IACP Position on FDA Oversight of Compounding Pharmacy

The International Academy of Compounding Pharmacists (IACP) is and has been committed to working in collaboration with state and federal officials to determine how best to prevent a tragedy such as occurred in October 2012 when compounded preparations dispensed by a Massachusetts licensed pharmacy caused an outbreak of fungal meningitis.

IACP developed and issued a series of recommendations in early December 2012 to develop and implement changes in pharmacy practice acts that protect the public health and preserve the professional decision making of pharmacists in the selection and preparation of customized medication solutions. Those recommendations emphasize the importance of quality, compliance and enhanced inspection authority by the state Boards of Pharmacy.

IACP has also been asked to respond to a “new model” of Food and Drug Administration authority over the practice of compounding. Although the Academy has stated repeatedly in its public statements and in its formal Congressional testimony that the agency has sufficient authority extant that enables it to take action against entities engaged in the manufacture of prescription drugs, it has very serious concerns that expanded authority may serve to overly restrict an important part of medication therapy delivery as well as impinge upon long-standing state authority.

Our Core Principles - State Authority Over Compounding Pharmacy Practice

Each state’s Board of Pharmacy is ultimately responsible for determining when a pharmacist or pharmacy exceeds its scope of practice. It is the Board of Pharmacy’s decision and responsibility to inform other regulatory agencies at the state and federal level when it deems such action appropriate and necessary to protect public health.

The dispensing of a medication upon the existence of a prescriber-generated prescription/order, regardless of to whom it is dispensed or to where it is shipped, is a function of pharmacy practice and is not nor should be subject to FDA jurisdiction.

In the course of medical practice, prescribers are authorized to prescribe or order medications as they deem appropriate. Medical practice is also a state regulated activity and should not be subject to FDA oversight or intervention.
FDA Conceptual Framework to Oversee Compounding Pharmacy

Members and staff of the Senate HELP Committee have asked for IACP’s position on a proposal put forward by the FDA that would ostensibly ensure the safety of compounded drug preparations. Unfortunately, FDA has not provided Senate HELP with any written materials beyond the framework outlined in their testimony before the committee on November 15, 2012. IACP has not received any formal proposal either and, as such, can only respond based upon the following outline based upon FDA’s testimony verbal information provided to us by Congressional staff:

There would be a three-part test will be used to determine whether or not an entity is engaged in traditional drug compounding:

1. Is the compounded product a sterile preparation?
2. Is the compounded product being shipped across state lines?
3. Is the compounded product being prepared prior to the receipt of a prescription or order for a particular patient?

If the answer to all three questions is “yes,” then these products would fall under a new category of product overseen by FDA. Based on FDA’s testimony before the Senate HELP Committee, FDA will likely categorize such products as “non-traditional compounding,” rather than as a new tier of drug manufacturing. For such products:

1. No pre-market approval requirements would be required.
2. No adverse event reporting would be required.
3. Current good manufacturing practices (cGMPs) would be required. It is unclear whether FDA would develop any alternative standards.

Hospital system pharmacies engaged in sterile compounding would be exempted from these requirements, even if they satisfy all three prongs of the aforementioned test.

IACP believes that the oversight and regulation of prescription drug manufacturing rests with the FDA. The agency currently has the authority to identify and require registration by those entities which it believes to be engaged in manufacturing. Despite the agency’s statements to the contrary, no court decision prevents the FDA from taking appropriate action against a business which is engaged in manufacturing without appropriate registration. Based upon this proposal, it appears that the FDA wishes to extensively expand its authority to include oversight of pharmacies and the practice of pharmacy.
IACP believes that the compounding of prescription medications is a core component of pharmacy practice. IACP opposes giving the FDA expanded authority of any type to regulate or oversee pharmacy practice. Pharmacy practice is regulated by the states and should remain so.

IACP strongly opposes the use of the terms “traditional compounding” or "non-traditional compounding." Those terms are not defined in any professional or scientific literature. The continued use of those terms by the FDA serves only to create greater confusion.

IACP observes that the first “test” of the FDA proposal is limited to only sterile compounded preparations. The agency has not explained why public safety is limited to only sterile preparations with no mention of non-sterile preparations.

IACP observes that the second “test” of the FDA proposal – interstate shipment – will have unintended consequences on public health. Currently, states have and do decide when the licensure of a non-resident pharmacy is appropriate and consistent with their laws and regulations. The interstate shipment of prescription drugs – whether manufactured or compounded – is a critical, necessary and appropriate component of healthcare. The dispensing of a medication upon the existence of a prescriber-generated prescription/order, regardless of to whom it is dispensed or to where it is shipped, is a function of pharmacy practice and not subject to FDA jurisdiction.

IACP is especially concerned with the FDA’s third “test” and statement that a pharmacy may not prepare a compounded medication prior to the receipt of a valid prescription or medical order. As proposed, such a position would essentially eliminate the preparation of compounded medications commonly referred to as “anticipatory compounding.” “Anticipatory compounding” is the preparation of compounded medications based upon historical prescriptions received by the pharmacy and is in no way associated with manufacturing activities. “Anticipatory Compounding” is a form of inventory management which enables the pharmacy and pharmacist to prepare compounded preparations in amounts sufficient to meet the needs of patients and prescribers and is recognized both within the profession and in state law.

IACP also believes that the FDA’s third “test” contradicts existing state authority to permit authorized prescribers from issuing prescriptions or medical orders for medications to be used as “office-use.” By specifically requiring only patient-specific prescriptions, the FDA appears to be circumventing individual state’s laws, regulations and rules that enable prescribers to obtain compounded preparations for administration to or treatment of patients within their practices. “Office-use” dispensing is the preparation, labeling, and dispensing of a non-controlled medication by a pharmacist and pharmacy upon the receipt of a prescription or medical order from an identified authorized prescriber (e.g., physician, nurse practitioner, dentist, veterinarian, etc.) for that prescriber’s use in the treatment of or administration to a patient during their normal course of medical practice. “Office-use” includes both manufactured prescription drug products and compounded preparations.
IACP strongly supports the application of any legislation or regulations pertaining to compounding to all pharmacy practices. Exempting any practice site – hospitals, for example – create two distinctly different categories of patient safety protection.

Additional FDA Concepts

According to FDA’s testimony, it is possible that FDA may also seek the following authorities with respect to this new category of products:

- The authority to collect and test samples of such compounded drugs and to examine and collect records belonging to that compounding pharmacy, including records of prescriptions received, products shipped, volume of operations, and operational records such as batch records, product quality test results, and stability testing results.
- A label identifying the nature and source of the compounded product.
- Establish a list of prescription medications which should not be compounded.

IACP notes that the FDA has and always has had the authority to collect and test samples of compounded preparations upon the presentation of the agency’s Form 484 and in compliance with its established policies and procedures.

IACP notes that the FDA already has the ability to obtain access to records of prescriptions, products shipped, volume of operations, and other such documents through a court- affirmed process. Since 1962, under Section 704(a)(2)(A), a pharmacy may claim an exemption from the FDA’s broad inspectional authority under certain circumstances:

Pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail.

In the event that a pharmacy exercises its right to claim the FDCA provided exemption, the agency is empowered to obtain a court order, warrant or subpoena to obtain those records if it deems such an action necessary. IACP has seen no evidence that the FDA has been unable to obtain access to the records they seek under existing process. The agency has provided no data on the number of pharmacies it has inspected, the number of pharmacies which did or did not claim the exemption, the number of court orders, warrants, or subpoenas that were
requested to obtain those records after an exemption was claimed, nor whether any of those court requests were declined.

IACP has a formal guideline for its members that requires all compounded preparations be labeled as such so that the prescriber and/or patient is readily aware that the medication has been compounded.

IACP continues to point out that the recommendation to create and maintain a “do not compound” list by the FDA based upon patient safety already exists within the Food Drug and Cosmetic Act (FDCA). Such a list was created by the agency and is continually promoted to the compounding profession by IACP to educate practitioners*. IACP believes that the ongoing review and input into this list must be done in an open, structured manner that solicits and accepts the position and opinions of the medical and pharmacy community. IACP also believes that if the collective professional community and the FDA determine that a product should not be compounded due to evidence of patient safety, it should also not be available from a manufacturer.


For additional information regarding this or other IACP Position Statements, please contact:

David G. Miller, R.Ph.  Sarah R. Dodge
Executive Vice President & CEO  Vice President, Government Affairs

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