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SEEKING GREATER CLARITY AND DIRECTION FROM FDA, IACP SUPPORTS CONGRESSIONAL FUNDING RESTRICTION

Implementation of DQSA Not Consistent With Intent of the Law

Washington, D.C. (June 10, 2014) – The [International Academy of Compounding Pharmacists](http://www.iacprx.org) (IACP), citing a lack of direction from the U.S. Food and Drug Administration (FDA) regarding the implementation of the federal Drug Quality and Security Act (DQSA), as well as the FDA's misinterpretation of Congressional intent, supports the efforts of the U.S. House of Representatives to restrict an additional \$7 million that the agency has requested for inspections.

“We believe in providing FDA with the tools that it needs to do its job and ensure the quality and safety of all medications,” said IACP Executive Vice President & CEO David G. Miller, R.Ph. “The fact that the agency, however, has not issued any guidelines or regulations that clearly direct the new outsourcing facility entities created under the law, so that these facilities can ensure compliance with standards, is troublesome to our profession. Additionally, the FDA is interpreting the law in a manner that is not consistent with Congressional intent, by seeking to prohibit traditional compounding pharmacies from preparing medications for office use or from re-packaging medications, even when both practices are allowed in some instances under state law.”

The DQSA created a new, voluntary category of sterile compounders that serve mainly physicians and hospitals in multiple states, called outsourcing facilities. The law left in place traditional compounding pharmacies that are subject to oversight by their state boards of pharmacy. While FDA is collecting fees from outsourcing facilities, it sought a supplemental appropriation since the fees collected are not adequate for inspection and oversight of outsourcing facilities. It also sought funds to inspect and oversee traditional compounding pharmacies, even though it is the states that have this primary function.

FDA has yet to issue regulatory guidance for outsourcing facilities even though it has already registered over 40 such facilities. Moreover, it has begun taking action against traditional compounding pharmacies that are engaged in office use, by evaluating these pharmacies against manufacturing standards that do not apply to such pharmacies and prohibiting them from engaging

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in office use and the re-packaging of medications, even though in some cases these practices are explicitly allowed under state law.

“Pharmacists believe in a strong and effective FDA and support funding to make that happen,” said Miller. “What we are dealing with, however, is the lack of proper implementation of a new law that has led to ambiguity and uncertainty for those in our profession. Pharmacists want to do right and to comply with all requirements; we just don’t know what they are because FDA has not promulgated the guidance that we need.”

“Senator Lamar Alexander repeatedly asked, during Senate hearings, for a bill that would make clear ‘who is on the flagpole,’ or who has ultimate responsibility,” Miller added. “Through its actions, particularly those in conflict with state law and regulation, FDA is perpetuating confusion, which we believe does not advance either quality or safety.”

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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, student pharmacists, and members of the pharmacy community who focus on the specialty practice of medication 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.