



## **FOR IMMEDIATE RELEASE**

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### **IACP SEEKS TO ENSURE PATIENT ACCESS TO VITAL COMPOUNDED MEDICATIONS IN COMMENTS TO FDA**

**WASHINGTON, D.C.** – The [International Academy of Compounding Pharmacists \(IACP\)](http://www.iacprx.org) has raised serious concerns about patient access to vital medications in comments submitted yesterday to the U.S. Food and Drug Administration, as the agency develops a new regulatory framework for pharmacy compounding based upon the Drug Quality and Security Act (DQSA) of 2013.

“We believe the FDA’s draft guidance overreaches far beyond the intentions of Congress and contradicts the clear language of the DQSA and previous federal legislation – to the point that, if left intact, it will hinder patient access to compounded medications, limit patient choice of their pharmacist, and disrupt the essential physician-patient-pharmacist triad relationship,” said David G. Miller, RPh, the IACP’s Executive Vice President and Chief Executive Officer.

“Our organization, along with a diverse group of stakeholders in the health care industry, has worked cooperatively with the FDA as the agency implements the DQSA, and we urge the FDA to incorporate our feedback,” Miller said. “The fact that more than 3,000 individuals and organizations have commented on the draft guidance underscores that the agency has a great deal of work to do before finalizing this document and ensuring that it does not negatively impact patient access to compounded medications.”

As part of the public comment process, the IACP expressed four major concerns with the FDA’s *Draft Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products between the States and the Food and Drug Administration*:

- FDA’s attempt to regulate “dispensing” to an individual patient through the definition of “distribution” of compounded medications in interstate commerce – a contradiction to the statute and to congressional intent.
- FDA’s proposed prohibition of all office-use compounding by 503A pharmacies – a limitation on patient access to vital non-sterile and sterile medications.

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- FDA’s attempt to enforce an arbitrary cap with no scientific basis on compounded medications shipping in interstate commerce – a hindrance to patient access and choice.
- FDA’s placement of a tremendous burden on states with unfunded mandates to regulate pharmacy compounding – a commandeering of state authority.

“We strongly oppose any arbitrary cap on shipments,” Miller said. “This would limit patients’ access to essential compounded medications and also put pharmacists in the difficult position of denying care based upon an arbitrary quantity. Consider, for example, the compounding pharmacist who serves patients from a pharmacy located near the borders of multiple states. Such a compounder could easily surpass the FDA’s arbitrary shipment ceiling, and be forced to limit its shipments and turn patients away from their chosen pharmacist.”

The IACP’s comments are accessible here: <http://bit.ly/1LofFCG>

### **About the International Academy of Compounding Pharmacists**

The [International Academy of Compounding Pharmacists \(IACP\)](http://www.iacprx.org) is an association representing nearly 4,000 pharmacists, technicians, students, and members of the compounding community who focus upon the specialty practice of pharmacy compounding. Compounding pharmacists work directly with prescribers including physicians, nurse practitioners and veterinarians to create customized medication solutions for patients and animals whose health care needs cannot be met by manufactured medications.

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