REPORT OF THE CHIEF LEGISLATIVE ANALYST

DATE: January 14, 2016

TO: Honorable Members of the Rules, Elections, Intergovernmental Relations, and Neighborhoods Committee

FROM: Sharon M. Tso for Chief Legislative Analyst

Council File No.: 15-0002-S104
Assignment No.: 15-11-0907

SUBJECT: Resolution (O'Farrell – Ryu) to SUPPORT H.R. 1552 and S. 621

CLA RECOMMENDATION: Adopt the attached Resolution (O'Farrell – Ryu) to include in the 2015-16 Federal Legislative Program SUPPORT for H.R. 1552 (Slaughter) and S. 621 (Feinstein) which would ensure the safety and effectiveness of medically important antimicrobials approved for use in the prevention and control of animal diseases in order to minimize the development of antibiotic-resistant bacteria.

SUMMARY

The Resolution (O'Farrell – Ryu), introduced on October 13, 2015, states that 80 percent of the antibiotics sold in the United States are used in livestock production. The Resolution indicates that low doses are routinely given to livestock in order to compensate for crowded, unsanitary conditions in a practice known as "non-therapeutic use." The Resolution further states that antibiotic resistant bacteria have resulted from the use of nontherapeutic use of antibiotics in agriculture and are the cause of several food-borne illness outbreaks.

H.R. 1552 and S. 621 would require that antibiotics used in the treatment of human and animal diseases to demonstrate that there is a reasonable certainty of no harm to human health from the antimicrobial resistance attributable to the nontherapeutic use of the drug.

The Resolution requests that the City support H.R. 1552 and S. 621.

BACKGROUND

Antibiotics have been in use since the 1940s, and have greatly reduced illness and death caused by bacterial pathogens. However, the extensive use of these drugs during the past 70 years has spurred the development of pathogens which are difficult or impossible to kill with existing antibiotics. The World Health Organization (WHO) states that antibiotic resistance is occurring in all regions of the world and constitutes a major threat to public health. According to the WHO, in the absence of urgent action, the world may be entering a "post-antibiotic era" in which common bacterial infections can cause serious illness or death.

The Centers for Disease Control and Prevention (CDC) states that 2 million individuals within the United States become infected with antibiotic-resistant bacteria per year. Of these individuals, 23,000 people die as a result of the infection. The CDC indicates that such resistance develops through the inappropriate use of antibiotics and person-to-person spread of disease-resistant pathogens. In addition, the CDC states that there is a link between the use of antibiotics in food-producing animals and antibiotic-resistant illnesses in humans. According to the CDC, antibiotics should only be provided to food-producing animals for the treatment of infectious disease rather than the promotion of growth.

The CDC indicates that immunization, safe food preparation, handwashing, and using antibiotics as directed and as necessary will help prevent the development of antibiotic-resistant bacteria. The CDC further states that more effective disease tracking and the development of new drugs and diagnostic tests will also help prevent the development of these organisms.

On March 2, 2015, S. 621 (Feinstein) was introduced in the United States Senate. The bill, also known as the Preventing Antibiotic Resistance Act of 2015, would require the Food and Drug Administration (FDA) to reject a new animal drug application if the applicant fails to demonstrate the following: the drug is effective, the drug is targeted to animals at risk of developing a specific bacterial disease, and there is reasonable certainty of no harm to human health from microbial resistance to the drug. Antibiotics already approved for use in food-producing animals must submit documentation to the FDA verifying that the drug meets this criteria. Under S. 621, the FDA is required to withdraw approval of a drug if it determines there is insufficient evidence that the drug meets this criteria. According to the author, this bill will help to prevent the rise of antibiotic-resistant pathogens by ensuring the careful use of antibiotics in the agriculture industry. On March 23, 2015, H.R. 1552 (Slaughter) was introduced in the United States House of Representatives and contains similar provisions as S. 621.

The Emergency Management Department states that these bills, if enacted, would not affect City operations. However, both bills are consistent with existing City policies and practices which ensure the health and safety of City residents. Therefore, we recommend that the City support S. 621 and H.R. 1552.

Department Notified
Emergency Management

Bill Status

S. 621 (Feinstein):
March 2 Introduced and referred to Committee on Health, Education, Labor, and Pensions.

H.R. 1552 (Slaughter):
March 23 Introduced in House.

Brian Randol
Analyst

Attachments:
1. Resolution
2. Text of S. 621
3. Text of H.R. 1552

SMT MF PS BMR

RESOLUTION

WHEREAS, any official position of the City of Los Angeles with respect to legislation, rules, regulations or policies proposed to or pending before a local, state or federal governmental body or agency must have first been adopted in the form of a Resolution by the City Council with the concurrence of the Mayor; and

WHEREAS, eighty percent of the antibiotics sold in the United States are used in livestock production with the Centers for Disease Control and Prevention reporting that most of those antibiotics are used irresponsibly; and

WHEREAS, low doses of antibiotics are routinely fed to livestock for growth promotion and disease prevention to compensate for crowded, unsanitary conditions, in a practice known as "nontherapeutic use"; and

WHEREAS, "nontherapeutic use" creates ideal conditions for the development of antibiotic resistant bacteria; and

WHEREAS, antibiotic resistant bacteria on livestock operations are known to spread to retail meat, farmers, farm workers and rural environments; and

WHEREAS, antibiotic resistance in pathogens as the result of the "nontherapeutic use" of antibiotics in livestock production has been a public health concern since the 1960s; and

WHEREAS, antibiotic resistant bacteria are the cause of several food borne illness outbreaks, including a 2011 outbreak of antibiotic resistant *Salmonella* in ground turkey which sickened 136 people, hospitalized 37, and killed one which led to the third largest meat recall in the USDA's records and a 2013 outbreak of antibiotic resistant *Salmonella* in chicken that sickened 416 people and hospitalized 162; and

WHEREAS, the Centers for Disease Control and Prevention reported that at least two million Americans suffer from antibiotic resistant bacterial infections each year and twenty-three thousand Americans die from those infections; and

WHEREAS, the medical and social costs of antibiotic-resistant infections in just one hospital, for one year, have been estimated to be between $13 million and $18 million; and

WHEREAS, Representative Louise Slaughter has introduced H.R. 1552, the Preservation of Antibiotics for Medical Treatment Act (PAMTA), to amend the Federal Food, Drug, and Cosmetic Act, to preserve the effectiveness of medically important antimicrobials used in the treatment of human and animal diseases by requiring approval for use of an animal drug, which is a medically important antimicrobial, to demonstrate that there is reasonable certainty of no harm to human health from antimicrobial resistance attributable to the nontherapeutic use of the drug; and

WHEREAS, Senator Diane Feinstein has introduced S. 621, the Prevention of Antibiotic Resistance Act (PARA), to amend the Federal Food, Drug, and Cosmetic Act to ensure the safety and effectiveness of medically important antimicrobials approved for use in the prevention and control of animal diseases, in order to minimize the development of antibiotic-resistant bacteria. The bill instructs the Federal Drug and Food Administration to start the process of examining drug approvals, and defines a veterinarian client-patient relationship;

NOW, THEREFORE, BE IT RESOLVED, with the concurrence of the Mayor, that by the adoption of this Resolution, the City of Los Angeles includes in its 2015-2016 Federal Legislative Program **SUPPORT** of H.R. 1552, the Protection of Antibiotics for Medical Treatment Act (PAMTA), and S. 621, the Prevention of Antibiotic Resistance Act (PARA), which would preserve the effectiveness of medically important antimicrobials used in the treatment of human and animal diseases and to ensure the safety and effectiveness of medically important antimicrobials approved for use in the prevention and control of animal diseases, in order to minimize the development of antibiotic-resistant bacteria.

PRESENTED BY: _____
MITCH O'FARRELL
Councilmember, 13th District

SECONDED BY: _____

ORIGINAL

114TH CONGRESS
1ST SESSION

S. 621

To amend the Federal Food, Drug, and Cosmetic Act to ensure the safety and effectiveness of medically important antimicrobials approved for use in the prevention and control of animal diseases, in order to minimize the development of antibiotic-resistant bacteria.

IN THE SENATE OF THE UNITED STATES

MARCH 2, 2015

MRS. FEINSTEIN (for herself, Ms. COLLINS, Mrs. GILLIBRAND, and Ms. WARREN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to ensure the safety and effectiveness of medically important antimicrobials approved for use in the prevention and control of animal diseases, in order to minimize the development of antibiotic-resistant bacteria.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Preventing Antibiotic Resistance Act of 2015".

SEC. 2. PURPOSE.

The purpose of this Act is to ensure the safety and effectiveness of medically important antimicrobials approved for use in the prevention and control of animal diseases, in order to minimize the development of antibiotic-resistant bacteria.

SEC. 3. EVIDENCE OF SAFETY OF MEDICALLY IMPORTANT VETERINARY ANTIMICROBIALS.

(a) APPLICATIONS PENDING OR SUBMITTED AFTER ENACTMENT.—Section 512(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(d)(1)) is amended—

(1) in the first sentence—

(A) in subparagraph (H), by striking "or" at the end;

(B) in subparagraph (I), by inserting "or" at the end; and

(C) by inserting after subparagraph (I) the following:

"(J) with respect to a medically important antimicrobial (as defined in subsection (q)), the applicant has failed to demonstrate that a New Animal Drug Application for an antimicrobial labeled for disease prevention or control fails to meet the criteria in subsection (q)(2)(A);"; and

(2) in the second sentence, by striking "(A) through (I)" and inserting "(A) through (J)".

(b) ENSURING JUDICIOUS USE IN ANIMALS OF MEDICALLY IMPORTANT ANTIMICROBIALS.—Section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) is amended by adding at the end the following:

"(q) ENSURING JUDICIOUS USE IN ANIMALS OF MEDICALLY IMPORTANT ANTIMICROBIALS.—

"(1) APPLICABILITY.—This subsection applies to medically important antimicrobials approved for use in a food-producing animal—

"(A)(i) for which there is in effect an approval of an application or an exemption under subsection (b), (i), or (j) of section 505; or

"(ii) that is otherwise marketed for human use;

"(B) for which the Food and Drug Administration has initiated or completed withdrawal or modification of an approved label for growth promotion, feed efficiency, or other production use or over-the-counter use, in accordance with the Guidance for Industry entitled, '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', published in December 2013; and

"(C) for which the Food and Drug Administration has approved a label—

"(i) for disease control or prevention at the same or similar dosage level as applicable for the approved production use described in subparagraph (B);

"(ii) that does not specify an explicitly defined duration of therapy; or

"(iii) specifying a dosage that is not expected to treat a specific bacterial pathogen.

"(2) REVIEW OF DISEASE PREVENTION AND CONTROL APPROVALS.—

"(A) IN GENERAL.—Not later than January 1, 2017, the Secretary shall initiate a process whereby—

"(i) not later than January 1, 2018, a sponsor of an antimicrobial drug described in paragraph (1) shall submit to the Secretary evidence demonstrating that, with respect to such drug—

"(I) there is evidence of effectiveness in controlling or preventing bacterial disease;

"(II) an approved use is consistent with accepted veterinary practice;

"(III) an approved use is linked to a specific etiologic agent;

"(IV) an approved use is appropriately targeted to animals at risk of developing a specific bacterial disease;

"(V) an approved use has an explicitly defined duration of therapy; and

"(VI) there is reasonable certainty of no harm to human health due to the development of antimicrobial resistance; and

"(ii)(I) if the Secretary determines that the evidence submitted under clause (i) is sufficient to demonstrate that the drug meets the requirements described in subclauses (I) through (VI) of such clause, not later than December 31, 2018, the Secretary shall issue a revised label ap-

proval for the antimicrobial drug, as necessary; or

"(II) if the Secretary determines that the evidence submitted under clause (i) is insufficient to demonstrate that the drug meets the requirements described in subclauses (I) through (VI) of such clause, not later than December 31, 2018, the Secretary shall withdraw approval of any indication claims described in paragraph (1)(C) for which the Secretary determines the evidence is insufficient and, as necessary, issue a revised label approval.

"(B) WITHDRAWAL OF CLAIMS.—On or before January 1, 2018, the sponsor of a drug described in paragraph (1) may request the approval of the Secretary to remove any label claim described in paragraph (1)(C), and the Secretary shall approve any such request and, as necessary, issue a revised label. The sponsor shall not be required to submit the evidence required under subparagraph (A)(i) with respect to any claim so withdrawn.

"(3) EXEMPTIONS.—In the case of a drug that is a medically important antimicrobial for which the

Secretary grants an exemption under section 505(i), the withdrawal of indication claims in a food-producing animal in accordance with paragraph (2)(B) shall be effective on the date that is 2 years after the date on which the Secretary grants the exemption, unless, not later than 2 years after the date on which the Secretary grants the exemption, the Secretary provides a written determination of intent to extend the exemption.

"(4) DEFINITION.—In this subsection, the term 'medically important antimicrobial' means a drug that—

"(A) is intended for use in food-producing animals; and

"(B) is composed wholly or partly of—

"(i) any kind of penicillin, tetracycline, macrolide, lincosamide, streptogramin, aminoglycoside, sulfonamide, cephalosporin, or fluoroquinolone; or

"(ii) a drug from an antimicrobial class that is listed as 'highly important', 'critically important', or 'important' by the World Health Organization in the latest edition of its publication entitled 'Critically

Important Antimicrobials for Human Medicine' (or a successor publication).".

SEC. 4. SENSE OF THE SENATE REGARDING VETERINARY OVERSIGHT OF USE OF MEDICALLY IMPORTANT ANTIMICROBIALS.

(a) IN GENERAL.—It is the sense of the Senate that a valid veterinarian-client-patient relationship should exist to ensure that medically important antimicrobials are used in food-producing animals in a manner that is consistent with professionally accepted best practices.

(b) VETERINARIAN-CLIENT-PATIENT RELATIONSHIP.—In this section, the term "veterinarian-client-patient relationship" means a relationship in which all of the following criteria are met:

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

(2) The veterinarian has sufficient knowledge of the patient to initiate at least a general or preliminary diagnosis of the medical condition of the patient. This means that the veterinarian is personally acquainted with the keeping and care of the patient by virtue of—

(A) a timely examination of the patient by the veterinarian; or

(B) medically appropriate and timely visits by the veterinarian to the premises where the animal or animals are kept.

(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.

(5) Patient records are maintained.

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114TH CONGRESS
1ST SESSION

H. R. 1552

To amend the Federal Food, Drug, and Cosmetic Act to preserve the effectiveness of medically important antimicrobials used in the treatment of human and animal diseases.

IN THE HOUSE OF REPRESENTATIVES

MARCH 23, 2015

Ms. SLAUGHTER (for herself, Mr. BLUMENAUER, Mr. CARTWRIGHT, Ms. CLARKE of New York, Mr. CONNOLLY, Ms. DELAURO, Mr. DEUTCH, Ms. EDWARDS, Ms. ESHOO, Mr. FARR, Mr. LEVIN, Mr. LOWENTHAL, Mrs. CAROLYN B. MALONEY of New York, Ms. MOORE, Ms. PINGREE, Mr. RANGEL, Ms. SCHAKOWSKY, Mr. SCHIFF, Ms. SPEIER, Ms. TSONGAS, Mr. WELCH, and Mr. GRIJALVA) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to preserve the effectiveness of medically important antimicrobials used in the treatment of human and animal diseases.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Preservation of Antibiotics for Medical Treatment Act of 2015".

SEC. 2. FINDINGS.

The Congress finds the following:

(1) All uses of antibiotics, including for food-producing animals, have the potential to cause resistance and contribute to the development of antibiotic-resistant bacterial infections in people.

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

(3) In 2012, the Food and Drug Administration Guidance for Industry #209 provided a summary of over 40 years of peer-reviewed scientific literature regarding use of antimicrobial drugs in livestock which reiterated that the use of antibiotics in animals contributes to the resistance in human pathogens and concludes that strategies for controlling antibiotic resistance, including limiting medically important antimicrobial drugs in food-producing animals only to uses that are considered necessary for assuring animal health are needed.

(4) The 2014 President's Council of Advisors on Science and Technology Report to the President

on Combating Antibiotic-Resistant Bacteria also concludes that substantial evidence exists that the use of antibiotics in food animals promotes the development and spread of antibiotic resistance in bacteria that can spread to people and that it is clear that agricultural use of antibiotics can affect human health.

(5) Recently published scientific studies have shown that food-producing animals, and animal production facilities, are a source of antibiotic-resistant bacteria which have infected humans and present an increased risk of acquiring and antibiotics resistant infection.

(6) Antibiotic resistance is a crisis which threatens public health, the economy, and national security.

(7) In 2013, the Centers for Disease Control and Prevention estimated that antibiotic-resistant infections cause at least 2 million infections, 23,000 deaths, 8 million additional hospital days, and $20 to $35 billion in excess direct health care costs each year in the United States.

(8) The 2014 World Health Organization report, "Antimicrobial Resistance: Global Report on Surveillance 2014", concluded that antimicrobial re-

sistance is a current reality and the problem is so serious that it threatens the achievements of modern medicine.

(9) Without effective antibiotics—

(A) common infections could become untreatable—even fatal; and

(B) medical advances such as joint replacements, Cesarean sections, organ transplants and chemotherapy could become nonviable.

(10) Antibiotic resistance, resulting in a reduced number of effective antibiotics, may significantly impair the ability of the United States to respond to terrorist attacks involving bacterial infections, such as anthrax and smallpox, or to an event resulting in a large influx of hospitalized patients.

(11) In 2011, the Food and Drug Administration determined that—

(A) 13.5 million kilograms of antibacterial drugs were sold for use on food animals in the United States in 2010;

(B) 3.3 million kilograms of antibacterial drugs were used for human health in 2010; and

(C) therefore, 80 percent of antibacterial drugs disseminated in the United States in

2010 were sold for use on food animals, rather than being used for human health.

(12) The "FDA Annual Summary Report on Antimicrobials Sold or Distributed in 2012 for Use in Food-Producing Animals" showed that the use of medically important antibiotics in food-producing animals increased 16 percent from 2009 to 2012.

(13)(A) In 2003, the Food and Drug Administration modified the drug approval process for antibiotics to recognize the development of resistant bacteria as an important aspect of safety, but most antibiotics currently used in animal production systems for nontherapeutic purposes were approved before the Food and Drug Administration began considering resistance during the drug-approval process.

(B) The Food and Drug Administration has not established a schedule for reviewing those existing approvals.

(14) A stated goal of FDA Guidance documents 209 and 213 is a reduction in the overall consumption of antibiotics. The FDA policy continues to allow the use of antibiotics for routine disease prevention without requiring evidence of the presence of a specific disease or requiring the mitigation of conditions which elevate disease risk.

(15) There is inadequate distinction between usage for disease prevention and production purposes, such as growth promotion, on FDA approved drug labels. A 2014 analysis of the approved animal drugs affected by Guidance 213 by the Pew Charitable Trusts found that numerous approved drug labels contained overlapping indications for growth-promotion and disease prevention.

(16) The European Union (EU) banned the use of antibiotics for growth promotion in 2006, a full decade before the FDA's voluntary approach will go into effect.

(17) Since the EU ban, antibiotic usage has decreased without affecting livestock production.

(18) 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.

(19) The experience in the Netherlands has shown that during the phaseout use indications for growth promotion were completely supplanted by disease prevention. Total antibiotic consumption remained constant. After the implementation of man-

datory reduction targets and improved surveillance of usage practices antibiotic consumption declined ahead of target without impacting production levels.

(20) In 2009, the Congressional Research Service concluded that without restrictions on the use of antimicrobial drugs in the production of livestock, export markets for livestock and poultry could be negatively impacted due to restrictions on the use of antibiotics in other nations.

(21) The American Medical Association, the Infectious Disease Society of America, the American Public Health Association, the National Association of County and City Health Officials, and the National Sustainable Agriculture Coalition are among the over 400 organizations representing health, consumer, agricultural, environmental, humane, and other interests that have supported enactment of legislation to phaseout nontherapeutic use in farm animals of medically important antimicrobials.

SEC. 3. PURPOSE.

The purpose of this Act is to preserve the effectiveness of medically important antimicrobials used in the treatment of human and animal diseases.

SEC. 4. PROOF OF SAFETY OF MEDICALLY IMPORTANT ANTIMICROBIALS.

(a) APPLICATIONS PENDING OR SUBMITTED AFTER ENACTMENT.—Section 512(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(d)(1)) is amended—

(1) in the first sentence—

(A) in subparagraph (H), by striking "or" at the end;

(B) in subparagraph (I), by inserting "or" at the end; and

(C) by inserting after subparagraph (I) the following:

"(J) with respect to a medically important antimicrobial (as defined in subsection (q)), the applicant has failed to demonstrate that there is a reasonable certainty of no harm to human health due to the development of antimicrobial resistance that is attributable, in whole or in part, to the nontherapeutic use (as defined in subsection (q)) of the medically important antimicrobial or drug;"; and

(2) in the second sentence, by striking "(A) through (I)" and inserting "(A) through (J)".

(b) PHASED ELIMINATION OF NONTHERAPEUTIC USE IN ANIMALS OF MEDICALLY IMPORTANT

ANTIMICROBIALS.—Section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) is amended by adding at the end the following:

"(q) PHASED ELIMINATION OF NONTHERAPEUTIC USE IN ANIMALS OF MEDICALLY IMPORTANT ANTIMICROBIALS.—

"(1) APPLICABILITY.—This paragraph applies to the nontherapeutic use in a food-producing animal of a drug—

"(A) that is a medically important antimicrobial; or

"(B)(i) for which there is in effect an approval of an application or an exemption under subsection (b), (i), or (j) of section 505; or

"(ii) that is otherwise marketed for human use.

"(2) WITHDRAWAL.—The Secretary shall withdraw the approval of a nontherapeutic use in food-producing animals of a drug described in paragraph (1) on the date that is 2 years after the date of enactment of this subsection unless—

"(A) before the date that is 2 years after the date of the enactment of this subsection, the Secretary makes a final written determination that the holder of the approved application

has demonstrated that there is a reasonable certainty of 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; or

"(B) before the date specified in subparagraph (A), the Secretary makes a final written determination under this subsection, with respect to a risk analysis of the drug conducted by the Secretary and other relevant information, that there is a reasonable certainty of 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.

"(3) EXEMPTIONS.—Except as provided in paragraph (5), if the Secretary grants an exemption under section 505(i) for a drug that is a medically important antimicrobial, the Secretary shall rescind each approval of a nontherapeutic use in a food-producing animal of the medically important antimicrobial as of the date that is 2 years after the date on which the Secretary grants the exemption.

"(4) APPROVALS.—Except as provided in paragraph (5), if an application for a drug that is a

medically important antimicrobial is submitted to the Secretary under section 505(b), the Secretary shall rescind each approval of a nontherapeutic use in a food-producing animal of the medically important antimicrobial as of the date that is 2 years after the date on which the application is submitted to the Secretary.

"(5) EXCEPTIONS.—Paragraph (3) or (4), as the case may be, shall not apply if—

"(A) before the date on which approval would be rescinded under that paragraph, the Secretary makes a final written determination that the holder of the application for the approved nontherapeutic use has demonstrated that there is a reasonable certainty of no harm to human health due to the development of antimicrobial resistance that is attributable in whole or in part to the nontherapeutic use in the food-producing animal of the medically important antimicrobial; or

"(B) before the date specified in subparagraph (A), the Secretary makes a final written determination, with respect to a risk analysis of the medically important antimicrobial conducted by the Secretary and any other relevant infor-

mation, that there is a reasonable certainty of 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 medically important antimicrobial.

"(6) DEFINITION.—In this subsection:

"(A) The term 'medically important antimicrobial' means a drug that—

"(i) is intended for use in food-producing animals; and

"(ii) is composed wholly or partly of—

"(I) any kind of penicillin, tetracycline, macrolide, lincosamide, streptogramin, aminoglycoside, sulfonamide, or cephalosporin; or

"(II) a drug from an antimicrobial class that is listed as 'highly important', 'critically important', or 'important' by the World Health Organization in the latest edition of its publication entitled 'Critically Important Antimicrobials for Human Medicine' (or a successor publication).

"(B) The term 'therapeutic use', with respect to a medically important antimicrobial,

means the use of antimicrobials for the specific purpose of treating an animal with a documented disease or infection. Such term does not include the continued use of such an antimicrobial in the animal after the disease or infection is resolved.

"(C) The term 'nontherapeutic use'—

"(i) means administration of antibiotics to an animal through feed and water (or, in poultry hatcheries, through any means) for purposes (such as growth promotion, feed efficiency, weight gain, or disease prevention) other than therapeutic use or nonroutine disease control; and

"(ii) includes any repeated or regular pattern of use of medically important antimicrobials for purposes other than therapeutic use or nonroutine disease control.

"(D) The term 'noncustomary situation' does not include normal or standard practice and conditions on the premises that facilitate the transmission of disease.

"(E) The term 'nonroutine disease control' means the use of antibiotics on an animal that

is not sick but where it can be shown that a particular disease or infection is present, or is likely to occur because of a specific, noncustomary situation, on the premises at the barn, house, pen, or other level at which the animal is kept.".

SEC. 5. LIMITATIONS ON USE OF MEDICALLY IMPORTANT ANTIMICROBIALS FOR NONROUTINE DISEASE CONTROL.

(a) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

"(ccc) The administration of a medically important antimicrobial to a food-producing animal for nonroutine disease control in violation of the requirements of section 512A.".

(b) REQUIREMENTS.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 512 of such Act (21 U.S.C. 360b) the following:

"SEC. 512A. LIMITATIONS ON USE OF MEDICALLY IMPORTANT ANTIMICROBIALS FOR NONROUTINE DISEASE CONTROL.

"(a) PROHIBITION.—It shall be unlawful to administer (including by means of animal feed) a medically im-

portant antimicrobial to a food-producing animal for non-routine disease control unless—

"(1) there is a significant risk that a disease or infection 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 described in paragraph (1);

"(3) the medically important antimicrobial is administered to the food-producing animal for non-routine disease control for the shortest duration possible to prevent or reduce the risk of transmission of the disease or infection described in paragraph (1) to the animal; and

"(4) the medically important antimicrobial is administered—

"(A) at a scale no greater than the barn, house, or pen level; and

"(B) to the fewest animals possible to prevent or reduce the risk of transmission of the disease or infection described in paragraph (1).

"(b) DEFINITIONS.—In this section:

"(1) The term 'food-producing animal' means a food-producing animal intended for sale in interstate commerce.

"(2) The terms 'medically important antimicrobial' and 'nonroutine disease control' have the meanings given to such terms in section 512(q).".

(c) APPLICABILITY.—The amendments made by this section apply beginning on the date that is 6 months after the date of the enactment of this Act.

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