

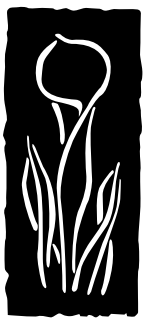
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1515 Oak Street
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RxTriad

VOLUME 13
NUMBER 3

RxTriad Compliments of



**Broadway
Apothecary**

Customized Prescriptions for Healthy Living

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Serving You and Your Patients: The Compounding Pharmacist

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⋮ **Pharmacy compounding involves the preparation, mixing, assembling, packaging, and labeling of a drug or device in accordance with a licensed practitioner's prescription or medication order.**

Pharmacy compounding now makes up an estimated 10% to 15% of prescribed drugs. This may seem like a large number, but one should consider that this number includes all intravenous admixtures, in-syringe admixtures, total parenteral solutions, cancer cocktails, cardioplegia solutions, pediatric liquids, geriatric formulations, pain management medications, infusion combinations, high-dose pain medications, ointments, creams, gels, other topicals and transdermals, dye-free/preservative-free/fragrance-free medications, etc. In fact, any modification of a U.S. Food and Drug Administration (FDA)-approved, commercially manufactured product is considered compounding.

Actually, the history of pharmacy (and to a certain extent, medicine) involves compounding, as this was the only way that medications were made available until the last of the 19th century and into the 20th century. With the industrial revolution, pharmacists began purchasing "ready-made" drug products instead of making them in their apothecary shops (pharmacies). The FDA was formally established in 1938 with the purpose of overlooking the pharmaceutical manufacturing industry and approving commercially manufactured new drugs. At that time, they also "grandfathered" in a lot of drugs (see Table 1). These drugs have never received FDA approval and are essentially "unapproved" drugs that have remained on the market. However, the FDA is now slowly requiring clinical studies for these unapproved drugs so they can become approved drugs if a company wishes to spend the money for the approval process.

Most prescription drugs on the market today are designed for adults; with only a few that are commercially manufactured for children, the elderly, etc. Let's look at some of the reasons why compounding is so important for you and your patients.

TABLE 1. EXAMPLES OF "PRE-1938" DRUGS THAT HAVE NOT BEEN APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION.

- Acetaminophen, codeine phosphate and caffeine capsules and tablets
- Codeine phosphate injection, oral solution and tablets
- Codeine sulfate tablets
- Digoxin elixir and tablets
- Ergonovine maleate injection and tablets
- Ergotamine tartrate tablets
- Hydrocodone bitartrate tablets
- Hydrocodone hydrochloride ophthalmic solution
- Oxycodone tablets
- Oxycodone hydrochloride oral solution
- Paregoric
- Phenobarbital capsules, elixir, and tablets
- Phenobarbital sodium injection
- Pilocarpine hydrochloride ophthalmic solution
- Potassium chloride oral solution
- Potassium gluconate elixir and tablets
- Potassium iodide oral solution
- Salsalate capsules
- Sodium fluoride oral solution and tablets
- Thyroid tablets

WHY DO WE NEED COMPOUNDING?

Table 2 provides a number of reasons for the need for compounded medications and their contribution to the growth of compounding. Most drug manufacturers only provide a solid oral dosage form and/or injectable when a new drug is introduced into the market, unless it is for topical/transdermal admin-

istration, etc. These limited dosage forms and strengths (one or two) cannot meet the needs of all patients and must be modified for some patients.

Caring for **home healthcare and hospice patients** has resulted in many innovative approaches to provide for patients' increased compliance, comfort, and quality of life. For example, if a terminal cancer patient cannot take a drug orally and the rectal route of administration is not preferred, then topical/transdermal formulations or solutions for inhalation can be compounded.

There have been numerous mergers in recent years of drug companies, and it is not unusual for them to discontinue the drugs that are not making enough money to keep them on the market. These **discontinued drugs** now number in the thousands of drug products that are no longer available due to economic issues—not safety or efficacy.

Drug shortages are becoming more common. Between 70% and 80% of active drug substances are now synthesized in either China or India. Consequently, since these drug substances are imported and must come through customs and the quality is not always what is required, shortages are becoming more common and compounding pharmacists can often bridge the gap until the product is back on the market.

New or unavailable therapeutic approaches and drugs require compounding pharmacists. If a patient is not responding to therapy that is available in the U.S., but there is a drug overseas or a drug is presented in the literature, in many cases, the compounding pharmacist can prepare the drug for your patient.

Finally, let's look at **special patient populations**. These are groups of patients that have unique needs that are often not met by commercially manufactured drugs. These

patient populations include those listed in Table 3.

CAN ALL PHARMACISTS COMPOUND?

Legally, all pharmacists can compound. Pharmacy compounding is a part of the “practice of pharmacy” and is covered by the individual State Board of Pharmacy laws and regulations. However, not all pharmacists do extensive compounding and may not be as “up-to-date” on the new methods, techniques, etc. Therefore, it is best to use pharmacists that routinely compound, as they will generally have better facilities, equipment, trained personnel, quality control procedures, etc.

WHAT QUALITY STANDARDS ARE USED BY PHARMACISTS WHO COMPOUND?

Pharmacy compounding, as mentioned above, is governed by the individual State Boards of Pharmacy **laws and regulations**. Pharmacy compounding **standards** are described in great detail in *United States Pharmacopeia (USP) Chapter <795>* for nonsterile compounding and *USP Chapter <797>* for sterile compounding. *USP Chapter <1163>* describes in detail the quality assurance standards that should be followed. The United States Pharmacopeial Convention has been setting official standards for drugs and drug products in the U.S. since 1906. Compounding pharmacists must meet the *USP* standards.

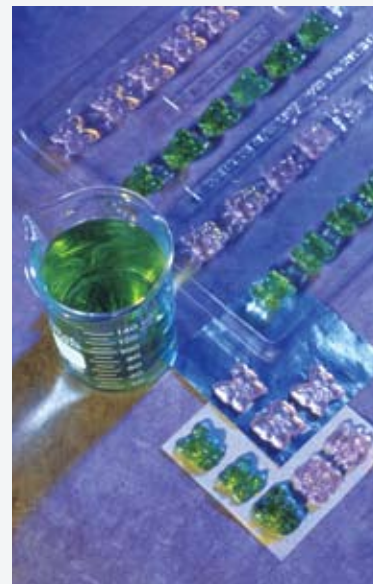
In addition some pharmacies obtain an accreditation in compounding by the Phar-

TABLE 2. REASONS FOR THE GROWTH OF PHARMACY COMPOUNDING.

- Discontinued drugs
- Drug shortages
- Home health care
- Hospice
- Limited dosage forms
- Limited strengths
- New or unavailable therapeutic approaches and needs
- Orphan drugs
- Special patient populations
- Unavailable drug products/combinations
- Veterinary compounding

TABLE 3. SPECIAL PATIENT POPULATIONS.

- Bioidentical hormone replacement therapy
- Dental
- Environmentally and cosmetic sensitive
- Geriatrics
- Pain management
- Pediatrics
- Sports injuries
- Veterinary compounding (small, large, herd, exotic, and companion animals)



macy Compounding Accreditation Board. This involves adherence to documented standard operating procedures, preparation testing, etc., and the accreditation must be renewed periodically.

WHAT IS AN “FDA-APPROVED” DRUG?

An FDA-approved drug is one that has gone through the FDA drug-approval process; a long and expensive process whereby a drug sponsor conducts the necessary studies, submits them to the FDA for evaluation, and, hopefully, receives approval.

Any drug that has not undergone this process is considered an “unapproved” drug. The pre-1938 drugs listed in Table 1 are unapproved drugs; compounded medications are unapproved drugs; any combination of approved drugs into a single prescription becomes an unapproved drug; any manipulation of an approved drug outside its official, FDA-approved labeling, renders a drug “unapproved.” If you mix two drugs together in your office, it becomes an “unapproved” drug. Currently, health care is dependent in large part on the use of unapproved drugs.

WHAT IS THE FUTURE OF COMPOUNDING?

The trend in health care is towards individualization of drug therapy. The fields of pharmacogenomics is gaining a foothold and prominence in pharmacotherapy. In the future, as drugs are “individualized” for patients, this need will be met by compounding pharmacists that are already involved in this practice. Pharmacotherapy will be more specific and physicians working hand-in-hand with compounding pharmacists will be at the forefront of health care.

EXAMPLE COMPOUNDED FORMULATIONS FOR SPECIFIC PATIENT NEEDS

- Rx**
Lorazepam Rapid-Dissolving Tablets
- Rx**
Fentanyl Citrate Gummy Gels
- Rx**
Vancomycin Oral Paste
- Rx**
Dental Anti-Gag Lollipops
- Rx**
Nystatin Popsicles
- Rx**
Testosterone 2-mg Troches
- Rx**
Testosterone Sublingual Drops
- Rx**
Promethazine Transdermal Pluronic Lecithin Organogel
- Rx**
Ceftazidime Ambulatory Pump Infusion Solution
- Rx**
Fentanyl Citrate Intrathecal Injection
- Rx**
Psoriasis Nail Treatment
- Rx**
Oral Inhalation Mini-Flow Devices
- Rx**
Fentanyl Nasal Spray-Gel for Pain