

Sterile Medications Issue

updates from koshland pharm

Sterile Lab Up and Running

We are pleased to announce that our sterile services are now open at Koshland Pharm. This means that we are able to make medications for injection, inhalation, and ophthalmic administration. In the following article, Dr. Cantwell discusses one medication, glutathione, which is sometimes administered in an injectable or inhalation form.

In our sterile lab, Koshland Pharm is carefully developing certain formulations with "method suitability testing," which allows us to perform in-house sterility tests. This allows us to ensure the highest quality testing possible.

The current formulations we have developed include:

- Methylcobalamine (B12) injections
- Glutathione injections
- Glutathione inhalation therapies
- Tri-mix

As always, we are able to accept customized orders for any needed medication. For sterile orders, if it is not on our formulation list, please allow extra time for off-site sterility testing.

We are currently developing formulations for the following medications:

- HCG injections
- Testosterone for IM and SQ injections
- Magnesium sulfate

Prescriptions for Health

Koshland Pharmacy Custom Compounding Pharmacy

featured **PRACTITIONER**

At **Koshland Pharm**, we have the unique opportunity to meet doctors in different fields who have useful approaches to health and healing. In our **Prescriptions for Health** newsletter, we share highlights from interviews with doctors about their practices and their experiences prescribing compounded medications. If you'd like to read more about practitioners whom we have met and seen excel in patient care, see **koshlandpharm.com/referrals**.



Michael Cantwell, MD, MPH is board certified in pediatrics and sees both adults and children in the complementary/alternative medicine practice Rising Phoenix Integrative Medicine Center in San Francisco.

Practice Approach

I believe a doctor needs to be a three dimensional diagnostician - looking at the body, mind, and spirit. It's important to be fluent in those three areas. A doctor might treat some of those areas himself or refer out for others.

When it comes to the body, I look at issues such as the liver's detoxification system. Some of what alternative medicine does is to see beyond the normal ways of looking at the body. Detoxification is something that is studied in conventional medicine but is often forgotten. The body's detoxification system determines whether a person gets toxin-mediated inflammation, which probably contributes to many cases of affective disorders like anxiety, depression, and bipolar disease, and even possibly to diseases such as autism, Parkinson's and Alzheimer's. So detoxification can be very helpful to look at.

When it comes to the mind, there are different psychological systems of how we progress and develop our personalities, and there are subconscious factors as well. I do a lot of subconscious work in my practice, such as hypnotherapy and guided imagery, because it's often an area that is neglected. I also send people out for regular therapy.

Then there's the spiritual part. I've written a book, Map of the Spirit, that discusses how transitions in spirituality affect health. It gives people a clear way of making that calculation. It includes all religions, including existentialism, and puts them on a level playing field. There's a lot of spiritual disease in our society, and to not be able to treat that would mean I couldn't really live with myself.

Compounding Success Story

I prescribe glutathione for many of my patients in various forms – oral forms that are mass-manufactured, and creams, suppositories, injections, and IV drips

more about

RISING PHOENIX INTEGRATIVE MEDICINE CENTER

Described by Helen Ye, MS, LAc, acupuncturist and executive director at Rising Phoenix Integrative Medicine Center:

For me, the vision has always been to create a center where we figure out together, as like-minded practitioners, how we can create integrative medicine together. It sounds easy and trendy to work collaboratively, but practicing integrative medicine well is not an easy endeavor.

It is very much a relationship the way we work at Rising Phoenix. This clinic is a blend of people, of mature clinicians, all of whom have their own independent practices. We want to not only provide the best in patient care and outcomes, but also to extend our own comfort zones, both in our professional and clinical capacities. We are willing to hear feedback, which may not always be easy, whether in an operational kind of way or in a more clinical way. By working together, we get to share knowledge and be a sounding board for each other, asking, "What do you think of that?" to really tease out things we may not be seeing, or things we could be further seeing.

Some patients start with one clinician at our clinic or see multiple practitioners concurrently or over time. There is usually one lead person, one primary cook if you will, who helps facilitate communication and comradery.

A term that one of our clinicians has coined is "cornerlapping," which is the place where one clinician might meet another clinician's work. It's not a duplication, but there's an understanding of how we can work together as a team, where we might push each other's comfort zones, but in a very loving way, for professional and personal growth for ourselves, and also for patient care and for improving clinical outcomes.

featured PRACTITIONER

(continued)



that are compounded. As more toxins are put in the environment (such as organophosphates and parabens), more optimal function of the body's detoxification system is required. This increase in environmental toxins can unmask places genetically where we might have weaknesses.

Through both blood tests and genetic tests, you can get a really good idea if there are deficits in the liver's detoxification system. In the first stage of detoxification, the liver is trying to put hydroxyl groups on everything it needs to get rid of. It then needs to substitute another group for the hydroxyl group in order to put it through the bile. The two main groups that can be substituted for the hydroxyl group are a methyl group and a glutathione group. The liver's ability to make methyl and glutathione groups are the main variables in whether a person gets toxin-mediated inflammation.

I've had many successes prescribing glutathione when patients have defects of glutathione synthesis. I had one patient with poor immune function who had symptoms including rashes, nerve pain, herpes, and low energy level symptoms which would come and go. With glutathione 500mg suppositories from Koshland Pharm, my patient's symptoms went away and his quality of life greatly improved.

Current Inspirations

I found that working within the insurance system as a holistic doctor is very difficult. Insurance really wants to reimburse doctors to treat bodies. In the insurance system, if you're not treating a body, it's not reimbursable. If you're a psychiatrist, you can bill as a psychiatrist, but you're still treating the body as a biochemical mechanism and giving medication. Also, there is no Medicare billing for more than forty minutes. That's the most you're ever supposed to spend with people. I was finding forty minutes to be way too cramped. I was losing the part that really mattered to me, which was the spiritual connection.

At Rising Phoenix Integrative Medicine Center, we set up a place that was off insurance. I keep my overhead down and pass that saving on to patients, so I can charge a reasonable hourly rate. They can then submit the bills directly to their insurance and get half of it back.

I enjoy my work at Rising Phoenix because patients really come first. It's an old school place where pretty much if it needs to get done for a patient, we'll find a way to do it. In a corporate environment, many times it's easier to say "no," but here there's no one to say that.

Now I think I'm ready for my next book. It's about the four things you need to have a joyful life. The first is to know the limits of your control – know what's under your control, what's out of your control, and what's mixed. The second is to have a theory of why that control exists, which relates to my book, *Map of the Spirit*. The third is to have a purpose, and the fourth is to carry out that purpose. Nobody ever tells you it's that simple, but that's it. That's really all you need to know.

To read more about Dr. Cantwell and Rising Phoenix Integrative Medicine Center, see:

risingphoenixmedicine.com

To read a synopsis of Map of the Spirit, see: koshlandpharm.com/books



why sterile compounding?

Peter Koshland, head pharmacist at and founder of Koshland Pharm, wanted Koshland Pharm to be a fullservice compounding pharmacy that could make sterile medications just as it did non-sterile medications, with a focus on quality and positive patient outcomes.

Peter implemented Koshland's sterile lab at a time when new federal and state legislation was being passed to more strictly regulate compounding pharmacies. He has put quality and safety first in all steps of this process. This has meant turning to the pharmaceutical industry for much of his training, for this is the industry with the most experience in sterile procedures.

Peter also brought much of the testing (including sterility and endotoxin testing) inside the pharmacy in order to have control over the quality of testing procedures. In order to do this kind of testing, he and Sterile Compounding Technician Stephen O'Neill are carefully conducting method suitability development, which ensures that the procedures are sound and cannot produce false negative results.

The other main quality assurance priority Peter has focused on throughout the implementation of sterile services has been to develop procedures for staff training and monitoring and for facility maintenance and monitoring that comply with every guideline laid out by the United States Pharmacopeia (USP <797>). The lab is also in compliance with every requirement of the California State Board of Pharmacy, whose regulations are some of the strictest in the country.

Peter encourages doctors to tour Koshland Pharm's facility or that of any compounding pharmacy they are ordering sterile medications from. His "How to Evaluate Quality in a Compounding Pharmacy Making Sterile Medications" hand-out provides detailed questions that are important to ask of any pharmacy entrusted with this important task.

To read more, see: koshlandpharm.com/sterilequality



ask the PHARMACISTS



Why does my medication typically take a day to be ready and sometimes longer?

There are several factors that can affect how quickly each medication is made. These factors include:

[1] Number of orders ahead of prescription

The number of prescriptions we receive on any given day is one factor we can't always predict as a pharmacy. We do our best to catch up when we are especially busy by taking measures such as bringing our staff in on weekends to make medications.

[2] Dosage form of medication

Capsules, for example, are one of the most timeconsuming medications to make. Each capsule is hand-packed, and a random capsule weight check is performed on each finished batch to ensure each capsule holds the proper amount.

[3] The availability of ingredients

We stock the active ingredients of the medications we most often make; sometimes, however, a customized medication is prescribed with an active ingredient that we need to order before making.

[4] <u>Communication needed between doctor,</u> <u>pharmacist, and patient</u>

Because each medication is formulated specifically for an individual patient, sometimes the prescribing doctor and pharmacist need to talk to clarify or adjust an order. This can make the process take a little bit longer. Also, because each prescription is made from scratch and by hand, we only begin the process after both receiving the prescription (or refill authorization) from the doctor and also verifying with the patient that we should go ahead with the order.

It always helps us to have as much advance notice as possible when filling a customized prescription. We greatly appreciate any advance planning that is possible, especially for refills. We also encourage patients to choose our expedited, trackable shipping option if they are going out of town and needing the medication on an exact date.

Need to order a refill? Use our secure online form at koshlandpharm.com/refills or give us a call at 415.344.0600.

Koshland

Pharm makes prescription medications tailored to a patient's specific needs. For example, a patient who experiences toxinmediated inflammation might benefit from the antioxidant glutathione in a customized dosage form. To address this and other kinds of specialized needs, Koshland Pharm makes highquality, customized prescriptions and works closely with patients and their doctors to ensure optimal treatment outcomes.

did you KNOW...

.....that you can order customized prescription refills online on our secure website? Check it out at :

koshlandpharm.com/refills





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how to evaluate a pharmacy MAKING STERILE MEDICATIONS

Medications that are dispensed in certain dosage forms - injections, inhalation therapies, and eye dropsmust be made with labor-intensive procedures and within a facility that is maintained and monitored in a very specific way. These sterile medications enter parts of the body such as the bloodstream and eyes that are vulnerable to infection and therefore must be carefully protected from any kind of contamination, visible or invisible.

In the compounding industry, the gold standard of guidelines to follow for sterile compounding come from Chapter 797 (USP <797>) of the United States Pharmacopeia, an organization which sets guidelines for medication safety in the U.S. and around the world. Quality is always important in compounded medications to ensure successful patient outcomes. When it comes to sterile medications, the stakes are even higher. Here are four key questions to ask a compounding pharmacy to ensure the quality of their sterile medications:

Four Key Questions:

- 1. What is your overall quality assurance program? Is your pharmacy in compliance with EVERY requirement outlined in the USP <797> and by the CA State Board of Pharmacy?
- 2. How is your staff trained and monitored? May I see your standard operating procedures for staff training and monitoring?
- 3. How do you maintain and monitor your sterile facility and equipment? May I see your standard operating procedures for facility maintenance and monitoring?
- 4. How do you test your finished products? Will you provide sterility test results on every sterile medication you dispense?

For further tips, see: koshlandpharm.com/sterilequality

This newsletter is intended as a source of general information about health and healing. Because every patient and health condition is unique, it is important to always consult your doctor for medical advice to determine if a particular treatment is right for you.