

Antibiotics: New Rule, Use and Vet-Client-Patient Relationship

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Disclosure

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- This project was made possible, in part, by a Cooperative Agreement from the USDA's Animal and Plant Health Inspection Service (APHIS). It may not necessarily express APHIS' views.
- I am a Veterinarian in Private Practice. I am not an employee of ASI or USDA.
- I work with Sheep Producers daily. I am actively involved in antibiotic use on farms and understand my role as a Veterinarian.

Why does anyone care what happens on your farm/ranch?

- Is it really their business?
- You obviously care. You treat animals to preserve life, profit, business interest and out of a stewardship obligation of taking care of the animal.
- The public cares. The public expects you to treat the animal with dignity, provide feed and water and appropriate animals care including treatment of sick animals.
- The USDA cares. APHIS is mandated by the public to control spread of animal diseases. They cannot do this without the support of producers.

FDA Guidance for Industry #263

- Published on June 11, 2021
- Removing Medically Important Antibiotics from OTC (over the counter) marketing channels
- 2-year timeline for implementation
- Essentially requiring medication manufacturers to voluntarily move these antibiotics to prescription (Rx) status
 - “Caution: Federal law restricts this drug to use by or on the order of a licensed Veterinarian”
- Deadline is June 11, 2023

What antibiotics are currently OTC

- Penicillin
 - Injectable
 - Intramammary Tubes
- Oxytetracycline
 - Injectable
 - Boluses
- Sulfa
 - Injectable
 - Boluses

What antibiotics are currently OTC

- Tylosin
 - Injectable
- Cepharin
 - Intramammary Tubes
- Lincomycin
 - Injectable
- Gentamicin
 - Oral
- Spectinomycin
 - Oral

How did we get here?

- Pre 1940 the only antibiotic that was used in animals was Sulfa
 - There were other treatments for infections that historically are not considered antibiotics and are not used today.
- In 1950's – 60's penicillin began to be used in animals.
- In the 1970's the FDA began requiring manufacturers to seek label approval from the FDA for animal treatment products.
- At this time an over-the-counter approval was allowed for antibiotics which:
 - Had a wide margin of safety
 - Were not dangerous to handle (no human risk of accidental injection)
 - Did not pose a significant human health residue risk

Things began to change in the 1980's

- Widespread antibiotic resistance became recognized
- The public became aware of the use of antibiotics in food animals
- Speculation of the use of antibiotics in food animals ***causing*** resistance and thus threatening human health.
- FDA began to be pressured by the public

The 1990's

- The FDA required new animal antibiotics to be approved as prescription drugs (Rx).
- Previously approved OTC drugs were grandfathered in.
- Mounting pressure from the medical community and public about antibiotic stewardship in food animals.

2000 to current

- All new animal drug approvals are Rx or VFD
- OTC class becomes an undefendable problem for the public and FDA
- FDA is called upon by the public to only allow antibiotic use under the supervision of a medical professional (Veterinarian)
- Follows the trend in Europe, just 20-30 years behind
- Pressure is from the public, not from the Veterinary Community, antibiotic manufacturers or food animal producers.

Today

- The public supports prudent and appropriate antibiotic treatment of sick animals for the **welfare** of the animal, not for **profit**.
- The public expects that this treatment is under the direction and knowledge of a medical professional (Veterinarian).
- The public is aware of the extensive use of antibiotics in food animals.
- There is a perception that antibiotics will not be necessary if the animals are kept in smaller operations with better environment, better housing, better nutrition and better care.
- There is a perception that antibiotics are used in large operations because the environment and care are so bad the animals are sick and it is the only way to keep them alive.

Today

- Consumers will pay more for meat that comes from animals that were never treated with antibiotics.
- Consumers will pay more for meat from animals that were not kept in confinement.
- Consumers will pay more for meat and milk from animals that were grown on an “organic” farm.

Posilac (r BST)

- Bovine somatotropin (growth hormone)
- Approved around 1998 to increase milk production in dairy cattle.
- Non-antibiotic with no detectable difference in milk.
- Was not pulled off the market by the FDA.
- Marketing companies “convinced” consumers that milk that was from non-treated cows was better, safer and more healthy.
- Market pressure caused entire processing industry to not take milk from farms that used rBST.
- Is still approved in the U.S. Sales in the U.S. are zero.

What exactly will change as of June 11, 2023

- Penicillin, sulfa, mastitis tubes, etc will not be available at farm stores
 - The only way that a farm store can sell these products is to fill a prescription from a Veterinarian. In order to fill a prescription, you need to be a pharmacist.
- Sales from Veterinary Clinics and Veterinary distributors will not change
 - Veterinary distributors already are filling prescriptions with a licensed pharmacist on staff.
 - Veterinary Clinics can fill prescriptions from Veterinarians that are working for them as well as Veterinarians from other clinics.

What is required for a Veterinarian to be able to write a Rx?

- VCPR (Veterinarian-Client-Patient Relationship)
 - The Veterinarian assumes the role of making Veterinary Medical decisions for the patient/farm. The owner agrees to follow the Veterinarian's instructions.
 - The Veterinarian has knowledge of the animals and/or the farm such that he/she can make at least a preliminary diagnosis and an acceptable treatment plan.
 - The Veterinarian is available for follow-up in case of an adverse medical reaction or a treatment failure.
 - The Veterinarian is licensed in the state which the animals are located.

VCPR

- The burden is on the Veterinarian. It relies on his/her judgement
- Flexibility is intentional
 - However, it is generally accepted that in order to fulfill a VCPR the Veterinarian should visit the farm at least once annually or more frequent if necessary.
- Vague – again intentional
 - It relies on the ethical beliefs of the Veterinary Community to uphold the standards.
 - It is up to the Veterinarian to defend to his/her peers, the public and licensing boards.

The case of New Alta Dairy

- A chronic, poor doer heifer was delivered to the Pipestone Sale Barn, with New Alta Dairy as the owner.
- Heifer had violative residue from Gentamicin.
- Owner was contacted and immediately called his Veterinarian because he has never had a bottle of Gentamicin on his dairy.
- Veterinarian traced back the animal with the residue through sale barn records and determined it was a heifer from a custom heifer grower.
- Upon investigation it was determined that the heifer was treated by a Veterinarian from a different clinic with Gentamicin.

The case of New Alta Dairy

- The heifer was presented for sale by New Alta Dairy
- When presented for sale you are guaranteeing that it is free of violative residues. You cannot blame it on the herdsman, your kid, your spouse, your neighbor. The owner is responsible.
- First offense is your name on a public record that is searchable
- Repeated offense – Felony for contaminating the US Food Supply

The case of Bruce Novak

- Bruce sold fed cattle at Pipestone Livestock Auction Market.
- Cattle went to slaughter and one steer has a violative residue for penicillin.
- Upon the visit from the MN Department of Agriculture, Bruce could not produce any treatment records. There was record of purchasing the bottle of penicillin from my clinic.
- Who dropped the ball?

The case of Bruce Novak

- My clinic did not fulfill a valid VCPR. We instructed a treatment dose that exceeded the label dose but did not recommend an extended slaughter withdrawal, nor did we insist on treatment records and animal identification. If I am unsure that my instructions will be followed, I am bound by Veterinary Code of Ethics to refuse to write the prescription.
- Bruce did not have treatment records or ID processes in place to guarantee that an animal with a violative residue did not enter the food chain.

How good is the testing for antibiotic residues?

- Slaughter tolerances are in the order of parts per million. For example: If there are 10 people at this webinar and there are 5 million people in Minnesota the amount of Minnesota people at my talk is 2 parts per million.
- Antibiotic testing can currently be detected on the order of Parts Per ***Billion*** (ppb).
- For example, if there are 80 people at this webinar and there are 8 billion people in the world then the amount of people in the world that came to the webinar is 10 ppb.

The future...according to me

- Both Veterinarians and Producers are and will be held accountable for antibiotic use in animals.
- We answer to the consumers who choose to eat our product.
- They expect it to be raised in a safe and wholesome manner.
- Rules are in place to keep us safe and prevent us from doing something stupid.
- Follow the rules!

The case of K.C. Dairy

- A slaughter cow that was sold at Pipestone Livestock Auction Market was delivered to a cull cow plant in Wisconsin and had violative residues for Sulfa
- K.C. Dairy was implicated based off a plastic purple 71 ear tag
- K.C. Dairy had both electronic and written treatment records along with 2 forms of USDA tamperproof official ID.
- K.C. Dairy cows were backtagged with an USDA official slaughter back tag at PLAM

USDA Official Animal ID

- Vital for animal disease tracing and control by the USDA – APHIS
- Can be used as support of ownership – Identifies that you are the owner at the time of tag application
- Supports transfer of ownership to others at a define time
- With complete written or electronic treatment records can be used to defend practices on your farm.
- Official tags must be acquired through a USDA official vendor
- <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-disease-information/sheep-and-goat-health/scrapie-tags/id>

USDA Official Identification

- Tag with USDA Shield
- Unlawful to Remove
- May be RFID with 840 prefix
- Recorded at the time of application/issue



The Case of K.C. Dairy

- Upon inspection of the Dairy and at the request of the attending Veterinarian the inspector reported to the FDA that there was zero chance of the dairy being responsible for the violative residue.
- FDA sent a formal apology to K.C. Dairy for accusing them of the residue violation.
- The burden of proof is on the producer.
- Records and Identification matter.
- Official USDA tamperproof identification is important.
- Do what is expected and don't be afraid to show the world that you follow the rules.



Jack

- 12 years ago Jack was born.
- At 24 hours old Jack had an elevated White Blood Cell count and a fever suggestive of a bacterial infection.
- Blood Cultures were negative.
- Jack was admitted to Neonatal ICU.
- Antibiotics were started based on the fever and elevated WBC.
- Which Antibiotic?

Jack

- Antibiotic choice was determined based on the culture and sensitivity of patients of the neonatal ICU for the previous 12 months.
- Jack was treated with Gentamicin and potassium penicillin which combined are broad spectrum and synergistic with very little documented resistance to the combination in the hospital where Jack was admitted to ICU.
- Gentamicin has been used in humans since the 1970's and as an OTC drug in animals since the 1980's.
- Penicillin has been used as an OTC drug in animals since 1950's.
- Neonatal Doctors, Nurses and parents of neonatal patients all would consider Penicillin and Gentamicin as ***Medically Important Antibiotics***.

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