



BACKGROUND ON COMPOUNDING PHARMACY

Compounding pharmacy and regulation of the profession has become a complex, evolving issue in recent years. In the interest of accuracy and public understanding, the International Academy of Compounding Pharmacists (IACP), an association representing nearly 4,000 pharmacists, technicians, students, and members of the compounding community, offers the following facts and background information.

Compounding Profession

- [Compounding pharmacists](#) prepare customized prescription medications using FDA-approved drugs and other drug ingredients manufactured in FDA-registered facilities to meet vital individual patient needs.
- All pharmacies and pharmacists are licensed and strictly regulated by state boards of pharmacy, which regularly update their standards. In almost every state in the country, a pharmacy that sends medications to patients or health care professionals in another state must also have a license there as well.
- It is not known how many pharmacies in the U.S. define themselves as compounding pharmacies because many pharmacies perform some degree of non-sterile compounding. For example, many pharmacies can take a medication in pill form and convert it into a liquid for a child, a very common compounding practice. There are far fewer sterile compounding pharmacies.
- One to three percent of prescriptions filled in the U.S. by community pharmacies are estimated to be for compounded medications. The percentage of compounds used in hospitals, especially those for intravenous therapy, is significantly greater. Physicians, veterinarians, dentists, and other health care professionals also compound medications.
- Compounders follow established [U.S. Pharmacopeia practice guidelines](#), USP chapter <795> (non-sterile preparations) and USP chapter <797> (sterile preparations), as well as requirements under Section 503(a) of the Federal Food, Drug and Cosmetic Act. Many compounding pharmacies obtain accreditation from organizations such as PCAB pharmacy compounding accreditation through the Accreditation Commission for Health Care.

NECC Tragedy

- Serious problems at the New England Compounding Center, a Framingham, Mass., company that's no longer in business, were responsible for 64 deaths and 750 illnesses from fungal meningitis in several states in late 2012. As determined by the

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Massachusetts Board of Pharmacy, NECC had exceeded its permit and engaged in manufacturing, preparing high volumes of sterile compounded products.

- Both the U.S. Food and Drug Administration [under Section 704(a) of the Food, Drug, and Cosmetic Act] and the Massachusetts Board of Pharmacy had clear authority to investigate and take action that would have stopped the operations at NECC, and both had been informed of problems there. Neither did.

Current Oversight

- The FDA is legally tasked with regulating drug manufacturers and appropriately holds such operations to [cGMPs](#), or current Good Manufacturing Practices, which are more far-reaching than USP <795> and <797>. Additionally, the FDA may inspect any pharmacy at any time to assure that the medications they have available for patients are being stored correctly.
- The U.S. Congress passed the Drug Quality and Security Act (DQSA), and President Obama signed it into law in November 2013.
- The DQSA created a new “outsourcing facilities” category for those facilities that produce large quantities of sterile medication that are not patient-specific prescriptions. Registration with the FDA is voluntary.

IACP Concerns

- Prior to the DQSA’s passage, the IACP worked cooperatively for months with legislative leaders and their staff in an attempt to reach a legislative solution that would address the problems that allowed NECC to occur while ensuring that compounding pharmacists could continue to serve the thousands of patients who depend on them.
- As reported widely in the news media, the FDA increased inspections of compounding pharmacies following the NECC outbreak and prior to the DQSA’s passage. However, the FDA in many cases inappropriately applied the more stringent cGMP standards – rather than USP <795> and <797> – that are applicable to drug manufacturers, not to compounders.
- The IACP believes that the implementation of the DQSA does not square with Congressional intent and will not prevent another NECC-like tragedy. In addition, the IACP believes some elements of the bill would restrict compounding pharmacists’ ability to serve patients and prescribers. For these reasons, IACP is leading an effort to make corrections to the DQSA law through work with other health care organizations and members of Congress.

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