Ask your Congressman to Support FY18 FDA Appropriations Bill and Report Language on the DQSA

Since passage of the Drug Quality and Security Act (DQSA) in 2013, the FDA has implemented and enforced the law in a way that is inconsistent with its congressional intent as has been expressed to the agency multiple times in the form of statements in the congressional record, letters from Congress, questions for the record asked in congressional hearings, directives in the reports accompanying FDA's appropriations bills, stakeholder input, and in some cases, the plain language of the statute. FDA's regulatory overreach has led to state licensed and compliant compounding pharmacies being inspected and otherwise treated like drug manufacturers, and more importantly, has jeopardized patient access to compounded medications.

For over three years, IACP has been working with a coalition of 30+ pharmacy and physician organizations who rely on compounded medications to treat their patients to try to work with the FDA and the Congress on improving the agency's compounding policies in a way that better balances public safety with patient access to critical medications. Unfortunately, despite these efforts, FDA continues to misinterpret the DQSA and assert regulatory authority over the practice of pharmacy in a way Congress never intended. Congress has, in the last two bills funding the FDA (FY16 and FY17), included report language directing the FDA to alter their policies on compounding to align with congressional intent and the language of the statute. FDA has, to date, ignored those congressional directives and continues to substitute their desired regulatory authority over compounding for the authority given to the FDA under federal law.

As such, it is now essential that Congress direct FDA to act within Congressional intent by including appropriations requests for FY18 that would limit funding for FDA to go through the rulemaking process to issue new policies that adhere to the intent and language of the statute. **Ask your Congressman to contact the House Appropriations Committee (Subcommittee on Agriculture, Rural Development and FDA) to express support for FY18 FDA bill and report language to:**

- Remind the FDA that compounding pharmacies are not drug manufacturers and are to be inspected under USP or other inspection standards adopted by state laws.

- Limit funding for the FDA to continue to enforce against state licensed and compliant pharmacies for "office-use" compounding where authorized by state law.

- Limit funding for the FDA to finalize or enforce any guidance document, rule or MOU that defines the term "distribution" to include the patient-specific dispensing of compounded medications.

- Clarify that compounding pharmacies can compound with dietary supplements that have a USP or National Formulary Monograph.

Preserve patient access to vital compounded medications by supporting bill and report language in the FDA's FY18 appropriations legislation to reign in the agency's regulatory overreach of compounding pharmacies.