

# THE CASE FOR COMPOUNDED MEDICATIONS FOR OFFICE USE:

Why limitations on office use threaten the health and safety of men, women, children and pets



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June 12, 2013

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## SUMMARY

The prohibition of dispensing medication for office use, or the requirement that any pharmacy doing so must be regulated by FDA against manufacturer-like standards, is most likely the result of misunderstanding this much needed—and in many states explicitly permitted—healthcare practice.

Dispensing for office use is a pharmacy practice, regulated by state boards of pharmacy, in which a pharmacist receives an order from a licensed prescriber for a specified medication, and then dispenses that medication to that prescriber for use in treating their patients. The key component of this practice is the prescriber-pharmacist relationship that exists at the time the order is being placed. Under no circumstances is the pharmacist dispensing medication without that relationship with the prescriber who is directly involved in treating patients.

Without the pharmacist-prescriber relationship, it is manufacturing and/or wholesale distribution; and, as such, should be regulated by the FDA.

The New England Compounding Center (NECC), while it called itself a pharmacy and may have tried to explain its activities as “dispensing for office use,” was in reality distributing many of its medications without the pharmacist-prescriber relationship, and therefore was acting as a manufacturer/wholesaler.

Dispensing for office use is critical to effective patient care in many settings. While emergency-use preparations are most widely recognized, prescribers in many specialties rely on office use to effectively treat their patients.

## MATERNAL FETAL MEDICINE

17 alpha-hydroxyprogesterone caproate (17P) is commonly prescribed to reduce the risk of preterm delivery among women who are at particularly high risk for preterm delivery. 17P may be administered in a doctor’s office to avoid delays in treatment, to ensure patient compliance, to monitor injection site reactions and for those patients not comfortable with giving themselves an injection.

## UROLOGY

For men with erectile dysfunction, urologists may prescribe penile self-injection therapy. The compounded medications used for this therapy are a blend of ingredients customized for the individual patient. As part of the therapy, many urologists will “titrate” (i.e. determine the proper dosage for) their patients in the office to determine the customization appropriate for the patient. Instructing the patient how to self-administer the injection is critical to the patient’s confidence and ability to comply when at home.

Other commonly used compounded medications used in Urologists’ offices are Lidocaine urethral gel and solutions to treat Interstitial Cystitis.

## OPHTHALMOLOGISTS AND RETINA SPECIALISTS

Ophthalmologists require an inventory of compounded medications to treat eye-infections. Compounding pharmacies prepare a number of medications—anti-bacterial, anti-fungal, anti-viral solutions—that may be used to treat such infections in immediate if not emergent circumstances.

Ophthalmologists and retina specialists may use compounded mitomycin ophthalmic solutions prophylactically to increase success of ocular surgeries, including glaucoma, pterygium and corneal refractive surgery.

In the battle against wet macular degeneration (WMD), retina specialists keep an inventory of pre-filled syringes of bevacizumab (Avastin®) on hand when they deem appropriate. Compounding pharmacies provide the service of pre-filling dozens of syringes from a single vial of the medication, saving patients and Medicare billions of dollars annually. It is imperative that this medication be kept under the tight control of the physician's office to ensure that it remains refrigerated and in its sterile packaging.

Finally, compounded PHMB eye drops are the only treatment option for certain types of amoeba infections.

## ADDICTION MEDICINE

There is no more critical aspect of treating an addict than immediate access to therapy. When a person addicted to drugs or alcohol makes the decision to walk through the door of a treatment facility, he or she needs to begin treatment right away. If patients are sent away without having begun therapy, chances are they won't return.

There are a variety of compounded medications that physicians may use in treating addiction, including naltrexone and disulfiram. Compounded naloxone injections are commonly used to reverse an overdose.

Easing an addict's withdrawal symptoms is also very important and doctors need to have this medication readily available to ensure their patients do not suffer unnecessarily. Buprenorphine HCl (Buprenex®) injection manufacturers often have this product listed as backordered with the FDA. When on backorder, compounding pharmacies are filling the void.

## DERMATOLOGY

Compounded benzocaine/lidocaine/tetracaine (BLT) cream, glycolic peels and neutralizers are necessary in the dermatology office but it makes no sense to put these preparations in the hands of patients as they can be damaging or even life-threatening if used improperly.

## DENTISTRY

It is very common for dentists to have compounded medications that are local anesthetics customized to their unique practice needs.

## AUTISM

For physicians treating children with autism, compounded glutathione is used for IV infusion. Additionally, physicians must train parents how to give B12 shots to their children.

## GENERAL PRACTICE AND PEDIATRICS

The first dose of Promethazine gel must be administered in a physician's office so that the parents can learn how to give injections safely to young children.

## EAR, NOSE & THROAT SPECIALISTS

These medical specialist frequently use compounded anesthetics, usual for minor surgeries involving the nasal cavity.

## PAIN MANAGEMENT

For severe and chronic pain, intrathecal pump are implanted in patients to deliver very small quantities of compounded medications directly to a patient's spinal fluid. Medications are delivered in this manner to minimize the side effects often associated with the higher dosages commonly found in oral medications of the same type.

## COMPOUNDED MEDICATIONS FOR EMERGENCY USE IN HUMANS

The list below exemplifies the critical need for office use and dispensing for emergency use. Often, these medications were commercially available and have either been discontinued or are on backorder, requiring compounding pharmacies to fill the void.

- Acetylcysteine – acetaminophen overdose
- Atropine injection – bradycardia/organophosphate poisoning
- Diazepam injection (and other benzodiazepines) – seizures
- Dopamine injection – shock/hypotension
- Epinephrine injection – anaphylaxis/shock
- Furosemide injection – congestive heart failure
- Lidocaine injection – arrhythmias
- Magnesium sulfate injection – arrhythmias/ecclampsia
- Naloxone/naltrexone injection – opioid overdose
- Sodium bicarbonate – metabolic acidosis
- Verapamil injection – arrhythmias

## COMPOUNDED PREPARATIONS TOO DANGEROUS TO DISPENSE TO PATIENTS

- Benzalkonium chloride – disinfectant
- Cantharidin – wart removal
- Glycolic acid preparations – dermatologic conditions
- Lactic acid/resorcinol/salicylic acid – dermatologic conditions
- Podophyllin – wart removal
- Silver nitrate – cauterizing agent
- Squaric acid – wart removal
- Trichloroacetic acid – wart removal

## COMPOUNDED PREPARATIONS AND DOSAGE FORMS THAT REQUIRE A PHYSICIAN TO ADMINISTER

- Glycerin 74% injection – sclerosing agent
- Non-steroidal anti-inflammatory drug (NSAID), acetic acid, and corticosteroid Phonophoresis and iontophoresis gels – pain

## VETERINARY MEDICINE

Veterinary medicine, and how it is practiced, is not the same as human medicine. Practices are called clinics and hospitals because they offer a full range of services, from routine examinations to emergency surgeries. Much as in a human hospital, veterinarians perform medical procedures all day long, which necessitate keeping medications in stock in order to perform those procedures, some of which are not planned in advance. In addition, some veterinarians need the ability to keep medications in trucks to take to their patient, whether it at a farm, stable or zoo, because some animals are not easily moved into a clinic or hospital environment for treatment.

Having the ability to treat a sick patient immediately can speed the healing process, reduce discomfort, or, in an emergency, save a life. Explaining to pet owners of a dog or that they cannot start treatment of an antibiotic to treat their infection for 1-3 days because the medication must be prescribed, compounded by hand, then delivered while their pet continues to suffer is not good medicine.

At the most, a delay in treatment could mean the death of a beloved pet. Apomorphine is a drug that is used to treat poisoned patients. It is administered to pets in a clinic to induce vomiting to rid the body of a poisoning. It simply is not practical *not* to have the

medication in stock in veterinary hospitals when it is needed by the patient. Delaying for even an hour could cause the death of the patient.

## COMPOUNDED MEDICATIONS FOR EMERGENCY USE IN ANIMALS

- Acepromazine capsules – sedation
- Aminopentamide tablets/injection – anti-diarrheal
- Apomorphine conjunctival sac tablets & injection – emetic for poisoning situations
- Atropine injection – adjunct to anesthesia & bradycardia & shock
- Barium sulfate suspension – diagnostic
- Buprenorphine – pain
- Cabergoline capsules – abortifacient
- Calcium chloride – hypocalcemia, cardiac arrest
- Calcium gluconate – hypocalcemia
- Calcium glycerophosphate/calcium lactate injection – hypocalcemia
- Corticotrophin – diagnostic agent
- Dexamethasone – allergic reactions
- Dextrose injection – hypoglycemia
- Diazepam – anti-epileptic
- Diethylstilbestrol – incontinence
- Diphenhydramine – allergic reactions
- Dipyrone injection – fever
- Dobutamine injection – shock
- Doxapram injection – anesthetic
- Epinephrine – anaphylaxis
- Etomidate injection – anesthetic
- Furosemide – congestive heart failure
- Guaifenesin – sedation
- Heparin – anticoagulant
- Lidocaine – arrhythmias
- Mannitol injection – congestive heart failure
- Medetomidine – anesthetic
- Meloxicam injection – pain
- Metronidazole tablets, suspension – anti-diarrheal
- Natamycin ophthalmic – ophthalmic fungal infections
- Pentobarbital injection – anesthesia
- Phenobarbital injection – in conjunction with diazepam during an active seizure event
- PZI insulin – hyperglycemia

- Reserpine injection – sedation
- Vitamin K – poisoning
- Xylazine injection – anesthetic
- Yohimbine – anesthetic reversal agent

## SURVEY OF VETERINARIANS – MAY 2013

In a survey of veterinarians in May of 2013, verbatim responses spoke to the critical need of compounded medications in an office setting. For the complete survey and all responses, please visit <http://mymedsmatter.com/veterinarian-survey>.

- Why must our patients wait to receive effective treatment? With office stock of compounded medications I can often resolve symptoms and cure disease before a special order can be received and dispensed to the client - wouldn't you want that for yourself, why not our patients, too.
- Some patients/cases need the medicine ASAP and could suffer from the delay it takes to get the medicine compounded. Many clients run out of a medicine AND THEN come to the office. Having to then compound it means the patient misses a dose or two.
- Having office stock increases owner compliance and in turn the well-being of the animals.
- Without an office stock of compounded medications, patients' health would suffer and be at risk due to unavailability of immediate access of necessary medications. For certain situations, any delay or change in treatment that would be caused by not having medication on hand could even be life threatening.
- As a veterinarian, it is critically important that compounded medications are available and in-stock in office & on our ambulatory vehicles in order to begin immediate treatment. In-stock access to compounded medication is a vital component in mitigating the disease process; without the ability to have compounded medications in-stock, our patients would suffer unnecessary pain and potentially disabling or fatal outcomes if there was a delay in the availability of compounded medicine. To state it clearly - Our ability to practice veterinary medicine in the best interest of the animal and client is fundamentally compromised when we are limited in our ability to keep compounded medications in-stock.
- Many times office stock of certain medications means the animal can start treatment when necessary, not have to wait until shipments arrive, which could be several days depending.

- Owners appreciate having the medication on hand to treat a sick pet immediately. We can give the first dose in the office to start care immediately.
- There are many occasions where the quality of care to our patients would be dramatically compromised if we do not have the ability to have in-stock compounded medications immediately available for our patients. Not to mention the financial impact it would have on our practice & the pet owner if we had to order each time a patient needed a medication rather than taking from our office stock.