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# Explanation of Pharmaceutical Compounding and What to Look for in a Compounding Pharmacy

By Douglas Yoch, Pharm.D.

## WHAT IS PHARMACEUTICAL COMPOUNDING?

Pharmaceutical compounding is the art and science of preparing customized medications for patients. Its practice dates back to the origins of pharmacy; yet, compounding's presence in the pharmacy profession has changed over the years. In the 1930s and 1940s, approximately 60% of all medications were compounded. With the advent of drug manufacturing in the 1950s and '60s, compounding rapidly declined. The pharmacist's role as a preparer of medications quickly changed to that of a dispenser of manufactured dosage forms.

Within the last two decades though, compounding has experienced resurgence as modern technology, innovative techniques and research have allowed more pharmacists to customize medications to meet specific patient needs.

## WHY USE COMPOUNDED MEDICATIONS FOR YOUR PATIENTS?

Pharmaceutical compounding can enhance any physician's practice. You can improve patient compliance and outcomes by taking time to understand your patient's needs and then combine your skills with those of a compounding pharmacist to develop a pharmaceutical product that meets the specific needs of the patient.

Many patients are allergic to preservatives or dyes, or are sensitive to standard drug strengths. With a physician's consent, a compounding pharmacist can change the strength of a medication, alter its form to make it easier for the patient to ingest or add flavor to make it more palatable. The pharmacist also can prepare the medication using several unique delivery systems, such as a sublingual troche or lozenge, a lollipop, rapid dissolve tablet or a transdermal gel or cream that can be absorbed through the skin. For those patients who are having a hard time swallowing a capsule, a compounding pharmacist can make a liquid suspension instead.

Familiar medications may be used in novel combinations and administration routes. No longer are physicians limited to commercially available medicine. Now the physician and compounding pharmacist can come up with novel and potentially helpful pharmaceutical combinations and/or delivery methods.

## WHAT TO LOOK FOR IN COMPOUNDING PHARMACY?

Pharmaceutical compounding involves more than just the simple mixing. The pharmacist and all other compounding personnel should be specifically trained and knowledgeable in the art and science of compounding. The pharmacist needs to understand both the potential and limitations of each pharmaceutical to be used in a compound. They should also have the desire and ability to research chemical compatibility, stability, proper storage, etc.

The pharmacist's appropriate knowledge and experience base is only part of the requirements you should look for in a compounding pharmacy. The compounding pharmacy you choose should be committed to quality. Proper and documented "Standard Operations Procedures" (SOPs) should



be in place. SOPs should address all areas of the pharmacy's operations from the preparation of compounds, to the proper maintenance of equipment and facilities, to how the medication is dispensed.

Also consider the facility and equipment the pharmacist and staff will be using in compounding. There is more to modern compounding than just using a mortar and pestle. This modern equipment includes such items as an electronic balance, capsule machine, automated electronic mortar and pestle, v-blenders, ointment mill, autoclave, convection oven, incubator, pH meter, powder hood and other sophisticated equipment. In addition, equipment calibration and maintenance (along with a record of these activities) is a must. A compounding pharmacist, like a surgeon, is only as good as his tools allow him to be.

The compounding facility must also be properly designed and equipped. One example is a powder hood, which allows the manipulation of drug powders without exposing the compounding personnel to the powders, prevents the spread of the drug powders about the facility and prevents contamination of other compounded preparations. If sterile products are prepared by a compounding pharmacy, a properly designed clean room must be in place. The clean room must meet the strict and complex requirements of the United States Pharmacopeia (USP). USP clean room requirements include proper cleaning routines, personnel training, testing, grooming and gowning, and routine environmental monitoring.

A compounding pharmacy should also have a formalized quality assurance program in place. Examples of what should be included are:

- Written records of all facility and equipment calibration and maintenance
- Compounding formula recordkeeping
- In-house and third party testing of potency and sterility of compounded preparations

Proper patient counseling is another area you should be concerned with when selecting a compounding pharmacy. Ideally, the pharmacist who prepared the medication counsels the patient on a one-on-one basis. This will allow the patient to get instructed on the proper use, storage and potential side effects of the medication. Proper counseling will enhance patient compliance and outcomes.

In an effort to assist physicians and patients to identify qualified compounding pharmacies, the Pharmacy Compounding Accreditation Board (PCAB) was formed. PCAB is a not-for-profit voluntary accreditation body formed by several national pharmacy organizations to establish high-quality standards for compounding pharmacies. PCAB has just recently begun to accredit compounding pharmacies in late 2006. As of the publishing of this article, only three pharmacies in the United States have earned PCAB accreditation, but many more pharmacies have begun the application process. Hopefully, soon PCAB accredited compounding pharmacies will be as common as JCAHO accredited facilities.

Integrating compounded medications into one's practice is simple. It requires no special equipment, training or investment on the physician's part. A simple investment of time to better understand your patients' individual needs and a minimal amount of your time to develop a relationship with a compounding pharmacist is all that is needed. The investment of time will yield far greater dividends than you may expect. In fact, your local compounding pharmacist probably already has many compounded medication formulations specific to your specialty, which he can share with you now.

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