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# S. 1211

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

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IN THE SENATE OF THE UNITED STATES

JUNE 15, 2011

Mrs. FEINSTEIN (for herself, Ms. COLLINS, Mr. REED, 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 antibiotics 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 2011''.

**SEC. 2. FINDINGS.**

The Congress finds the following:

(1) 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.

(2) 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.

(3)(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, title I; 114 Stat. 2315), but has not yet addressed antibiotic overuse in agriculture.

(4) 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.

(5) In 2010, the FDA determined that—

(A) 1,300,000 kilograms of antibacterial drugs were sold for use on food animals in the United States in 2009;

(B) 3,300,000 kilograms of antibacterial drugs were used for human health in 2009; and

(C) therefore, 80 percent of antibacterial drugs disseminated in the United States in 2009 were sold for use on food animals, rather than being used for human health.

(6)(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; and

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

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

(8) The periodical entitled ''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) 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.

(10) An April 1999 study by the General Accounting Office concluded that resistant strains of 3 microorganisms that cause food-borne illness or disease in humans (Salmonella, Campylobacter, and E. coli) are linked to the use of antibiotics in animals.

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

(12) 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.

(13)(A) In January 2003, Consumer Reports published test results on poultry products bought in grocery stores nationwide showing disturbingly high levels of Campylobacter and Salmonella bacteria that were resistant to the antibiotics used to treat foodborne illnesses.

(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.

(C) In December 2007, the USDA issued a fact sheet on the recently recognized link between antimicrobial drug use in animals and Methicillin Resistant Staphylococcus Aureas (MRSA) infections in humans.

(14) In October 2001, the New England Journal of Medicine published an editorial urging a ban on nontherapeutic use of medically important antibiotics in animals.

(15)(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.

(16) The American Medical Association, the American Public Health Association, the National Association of County and City Health Officials, and the National Campaign for Sustainable Agriculture are among the more than 300 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 antibiotics.

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

(18) In 2009, the Congressional Research Service concluded that restrictions overseas on the use of antimicrobial drugs in the production of livestock could impact U.S. export markets for livestock and poultry.

(19) 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.

(20)(A) The Food and Drug Administration recently 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 be-

fore 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.

(21) Certain non-routine uses of antibiotics in animal agriculture are legitimate to prevent animal disease.

(22) An April 2004 study by the General Accounting Office—

(A) 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

(B) recommends 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.

**SEC. 3. PURPOSE.**

The purpose of this Act is to preserve the effectiveness of medically important antibiotics used in the treatment of human and animal diseases by reviewing the safety of certain antibiotics for nontherapeutic purposes in food-producing animals.

**SEC. 4. PROOF OF SAFETY OF CRITICAL ANTIMICROBIAL ANIMAL DRUGS.**

(a) DEFINITIONS.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

''(ss) CRITICAL ANTIMICROBIAL ANIMAL DRUG.—The term 'critical antimicrobial animal drug' means a drug that—

''(1) is intended for use in food-producing animals; and

''(2) is composed wholly or partly of—

''(A) any kind of penicillin, tetracycline, macrolide, lincosamide, streptogramin, aminoglycoside, or sulfonamide; or

''(B) any other drug or derivative of a drug that is used in humans or intended for use in humans to treat or prevent disease or infection caused by microorganisms.

''(tt) NONTHERAPEUTIC USE.—The term 'nontherapeutic use', with respect to a critical antimicrobial animal drug, means any use of the drug as a feed or water additive for an animal in the absence of any clinical sign of disease in the animal for growth promotion, feed efficiency, weight gain, routine disease prevention, or other routine purpose.''.

(b) 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 critical antimicrobial animal drug or a drug of the same chemical class as a critical antimicrobial animal drug, 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 of the drug;''; and

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

(c) PHASED ELIMINATION OF NONTHERAPEUTIC USE IN ANIMALS OF CRITICAL ANTIMICROBIAL ANIMAL DRUGS IMPORTANT FOR HUMAN HEALTH.—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 CRITICAL ANTIMICROBIAL ANIMAL DRUGS IMPORTANT FOR HUMAN HEALTH.—

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

''(A)(i) that is a critical antimicrobial animal drug; or

''(ii) that is of the same chemical class as a critical antimicrobial animal drug; and

''(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 use.

''(2) WITHDRAWAL.—The Secretary shall withdraw the approval of a nontherapeutic use in food-producing animals 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, 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 critical antimicrobial animal drug, the Secretary shall rescind each approval of a nontherapeutic use in a food-producing animal of the critical antimicrobial animal drug, or of a drug in the same chemical class as the critical antimicrobial animal drug, 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 critical antimicrobial animal drug 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 critical antimicrobial animal drug, or of a drug in the same chemical class as the critical antimicrobial animal drug, as of the date that is 2 years after the date on which the application is submitted to the Secretary.

''(5) EXCEPTION.—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 critical antimicrobial animal drug; or

''(B) before the date specified in subparagraph (A), the Secretary makes a final written

determination, with respect to a risk analysis of the critical antimicrobial animal drug 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 drug.''.

**SEC. 5. COMMITTEE HEARINGS ON IMPLEMENTATION.**

(a) IN GENERAL.—The Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate shall each hold a hearing on the implementation by the Commissioner of Food and Drugs of section 512(q) of the Federal Food, Drug, and Cosmetic Act, as added by section 4 of this Act.

(b) EXERCISE OF RULEMAKING AUTHORITY.—Subsection (a) is enacted—

(1) as an exercise of the rulemaking power of the House of Representatives and Senate, and, as such, they shall be considered as part of the rules of the House or Senate (as the case may be), and such rules shall supersede any other rule of the House or Senate only to the extent that rule is inconsistent therewith; and

(2) with full recognition of the constitutional right of either House to change such rules (so far as relating to the procedure in that House) at any time, in the same manner, and to the same extent as in the case of any other rule of that House.

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