

California Senate Bill 27 Livestock: Use of Antimicrobial Drugs (An Interesting Journey)



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2014 Legislative Foreshadowing

- ▶ AB 1437 Mullin → Held in Committee
 - ❖ Prohibit sale of products in CA if from livestock or poultry that were given medically important antibiotics for non-routine disease control unless certain condition were met
 - ❖ Required all products sold to be from a slaughter plant that reports the use of antibiotics during the lifetime of animals harvested at the plant - type, dosage, purpose and disease or infection that was treated
 - ❖ CDFA must report antibiotic use data on a “searchable, consumer friendly public website” that allows for comparisons
 - ❖ Exempted small producers (“<250 animals or 10,000 birds”) (I thought birds were animals...)
- ▶ SB 835 Hill → vetoed
 - ❖ Basically made FDA GFI 213 mandatory in CA Jan 1, 2017
 - ❖ Passed both houses but vetoed → “Do More”

CDFA Lead Working Group

Briefing Document: Antibiotic Resistance

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Executive Summary

“Antibiotics” are generally drugs that have a biologic effect on bacteria, either killing them outright or slowing them to allow a patient’s immune system to better respond to the infection. “Antibiotic resistance” can occur when bacteria develop an ability to survive despite the effects of an antibiotic(s). Many factors, including the specific bacteria, the specific antibiotic(s), and the condition of the host’s immune system, may contribute to the likelihood that resistance will develop.

Senator Hill

- ▶ Previous Bill through Senate and Assembly
- ▶ Hospital Stewardship
- ▶ Good Track Record of Collaboration
- ▶ 2015 → Active input from diverse stakeholders
- ▶ SB 27 Livestock: Use of Antimicrobial Drugs

SB 27 Hill - Signed by Governor

(Issues considered during the legislative process)

- ▶ Veto in 2014 - “Do more” ✓ Yes
- ▶ Medically important FDA GFI 152
- ▶ Implementation date (label & compliance issues) 1/1/2018
- ▶ ~~Feed & water vs~~ all inc “injectables” (access) Vet Retail License
Annual visit
CDFA Regulations
- ▶ Livestock ~~vs all animals~~
- ▶ ~~Veterinarian training~~ → SB 361 Judicious Use CE
- ▶ Tracking use Confidentiality; Comprehensive inc. Outcomes
- ▶ Prevention/prophylaxis Yes, but defined
- ▶ Stewardship - ~~regulated vs~~ outreach and training
- ▶ ~~National agenda vs~~ State agenda
- ▶ AMR ~~vs how animals are raised~~

SB 27 Livestock: Use of Antimicrobial Drugs

- I. Limits Use (January 1, 2018)
- II. Stewardship Guidelines
- III. Monitoring/Surveillance

Limits Use

- Effective January 1, 2018
- Applies to use in livestock, but not bees or species usually kept as pets
- Specific to medically important antimicrobials as defined by FDA GFI 152 Appendix A, including updates
- Can only be administered if ordered by a veterinarian via prescription or veterinary feed directive, under a valid veterinarian-client-patient relationship

Limits Use

- Can only be used when in the judgement of a licensed veterinarian is necessary to treat, control and in some cases, prevent disease or infection
- Prevention / Prophylaxis
 - ❖ If related to surgery or medical procedure
 - ❖ If “in the professional judgement of a licensed veterinarian, it is needed for prophylaxis to address an elevated risk of contraction of a particular disease or infection”
 - ❖ If used to prevent disease beyond when related to surgery or medical procedure, *can not be used in a “regular pattern”*
- Can never use solely for weight gain or feed efficiency

Limits Use

- Medically important antibiotics labeled by FDA for over the counter (OTC) sales can still be obtained from retailers *with prescription or VFD*
 - ❖ Veterinary Food Animal Drug Retailer (B&P)
 - ❖ Retail License for Restricted Drugs (FAC)
 - ❖ May need regulations to add clarity
- Violations
 - ❖ Licensed veterinarian: Practice Act disciplinary sanctions
 - ❖ Others: Up to \$250/day; second violation up to \$500/day

Stewardship

- ▶ No delay in implementation
- ▶ Requires that CDFA work with others to develop “antimicrobial stewardship guidelines and best management practices for veterinarians and livestock owners and employees”
- ▶ Must include scientifically validated best practices such as vaccination, sanitation and other management practices that may limit the need for antibiotics

Stewardship

- ▶ Must include guidance on selection of most appropriate antimicrobial drug, dose, duration and route of administration
- ▶ Must include guidance on limiting the number of animals treated and minimizing the duration of treatment

Monitoring

- ▶ No delay in implementation
- ▶ Leveraging federal efforts, gather information that may lead to a better understanding of the links between use patterns and resistance
- ▶ Gather antimicrobial sales and use data, conduct surveillance for resistance, and gather management practice data (including health outcomes)
 - ❖ California's major livestock segments
 - ❖ Regions with significant livestock production
 - ❖ Representative segments of the food production chain

Monitoring

- ▶ Willing participants and respecting veterinary-client-patient confidentiality
- ▶ Authority to request and receive copies of VFD's
- ▶ Information must be held confidential unless aggregated
 - ❖ Can be shared with VMB for enforcement of Practice Act or Federal entities if confidentiality will also be protected under federal law
- ▶ Report to the legislature January 1, 2019

What now?

- ▶ Extensive use of ad hoc advisory committees comprised of stakeholders as well as technical specialists and scientific advisors for specific topics
- ▶ Stakeholders include:
 - ✓ Department of Public Health
 - ✓ Board of Pharmacy
 - ✓ Veterinary Medical Board
 - ✓ Producers and producer organizations
 - ✓ Feed mills and feed industry organizations
 - ✓ Retail stores distributing or potentially distributing antibiotics
 - ✓ Pharmaceutical companies and business organizations
 - ✓ Veterinarians and veterinarian professional organizations
 - ✓ Schools of Veterinary Medicine
 - ✓ Consumer advocates
 - ✓ CA Animal Health and Food Safety Laboratory
 - ✓ United States Department of Agriculture (USDA)
 - ✓ Food and Drug Administration
 - ✓ Others TBD

What now?

- ▶ Funding will determine ability to implement
- ▶ Pending the 2016/17 Budget Process
 - ❖ Proposed CA Governor's Budget: 8 Positions and \$1.393 million General Fund
 - ❖ Estimated total cost for SB 27 implementation is ~ \$4 million, *if* USDA is funded for Action Plan
 - ❖ 2016/17 President's budget: USDA Zoonotic Disease Line Item ~\$10 million additional for AMR efforts
 - ❖ FDA: Some funds from NARMS

Antibiotic Resistance

► My Take Home

- ❖ This is a real issue and we all should be proactive
- ❖ Use in humans is unquestionably the driver of the most concerning antibiotic resistance
- ❖ Use in animals can lead to antibiotic resistance affecting animal health as well as human health
- ❖ Stay tuned as many States, USDA and FDA gear up for change
- ❖ MUST be a collaborative approach
- ❖ NIAA is a step ahead → Good job!!!!



Thanks!

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