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**REPORT ON LEGISLATION BY THE
ANIMAL LAW COMMITTEE**

S.1844

Sen. Squadron

AN ACT to amend the Agriculture and Markets Law, in relation to non-therapeutic use of antimicrobial agents in animals.

THIS BILL IS APPROVED WITH RECOMMENDATIONS

SUMMARY OF THE PROPOSED LEGISLATION

The proposed legislation (S.1844) is intended to combat the proliferation of antibiotic-resistant bacteria, and the resultant serious risk to public health, the environment, and animal welfare, as a consequence of the non-therapeutic uses of certain drugs on food-producing animals. The proposed legislation would add Section 84 to Article 5 of the Agriculture and Markets Law to prohibit the non-therapeutic use of antimicrobial agents in animals raised for human consumption and allow the Commissioner of the Department of Agriculture and Markets to promulgate and adopt rules and regulations to give effect to the law.

The proposed legislation defines antimicrobial agents and the non-therapeutic use of such agents, prohibits the transport and sale of animal products produced using non-therapeutic antimicrobial agents, and provides that violation of the section will constitute a class A misdemeanor.¹ The legislation would ban the non-therapeutic use of antimicrobial agents in animals raised for human consumption and animals that provide non-meat food products, including but not limited to cattle, sheep, swine, and poultry.² The administration of antimicrobial agents to animals where there is a clinical sign of disease in the animal would still be permitted.³

¹ Proposed Agric. & Mkts. Law § 84 defines “antimicrobial agent” as “any drug or derivative of a drug that is used in humans or intended for use in humans to treat or prevent disease or infection, or any substance, whether produced synthetically or naturally, used to kill or inhibit the growth of bacteria, viruses, fungi, parasites, or other microorganisms.” Proposed Agric. & Mkts. Law § 84 defines “non-therapeutic use of antimicrobial agents” as “any use of antimicrobial agents, including without limitation as a feed or water additive, for an animal for growth promotion, feed efficiency, weight gain, routine disease prevention, or other routine purpose, in the absence of any clinical sign of disease in the animal.”

² N.Y. Senate Bill No. 1844, § 1 (2017), <https://www.nysenate.gov/legislation/bills/2017/S1844> (all websites last accessed April 18, 2017).

³ *Id.*

The proposed legislation would take effect 180 days after it is enacted.⁴ However, effective immediately upon enactment, any rule or regulation that must be amended and/or repealed in order to implement the proposed legislation must be amended or repealed on or before the effective date.⁵

JUSTIFICATION

Although the development of antibiotics was one of the most important scientific achievements in the treatment of disease in the twentieth century, the proliferation of antibiotic-resistant bacteria due to the overuse of antibiotics now represents one of the greatest public health threats of the twenty-first century. The Centers for Disease Control and Prevention (“CDC”) has issued multiple reports urging immediate action to prevent potentially catastrophic consequences arising from the increase in antibiotic-resistant bacterial infections, which reportedly afflict more than two million people annually in the United States, with at least 23,000 dying as a result.⁶ While the Federal government has taken steps to curb antibiotic overuse,⁷ it

⁴ *Id.* § 2.

⁵ *Id.*

⁶ U.S. DEPT. OF HEALTH & HUMAN SVCS, CTRS FOR DISEASE CONTROL & PREVENTION MAKING HEALTH CARE SAFER: STOP SPREAD OF ANTIBIOTIC RESISTANCE (Aug. 4, 2015), <http://www.cdc.gov/vitalsigns/stop-spread/index.html>; (All Internet sources last visited Feb. 22, 2017); U.S. DEPT. OF HEALTH & HUMAN SVCS, CTRS FOR DISEASE CONTROL & PREVENTION, ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES, 2013 6 (Apr. 23, 2013), <http://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf>. A study performed by scientists from Johns Hopkins, the University of North Carolina, and George Washington University found that the heavy use of antibiotics in livestock raised for human consumption may be behind the increase in superbugs, including Methicillin-Resistant Staphylococcus aureus (MRSA). See JL Rinsky JL *et al.*, *Livestock-Associated Methicillin and Multidrug Resistant Staphylococcus aureus Is Present among Industrial, Not Antibiotic-Free Livestock Operation Workers in North Carolina*, PLoS ONE 8(7), (July 2, 2013), <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0067641>.

⁷ THE WHITE HOUSE, THE NATIONAL ACTION PLAN FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA (2015), https://obamawhitehouse.archives.gov/sites/default/files/docs/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf (sets forth a plan to combat antibiotic-resistant bacteria, but contains a limited focus on antibiotics in animal agriculture and supports a guidance approach rather than legal requirements); Veterinary Feed Directive, 21 CFR Part 558 (2015) (outlines the process for authorizing the use of animal drugs in or on animal feed and provides an outline by which states are encouraged to manage the veterinarian-client-patient-relationship); U.S. DEPT. OF HEALTH & HUMAN SVCS., FOOD & DRUG ADMIN., CTR. FOR VETERINARY MEDICINE, GUIDANCE FOR INDUSTRY #209, THE JUDICIOUS USE OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS IN FOOD-PRODUCING ANIMALS, (Apr. 13, 2012), <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf> (hereinafter FDA JUDICIOUS USE GUIDANCE) (voluntary industry guidelines against the use of antibiotics for growth promotion and requiring veterinary oversight); U.S. DEPT. OF HEALTH & HUMAN SVCS., FOOD & DRUG ADMIN., CTR. FOR VETERINARY MEDICINE, GUIDANCE FOR INDUSTRY #213, NEW ANIMAL DRUGS AND NEW ANIMAL DRUG COMBINATION PRODUCTS ADMINISTERED IN OR ON MEDICATED FEED OR DRINKING WATER OF FOOD-PRODUCING ANIMALS: RECOMMENDATIONS FOR DRUG SPONSORS FOR VOLUNTARILY ALIGNING PRODUCT USE CONDITIONS WITH GFI #209 (Dec. 12, 2013), <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf> (provides timelines and implementation strategies for the voluntary guidelines of Guidance for Industry #209).

has not yet set forth requirements to limit the use of antibiotics in agriculture, which the CDC and other public health authorities have recognized as a primary cause of the proliferation of antibiotic-resistant bacteria.⁸

Antibiotics are used for three main purposes in livestock production: (1) as therapeutics for managing clinically apparent diseases, (2) as prophylactics for disease prevention, and (3) to promote growth.⁹ Intensive confinement of food-producing animals, such as gestation crates for pigs,¹⁰ veal crates for calves,¹¹ and battery cages for hens,¹² so severely restricts movement and natural behaviors that the animals in these facilities may not be able to turn around or walk. Non-therapeutic antibiotics are administered to food-producing animals in such facilities both to manage existing disease induced by such crowded and restrictive conditions and to prevent disease commonly associated with such conditions.¹³ Additionally, antibiotics are commonly used to promote growth of farm animals in intensive confinement farming facilities, and the use

⁸ 2013 CDC Report, *supra* note 6, at 37 (“[b]ecause of the link between antibiotic use in food-producing animals and the occurrence of antibiotic-resistant infections in humans, antibiotics should be used in food-producing animals only under veterinary oversight and only to manage and treat infectious diseases, and not to promote growth”); *id.* at 11 (concluding that “the use of antibiotics for promoting growth is not necessary and the practice should be phased out”).

⁹ U.S. DEPT. OF AGRICULTURE, ANIMAL AND PLANT HEALTH INSPECTION SERVICE ET AL., ANTIMICROBIAL RESISTANCE ISSUES IN ANIMAL AGRICULTURE 16 (May 2007), available at http://www.aphis.usda.gov/animal_health/emergingissues/downloads/antiresist2007update.pdf.

¹⁰ Gestation crates for breeding sows are individual, concrete-floored metal stalls measuring 2–2.3 feet wide by 6.6–6.9 feet long, which is only slightly larger than the animal and so severely restrictive of her movement that a sow is unable to turn around within the crate. See COMMISSION OF THE EUROPEAN COMMUNITIES, 2001. COM (2001) 20 FINAL 2001/0021 (CNS) COMMUNICATION FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT ON THE WELFARE OF INTENSIVELY KEPT PIGS IN PARTICULARLY TAKING INTO ACCOUNT THE WELFARE OF SOWS REARED IN VARYING DEGREES OF CONFINEMENT AND IN GROUPS (Jan. 16, 2001), <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52001DC0020>. See also PROPOSAL FOR A COUNCIL DIRECTIVE 91/630/EEC LAYING DOWN MINIMUM STANDARDS FOR THE PROTECTION OF PIGS, as cited in HUMANE SOCIETY OF THE UNITED STATES, AN HSUS REPORT: WELFARE ISSUES WITH GESTATION CRATES FOR PREGNANT SOWS (Feb. 2013), <http://www.humanesociety.org/assets/pdfs/farm/HSUS-Report-on-Gestation-Crates-for-Pregnant-Sows.pdf>.

¹¹ Veal calves may be tethered or confined for as long as sixteen weeks in two-foot-wide crates that do not permit them to walk or extend their limbs, leading to such physical ailments as digestive problems, discomfort, impaired locomotion, and a greater susceptibility to disease. See HUMANE SOCIETY OF THE UNITED STATES, AN HSUS REPORT: THE WELFARE OF ANIMALS IN THE VEAL INDUSTRY (July 2012), <http://www.humanesociety.org/assets/pdfs/farm/hsus-the-welfare-of-animals-in-the-veal-industry.pdf>; FARM SANCTUARY, THE WELFARE OF CATTLE IN DAIRY PRODUCTION: A SUMMARY OF THE SCIENTIFIC EVIDENCE (Apr. 2011).

¹² Approximately 94% of egg-laying hens in the United States are confined in battery cages, where they also cannot turn around or spread their wings. The United Egg Producers recommend that each bird be allotted an average space of about 67-86 square inches, smaller than an 8 ½ by 11-inch piece of paper in most instances. See UNITED EGG PRODUCERS, UNITED EGG PRODUCERS ANIMAL HUSBANDRY GUIDELINES FOR U.S. EGG LAYING FLOCKS 21 (2016), <http://unitedegg.com/information/pdf/UEP-Animal-Welfare-Guidelines2016.pdf>.

¹³ PEW COMMISSION ON INDUSTRIAL FARM ANIMAL PRODUCTION, PUTTING MEAT ON THE TABLE: INDUSTRIAL FARM ANIMAL PRODUCTION IN AMERICA, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH (2008), <http://www.pewtrusts.org/~media/legacy/uploadedfiles/peg/publications/report/PCIFAPFINALpdf.pdf> (noting that “Industrial farm animal production systems are also highly dependent on intensive animal confinement, which commonly requires the use of antimicrobials to prevent disease, not just to treat it”).

of such drugs has increased exponentially since this growth-promoting method was first introduced in the 1940s.¹⁴ The precipitous increase in antibiotic use is due, in part, to the fact that their effectiveness as a growth promoter has declined, so more antibiotics are required to yield the desired growth.¹⁵ It is estimated that at least 80% of all antibiotics disseminated in the United States are administered to food-producing animals for non-therapeutic purposes, including growth promotion, and to compensate for crowded, unsanitary, and stressful farming and transportation conditions, rather than being used for human health.¹⁶

The overuse of antibiotics in animal agriculture has been widely recognized as a primary cause of the proliferation of antibiotic-resistant bacteria. For example, the CDC and the Food and Drug Administration (“FDA”) have identified the widespread use of antibiotics in food-producing animals as a significant factor in the emergence and transmission of antibiotic-resistant bacteria to humans.¹⁷ Accordingly, public health authorities such as the Pew Commission on Industrial Farm Animal Production and the Johns Hopkins Center for a Livable Future have called for a ban on the non-therapeutic use of antibiotics in food-producing animals to reduce the risk of antimicrobial resistance to medically important antibiotics and other antimicrobials.¹⁸

While chicken, turkey, pork, and beef raised without the routine use of antibiotics account for only around 5% of the meat sold in the United States, customer demand for these products is growing and changing the marketplace.¹⁹ Sales of meat and poultry raised without

¹⁴ Robyn L. Goforth & Carol R. Goforth, *Appropriate Regulation of Antibiotics in Livestock Feed*, 28 B.C. ENVTL. AFF. L. REV. 39, 46 (2000), <http://lawdigitalcommons.bc.edu/cgi/viewcontent.cgi?article=1183&context=ealr>.

¹⁵ *Id.* at 46-47.

¹⁶ Helena Bottemiller, *Most U.S. Antibiotics Go to Animal Agriculture*, FOOD SAFETY NEWS (Feb. 24, 2011), <http://www.foodsafetynews.com/2011/02/fda-confirms-80-percent-of-antibiotics-used-in-animal-ag/#.UmFiPZTSM9I> (quoting Congresswoman Louise Slaughter (D-NY) as stating “We already knew that 13.1 million kilograms of antibacterial drugs were sold for use on animals in 2009. Recently, I was able to confirm with the FDA that only 3.3 million kilograms . . . [were] sold each year for human use in 2009. Using these figures, I have determined that 80 percent of all antibacterial drugs are dedicated to use on animals”). *See also* U.S. FOOD & DRUG ADMIN., 2013 SUMMARY REPORT ON ANTIMICROBIALS SOLD OR DISTRIBUTED FOR USE IN FOOD-PRODUCING ANIMALS (2015), <http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM440584.pdf> (indicating that in 2013, 32.6 million pounds of antibiotics were sold and distributed for use in food-producing animals in the United States).

¹⁷ *See* 2013 CDC Report, *supra* note 6, at 37 (“[b]ecause of the link between antibiotic use in food-producing animals and the occurrence of antibiotic-resistant infections in humans, antibiotics should be used in food-producing animals only under veterinary oversight and only to manage and treat infectious diseases, and not to promote growth”); FDA JUDICIOUS USE GUIDANCE, *supra* note 7.

¹⁸ PEW COMMISSION ON INDUSTRIAL FARM ANIMAL PRODUCTION, *supra* note 13; JOHNS HOPKINS CENTER FOR A LIVABLE FUTURE, INDUSTRIAL FOOD ANIMAL PRODUCTION IN AMERICA: EXAMINING THE IMPACT OF THE PEW COMMISSION’S PRIORITY RECOMMENDATIONS (Fall 2013), http://www.jhsph.edu/research/centers-and-institutes/johns-hopkins-center-for-a-livable-future/pdf/research/clf_reports/CLF-PEW-for%20Web.pdf.

¹⁹ NATURAL RESOURCES DEFENSE COUNCIL, GOING MAINSTREAM: MEAT AND POULTRY RAISED WITHOUT ROUTINE ANTIBIOTICS USE 2 (Dec. 2015), <http://www.nrdc.org/food/files/antibiotic-free-meats-CS.pdf>.

antibiotics increased 25%, according to reporting published in 2012, over the three prior years.²⁰ Sales of antibiotic-free chicken in the United States increased 34% by value and consumer spending on such poultry topped \$1 billion in 2013, not including restaurant and other commercial purchasing.²¹ In 2015, McDonald's, Wal-Mart, Tyson's Foods, Foster Farms and Perdue announced plans to stop or reduce their sales of chicken raised with antibiotics.²² More than one-third of the entire U.S. chicken industry has now eliminated or pledged to eliminate routine use of medically important antibiotics, and chicken raised without routine use of antibiotics is no longer a niche business.²³

Despite these recommendations and consumer demand for food products derived from animals raised without antibiotics, there is currently no meaningful federal oversight to ensure the judicious use of antibiotics in animal agriculture.²⁴ As a result, some states, such as California, have taken steps to provide more meaningful oversight and limitations on the use of antimicrobials in animal agriculture.²⁵ The proposed legislation would serve as an important step in the regulation of the non-therapeutic use of antibiotics in animal agriculture in New York.

RECOMMENDATION

The proposed legislation is necessary to address the widespread overuse and misuse of antibiotics in animal agriculture, both to improve the welfare of food-producing animals and to preserve the efficacy of vital antibiotics in treating serious diseases in humans, including pneumonia, scarlet fever, rheumatic fever, sexually transmitted infections, skin infections, and pandemics like malaria and plague, as well as exposure to bioterrorism agents such as anthrax.

²⁰ Matthew Perrone, *Does Giving Antibiotics to Animals Hurt Humans*, USA TODAY (Apr. 20, 2012), <http://usatoday30.usatoday.com/news/health/story/2012-04-20/antibiotics-animals-human-meat/54434860/1>.

²¹ David Kesmodel *et al.*, *Meat Companies Go Antibiotics-Free As More Consumers Demand It*, WALL STREET JOURNAL, (Nov. 3, 2014), <http://www.wsj.com/articles/meat-companies-go-antibiotics-free-as-more-consumers-demand-it-1415071802>.

²² John Tozzi, *California Enacts Strictest Animal Antibiotic Law in the U.S.*, BLOOMBERG BUSINESS, <http://www.bloomberg.com/news/articles/2015-10-11/california-enacts-strictest-animal-antibiotic-law-in-the-u-s->.

²³ Natural Resources Defense Council, *supra* note 19, at 3.

²⁴ We note that in December 2013 the FDA announced a “voluntary plan with industry to phase out the use of certain antibiotics for enhanced food production.” See U.S. FOOD & DRUG ADMIN., PHASING OUT CERTAIN ANTIBIOTIC USE IN FARM ANIMALS (Dec. 11, 2013), http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm378100.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery. As a voluntary program however, this initiative does not mandate compliance with any proposed phase-out. The FDA also amended its animal drug regulations in the Veterinary Feed Directive Rule, *supra* note 7, which requires veterinary oversight of medically important antibiotics administered to food producing animals, but largely defers to states in implementing the rule and still permits the prophylactic use of antibiotics. Proposed legislation that would provide more meaningful limitations and oversight, prohibiting the administration of medically important antimicrobials to food-producing animals for nontherapeutic use, has been introduced in Congress but has not gained much traction. See Preservation of Antibiotics for Medical Treatment Act, H.R. 1552, 114th Cong., (2015).

²⁵ We note that California recently adopted legislation that will, beginning on January 1, 2018, prohibit the administration of medically important antimicrobial drugs to livestock unless directed by a veterinarian when animals are sick or there is an elevated risk of infection and will prohibit the administration of such drugs for promoting weight gain or improving feed efficiency. CA Food & Agric. Code, § 14400, *et seq.*

Although we support the proposed legislation, we recommend revising the definition of “antimicrobial agent” in order to limit potential loopholes and ensure the inclusion of all antimicrobials deemed medically important for human medicine in the scope of the proposed legislation. Proposed Agric. & Mkts. Law § 84 defines “antimicrobial agent” as “any drug or derivative of a drug that is used in humans or intended for use in humans to treat or prevent disease or infection, or any substance, whether produced synthetically or naturally, used to kill or inhibit the growth of bacteria, viruses, fungi, parasites, or other microorganisms.” While this definition is broad, we are concerned that, without reference to a specific list of antimicrobial agents, there may be room to argue for the exclusion of a particular antimicrobial agent.

Therefore, the Committee suggests that “antimicrobial agent” in Proposed Agric. & Mkts. Law § 84 be defined as “any drug or derivative of a drug that is used in humans or intended for use in humans to treat or prevent disease or infection, or any substance, whether produced synthetically or naturally, used to kill or inhibit the growth of bacteria, viruses, fungi, parasites, or other microorganisms. Antimicrobial agent shall include, without limitation, any drug or derivative of a drug that includes an ‘important’, ‘highly important’, or ‘critically important’ antimicrobial, as defined by the World Health Organization in Critically Important Antimicrobials for Human Medicine, 3rd Rev.” The World Health Organization’s listing of highly and critically important antimicrobials²⁶ is a widely accepted authority on antimicrobial classification as it relates to antimicrobial resistance and it is crucial that the proposed legislation apply to all such antimicrobials.

We also recommend that the penalty, which is a class A misdemeanor (up to a year in jail and \$1,000 in fines), be amended to be punishable by an appropriate civil fine.

CONCLUSION

For the aforementioned reasons, the Committee supports the proposed legislation, subject to the proposed revision to the definition of “antimicrobial agent” and the change in penalty.

Animal Law Committee
Lori Barrett, Chair

April 2017

²⁶ WORLD HEALTH ORGANIZATION, CRITICALLY IMPORTANT ANTIMICROBIALS FOR HUMAN HEALTH, 3RD REV. (2011), http://apps.who.int/iris/bitstream/10665/77376/1/9789241504485_eng.pdf?ua=1&ua=1.