Federal laws/regulations pertaining to the use of veterinary prescription products in food-producing animals

- Food Drug and Cosmetic Act of 1938 (as amended)
  - veterinary prescription products may be used “by or on the order of a licensed veterinarian”
Veterinary prescription drug use

- veterinarians are “licensed” to practice veterinary medicine on a state-by-state basis
- be sure your veterinarian is licensed in your state of residence
Veterinary prescription drug use

- AMDUCA (animal medicinal drug use clarification act of 1994 [as amended])
- defined:
  - extra-label drug use (ELDU)
  - VCPR (veterinarian - client - patient relationship)
Extra-label drug use

- any use that is NOT in accordance with the approved label use, such as:
  - in a different species
  - for a different purpose
  - at a different dose, frequency, or route of administration
  - etc.
Extra label drug use

- permitted under certain circumstances such as (not an exhaustive list):
  - to save the life of an animal
  - to reduce suffering of an animal when an approved product is not available or is clinically ineffective
Extra label drug use

- can **NOT** be used:
  - to enhance performance, or
  - for production purposes
ELDU requires a valid VCPR

1) DVM has assumed responsibility for making medical judgments regarding the health of the animal, the need for medical treatment, and the client has agreed to follow instructions.
2) DVM has sufficient knowledge of the animal to make a general or preliminary diagnosis of the medical condition
3) DVM is readily available for follow-up and is personally acquainted with the keeping and care of the animal by virtue of:

- examination of the animal
- medically appropriate and timely visit to the premises where the animal is kept
Recommendation

- always get a written order from your DVM indicating (as a minimum):
  - name of prescribed product
  - prescribed dose
  - frequency and route of administration
  - withdrawal time
  - intended use of product
Approved products for sheep

- very few
- usually takes ~3 years and ~$40 M to get a product approved for use in food-producing animals
  - Food & Drug Administration
  - Center for Veterinary Biologics (Ames)
Disclaimer

- I do **NOT** promote or condone illegal drug use in sheep or any other food-producing animal
Control of the ewe estrous cycle

- synchronization of estrus
  - during the breeding season

- induction of estrus
  - in the non-breeding season
  - requires use of gonadotropin hormones
    (e.g., FSH or eCG)
**Synchronization of estrus**

- prostaglandin $\text{F}_2\alpha$ (PGF)
  - produced by the ewe (endometrium)
  - kills the corpus luteum (CL) on the ovary
  - ewes with a CL come into estrus in ~ 60-72 hours after exposure to exogenous PGF
Synchronization of estrus with PGF

- pre-requisites for use of exogenous PGF
  - ewe must be cycling
    - must have reached puberty
    - must not be in the non-breeding season
    - must be in the diestrus stage of the estrous cycle
  - ewe should not be pregnant
    - can (but does not always) cause abortion
Synchronization of estrus with PGF

• protocol:
  – give 2 injections 9 days apart

• may induce changes in cervical mucus that interfere with sperm transport
Synchronization of estrus with PGF

- **Products available:**
  - dinoprost (2-3 cc dose)
    - Lutalyse
    - ProstaMate
    - InSynch
  - cloprostenol (1-1.25 cc dose)
    - Estrumate
    - estroPLAN
Synchronization of estrus with PGF

- always wear gloves when handling this product, as it can:
  - alter menstrual cycle
  - cause miscarriage
  - induce bronchial spasms
  - stimulate GI tract
Synchronization of estrus with progesterone

- Progesterone communicates with the hypothalamus to suppress estrus and ovulation.
- Can administer exogenous progesterone or a progesterone analogue (progestin, progestagen).
**Synchronization of estrus with progesterone**

Methods of delivery:
1) orally (in the feed)
   - MGA (melengestrol acetate)
   - 0.25 mg/head/day† for 12 days (in season) or 14 days (out of season; requires FSH or eCG)
   - don’t buy an MGA pre-mix with added Cu!

† 0.125 mg in am and 0.125 mg in pm
Synchronization of estrus with progesterone

2) CIDR [controlled internal drug-releasing device]
   - contains progesterone
   - approved for use in the US Nov 2009
Synchronization of estrus with progesterone

3) pessary (sponge)
   - MAP (medoxyacetoprogesterone)
     - 60 mg (Repromap)
   - FGA (fluorogestone acetate)
     - 30 mg (out of season)
     - 40 mg (in season)
     - 45 mg (goats; in and out of season); all marketed as Cronogest
Synchronization of estrus with progesterone

- one approved sponge (20 mg FGA) no longer manufactured
- all pessaries have a 12-day (in season) or 14-day (out of season) treatment
- out of season requires use of gonadotropin hormone (FSH or eCG)
Induction of estrus

- melatonin
  - produced by the pineal gland during hours of darkness
  - requires ≥ 40-day treatment
    » oral daily drench
    » implant

- Regulin implant not approved in the US
**Induction of estrus**

- biostimulation
  - can use for “transitional” ewes
- “ram effect”
  - sudden introduction of a ram into a group of isolated ewes will cause ~90% to ovulate within 6 days
    - isolate for $\geq 35$ days
    - isolate for $\geq \frac{1}{4}$ mile
      - isolate from ram fleeces (pheromones)
Biostimulation

- ewes respond to ram introduction:
  - ovulate, with short cycle (CL dies early)
  - ovulate, with normal cycle length
  - ovulate AND exhibit estrus
    » short cycle
    » normal cycle (this one is fertile!!)