113TH CONGRESS
1ST SESSION

S. 1256

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 SENATE OF THE UNITED STATES

JUNE 27, 2013

Mrs. FEINSTEIN (for herself, Ms. COLLINS, Mr. REED, Ms. CANTWELL, and Mrs. BOXER) 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 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 ''Preventing Antibiotic Resistance Act of 2013''.

SEC. 2. FINDINGS.

The Congress finds the following:

(1)(A) In 1977, the Food and Drug Administration 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.

(B) In 2012, the Food and Drug Administration was ordered by a Federal court to address the use of antibiotics in livestock, as the result of a lawsuit filed against the agency citing the agency's failure to act in response to the 1977 findings.

(2)(A) In 1998, the National Academy of Sciences noted that antibiotic-resistant bacteria generate a minimum of $4,000,000,000 to $5,000,000,000 in costs to United States society and individuals yearly.

(B) In 2009, Cook County Hospital and the Alliance for Prudent Use of Antibiotics estimated that the total health care cost of antibiotic resistant infections in the United States was between $16,600,000,000 and $26,000,000,000 annually.

(3) An April 1999 study by the Government Accountability Office concluded that resistant strains of 3 microorganisms that cause foodborne ill-

ness or disease in humans (Salmonella, Campylobacter, and E. coli) are linked to the use of antibiotics in animals.

(4)(A) Large-scale, voluntary surveys by the Department of Agriculture's Animal and Plant Health Inspection Service in 1999, 2001, and 2006 revealed that—

(i) 84 percent of grower-finisher swine farms, 83 percent of cattle feedlots, and 84 percent of sheep farms administer antimicrobials in the feed or water for health or growth promotion reasons; and

(ii) many of the antimicrobials identified are identical or closely related to drugs used in human medicine, including tetracyclines, macrolides, Bacitracin, penicillins, and sulfonamides.

(B) Such drugs are used in people to treat serious diseases such as pneumonia, scarlet fever, rheumatic fever, sexually transmitted infections, skin infections, and even pandemics like malaria and plague, as well as bioterrorism agents such as anthrax.

(5)(A) Any overuse or misuse of antibiotics contributes to the spread of antibiotic resistance, whether in human medicine or in agriculture.

(B) Recognizing the public health threat caused by antibiotic resistance, Congress took several steps to curb antibiotic overuse in human medicine through amendments to the Public Health Service Act (42 U.S.C. 201 et seq.) made by section 102 of the Public Health Threats and Emergencies Act (Public Law 106–505; 114 Stat. 2315), but has not yet addressed antibiotic overuse in agriculture.

(6) In January 2001, a Federal interagency task force—

(A) released an action plan to address the continuing decline in effectiveness of antibiotics against common bacterial infections, referred to as antibiotic resistance;

(B) determined that antibiotic resistance is a growing menace to all people and poses a serious threat to public health; and

(C) cautioned that if current trends continue, treatments for common infections will become increasingly limited and expensive, and, in some cases, nonexistent.

(7) The United States Geological Survey reported in March 2002 that—

(A) antibiotics were present in 48 percent of the streams tested nationwide; and

(B) almost half of the tested streams were downstream from agricultural operations.

(8) The peer-reviewed journal ''Clinical Infectious Diseases'' published a report in June 2002 that—

(A) was based on a 2-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; and

(B) recommended that antimicrobial agents should no longer be used in agriculture in the absence of disease, but should be limited to therapy for diseased individual animals and prophylaxis when disease is documented in a herd or flock.

(9) In a March 2003 report, the National Academy of Sciences stated that—

(A) a decrease in antimicrobial use in human medicine alone will have little effect on the current situation; and

(B) substantial efforts must be made to decrease inappropriate overuse in animals and agriculture.

(10) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)—

(A) requires that all drugs be shown to be safe before the drugs are approved; and

(B) places the burden on manufacturers to account for health consequences and prove safety.

(11)(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.

(12)(A) In an April 2004 report, the Government Accountability Office—

(i) concluded that Federal agencies do not collect the critical data on antibiotic use in animals that they need to support research on human health risks; and

(ii) recommended that the Department of Agriculture and the Department of Health and Human Services develop and implement a plan to collect data on antibiotic use in animals.

(B) In a September 2011 update to that report, the Government Accountability Office—

(i) concluded that Federal agencies had made limited progress in addressing antibiotic use in animals;

(ii) recommended that Federal agencies fund research on alternatives to current antibiotic use practices; and

(iii) recommended that Federal agencies track the effectiveness of policies that curb antibiotic resistance, including the Food and Drug Administration's voluntary guidelines reducing antibiotic use in food animals.

(13) 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.

(14) In 2010, the peer-reviewed journal ''Molecular Cell'' published a study demonstrating that 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.

(15) 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.

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

(A) 13,500,000 kilograms of antibacterial drugs were sold for use on food animals in the United States in 2010;

(B) 3,300,000 kilograms of antibacterial drugs were used for human health in 2010; and

(C) 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.

(17) In 2011, a review of all scientific studies on antimicrobial use in farm animals, published in Clinical Microbiology Reviews, found that—

(A) use of antibiotics in food animals leads to development of reservoirs of antibiotic resistance;

(B) a ban on nontherapeutic antibiotic use in food animals would preserve the use of such antibiotics for medicine; and

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

(18) In April 2012, the Food and Drug Administration issued voluntary guidance to industry on reducing antibiotic use in livestock and poultry. As part of that guidance, it summarized over 35 years of peer-reviewed scientific literature regarding use of antimicrobial drugs in livestock. As a result, the Food and Drug Administration stated strategies for

controlling antibiotic resistance are needed, and are seeking voluntarily limits on antibiotic use.

(19)(A) In January 2013, Consumer Reports published test results on pork products bought in grocery stores nationwide showing disturbingly high levels of Salmonella and Yersinia enterocolitica bacteria that were resistant to the antibiotics used to treat foodborne illnesses. A 2003 Consumer Report study showed similar results in poultry products.

(B) The Food and Drug Administration's National Antimicrobial Resistance Monitoring System routinely finds that retail meat products are contaminated with bacteria (including the foodborne pathogens Campylobacter and Salmonella) that are resistant to antibiotics important in human medicine. The 2011 National Antimicrobial Resistance Monitoring System report found that the percentage of meat containing antibiotic resistant bacteria increases each year and that many of these bacteria exhibit multiple antibiotic resistance.

(20) 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 or a large influx of hospitalized patients.

(21) Many scientific studies confirm that the nontherapeutic use of antibiotics in agricultural animals contribute to the development of antibiotic-resistant bacterial infections in people.

(22) Epidemiological research has shown that resistant Salmonella and Campylobacter infections are associated with increased numbers of ill patients and bloodstream infections, and increased death.

(23) The American Medical Association, the American Public Health Association, the National Association of County and City Health Officials, and the National Sustainable Agriculture Coalition are among the more than 400 organizations representing health, consumer, agricultural, environmental, humane, and other interests that have supported enactment of legislation to phase out 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 subsection applies to the nontherapeutic use in a food-producing animal of a drug—

"(A) that is a medically important antimicrobial;

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

"(C) 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, effective on 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, effective on 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 applicable, 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 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 medically important antimicrobial.

''(6) DEFINITIONS.—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 or 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 in the feed or water of an animal that is not sick, where it can be shown that a particular disease or infection is, or is likely to be, present on the premises because of a specific, non-customary situation.''.

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 important antimicrobial to a food-producing animal for nonroutine disease control unless—

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

''(B) 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);

''(C) the medically important antimicrobial is administered to the food-producing animal for nonroutine 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

''(D) the medically important antimicrobial is administered—

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

''(ii) to the fewest animals possible to prevent or reduce the risk of transmission of the disease or infection described in paragraph (1); or

''(2) the Secretary determines 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 such use of the medically important antimicrobial and such use does not threaten the public health.

''(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 such terms in section 512(q).''.

(c) APPLICABILITY.—The amendments made by this section apply beginning on the date that is 2 years after the date of the enactment of this Act.

SEC. 6. 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 a manner that is consistent with professionally accepted best practices.

(b) VETERINARIAN-CLIENT-PATIENT RELATIONSHIP.—In ths 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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