# Supplement



# PHARMACY COMPOUNDING

## DO YOU KNOW THE FACTS WHEN IT COMES TO PHARMACY COMPOUNDING?

Pharmacy compounding is when a pharmacist makes a customized medication for a patient. Unlike commercial drug manufacturing, compounding takes place right there in the pharmacy. The pharmacist uses bulk ingredients that they purchase from a variety of places and combine them according to a recipe written by a physician, or someone else licensed to prescribe medication.

Some doctors or pharmacists choose to compound medications if their patients have a unique medical need that can't be treated with a commercially available drug. For example, if a patient has an allergy to a filler or a dye that is used in pill manufacturing, or because they cannot tolerate a particular form of a medication (they need a topical cream instead of an oral formulation for some reason). Sometimes pharmacists compound medications for children that cannot swallow large pills, or that simply won't take a bad-tasting medication.

Compounding has an important place in health care, however there are some risks that athletes need to be aware of when considering whether to use a compounded medication.

- Compounded formulations are not FDA-approved. Athletes may end up using ineffective treatments for conditions than can be treated with a proven commercial medication.
- Some compounding pharmacies may create unsafe mixtures of ingredients.
  This may occur when two drugs are compounded that are not supposed to be
  used together, or when a drug is mixed with a dietary supplement ingredient
  causing dangerous side effects or drug-drug (or drug-supplement)
  interactions.
- Compounded pharmacies may inadvertently purchase contaminated or low quality raw ingredients.
- Compounded drugs are more prone to human error than commercially manufactured drugs sometimes resulting in sub-potent, super-potent, or completely different medications than what was intended. Patients may end up using ineffective or toxic doses of their medications, or a different medication altogether!
- Some compounding pharmacies don't have good quality control processes in place, and contaminate their products with bacteria. Some of the most serious adverse events (blindness and death) that were recently investigated by the FDA were due to bacterial contamination of compounded medicines.

#### DID YOU KNOW?

Compounded medications are not FDAapproved. Some pharmacies will claim that their compounded medications are safer or more effective than commercially available FDA-approved drugs. The FDA considers such claims "false and misleading" because compounded medicines have not been proven to be safe or effective in high quality clinical trials.



## DID YOU KNOW?

Some compounding pharmacies prepare testosterone creams and ointments that contain a much higher dosage of testosterone than the dosages recommended by the American Endocrine Society. Any athlete that needs to use Testosterone (or any other prohibited substance) in sport must apply for a Therapeutic Use Exemption. If your TUE is approved, USADAs Therapeutic Use Exemption Committee will require the use of a commercially manufactured preparation of testosterone, and will not approve a compounded formulation unless there is a compelling reason why. Of particular concern is the lack of ability to monitor dosages appropriately with compounded preparations. To learn more, visit the TUE page on USADA.org.

- The compounding pharmacy may not use the appropriate equipment, or may not properly clean equipment between making products. If they compound medications with testosterone (or stimulants, glucocorticosteroids, diuretics or other prohibited substances) they may inadvertently contaminate a medication that an athlete purchases causing the athlete to test positive.
- Unlike commercial drug manufacturers, pharmacies aren't required to notify the FDA of serious adverse events (when someone gets really sick or injured from a compounded medication). If a compounding pharmacy is distributing medications that are substandard or contaminated and making people ill, there is no detection or warning system in place that will notify the public or protect athletes.

# WHAT IF I AM PRESCIBED A COMPOUNDED MEDICINE?

If you are prescribed a compounded medication there are many things that you can do to protect yourself from unsafe or contaminated products:

- If your doctor wants to prescribe a compounded medication for you, ask them why, and ask if a commercially prepared FDA-approved drug is available and appropriate for your treatment.
- If you arrive at your pharmacy and learn that they are preparing a compounded medication for you, ask if the doctor specifically requested that the medicine be compounded. Some pharmacies compound many medications regardless if there is commercially manufactured one available.
- If your medication really does need to be compounded, ask the pharmacist if he or she is familiar with compounding the product in your prescription. Ask who, exactly, will be compounding the product. Sometimes a licensed pharmacist will delegate the compounding to a lesser trained assistant that may not be as careful as you would like. Also, ask for a copy of the formulation sheet that the pharmacist used to make your product.
- Ask about the quality-control processes, and explain that you are an athlete subject to drug-testing. Let the pharmacist know that even slight contamination with a prohibited substance could result in a positive drug test. Bring a copy of the Prohibited List and ask the pharmacist if they compound with any substances in the categories on the List. If they do, ask them to explain to you how they will ensure that your medication won't be contaminated with any of those substances. If you are not convinced by the answer, or are still unsure, then find a different pharmacy or consider using a commercially manufactured medication instead.
- If you experience any problems or adverse events, contact your doctor or pharmacist immediately and stop using the product. Report any adverse events experienced while using the product to the FDA Medwatch Program http://www.fda.gov/Safety/MedWatch/default.htm

Ultimately you will need to work with your health care providers to determine if compounded medications are right for you. Learn more about compounding by visiting www.fda.gov and typing "pharmacy compounding" into the search field, or visit http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107836.htm.

