



BACKGROUND AND FACTS ON COMPOUNDING PHARMACIES FROM IACP October, 2012

- The International Academy of Compounding Pharmacists (IACP) is a professional association representing more than 2,700 pharmacists, technicians, student pharmacists, academicians and others who have a particular interest in the specialty practice of pharmacy compounding. IACP members are individuals; it does not represent or advocate on behalf of specific pharmacies, business or companies. 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 standardized medications manufactured by the pharmaceutical industry.
- Millions of patients have unique health needs that off-the-shelf, manufactured medications cannot meet. For these patients, personalized medication solutions – prescribed by licensed practitioners and prepared by trained, licensed pharmacists – are the only way to better health. Working with a physician, a compounding pharmacist can meet individual needs of children, adults and animals. Whether it's an allergy to a dye or ingredient, a need for a different strength, or a preference for a different dosage form, compounding pharmacists provide patients with solutions to their medication needs.
- The New England Compounding Center was licensed by the Commonwealth of Massachusetts as a pharmacy. It also held permits as a non-resident pharmacy in other states. IACP does not have information about the states in which NECC held licenses. NECC used the word “compounding” in its name and in descriptions of its services. Based upon the reports and from growing evidence being announced as part of the ongoing state and federal investigations, NECC appears to have exceeded its scope of authority as a pharmacy and engaged in the manufacture and distribution of prescription drugs without registering with the FDA or the Massachusetts State Board of Pharmacy as a manufacturer and distributor. Pharmacies, including compounding pharmacies, in the United States are regulated extensively by state boards of pharmacy, the Food and Drug Administration (FDA), and the Drug Enforcement Administration (DEA). State Boards of Pharmacy oversee all aspects of a pharmacy – the licensure and oversight of pharmacists and pharmacy technicians, the process of filling prescriptions, records, documents, environment, and compliance with the state's laws and regulations designed to protect the public. The FDA has authority to inspect unannounced any pharmacy at any time to assure that the medications stored, inventoried, dispensed, or sold by that pharmacy are safe. Any pharmacy engaged in the dispensing of controlled substances must also obtain a separate registration from the DEA and is also subject to unannounced inspections of their medication and records. Most states also provide for additional authority by the federal agencies within their state laws.

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- In addition to the states' regulations of and standards for compounding pharmacies, which are constantly updated, standards set by the United States Pharmacopeia are integrated into the practice of pharmacy compounding.
- The Pharmacy Compounding Accreditation Board has developed national standards to accredit pharmacies that perform a significant amount of compounding. The Pharmacy Compounding Accreditation Board is a profession-supported entity that operates independently from the IACP. IACP is a member of the PCAB Board of Directors but it is not involved in the survey, review or accreditation process of any individual pharmacy.
- The pharmacy industry includes not only independent pharmacies and pharmacies that are a part of larger companies and chain stores but also institutional, hospital, home infusion, hospice, assisted living, and long-term care pharmacies. Any change in regulation of “compounding” pharmacies would affect all of them.
- There are 7,500 pharmacies in the United States specializing in compounding. In addition, there are about 8,200 pharmacies associated with hospitals and other health institutions which are also engaged in compounding on a daily basis to meet their inpatient and outpatient care requirements.
- The IACP has a Code of Ethics and compounding pharmacists have a special knowledge and expertise. No other health care professional is trained in the preparation of drug products. In recognition of the compounding pharmacist's role in quality medical care, this Code of Ethics is designed to recognize the prominence of the compounding pharmacists and to advocate acceptance of a personal obligation to the highest ethical and professional standards of conduct for the professional practice of compounding pharmacy, patients and colleagues. The Code of Ethics of the International Academy of Compounding Pharmacists establishes minimum standards of conduct and may change to address issues that arise due to advancing knowledge, technology, and legal and regulatory changes.
- The IACP is determined to work with professionals, regulators, government officials, boards, and others to close any loophole or gap that could result in harm to patients. The apparent and tragic results of NECC's alleged behavior has undermined the fundamentals of pharmacy, which include doing no harm. We are determined to help find the problem and solve it.

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