Pharmaceutical use in the treatment of horses

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Horses are legally prescribed numerous medications (by veterinarians) that were originally intended for humans. Veterinarians, as licensed medical professionals, have the authority to prescribe human medicines to companion animals when veterinary drugs are not available. This greatly enhances the rather limited number of drugs developed for companion animals. This practice has sometimes been called "off label" prescribing. Because of the wide spread use of off label prescribing for horses the normal USDA testing protocols for illegal drugs (in meat producing animals) are not adequate. If all drugs from human pharmacology (and their tissue metabolites) commonly used for the treatment of horses were to be tested for and traced as tissue residues, the Center for Veterinary Medicine, Food and Drug Administration (CVM, FDA) and USDA would be have to spend a tremendous amount of time and resources to establish protocols and analysis.

"Wherever drugs are used to treat sick animals or prevent disease, there is a potential that residues may be incurred. The US Food and Drug Administration (USFDA), which must approve all drugs meant to be marketed for use in animals, establishes tolerances for drug residues (similar to speed limits) to insure food safety. The USFDA also establishes "withdrawal times" or "withholding periods" which are times after drug treatment when milk and eggs are not to be used for food, and during which animals are not to be slaughtered. This allows time to the animals to eliminate the drug residues." From the FARDA (a congressionally-mandated risk-management program that is supported by the United States Department of Agriculture) <u>http://www.farad.org/</u>

Restricted and Prohibited Drugs in Food Animals

"Under provisions of the American Medicinal Drug Use Clarification Act (AMDUCA) and <u>21 CFR part 530</u>, FDA can prohibit extra-label use of approved animal or human drugs or prohibit use of an entire class of drugs in selected animal species if FDA determines that: (I) an acceptable analytical method needs to be established and such a method has not or cannot be established; or (II) the extra-label use of the drug or drug class presents a public health risk. FDA can also limit the prohibition on extra-label use to specific species, indications, dosage forms, routes of administration, or a combination of these. In addition to the following lists, it should be noted that regulations related to the Pasteurized Milk Ordinance (PMO) prohibit the presence of dimethyl sulfoxide (DMSO) or colloidal silver on dairy farms. "

Pergolide myslate (generic) Prescend ®

Below is an example of a drug from human medicine that has been commonly prescribed by veterinarians for use in horses suffering from the common disease PPID (pars pituitary intermedia dysfunction) a.k.a. Cushings. The author is familiar with and prescribed this drug for many years from a compounding pharmacy. The drug has a long list of side effects and has been taken off the market for human use in the USA.

"Pergolid myslate **Pergolide** (trade name **Permax**) is an <u>ergoline</u>-based <u>dopamine</u> <u>receptor agonist</u> used in some countries for the <u>treatment</u> of <u>Parkinson's disease</u>. Parkinson's disease is associated with low levels of the <u>neurotransmitter dopamine</u> in the brain. Pergolide has some of the same effects as dopamine in the body. In 2007, pergolide was withdrawn from the U.S. market for human use, after several published studies revealed a link between the drug and increased rates of valvular dysfunction.[11] However, a veterinary form of Pergolide (trade name **Prascend**) is allowed to treat <u>Equine Cushing's Syndrome</u> (ECS) in horses.^[1] (Wikipedia)€"

Less than 2 years ago pergolide was extensively researched and approved as a medicine for horses labeled Prascend®, the testing included living horses, no drug residue testing appears to have been performed. It clearly states on the drug label, not to be used in horses intended for human consumption. The research did not include any withdrawal times. Boehringer Ingelheim Vetmedica, Inc

In a list of 118 drugs commonly used in horses and either labeled "not for use in horses intended for human consumption" or of unknown consequences has been compiled by an animal welfare association, pergolide was not on this list.

The drug approval process for medications intended for food animals.

Although FDA scientist do computer based statistical analysis on drug residues and metabolism, the main expense/initial expense of testing is done by the pharmaceutical company promoting the drug.

Excerpts are included from a typical study sponsored by a pharmaceutical company and carried out at a university to determine actual tissue residue levels and withdrawal periods for the particular drug intended for use in food animals. These studies are expensive and time consuming and required to assure public safety. Pharmaceutical companies probably would not perform these studies to insure that horse

meat were safe for human consumption.

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"A tissue residue study was conducted to determine the residues of estradiol and the two metabolites of trenbolone acetate (17 α -hydroxytrenbolone (17 α -TBA) and 17 β -hydroxytrenbolone (17 β -TBA)).

This residue analysis was conducted by Dr. Donald Henricks, Clemson University, Clemson, SC (Study #97U-040).

Three (3) steers and three (3) heifers were treated with 200 mg trenbolone acetate ... and one (1) control heifer in the study. All animals were sacrificed 60 days after implantation. Muscle, liver, kidney and fat samples were collected from each animal at the time of sacrifice. After collection, samples were immediately frozen in dry ice and held frozen until they were assayed for estradiol,17

Excerpt from NADA study - Freedom Of Information Act

Other considerations regarding drug use in horses:

Horse Owner Survey Shows NSAID Use Trends (2009)

In a recent survey, 96% of respondents said they used nonsteroidal anti-inflammatory drugs (NSAIDs) to control the joint pain and inflammation in horses, and 82% administer them without always consulting their veterinarian. More than 1,400 horse owners and trainers were surveyed to better understand attitudes toward NSAIDs, in a project sponsored by Merial, the maker of Equioxx (firocoxib). http://www.thehorse.com/ViewArticle.aspx?ID=14073

Also in light of the article from the Irish Veterinary Journal regarding phenylbutazone prescribing , the question arises could the prescribing DVM be held responsible for determining withdrawal times in horses when using these common "off label" drugs? According to FDA/FARDA regulations when using off label drugs in which withdrawal times have not been determined the livestock producer should consult with the veterinarian.