

# Regulating Compounding Pharmacies: What Do Pharmacists Think?

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## Editor's Note:

*With the recent outbreak of fungal meningitis associated with a tainted steroid solution prepared by a firm that called itself a compounding center, compounding pharmacies have received a level of scrutiny not previously seen. To date, more than 500 cases of fungal meningitis have been attributed to solutions prepared by the New England Compounding Center (NECC). What is compounding? Compounding pharmacies are typically community-based establishments that date back hundreds of years. According to the [International Academy of Compounding Pharmacists \(IACP\)](#), compounding is a traditional part of pharmacy practice and involves the preparation of medications on prescription to meet unique patient healthcare needs that cannot be met with commercially manufactured and marketed drug products. This includes providing different strengths, preparing a drug with different nonactive excipients for a patient with an allergy, or creating dosage forms that are more palatable for a patient.<sup>[1]</sup> Compounding pharmacies and pharmacists work directly with prescribers to create customized medication solutions for patients in doses and formulations not directly manufactured by the pharmaceutical industry. Compounding pharmacies create personalized medication solutions and do so in response to a specific prescription.*

*Pharmacies, including compounding pharmacies, in the United States are regulated extensively by state boards of pharmacy, the US Food and Drug Administration (FDA), and the Drug Enforcement Administration. While NECC used the word "compounding" in its name and in descriptions of its services, based on information available to date, it appears that NECC was preparing bulk orders of solutions without proof of individual prescriptions and was shipping large batches of drugs nationwide. The strong evidence so far is that NECC was practicing outside of the scope of compounding pharmacies. "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."<sup>[2]</sup>*

*The Institute for Safe Medication Practices (ISMP) reports that this latest tragic set of events is one of over 200 adverse events involving 71 compounding pharmacies in the last 20 years.<sup>[3]</sup> Compounding has become increasingly common, partly in response to ongoing drug shortages. A 2011 survey found that two thirds of hospital pharmacies outsourced some portion of their sterile compounding for reasons ranging from cost savings to difficulty in meeting standards required for compounding.<sup>[4]</sup> Yet ISMP reports that this practice is fraught with potential hazards, including "unsafe staff behaviors, untrained and unskilled personnel, improper use of equipment, extended beyond use dating outside of manufacturer labeling without sufficient testing, and/or a lack of basic compounding skills" at the compounding facility.<sup>[3]</sup>*

*How should prescribers evaluate a compounding pharmacy? What is the most appropriate education for patients and families? Medscape spoke with David G. Miller, RPh, Executive Vice President and Chief Executive Officer at the IACP about these and other important clinical questions.*

**Medscape: Can you provide a "regulation 101" tutorial for prescribers? Who regulates compounding pharmacies, and how can a prescriber check on the accreditation status of a particular pharmacy?**

**Mr. Miller:** The answer depends on the state you are in because compounding pharmacies are regulated by state boards of pharmacy. Those boards have varying levels of rules and practices, and the boards also have different levels of enforcement and oversight policies. The FDA does not have primary responsibility for regulating compounding pharmacies, but it does have the right to inspect compounding pharmacies and has exercised that right in the past.

**Medscape: ISMP urges healthcare providers to use commercially available, ready-to-use, FDA-approved products from pharmaceutical manufacturers as often as possible. When these products are not available, the agency suggests that prescribers carefully assess and select a compounding pharmacy for medically necessary medications. How can prescribers evaluate a compounding pharmacy?**

**Mr. Miller:** IACP actually has a tool that prescribers can use to assess the quality of compounding pharmacies. Our [Compounding Pharmacy Assessment Questionnaire](#) provides for exhaustive screening of the capabilities and quality of any compounder.

**Medscape: Guidelines for selecting a compounding pharmacy are available from the American Society of Health-System Pharmacists. What is IACP's view of these guidelines? Are they useful?**

**Mr. Miller:** Any tool developed by a professional association in pharmacy can potentially have a benefit to prescribers and help assure a good fit between prescriber and pharmacy. We often collaborate with the other pharmacy associations.

**Medscape: What should prescribers tell patients about selecting a compounding pharmacy?**

**Mr. Miller:** Patients should have confidence in compounding pharmacies. They perform a high quality and vital service to patients in need. They should also look for an accredited pharmacy because it means that the pharmacy adheres to the highest standards in practice. The Pharmacy Compounding Accreditation Board is one such accreditation agency.

**Medscape: Are prescribers required to report concerns about a compounding pharmacy? If so, how should this reporting occur?**

**Mr. Miller:** State boards of pharmacy have primary oversight for compounding pharmacies, and that is where concerns should be directed.

**Medscape: Is MedWatch reporting appropriate to notify the FDA about concerns related to a specific pharmacy?**

**Mr. Miller:** If prescribers have concerns about the practices of any specific compounding pharmacy, they should immediately report it to the board of pharmacy in the state where that pharmacy is located.

**Medscape: A recent article in the [New York Times](#) accused IACP of obstructing FDA efforts to investigate compounding pharmacies. Can you speak to this accusation and the FDA's role in both advocating for your members and protecting the public?**

**Mr. Miller:** The *New York Times* article inaccurately stated that the IACP discouraged its members from cooperating with the FDA. On the contrary, the IACP encourages its members to help the FDA do its job. The memo that the *New York Times* cited clearly referred to situations where some people were posing as FDA officials and seeking to obtain drug samples.

**Medscape: Unlike commercial drug manufacturers, compounding pharmacies are not bound by the FDA's good manufacturing rules, which require companies to report instances when their medicine might have harmed patients. Do you envision changes in FDA regulation to address this concern? What would be the appropriate level of regulation?**

**Mr. Miller:** The IACP believes that state boards, which currently have responsibility for regulating compounding pharmacies, are the proper authorities to perform that role. There will be a full discussion, including at the congressional level, of what, if any, changes need to be made in federal and/or state laws, regulations, and enforcement levels in order to prevent a tragedy like this one. We will eagerly participate in that dialogue and will work closely with Congress. As pharmacists, we want the safest system possible.

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