

COMPOUNDED HORSE MEDICATIONS: LEGAL AND ETHICAL ISSUES

TheHorse.com: Welcome to the webinar! We'll be starting the live Q&A in just a few minutes.

TheHorse.com: Hello everyone, and welcome to our Webinar, Compounded Medications for Horses: Legal/Ethical Issues! We'd like to introduce tonight's presenter, Scott Stanley, PhD, Professor of Equine Analytical Chemistry at the University of California, Davis, School of Veterinary Medicine. Dr. Stanley will be answering your questions during this live event along with John Tuttle, DVM, Equine Technical Manager at Boehringer Ingelheim Vetmedica. We'd also like to offer thanks to sponsor Boehringer-Ingelheim Vetmedica for bringing you this free event. Visit them online at <http://bi-vetmedica.com>.

TheHorse.com: If you have questions on this topic, type them in below! All questions will be moderated, so if you don't see your questions right away, just hang in there. If you need immediate assistance, please e-mail us at THWebinars@TheHorse.com.

Comment From Debbie: Please comment on compounded Omeprazole for ulcers in horses and how do we know if lab that prepared it made it with effective doses (in individual packets)?

Scott Stanley: The best practice is always to use the FDA approved formulation because the quality control and potency are supported by the original pharma company.

Compounding omeprazole is illegal practice as the sole patent is owned by Merial LTD, therefore, the best choice is to use the gastroGard or UlcerGard products.

Comment From Jeffrey Berk: To broaden the discussion from compounded products to unapproved products in general, there seem to be an increasing number of unapproved products masquerading as post-surgical joint lavage "devices". Clearly, these products are never used as post-surgical joint lavages, but are used IV and IA. Would you comment on the legality of "extralabel" use of unapproved products?

Dr. John Tuttle: With the use of any product in an extralabel fashion, ie: not labeled for the intended purpose, the Veterinarian assumes all liability for the use of that product in that fashion.

TheHorse.com: Kate: Which medications are most often compounded?

Scott Stanley: The "claimed" medical devices used either IV or IA therapeutics are very problematic. They are, in fact, not "extralabeled usage" simply because they are not actually approved by the FDA so they can't be used outside of the label claim.

Dr. John Tuttle: At the current time, pergolide mesylate (treatment for PPID/Cushings Dz) is probably the most commonly compounded product.

Comment From Karen Briggs: Here in Canada, we occasionally have trouble obtaining meds which, for one reason or another, are no longer allowed across the border. A recent example is Thyro-L, which I

use for my IR pony. If we are forced to switch to a compounded product, how can we best ensure we are buying something safe and with similar levels of active ingredient?

Scott Stanley: Ask lots of questions of the compounding pharmacy to establish a relationship and find out who does the compounding and whetheionship.relatr they will compound already approved FDA products, If they won't they have established some guidelines from which you can expand your trust.

Comment From Barbara: Tell me about products for ulcer use in horses. Gastrogard/Ulcergard are very expensive products. What else can a horse owner use which is effective.

Dr. John Tuttle: Gastroguard and Ulcerguard are FDA-approved products for the treatment of ulcers. With that approval comes proof of efficacy and safety. While there are other anecdotal reports of products which claim to decrease the incidence of ulcers, there is little to no research to back the claim up. I would recommend you discuss alternative treatment options with your veterinarian.

Comment From Jeffrey Berk: So therefore, when a company representative cites "extralabel" use for a product that is not FDA-approved (like Polyglycan), that type of usage is illegal and can increase legal exposure for the veterinarian using the product in an unlabeled fashion.

Scott Stanley: Yes

Comment From brenda zoppo: If compounded omeprazole is done illegally , how can they get away with it?

Scott Stanley: FDA does not have the resources to shut down ever illegal compounding operation, however this does not make them a wise or ethical choice,

Dr. John Tuttle: Unfortunately there are not available resources to adequately police illegal compounding of an FDA-approved product. Whenever possible, always use an FDA-approved product indicated for that use. You are assured safety, efficacy, as well as company support.

Comment From Jeannie: What examples can you give of drugs that a vet wouls have to have compounded?

Scott Stanley: Pergolide Mesylate still need to be copounded for the time being.

Comment From Jeffrey Berk: PCAB (the Pharmacy Compounding Accreditation Board) is an organization which functions as a form of quality control with regard to compounded medications. Why does PCAB condone the use of bulk product in the formulation of compounded drugs?

Comment From Jeannie: What else?

Scott Stanley: Drugs no longer commercially available, Drugs not available on animal health market, Reformulate drugs into suitable dosage forms

Comment From Francesca: What should we look for in compounded antibiotic formulations, for cost related issues (long term therapy, for example) or for flavoring? thank you

Dr. John Tuttle: Antibiotic formulations should only be compounded from FDA-approved products. Whenever the presentation of the product is changed, you cannot be be assured adequate delivery to your horse. Therefore you should only rely on compounded formulations whenever no other presentation is available for the indicated use of your horse.

Scott Stanley: Bulk drugs compounding typically means they use chemical grade and not pharmaceutical grade raw materials. In addition, the FDA believes this is manufacturing a new drug without their approval.

Comment From Shari Godano: So you are saying it is ok to compound pergolide just because it is not available? Even though you are suggesting it is not stable?

Dr. John Tuttle: At the current time, compounded pergolide is the only available product. The powdered or capsule form of the product appears to be more stable than the liquid based on stability data.

TheHorse.com: We've got some great questions coming in! Give us just a minute to type in the answers. :)

Comment From Jeffrey Berk: Approximately how many different compounded products do you think an equine veterinarian would need in order to practice quality veterinary medicine?

Scott Stanley: There isn't any right answer but my guess would be variable from 5-7 different products maximum for any equine practitioner.

Comment From Guest: My (20yr) horse has Cushings, we are in the Caribbean. She is on Pergolide which I purchase from a compounding lab in Florida...she did not respond very well to liquid but the powder has given her a real turn around (she looks great, lab tests not available down here)...should I be concerned about my supplier? How do I know if supplier is reputable or not? Jane in Antigua

Dr. John Tuttle: Only speculating with your horse, but the stability of the liquid form of pergolide has been shown to be less than the powder or capsule form. I would stick with the powder form. I would consult with your veterinarian with regards to the reputation of the compounding pharmacy. There are certain questions that he/she can ask, which can be found on the AAEP website (aaep.org) under compounding.

Comment From Jeannie: If a drug is not available in the animal health market, does that mean it is not safe in animals? Why would I want to use something that is not appropriate for my animal?

Scott Stanley: The drug may have been withdrawn because of a complication with the human market/product which does not affect the animals being treated.

Comment From Jeannie: Sounds like take home message is don't use compounded drugs!

Scott Stanley: The use of compounded products need to be more closely considered than when using an FDA approved products.

Comment From Bobbi: my horse had been on isoxsuprine tablets for almost a year. However, recently, my vet had difficulty getting the tablets and now I am using a compounded power. Any comments on isoxsuprine in general? Thanks!

Dr. John Tuttle: As long as isoxsuprine is compounded from an FDA-approved source, you should be OK

Comment From Jeanne: How did that pharmacy manage to stay in business (that contributed to the death of the polo ponies)?

Scott Stanley: The compounding pharmacy responsible was shut down temporarily.

Comment From Jeannie: How does any of this affect nutritional supplements of any kind? Is there regulation on nutritional supplements being compounded?

Dr. John Tuttle: Nutritional supplements that do not make a specific medical claim are not regulated by the FDA/CVM

TheHorse.com: This Webinar will be archived for later viewing, along with a transcript from this chat on TheHorse.com.

TheHorse.com: For more information on equine medications and compounding, see more than 450 articles plus free reports and videos in our Medications category: www.thehorse.com/TopicSearch/Default.aspx?n=medications&nID=1&ID=1.

TheHorse.com: We hope you enjoyed the presentation! We'll stick around for a few more minutes to take any more questions you might have.

Comment From Lori: Is Acetyl-D Glucosamine safe to give to my young horse to help with his hocks?

TheHorse.com: Lori: I was told that that the acetyl d glucosamine is compounded and my vet said studies have been positive with its use

Dr. John Tuttle: With compounded products, very rarely, if ever, will you have safety and efficacy data, as compared to FDA-approved products. I am unaware of the studies supporting this.

TheHorse.com: We'd like to offer a special thanks to Drs. Stanley and Tuttle for taking the time to address this topic and answer your questions. And of course thanks to this event's sponsor, Boehringer-Ingelheim Vetmedica, for bringing you this free event. Visit them online at <http://bi-vetmedica.com>.

Comment From Jeannie: But it's not approved by the FDA

Dr. John Tuttle: That is correct.

Comment From Shari: Aren't certain states allowed to have compounded meds for "office use"?

Scott Stanley: "Office use" means they can keep a portion on hand but not that they can compound anything they want.

TheHorse.com: Hi Jeannie! Supplements and medications have two different regulatory situations; here is some information on supplement regulation: I was told that that the acetyl d glucosamine is compounded and my vet said studies have been positive with its use.

Comment From Jeanne: I have little choice but to use compounded pergolide (capsules) for my Cushings horses. The pharmacy I get it from is recommended by my vet, but how do I really know I'm getting what is labeled - is there any on-line resource "grading" compounding pharmacies?

Scott Stanley: The best way is to monitor the horses progress and track with the drug response and always make sure to replace the product frequently (don't order large quantities).

Comment From James: why can't compounders use bulk chemicals for horses? they are allowed to use bulk chemicals for humans, right?

Dr. John Tuttle: Whenever there is an FDA-approved product available, compounded products should be manufactured from the parent product. In only rare circumstances will FDA/CVM allow regulatory discretion with regards to the use of bulk product. An example is pergolide.

Comment From Shari: Thank you!

TheHorse.com: We hope you've enjoyed tonight's webinar! We'll be wrapping up in just a moment if no one else has a question.

Comment From Jacquelin: How do these people get away with putting these compounded meds on the market? Why are they not fined and/or put in jail?

Scott Stanley: The compounders are not violating any criminal laws so they won't go to jail at worst they will be shut down and have their product taken by the FDA.

TheHorse.com: Supplement regulation information: <http://www.thehorse.com/ViewArticle.aspx?ID=3398>.

Comment From Francesca: thank you. Good webinar

TheHorse.com: Thank you Francesca! We're glad you enjoyed it. :)

Comment From Jacquelin: I fail to understand how pergolide is supposed to help Cushing's horses in the first place. It is not used for humans any longer.

Dr. John Tuttle: Pergolide was used in the treatment in humans for Parkinsons dz. it no longer marketed in the US for this purposes. While the mode of action is similar in both horses and humans, the end results, with regards to hormonal regulation is quite different. It still is considered the treatment of choice for PPID in horses.

Comment From mindy: in the omeprazole paste graph, one pharmacy actually exceeded the manufactured product. What about that?

Scott Stanley: The same product rapidly deteriorated which may explain why the compounder choose to use more than the labeled dosage.

TheHorse.com: That's all the time we have for today's Webinar. Thanks for joining us! If you have suggestions for future topics or any feedback for us, please email us at THWebinars@TheHorse.com. Don't forget, this Webinar will be archived for later viewing, along with a transcript from this chat, at www.TheHorse.com/Video.aspx?vID=521.

TheHorse.com: Hope everyone has a good night!