

The art, science, and practice of pharmacy compounding

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Tragedy in the news focuses on compounding



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As we move into the new year, we leave behind a year in which compounding pharmacies/pharmacists became more scrutinized because of the tragic outcomes caused by fungal meningitis outbreak in multiple states that was traced back to tainted vials of methylprednisolone from a so-called compounding pharmacy in Massachusetts. These events have caused, and for good reason, concern for patients, health care providers, regulators, and legislators. Because the pharmacy called itself a compounding pharmacy, it did not have oversight from the Food and Drug Administration (FDA) even though it was mass producing sterile products and distributing across multiple state lines. This has caused the Institute for Safe Medication Practices (ISMP) to call for more oversight from FDA, state boards of pharmacy, and the Joint Commission for pharmacies that compound and to differentiate between practices that mass produce and those that provide compounded medications upon receipt of an individual patient's prescription.¹ As this story continues to unfold in 2013, pharmacists who compound may be witnessing more rules and regulations.

These tragic events brought to mind the Pharmacists' Oath and Code of Ethics. Perhaps it is an appropriate time for us to review these documents. ISMP summed it up

best when it said that all pharmacy staff have a moral and legal obligation to their patients and to adhere to the highest standards possible.¹

Evidence-based approach to compounding

As a co-owner of three community pharmacies and one compounding pharmacy, my partners and I follow an evidence-based practice approach to all of our practices. This means that we regularly look to the literature to find the best available clinical evidence to help us make our clinical decisions to improve the care of our patients. Although we often hear the term "the art of compounding," we also realize the importance of using our clinical skills, scientific knowledge, and understanding of the clinical evidence to ensure safe and effective

compounded medications for our patients. In fact, we have refused to make several compounded medications requested by patients and physicians because of weak or nonexistent evidence regarding the product. We review this information with clients so they can make good informed decisions. However, we also realize the positive impact we have had on patients when a dosage formulation is not commercially available and a patient has a unique need for a compounded medication.

We decided to pursue a compounding pharmacy practice because of the requests we were receiving from other providers, the gap that existed between what some patients needed and what was actually commercially available, and our desire to help our patients and community. As with any new clinical service that we develop and implement, we believe in policies, procedures, training, and documentation. We also understood the importance of creating a compounding area, purchasing the required equipment, and developing a documentation system. Needless to say, it was an



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expensive investment both in terms of time and money, but one that needed to be done if it was to be done correctly.

We made the decision to limit the scope of compounding in our practice to nonsterile compounded medications pursuant to a prescription, and we fully understand the limitations of our decision. By understanding our limitations, it keeps our practice focused in those areas that we have expertise and are able to manage effectively and efficiently. Ultimately, our goal is to provide quality products and services to our patients so that they can achieve their therapeutic goals.

Conclusion

As an individual, my thoughts and prayers go out to the victims and families affected by this tragedy. As a pharmacist, I am saddened and disappointed that this could happen in our modern health care system. The best that I can do is to learn from this and continue to improve my own practice—to ensure that my patients receive safe and effective medications. Compounding pharmacists who follow the rules play an important role in our health care system and provide products to which patients would not normally have access. This is a time for all pharmacists to remember our Oath and Code of Ethics. Serving our patients is a privilege, and we have an important responsibility to ensure that they achieve their therapeutic goals.

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Compounding's vital role in health care



Allen

Pharmacy compounding makes up the vast majority of the history of pharmacy and may very well play a prominent role in the future of pharmacy. Throughout several thousand years of history, the apothecary or pharmacist was the one in society possessing the skills and knowledge to prepare drugs from vegetable, animal, and mineral sources. With the industrial revolution, the shift occurred in the early 1900s to large-scale manufacturing of mass-produced drugs along with a one-size-fits-all approach. However, with fewer choices of dosage forms, dosage strengths, and less individualization of prescriptions, pharmacy compounding has again assumed a major role in health care. Let's look at the importance of compounding pharmacy today in *all* pharmacy practice sites:

- Health care today cannot exist without compounding pharmacy.
- Limited dosage forms are available from manufacturers.
- Limited strengths are available from manufacturers.
- Home health care requires individualized compounded medications.
- Hospice requires individualized compound medications.
- Nonavailable drug products/combinations are becoming more serious and often can be alleviated by compounding.
- Discontinued drugs are a problem as industry drops products that are not profitable.
- Drug shortages reached an all-time high in 2011; however, thanks to compounding pharmacists, thousands of lives were saved.

- Orphan drugs are commonly compounded.
- Veterinary medicine requires compounding due to the nature of the patient, drugs, and regulations. It involves small, large, herd, exotic, and companion animals.
- New therapeutic approaches often are available only through compounding.
- Special patient populations don't "fit the mold" for manufactured drug products.
- Pediatrics continues to require compounding as drug companies remain hesitant to produce a pediatric formulation for many drugs because of the small market size.
- Geriatrics often requires special formulations and dosages.
- Bioidentical hormone replacement therapy is largely provided through compounding pharmacists.
- Pain management is critical and special formulations are compounded.
- Dental patients and ophthalmologists often require compounding of special preparations.
- Dermatology patients routinely require compounding of special preparations.
- Environmentally sensitive and cosmetic-sensitive patients require compounded medications.
- Sports injuries often require individualized medications for specific needs.
- Nuclear/radiopharmacy is all about compounding.
- Hospital pharmacies compound intravenous admixtures.
- Hospital pharmacies compound parenteral nutrition solutions.
- Hospital/clinic pharmacies compound cancer chemotherapy cocktails.
- Compounding for investigational studies is increasing as many companies find it more advantageous to outsource this activity.

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