripped harmful provisions that exempt cigars from the tobacco deeming regulation and weaken compounding pharmacy regulations. I am disappointed that special interests prevailed and my amendments were rejected on voice vote. The bill has too many provisions that would harm the health and safety of Americans by underfunding our food safety regulators and failing to adequately address nutrition and farm worker protections. I urge all my colleagues to oppose this bill. ROSA DELAURO. (p. 204-206)