O'BRIEN PHARMACY

COMPOUNDING WITHOUT COMPROMISE SINCE 1962

COMPOUNDING

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FROM FOOD TO PHONES, and clothes to cars, people demand options. But when it comes to prescription medication, are there really that many choices? As a prescriber, how many options do you have when so many drugs overlap or are merely copies of another drug?

Drug companies are saddled with the unenviable and unrealistic expectation of supplying an antidote for every medical condition. The fact is, a drug company can only make the drugs that are patentable and/or will be used by large patient populations. In other words, profit determines what drugs will be available, and what drugs will not. While this certainly covers the majority of disease states, it also creates a colossal colander for millions of patients – individuals who fall through the holes of "drugs for the masses."

Where, then, can the physician turn when the drug most needed simply does not exist? A qualified compounding pharmacist can often literally save the day and sometimes help save the patient.

A 2003 study and editorial in the New England Journal of Medicine made clear the life-saving and cost-saving benefits of 17 alpha-hydroxyprogesterone in preterm delivery – a medication only available through a sterile-qualified compounding pharmacy.

Everyday hundreds of thousands of women take bio-identical hormone replacement therapy compounded by a pharmacist, and hospices across the country rely on compounding for patients unable to swallow or poorly controlled by commercial medications.

Fortified antibiotic and antifungal eye drops for infections resistant to conventional therapies are common in the compounding pharmacy.

When Wyeth discontinued Wydase®, thousands of ophthalmologists turned to sterile pharmacies for hyaluronidase used in cataract surgery.

Perhaps even more important is the consensual recognition by the FDA, practitioners and the drug industry of the need for "personalized medicine." This is medicine precisely formulated and dosed for an individual based on genetics, age, sex, weight, body surface area, biomarkers and other influences on blood levels, safety and effectiveness. Compounding pharmacists are uniquely qualified to deliver such individualized therapy.

Other reasons physicians rely on compounding include:

1. To reproduce safe and effective drugs that a manufacturer discontinues because of declining profits.
2. When drug shortages appear, often lasting months or years, compounding pharmacists can often make the medication.
3. To provide a well-known medication not available in the United States.
4. When adjustments need to be made in dosage form, concentration or preservatives.
5. To make a recently-published, cutting-edge therapy for a patient unresponsive to traditional treatments.

Many of today's commercial medications were first used as custom-compounded medications for individuals. Dihydroergotamine (DHE) nasal spray for migraines and 5-amino salicylic acid (5-ASA) enemas and suppositories for ulcerative colitis are two examples that improved the lives of countless patients. Others include prostaglandin injections for male impotence, budesonide for inhalation and oral natural progesterone. Such treatments have made valuable contributions to the physician's therapeutic resources.

Compounding is authorized by the boards of pharmacy in all 50 states, and practiced in all 50 states. It is

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taught in most schools of pharmacy, and for several institutions compounding is a curriculum spotlight. At the national level, the FDA affirms, "Such compounding of drugs is considered the practice of pharmacy/medicine."

Advances in equipment, materials and technique, coupled with improved standards and accreditation, have elevated this specialty of pharmacy out of the traditional setting and into a laboratory environment, in an exponential growth not unlike computers. In 2004, the United States Pharmacopeia greatly expanded and redefined the standards for compounding that now mirror manufacturing. The USP is the legally-recognized standard for all compounding and manufacturing.

Today's dedicated compounding pharmacy can be expected to have a laboratory equipped with a sterile barrier isolator or clean room, incubators, autoclaves, capsule machines, analytical balances, pH meters, software and procedures to document every temperature, weight and process. In addition, many focused compounders have a history of testing their medications for sterility, endotoxins and potency by independent laboratory analysis. This verifies that equipment, materials, procedures and personnel can prepare and dispense the medication exactly as requested and exactly as labeled.

Chemicals and other ingredients should come from FDA-inspected suppliers of pharmaceutical-grade materials. Many of these ingredients come from the same source used by the commercial drug companies. Compounding pharmacists must also consider factors of drug stability, compatibility, solubility, isotonicity, pH and preservatives for any given formulation.

But not all compounds are created equal. A phone call or visit to the lab can help determine a pharmacy's qualifications and commitment to compounding. Does a pharmacist or technician make the compounds? Other questions about equipment, special training, testing and quality assurance are legitimate and should be asked.

For centuries, pharmacists have made the medications prescribed by the physician. Nothing is new and different, except everything is new and different. From eye drops to IVs, and creams to capsules, today's compounding pharmacy provides individualized medications to meet the needs of the practitioner and the patient.