FY 2018 Congressional Appropriations Language Requests

MOU FY18 Appropriations Language

Suggested FDA FY18 Appropriations Bill Language on Distribute/Dispense Definitions:

None of the funds made available under this Act shall be used by the Food and Drug Administration to propose, promulgate, implement or enforce any provision of a Guidance for Industry or rule or sample MOU that defines the terms "distribute" or "distribution" to include the dispensing of compounded medications pursuant to a prescription order for an identified patient as authorized by state law.

Suggested FDA FY18 Appropriations Report Language on Distribute/Dispense Definitions:

The Committee remains concerned that the FDA continues to define, in Guidance for Industry (GFI) and rules, the terms "distribute" and "distribution" to include the dispensing of compounded medications pursuant to a prescription order for an identified patient. Specifically, the Committee is aware of language in the draft MOU the FDA proposed under Section 503A of the FDCA as well as language in the final GFI entitled "Prescription Requirement Under Section 503A of the Food, Drug and Cosmetic Act" that redefines the term "distribution" to include dispensing. It is inappropriate for the FDA to attempt to redefine key terms in a GFI or rule, and the Congress did not intend for the FDA to have regulatory authority over the dispensing of medications, including those that cross state lines. 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 that is consistent with the statutory language and congressional intent of the DQSA and that does not define "distribution" to include dispensing. Further, the Committee directs the FDA to, upon finalization of the sample MOU under Section 503A of the FDCA, to clarify that the term "distribution" does not include dispensing and that the MOU does not address dispensing of compounded medications over state lines pursuant to a prescription order for an identified patient as authorized by state law.

Office-Use FY18 Appropriations Language

Suggested FDA FY18 Appropriations Bill Language on "Office-Use" Compounding:

None of the funds made available under this Act shall be used by the Food and Drug Administration to propose, promulgate, implement or enforce any provision of a Guidance for Industry or rule that prohibits the distribution or dispensing of compounded medications by a licensed pharmacist to a licensed physician or licensed practitioner for administration in an office or clinical setting ("office-use compounding"). For the purposes of this section, the term "office-use compounding" means the compounding of medications consistent with the provisions of Section 503A of the Food, Drug and Cosmetic Act, by a licensed pharmacist or licensed practitioner, that is distributed or dispensed pursuant to a valid prescription order to a licensed prescriber for administration within the prescriber's practice setting, pursuant to state law.

Suggested FDA FY18 Appropriations Report Language on "Office-Use" Compounding:

The Committee is concerned that the FDA continues to interpret and implement the Drug Quality Security Act (DQSA) of 2013 in a manner that is inconsistent with the statute and that is jeopardizing patient access to compounded medications that are needed by physicians and other providers for administration to patients in an office or clinical setting ("office-use" compounding). "Office-use" compounding is authorized by the vast majority of states and is often medically necessary and critical to the safety of patients. Despite clear directives in previous reports accompanying FDA's appropriations bills for the agency to finalize guidance that authorizes "office-use" compounding, the Committee is aware that in December of 2016, the FDA finalized a Guidance for Industry (GFI) entitled "Prescription Requirement Under Section 503A of the Food, Drug and Cosmetic Act" that 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, that is consistent with the statutory language and congressional intent of the DQSA and that allows for "office-use" compounding as authorized by state law.

Inspections FY18 Appropriations Language

Drug Compounding Inspections.—The Committee understands that despite an FDA notice that went into effect on August 1, 2016 stating that FDA investigators will not include observations on Form 483s that represent deviations solely from FDA's current Good Manufacturing Practice (cGMP) requirements, the FDA continues to inspect state-licensed compounding pharmacies under cGMPs instead of under the official standards published by 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. In addition, the Committee understands that FDA is refusing to apply the records exemption found within 21 U.S. Code § 374 (a)(2)(A). 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 state regulations that establish sterility and other standards for the pharmacies operating within their states. Compounding pharmacies are more appropriately inspected using published USP standards or other pharmacy inspection standards adopted by state law or regulation in the state in which a pharmacy is licensed. In addition, the Committee reminds FDA that the records exemption found within 21 U.S. Code § 374 (a)(2)(A) applies to 503A compounding pharmacies.

Dietary Supplements FY18 Appropriations Language

Pharmacy Compounding and Applicable USP/NF Monographs. The Committee is deeply concerned about FDA's implementation of the Drug Quality and Security Act (DQSA) related to the agency's interpretation of statutory language in Section 503A, specifically the phrase "applicable United States Pharmacopeia or National Formulary monograph" to mean ***only*** USP or NF ***drug substance*** monographs**.** In its many compounding guidances issued to date, FDA states it does ***not*** consider USP ***dietary supplement*** monographs to be "applicable" monographs within the meaning of section 503A(b)(1)(A)(i)(I). The Committee reminds FDA that Congress placed no limitations on the specific USP/NF monographs used in compounding bulk substances, and advises FDA against moving forward in this manner absent statutory authority to do so. Given the long history and tradition of compounding using USP/NF "dietary" as well as "drug" substances, the Committee directs FDA to return to the statute's plain meaning, and permit compounding using bulk substances that are the subject of any USP/NF monograph. The Committee also reminds FDA that it cannot revise or otherwise narrow Congressional intent simply by repetitious use of an incorrect interpretation of the phrase "applicable" USP/NF monograph, which phrase expresses no limitation on which USP/NF monographs are "applicable."

PCAC - Composition FY18 Appropriations Language

The committee is concerned that the Pharmacy Compounding Advisory Committee (PCAC), established under the Drug Quality and Security Act of 2013, 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, FDA shall appoint voting members with recent, actual, and diverse experience in the preparation, prescribing, and use of compounded medications.

PCAC – API Bulk Drug Process FY18 Appropriations Language

Pharmacy Compounding and Criteria for Approval of Drug Ingredient Nominations: The Committee is deeply concerned about FDA's implementation of the Food Drug and Cosmetic Act (FDCA) and the Drug Quality and Security Act (DQSA) related to the agency's interpretation of statutory language in Section 503A, specifically that the criteria by which it is reviewing drugs pursuant to 503A(B)(1)(A)(i)(III) for inclusion on a list allowing use where neither a monograph or drug approval exists is not following the language of the statute nor

Congressional intent. Congress intended that drugs that have been used historically be allowed for use unless FDA found that they present an unacceptable health and safety risk. The FDA has been placing a burden on drug nominators to show clinical studies demonstrating safety and effectiveness even though no financially interested parties are available to promote such studies and physicians have learned through experience that these drugs play a valuable role in treatment. While Congress specifically pointed to historical use as part of the criteria for acceptance for the long-established practice of traditional compounding, 503A(D)(2), FDA has merely been noting whether there is historical use but not giving reasonable weight to such history. Further, FDA determinations that the existence of an approved drug for the proposed indication creates a presumption against the approval of a nominated ingredient is not rational health policy and FDA should, absent a finding of unreasonable health risk, give wide latitude to the judgment of a physician who determines that there is a basis for using the nominated ingredient over the drug approved for that indication. Finally, FDA has been minimizing the impact of a decision not to list an ingredient by claiming that these ingredients may still be accessed by physicians applying for Expanded Use INDs; Congress did not intend to place an extra barrier for use of compounded medication by requiring the Extended Use IND to be considered an alternative for patient access. The consideration of an ingredient to be placed on the list should consider the history of use and not ways to circumvent access to patients.