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The International Academy of Compounding Pharmacists Responds to Meningitis Outbreak Tied to Compounding Pharmacy

HOUSTON TX (October 4, 2012): The International Academy of Compounding Pharmacists (IACP) on behalf of its 2,700 member compounding pharmacists, technicians and student pharmacists, responds today to the tragic situation involving a Massachusetts compounding pharmacy. As pharmacists who care deeply about their patients, this situation causes the Academy and its entire membership great concern and empathy on behalf of all of the individuals involved.

As the investigation continues by the Centers for Disease Control (CDC), the Food and Drug Administration (FDA), and the Boards of Pharmacy in the six states in which clinical cases of fungal meningitis have occurred, IACP believes it is important to clarify the role and nature of compounding pharmacy.

Key Points:

How common is pharmacy compounding?

- Compounding is a traditional part of pharmacy practice. It involves the preparation of medications on prescription by physicians and other authorized prescribers who meet unique patient healthcare needs that cannot be met with commercially manufactured and marketed drug products. This might include providing different strengths, preparing a drug with different non-active excipients for which a patient may have an allergy, or creating dosage forms which are more palatable for a patient.
- Of the approximately 56,000 community-based pharmacies, more than half provide some level of basic compounding services to local patients and physicians. IACP estimates that there are 7,500 pharmacies in the United States that specialize in advanced compounding services of which approximately 3,000 provide sterile compounding. It is estimated that one to three

percent of all prescriptions dispensed in the United States are compounded on prescriptions for individual patients.

- The value of compounding pharmacy to the healthcare system has grown recently as pharmacists have worked with local physicians, hospitals and medical clinics to address the ongoing shortage of critical manufactured medications. As the number of medicines previously available through manufacturers have gone into backorder or long-term shortage status due to manufacturing problems, compounding pharmacists have been able to access the raw drug ingredients and collaborate to provide those medicines until manufacturing supply has been revived.

Is Compounding Pharmacy Regulated?

- All compounding pharmacists and pharmacies are subject to governmental oversight by three distinct regulatory bodies: their individual **State Boards of Pharmacy** for adherence to practice requirements, the **Food & Drug Administration (FDA)** for the integrity of the drugs and Active Pharmaceutical Ingredients (APIs) which they order, store and use; and, by the **Drug Enforcement Administration (DEA)** for their handling of controlled substances used in the preparation of compounded medications.
- In addition to government regulation, adherence to **United States Pharmacopeia USP <797>** standards for the compounding of sterile medications is expected. USP <797> is a national standard for the process, testing, and verification of any medication prepared for administration to patients. These standards are included as a requirement in many state regulations in addition to being a professional standard.
- The pharmacy profession has an accrediting body – the **Pharmacy Compounding Accreditation Board (PCAB)** – which provides an additional level of quality assurance recognition for sterile and non-sterile compounded preparations. Pharmacies with PCAB accreditation status have demonstrated that their policies and processes meet the highest possible quality standards. *New England Compounding Center is not a current PCAB accredited pharmacy.*

Was this pharmacy – NECC – compliant with state and federal laws?

- Given the nature of the ongoing investigation, the first priority for all parties must be the identification and prompt treatment of any additional patients who may be at risk from medications compounded by New England Compounding Center (NECC). The Academy will be working closely with regulatory authorities in any manner they deem necessary to assist in determining whether or not the pharmacy in question failed to meet legal and professional standards of practice.

How can a physician, hospital or clinic know that the compounding pharmacy they work with is reliable?

- IACP has developed a comprehensive tool for the medical community to help assess and select a compounding pharmacy. The objective of IACP's **Compounding Pharmacy Assessment Questionnaire** (CPAQ™) is to aid compounding pharmacists have a meaningful discussion with hospitals and practitioners regarding pharmacy compounding and to raise awareness of the stringent policies and procedures employed in compounding.
- IACP's CPAQ™ document emphasizes the importance of verifying licensure status, accreditation status, and face-to-face consultation between medical practitioners and the compounding pharmacists with whom they wish to establish a relationship.
- IACP is not aware of whether or not any of the facilities which purchased medications from New England Compounding Center pursued the due diligence the Academy recommends.

[Click here to view CPAQ.](#)

The International Academy of Compounding Pharmacists (IACP) is an association representing more than 2,700 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 healthcare needs cannot be met by manufactured medications. More than 164,000 patients and prescribers also belong to our organization via the grassroots advocacy group, P2C2 (Patients and Professionals for Customized Care). IACP's mission of protecting, promoting and advancing personalized medication solutions is critical for patient healthcare. Visit www.iacprx.org to learn more.

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