ASSEMBLY BILL No. 1437

Introduced by Assembly Member Mullin

January 6, 2014

An act to amend Sections 14200, 14203, 14289, and 14381 of, to add Sections 14203.5, 14207.3, 14207.5, 14207.7, 14220, 14297, and 14366 to, and to add Article 5.5 (commencing with Section 14335) and Article 5.6 (commencing with Section 14340) to Chapter 4 of Division 7 of, the Food and Agriculture Code, relating to livestock drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 1437, as introduced, Mullin. Medically important antimicrobials: nontherapeutic use.

Existing law requires the manufacturer of a livestock drug, including a restricted drug, as defined, to register with the Director of Food and Agriculture and requires the director to refuse to register the drug if he or she makes specified findings. Under existing law it is unlawful, among other things, to use or administer any registered livestock drug, except in accordance with the label instructions, as specified, and makes an initial violation of these provisions subject to an infraction and, for subsequent violations, a misdemeanor.

This bill, as of January 1, 2017, would redefine "restricted drug" to also include a livestock drug that is recognized by either the Center for Disease Control and Prevention or the World Health Organization to increase the prevalence of antibiotic-resistant bacteria, as specified. The bill would prohibit registration of a restricted drug if the director finds that the restricted drug poses a risk to public health through the increased prevalence of antibiotic-resistant bacteria. The bill would also authorize the director to revoke the registration of a medically important

antimicrobial, as defined, for use in livestock if he or she finds that the drug threatens the public health by increasing the prevalence of antibiotic-resistant bacteria.

The bill would prohibit the administration of a medically important antimicrobial to a food-producing animal for nonroutine disease control unless certain conditions are met. By prohibiting the administration of a medically important antimicrobial, this bill would create a crime, thereby imposing a state-mandated local program. The bill would also require a livestock producer that does administer a medically important antimicrobial to a food-producing animal to annually report specified information to the director relating to the administration of the medically important antimicrobial and would make the failure to make that report an infraction subject to specified penalties. The bill would require the department post this information on an Internet Web site.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. The Legislature find and declare all of the following:

(a) In 1977, the United States Food and Drug Administration (FDA) concluded that feeding livestock low doses of antibiotics that are used in human disease treatment could promote the development of antibiotic-resistance in bacteria. The FDA, however, did not act in response to these findings, despite laws requiring the agency to do so.

(b) The FDA has promulgated voluntary regulations on the nontherapeutic use of antibiotics, however these guidelines are unlikely to significantly reduce the nontherapeutic use of antibiotics in livestock.

(c) Not only do antibiotic-resistant bacteria affect the health of our society, but they also have a monetary impact. In 1998, the National Academy of Sciences noted that antibiotic-resistant

bacteria generate a minimum of four to five billion dollars in costs to United States society and individuals every year.

(d) In April 1999, the United States Government Accountability Office conducted a study concluding that three strains of microorganisms that cause foodborne illnesses or disease in humans are resistant to antibiotics and are linked to the use of antibiotics in animals. These microorganisms are salmonella, Campylobacter, and E. Coli.

(e) In 1999, 2011, and 2006, the United States Department of Agriculture's Animal and Plant Health Inspection Service conducted large-scale, voluntary surveys that revealed all of the following:

(1) Eighty-four percent of grower and finisher swine farms, 83 percent of cattle feedlots, and 84 percent of sheep farms administer antimicrobials in feed or water for either health or growth promotion reasons.

(2) Many of the antimicrobials that were identified were identical or closely related to drugs used in human medicine, including tetracyclines, macrolides, bacitracin, penicillins, and sulfonamides.

(3) These drugs are used in people to treat serious diseases, such as pneumonia, scarlet fever, rheumatic fever, sexually transmitted infections, and skin infections; pandemics such as malaria and plague; and bioterrorism agents such as anthrax.

(f) Overuse or misuse of antibiotics contributes to the spread of antibiotic resistance, whether in human medicine or in agriculture.

(g) In June 2002, the peer-reviewed journal, "Clinical Infectious Diseases," published a report based on a two-year review, by experts in human and veterinary medicine, public health, microbiology, biostatistics, and risk analysis, of more than 500 scientific studies on the human health impacts of antimicrobial use in agriculture. The report recommended that antimicrobial agents should not be used in agriculture in the absence of disease and should be limited to therapy for diseased individual animals or prophylaxis when disease is documented in a herd or flock.

(h) In a March 2003 report, the National Academy of Sciences stated that a decrease in antimicrobial use in human medicine alone will have little effect on the rise in antibiotic-resistant bacteria and that substantial efforts must be made to decrease the inappropriate overuse of antimicrobials in animals and agriculture.

(i) In 2010, the peer-reviewed journal, "Molecular Cell," published a study demonstrating that a low-dosage use of antibiotics causes a dramatic increase in genetic mutation, raising new concerns about the agricultural practice of using low-dosage antibiotics in order to stimulate growth promotion and routinely prevent disease in unhealthy conditions.

(j) In 2010, the Danish Veterinary and Food Administration testified that the Danish ban of the nontherapeutic use of antibiotics in food animal production resulted in a marked reduction in antimicrobial resistance in multiple bacterial species, including Campylobacter and Enterococci.

(k) In 2011, the FDA found that in 2010:

(1) Thirteen million five hundred thousand kilograms of antibacterial drugs were sold for use on food animals in the United States.

(2) Three million three hundred thousand kilograms of antibacterial drugs were used for human health.

(3) Eighty percent of antibacterial drugs disseminated in the United States were sold for use on food-producing animals, rather than being used for human health.

(*l*) In 2011, a review of all scientific studies on antimicrobial use in farm animals, published in Clinical Microbiology Reviews, found the following:

(1) The use of antibiotics in food-producing animals leads to the development of reservoirs of antibiotic resistance.

(2) A ban on nontherapeutic antibiotic use in food-producing animals would preserve the use of antibiotics for medicine.

(3) A Danish ban on nontherapeutic antibiotics in food-producing animals resulted in little change in animal morbidity and mortality, and only a modest increase in production cost.

(m) The FDA's National Antimicrobial Resistance Monitoring System routinely finds that retail meat products are contaminated with bacteria that are resistant to antibiotics that are important to human medicine.

(n) According to the American Academy of Pediatrics, "[t]he largest nonhuman use of antimicrobial agents is in food-producing animal production, and most of this is in healthy animals to increase growth or prevent diseases. Evidence now exists that these uses of antimicrobial agents in food-producing animals have a direct

negative impact on human health and multiple impacts on the selection and dissemination of resistance genes in animals and the environment. Children are at increased risk of acquiring many of these infections with resistant bacteria and are at great risk of severe complications if they become infected."

(o) Many scientific studies confirm that the nontherapeutic use of antibiotics in food-producing animals contributes to the development of antibiotic-resistant bacterial infections in people.

SEC. 2. Section 14200 of the Food and Agricultural Code is amended to read:

14200. *(a)* The Legislature hereby declares that this chapter, which prescribes the distribution and use of livestock drugs, is intended to assure that ~~such~~ *the* drugs are available to livestock producers for their use in protecting the health of the livestock population of the state, and that ~~such~~ *the* use will in turn benefit the general public by providing an abundant supply of wholesome food and fiber.

~~It~~

(b) It is further declared that nothing in this chapter is intended to prevent a livestock producer from administering livestock drugs safely and effectively when ~~such~~ *the* use is in accordance with the labeling directions for the drug used *and when the use protects public health*.

SEC. 3. Section 14203 of the Food and Agricultural Code is amended to read:

14203. *(a)* "Restricted drug" means ~~any livestock~~ *either of the following:*

(1) A livestock drug which is sold in ~~such~~ *a* form that it might be administered to ~~humans and~~ *a person and*, if so ~~administered~~ *administered*, would be dangerous to the health of ~~such humans or any livestock~~ *the person.*

(2) A livestock drug ~~which~~ *that* if improperly ~~administered~~ *administered, as defined in Section 14203.5*, to livestock, is dangerous to the health of ~~such~~ *the* livestock or to ~~humans~~ *persons* who consume products from ~~such~~ *the* livestock. ~~Restricted~~

(3) A livestock drug that is recognized by either the federal Centers for Disease Control and Prevention or the World Health Organization to increase the prevalence of antibiotic-resistant bacteria.

(b) Restricted drugs include all of the following:

~~(a)~~
(1) Arsenic compounds and preparations.
~~(b)~~
(2) Diethylstilbestrol and other substances which have a hormonelike action.
~~(c)~~
(3) Sulfanilamide or substitute sulfanilamides.
~~(d)~~
(4) Antibiotic preparations.
~~(e)~~
(5) A drug from an antimicrobial class that is listed as "highly important," "critically important," or "important" by the World Health Organization's "Critically Important Antimicrobial for Human Medicine," as updated by the World Health Organization, or its successor publication, unless the drug is used for therapeutic use, as defined in Section 14220.
~~Such other~~
(6) Other drugs and their preparations ~~which~~ *that* the director determines are hazardous to the health of livestock or the public safety.

SEC. 4. Section 14203.5 is added to the Food and Agricultural Code, to read:

14203.5. "Improperly administered" means either of the following:

(a) Administration of a medically important antimicrobial to a food-producing animal through either feed or water, or for purposes of poultry hatcheries through any means, for purposes other than therapeutic use, such as growth promotion, feed efficiency, weight gain, disease prevention, or nonroutine disease control.

(b) A repeated or regular pattern of administration of a medically important antimicrobial in food-producing animals for purposes other than therapeutic use or nonroutine disease control.

SEC. 5. Section 14207.3 is added to the Food and Agricultural Code, to read:

14207.3. "Medically important antimicrobial" means a drug that is both of the following:

(a) Intended for use in food-producing animals.

(b) Composed wholly or partly of either of the following:

(1) Any kind of penicillin, tetracycline, macrolide, lincosamide, streptogramin, aminoglycoside, sulfonamide, or cephalosporin.

(2) A drug from an antimicrobial class that is listed as either "highly important," "critically important," or "important" by the World Health Organization's "Critically Important Antimicrobial for Human Medicine," as updated by the World Health Organization, or its successor publication.

SEC. 6. Section 14207.5 is added to the Food and Agricultural Code, to read:

14207.5. "Noncustomary situation" means a situation that does not include normal or standard practices and conditions on the premises that facilitate the transmission of disease.

SEC. 7. Section 14207.7 is added to the Food and Agricultural Code, to read:

14207.7. "Nonroutine disease control" means the use of antimicrobials in the feed or water of a food-producing animal that is not sick, and where a particular disease or infection is, or is likely to be, present on the premises because of a specific, noncustomary situation.

SEC. 8. Section 14220 is added to the Food and Agricultural Code, to read:

14220. "Therapeutic use," with respect to a medically important antimicrobial, means the use of the antimicrobial for the specific purpose of treating an animal with a documented disease or infection. Therapeutic use does not include the continued use of the antimicrobial in the animal after the disease or infection has been resolved.

SEC. 9. Section 14289 of the Food and Agricultural Code is amended to read:

14289. If the livestock drug is a restricted drug, the director shall also refuse registration if he *or she* finds that the instructions for use do not contain adequate and satisfactory directions as to the methods of handling, caring for, holding, or otherwise managing the livestock to which the drug is administered so as to eliminate any danger to the health of any person who might consume food products ~~which~~ *that* are derived from ~~such~~ *that* livestock *or if he or she finds that the restricted drug poses a risk to public health by increasing the prevalence of antibiotic-resistant bacteria*.

SEC. 10. Section 14297 is added to the Food and Agricultural Code, to read:

14297. The director may revoke the registration of a medically important antimicrobial for use in livestock if he or she finds that the drug as used poses a risk to the public health by increasing the prevalence of antibiotic-resistant bacteria.

SEC. 11. Article 5.5 (commencing with Section 14335) is added to Chapter 4 of Division 7 of the Food and Agricultural Code, to read:

Article 5.5. Use of Medically Important Antimicrobials

14335. (a) A person who administers or causes to be administered a medically important antimicrobial to a food-producing animal shall have a valid veterinarian-client-patient relationship with a veterinarian to ensure that the medically important antimicrobial is used in a manner that is consistent with professionally accepted best practices.

(b) For purposes of this section, "veterinarian-client-patient relationship" means a relationship in which all of the following are met:

(1) The veterinarian has assumed the responsibility for making medical judgments regarding the health of the animal-patient, and the client has agreed to follow the veterinarian's instructions.

(2) The veterinarian has sufficient knowledge of the animal-patient to initiate at least a general or preliminary diagnosis of the medical condition of the animal-patient.

(3) The veterinarian is readily available for follow-up evaluation, or has arranged for veterinary emergency coverage, and continuing care and treatment.

(4) The veterinarian provides oversight of treatment, compliance, and outcome of the administration of the medically important antimicrobial.

(5) Animal-patient records are maintained.

(c) For purposes of this section, "sufficient knowledge" means the veterinarian is personally acquainted with the keeping and care of the animal-patient by virtue of either of the following:

(1) A timely examination of the animal-patient by the veterinarian.

(2) Medically appropriate and timely visits by the veterinarian to the premises where the animal-patient is kept.

14336. (a) If a livestock producer administers or causes to be administered a medically important antimicrobial to a food-producing animal, the producer, or the contracted entity, shall annually report to the director the following information on a schedule and in a format specified by the director:

(1) The total number of food-producing animals given a medically important antimicrobial in their feed.

(2) The type of medically important antimicrobial administered.

(3) The total amount of each medically important antimicrobial used.

(4) The target food-producing animal species that were administered the medically important antimicrobial.

(5) The length of time over which the medically important antimicrobial was intended to be provided to the food-producing animals and the dose of the active medically important antimicrobial ingredient the food-producing animals were intended to receive.

(6) The purpose for administering the medically important antimicrobial to a food-producing animal. The purpose shall be categorized in a manner determined by the director and shall include, at a minimum, the following categories:

(A) Growth promotion.

(B) Disease prevention.

(C) Disease control.

(D) Disease treatment.

(7) The type of disease or infection to be treated by the medically important antimicrobial, if applicable.

(8) The name of the processor, as defined in Section 20019, where the livestock product will be processed.

(b) On or before December 31, 2017, the department shall develop and make operational a consumer-friendly, publicly accessible Internet Web site that creates a database of the information collected pursuant to this section. The database shall be searchable and able to accommodate a wide range of users, including users with limited technical and scientific literacy. The Internet Web site shall be designed to be easily navigable and to enable users to compare and contrast livestock producers and the reported usage of medically important antimicrobials.

SEC. 12. Article 5.6 (commencing with Section 14340) is added to Chapter 4 of Division 7 of the Food and Agricultural Code, to read:

Article 5.6. Nontherapeutic Use of Medically Important Antimicrobials

14340. This article shall apply to the nontherapeutic use in a food-producing animal of a drug that is a medically important antimicrobial and is either of the following:

(a) A registered drug.

(b) A drug exempted under Article 3 (commencing with Section 14261).

14341. The registration or exemption of a drug subject to this article shall be ineffective on and after January 1, 2017, unless the director makes a final written determination that there is, with reasonable certainty, no harm to human health due to the development of antimicrobial resistance that is attributable in whole or in part to the nontherapeutic use of the drug, based on one of the following:

(a) The holder of the registration or exemption has demonstrated this fact.

(b) A risk analysis of the drug, taking into consideration other relevant information, conducted by the director.

SEC. 13. Section 14366 is added to the Food and Agricultural Code, to read:

14366. It is unlawful to administer, including through means of feed, a medically important antimicrobial to a food-producing animal for nonroutine disease control, unless either of the following apply:

(a) The director determines, with reasonable certainty, that there is no harm to human health due to the development of antibiotic-resistant bacteria that is attributable in whole or in part to the use of the medically important antimicrobial and the use does not threaten public health.

(b) All of the following conditions are met:

(1) There is a significant risk that a disease or infection that is present on, or is likely to be present on, the premises will be transmitted to the food-producing animal.

(2) The administration of the medically important antimicrobial to the food-producing animal is necessary to prevent or reduce the risk of transmission of the disease or infection.

(3) The medically important antimicrobial is administered to the food-producing animal for the shortest duration possible to prevent or reduce the risk of transmission of the disease or infection.

(4) The medically important antimicrobial is administered to the fewest food-producing animals possible in order to prevent or reduce the risk of transmission of the disease or infection.

SEC. 14. Section 14381 of the Food and Agricultural Code is amended to read:

14381. ~~A~~ *(a) Except as provided for in subdivision (b), a* violation of this chapter or of any regulation ~~which~~ *that* is adopted by the director pursuant to this chapter is an infraction punishable by a fine of not more than five hundred dollars ($500) for the first violation. A second or subsequent violation of this chapter is a misdemeanor punishable by a fine of not less than one hundred dollars ($100) and not more than one thousand dollars ($1,000).

(b) A violation of the reporting requirement in Section 14336 or of any regulation that is adopted by the director pursuant to that section is an infraction punishable by a fine of one hundred dollars ($100) for the first violation. A second or subsequent violation is an infraction punishable by a fine of not less than two hundred dollars ($200) and not more than one thousand dollars ($1,000).

SEC. 15. This act shall become operative on January 1, 2017.

SEC. 16. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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