

# Peter Koshland, PharmD

- Georgetown graduate Chemistry major, Math Minor 1996
- University of California San Francisco PharmD graduate, 2000
- Founder, pharmacist, CEO of Koshland Pharm: Custom Compounding Pharmacy, 2009
- Adjunct Clinical Professor of Pharmacy, UCSF School of Pharmacy, 2010 to present
- Invited speaker to doctors' groups since 2009 on topic of HRT
  - California Naturopathic Doctors' Association
  - PCCA's HRT Symposium
  - Grand Rounds One Medical Group

# Formulations

- Determining purity, quality, and pharmacokinetics of compounded products
  - Pharmacist and pharmacy responsibility
    - Pharmacokinetics at point of formulation - evidence-based determination based on studies
    - Purity – determined by API certificates of analysis and skip lot testing of 10% of daily volume of finished products
    - Quality – determined by procedures followed in making of each product
- Cost estimate
  - Depends on dosage form and how many drugs combined
  - Average 3-month supply \$130-\$170
- Insurance coverage
  - 90% of patients pay out of pocket
  - Compounded medications are often excluded from patient's pharmacy benefits
  - We provide universal claim form for those with insurances that can't be billed through our two contracted PBM's
  - Patients can use FSA/HSA accounts for payment

# Bioavailability testing

- Pharmacists review studies for general understanding of bioavailability of hormones
  - Highly dependent on route of administration
- Doctor-patient-pharmacist relationship used to monitor patients individually
  - We expect doctors to test patients in follow-up to therapy
  - We offer guidance to doctors about the bioavailability of different hormone replacement options as it pertains to proper and safe dosing

# Adverse Events

- Current systems to support reporting of adverse events
  - Doctor-patient-pharmacist relationship
  - We provide written guidance with all prescriptions on how to report adverse reactions to the FDA and to ACHC/PCAB
- Actions we take
  - Document internally
  - State requirement to document any dispensing error
  - Notify doctor if patient has not already done so
  - Plan next steps with patient and doctor for patient health

# Adverse Events: reporting instructions with compounded products

**Call your doctor for medical advice  
about side effects. You may report side  
effects to FDA at 1-800-FDA-1088**

This customized prescription medication was made specifically for you at the request of your doctor. For this reason, no standardized information or literature is available for your prescription.

**Please make sure you have discussed with your doctor:**

- (1) *Why you have been prescribed this customized medicine.*
- (2) *How to properly take this medicine.*
- (3) *How this medicine may interact with any other medicines you are taking.*
- (4) *Any allergies or other medical conditions that you may have.*

Additionally, please call your prescriber if you experience any side effects. Our staff at Koshland Pharm: Custom Compounding Pharmacy sincerely cares about your well-being. Our pharmacists are available to answer any questions you may have about your medication at (415) 344-0600.

**Please call us if:**

- (1) *Information on the medication label is not clear to you.*
- (2) *You have concerns regarding precautions, ingredients or proper storage of your medication.*
- (3) *You have any other questions or concerns about your customized medication.*

Should you have a concern that you don't feel we adequately addressed, you may report complaints about the safety or quality of your customized medication to the Accreditation Commission for Healthcare (ACHC), the organization through which Koshland Pharm is accredited, at (855) 937-2242.

# Consumer Education

- Actions
  - Extensive consultation for patients
    - When Rx comes in before patient has started medication
    - After medication has been dispensed
  - One-on-one training with doctors when requested
  - Pharmacists available by phone during business hours for ongoing consultation with doctors and patients
- Educational materials
  - Importance of quality in compounding hand-out on website for patients
  - Importance of quality in compounding hand-out sent by mail to all new doctors
  - Product specific hand-outs for certain drugs
    - i.e. testosterone

# Consumer Education: Quality Hand- out Side 1

## Koshland Pharm Custom Compounding Pharmacy

301 Folsom St., Suite B, San Francisco, CA 94105  
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### How to Evaluate A Compounding Pharmacy



(Negative Pressure Room, Koshland Pharm 2018)

Not all compounding pharmacies are the same. Quality differences among compounding pharmacies can come as a surprise to consumers. For a commercially available product, the drug is the same regardless of which pharmacy it comes from. This is not the case with a compounded medication, whose quality depends on the specific procedures used by the compounding pharmacy where it is made. It is important to ask a compounding pharmacy **6 questions to assess its commitment to quality.**

#### 1. **Where does the pharmacy source its chemicals?**

A compounding pharmacy should source the highest quality chemicals from reputable FDA-approved suppliers. **Koshland Pharm sources its active ingredients only from vendors who test and verify every chemical. Every chemical's certificate of analysis is reviewed by a pharmacist before being used and is readily retrievable and available.**

#### 2. **What kind of equipment is used?**

Not all pharmacies use the same equipment. If a topical dosage form is being made, the pharmacy should use specialized machines, such as ointment mills and electric mortar and pestles (homogenizers). An ointment mill pulverizes the active ingredients, making them micro-sized and thereby improving penetration through the skin. A homogenizer mixes the cream at a high speed so that each teaspoonful has the same amount of active ingredient. **Koshland Pharm uses the most advanced technology in the compounding industry, such as ointment mills and homogenizers for creams and acoustic resonant mixers for the dry ingredients that fill capsules.**

#### 3. **What in-house procedures does the pharmacy follow to ensure quality?**

Compounding pharmacies must have numerous procedures in place to ensure quality. Pharmacies should also have a rigorous *Continuing Quality*

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# Consumer Education: Testosterone Patient Hand-out



## Drug Information Sheet – Testosterone Supplementation

### **I) Before you start therapy, tell your doctor if you have any of the following conditions:**

- History of stroke, heart attack, or acute coronary syndrome
- History or diagnosis of prostate cancer
- History or diagnosis of breast cancer
- Heart failure
- Liver dysfunction
- Kidney dysfunction
- Severe or uncontrolled sleep apnea
- Enlarged prostate

### **II) Protect friends and family from exposure to testosterone:**

- Avoid skin-to-skin contact with other people and pets where testosterone has been applied as well as secondary items such as sheets, towels, and laundry. If such contact does occur, wash the area well with soap and water right away.
- If you expect to have skin-to-skin contact with another person, first wash the application area well.
- **Safe Application.**
  - Do not allow others to apply testosterone to your body.
  - Apply testosterone to areas that will be covered by a short sleeve shirt (eg shoulders, upper arms, abdomen) and wash your hands after application.
  - Wait 2 hours before showering or swimming to ensure that the full dose of testosterone is absorbed.

### **III) Possible side effects of topical testosterone include:**

- Acne
- Skin irritation where testosterone is applied
- Adverse changes in cholesterol levels
- Increased red blood cell count (increased risk of clotting)
- Worsening of symptoms from enlarged prostate
- Hypoglycemia
- Aggressive behavior or changes in mood
- Enlarged or tender breasts
- Lower sperm count and testicular atrophy at high doses

### **The following are serious side effects and require immediate medical attention:**

- Blood clots in the legs or lungs.
  - Signs and symptoms of a blood clot in your leg include pain, swelling, warmth and redness.
  - Signs and symptoms of a blood clot in your lungs include difficulty breathing or chest pain.
- Possible increased risk of heart attack or stroke
  - Signs and symptoms of heart attack include chest pain, shortness of breath, and radiating arm pain.
  - Signs and symptoms of stroke included severe headache, slurred speech, and weakness on one side of the body
- Excessive urination or urinary retention
- Severe allergic reaction indicated by swelling of the face/lips/throat, severe rash, difficulty breathing

### **IV) Drug Interactions**

- Insulin – testosterone may increase the blood sugar lowering effects of insulin and other diabetes medications
- Corticosteroids – testosterone may increase fluid retention
- Blood thinners – testosterone can enhance the effects of blood thinning medications

## Concerns and Recommendations

- Since NECC tragedy in 2011, regulations of compounding industry have become very stringent, especially in CA
  - i.e. NIOSH room requirement for compounding of hormones
  - Many compounding pharmacies in CA now no longer compounding hormones for this reason
- Many compounding pharmacies are in alignment with the FDA's purpose of ensuring patient safety
- A partnership model will be much more effective than a punitive model with pharmacies who have demonstrated a willingness to focus on quality (i.e. through voluntary accreditation with ACHC)
- Compounding pharmacies should be engaging in thorough quality assurance processes, including sending out a number of finished products for end-product testing commensurate to their daily Rx volume
- 503a compounding pharmacies great strength is their doctor-patient-pharmacist relationship

# Professional Education

- Every prescriber can benefit from having a relationship with a compounding pharmacy committed to quality
- Add compounding training to pharmacy and medical education curriculum
  - Opportunity to create successful collaboration between doctors and pharmacists in outpatient setting
- Actions my pharmacists and I take to stay up-to-date:
  - Attend yearly trainings at least on best practices in compounding and specifically in HRT compounding
    - Subsidized by pharmacy
  - Read current literature, i.e. Journal of Pharm. Compounding
  - Quarterly off-site with pharmacists focused on clinical compounding education
  - Ongoing sharing of information among practitioners