Legislative/Regulatory Update

FROM THE INTERNATIONAL ACADEMY OF COMPOUNDING PHARMACISTS: APPROPRIATIONS

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On Friday, December 18th, 2015, President Obama signed the Consolidated Appropriations Act of 2016, which is often referred to as the “Omnibus” bill. This legislation includes all twelve appropriations bills, including the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill, which funds the U.S. Food and Drug Administration (FDA). The Omnibus bill funds the government through the end of the 2016 fiscal year, which is September 30, 2016, and totals approximately $1.15 trillion.

The Appropriations Committees, as they traditionally do, submitted a Committee Report accompanying the bill making appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies for fiscal year 2016. The International Academy of Compounding Pharmacists (IACP) is thrilled to announce that the House Appropriations Committee Report language, which included all of the language requested by IACP regarding the Memorandum of Understanding (MOU), office-use, and active pharmaceutical ingredients (APIs), was retained in the final Omnibus agreement reached by the House and Senate.

IACP has spent the last year urging Congress to include protections within the 2016 appropriations legislation protecting compounding pharmacists from the FDA’s overbroad implementation of the Drug Quality and Security Act (DQSA). This work to protect patient access to vital medications was carried out for IACP, by Cynthia Blankenship, who recently joined Rose Law Firm after serving as Vice President of Government Affairs for IACP, and Arnold and Porter, with the support of the compounding pharmacy champions in Congress as well, as allies within the DQSA Coalition—which resulted from a strategic initiative from the IACP Board of Directors.

This language would not have been possible without the passionate pharmacy champions in both the House and Senate that stood firm during negotiations to provide these protections to pharmacists across the nation, as well as the support and resources from the members of the DQSA Coalition. Many of these members joined Cynthia and Arnold and Porter on the Hill for countless meetings and signed on to letters in support of language preserving office-use compounding, the use of APIs in compounding, and restricting the FDA’s ability to limit compounding under the MOU. This is a tremendous win, and IACP is extremely grateful to our champions in Congress who continue to fight on behalf of compounding pharmacists to preserve patient access to vital compounded medications.

Despite the FDA’s repeated requests for additional funding to implement the DQSA and specifically to target pharmacy compounding, the House Appropriations Committee states that the Committee will only maintain fiscal year 2015 funding levels for pharmacy compounding. As such, Congress denied the FDA’s requests to increase funding to target pharmacy compounding and to further aid in the implementation of the DQSA.

Regarding API, the House and Senate Appropriations Committees expressed its concern with the FDA’s failure to finalize API lists for all compounding pharmacists. As IACP has previously reported, the FDA has been hosting meetings with the Pharmacy Compounding Advisory Committee (PCAC). However, despite the PCAC’s voting on bulk ingredients to be placed on the positive list, the FDA has failed to release a final positive list. Instead, the FDA included within recently released 503A guidance language stating that “[u]ntil a bulk drug substances list is published in the Federal Register as a final rule, human drug products should be compounded using only bulk drug substances that are components of drugs approved under section 505 of the FD&C Act, or are the subject of USP or NF monographs.” Congress has taken great concern with the FDA’s failure to provide a finalized positive list to pharmacists and specifically addressed this issue within the House and Senate Appropriations Committee Report language requiring the FDA to report to Congress within 90 days on when the review of the APIs will be finalized. Specifically, the Committee stated:

The Committee is concerned that the FDA has not yet approved a list of Active Pharmaceutical Ingredients (APIs) for use by compounding pharmacists pursuant to the Drug Quality and Security Act (Public Law 112–43, 127 Stat. 587) and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a et seq.). Within 90 days of enactment of this Act, the FDA shall report to Congress on when its review of proposed APIs pursuant to § 503A(1)(a)(iii) will be completed.

Regarding office-use compounding, the Appropriations Committee included language on page 67 of the Report expressing grave concern with the FDA’s implementation of the DQSA to prohibit all office-use compounding. As IACP previously reported, contrary to six Congressional Statements on the Record during the passage of the DQSA stating that the FDA was given no authority to prohibit office-use compounding, the FDA released 503A guidance stating that all 503A compounding pharmacies are prohibited from compounding for office-use despite State laws allowing such practices. Despite multiple letters from Congress and letters from the DQSA Coalition providing pages of examples of drugs that would...
no longer be accessible for patients, the FDA continued to implement the DQSA to prohibit all office-use compounding. To stop this overreach by the FDA, Congress included the following language within the Appropriations Report that directs the FDA to issue guidance within 90 days allowing compounding pharmacists to continue to engage in office-use compounding. Specifically, the language states:

The Committee is concerned that, since passage of the Drug Quality and Security Act (DQSA) of 2013, the FDA has interpreted provisions of Section 503A of the FDCA in a manner inconsistent with its legislative intent and with the agency’s own previous positions. Specifically, the FDA has taken the position that under 503A, a pharmacist may not compound medications prior to receipt of a prescription and transfer the drugs to a requesting physician or other authorized agent of the prescriber for administration to his or her patients without a patient-specific prescription accompanying the medication. This practice, which is often referred to as “office-use” compounding, is authorized in the vast majority of states and was intended to be allowable under DQSA. The Committee is aware that in 2012, prior to passage of the DQSA, FDA was working on a draft compliance policy guide for 503A of the FDCA that provided guidance on how “office-use” compounding could be done consistent with the provisions of 503A. The Committee understands the intent of the DQSA was not to prohibit compounding pharmacists from operation under existing 503A exemptions; therefore, the Committee directs the FDA to issue a guidance document on how compounding pharmacists can continue to engage in “office-use” compounding before the receipt of a patient-specific prescription consistent with the provisions of 503A within 90 days after the enactment of this Act.

Lastly, the Appropriations Committee expressed strong concern with the draft MOU that the FDA recently released. With the final draft MOU expected any day, Congress wanted to make clear that the draft MOU did not adhere to Congressional intent. As IACP previously reported, the FDA’s draft MOU defined pharmacy “distribution” activities as “dispensing.” Within the DQSA, Congress only allows the FDA to regulate distribution activities. However, the draft MOU greatly exceeded this authority by restricting all dispensing as well as distribution activities. This was an unprecedented move by the FDA to regulate all compounding pharmacy activities that cross state lines. As such, Congress expressed concern with this broad overreach and instructed the FDA in finalizing the MOU to separate distribution and dispensing and treat them as the separate activities that they are. Specifically, the Appropriations Committee stated:

The Committee is very concerned with the draft MOU that the FDA has proposed under 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.

The IACP Board of Directors and Legislative Committee have been instrumental in leading IACP, as both have been deeply involved in the Appropriations effort. As the FDA begins to work on the guidance mandated by Congress, the IACP and the DQSA Coalition will continue to engage with our allies in the U.S. Congress and remains committed to working with the FDA to address the concerns regarding the FDA’s implementation of DQSA and specifically issues involving office-use, the API list, and the draft MOU between states. The IACP will continue to convey input from our membership to the FDA during this process and urge Congress to require the FDA to allow stakeholder input into the process and substance of any future guidance.

RESOURCES

3. See House Report 114-205 — Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2016: Page 64. Additionally, the Senate Appropriations Committee Report 114-82 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2016 included nearly identical language with the exception of the following: “Within 90 days of the enactment of this act, the FDA is directed to provide a timeline for when the remaining substances will be considered, and in the meantime re-consider its policy with regard to enforcement of the bulk drug substances provisions under section 503A.”: Page 83.

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