107TH CONGRESS
2D SESSION

S. 2508

To preserve the effectiveness of medically important antibiotics by restricting their use as additives to animal feed.

IN THE SENATE OF THE UNITED STATES

MAY 13 (legislative day, MAY 9), 2002

Mr. KENNEDY (for himself, Mr. REED, and Mr. BINGAMAN) 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 preserve the effectiveness of medically important antibiotics by restricting their use as additives to animal feed.

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 Human Treatment Act of 2002''.

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) Several antibiotics and classes of antibiotics either are used in or are related to antibiotics used

in humans to treat infectious diseases and are also routinely administered to healthy agricultural animals, generally via feed or water, in order to promote the animals' growth or to prevent disease. Such uses do not require a veterinarian's prescription.

(2) Mounting scientific evidence shows that this nontherapeutic use of antibiotics in agricultural animals can lead to development of antibiotic-resistant bacteria that can be transferred to people, making it harder to treat certain infections.

(3) In 1997 and in 2000, the World Health Organization recommended that antibiotics used to treat humans should not also be used to promote animal growth, although such antibiotics could still be used to treat ill animals. Most developed countries in the world, with the exception of the United States and Canada, restrict the use of antimicrobials in animal production systems for growth promotion.

(4) In July 1998, the National Academy of Sciences, in a report prepared at the request of the United States Department of Agriculture and the Food and Drug Administration, concluded ''there is a link between the use of antibiotics in food animals,

the development of bacterial resistance to these drugs, and human disease''.

(5) In July 1999, the European Union banned the use for animal growth promotion of remaining human-use antibiotics still in use to promote animal growth. Prior to that action, individual European countries, including the United Kingdom, Denmark, Finland, and Sweden, had banned the use in animal feed of specific antibiotics.

(6) In October 2000, the Food and Drug Administration issued a notice announcing its intention to withdraw approvals for use of fluoroquinolone antibiotics in poultry, in light of the fact that increased resistance to fluoroquinolones in certain bacteria followed approval of those antibiotics for such use in the mid-1990s. The Food and Drug Administration concluded that ''the use of fluoroquinolones in poultry is a significant cause of fluoroquinolone resistant infections in humans.'' One manufacturer of such drugs is contesting FDA's proposed withdrawal and continues to market its product. Previous proceedings by FDA to withdraw approval of animal drugs have taken substantial amounts of time following initiation of formal action by FDA, including 6 years in one instance and 20 in another.

(7) In June 2001, the American Medical Association adopted a resolution opposing nontherapeutic use of antimicrobials in animal agriculture. Medical professional organizations that have taken a similar position include the American College of Preventive Medicine, the American Public Health Association, and the Council of State and Territorial Epidemiologists.

(8) In October 2001, the New England Journal of Medicine published a guest editorial titled ''Antimicrobials in Animal Feed—Time to Stop''. The editorial urged a ban on nontherapeutic use in animals of medically important antibiotics.

(9) The National Academy of Sciences has found that eliminating the use of antibiotics as feed additives would cost each American consumer not more than $5 to $10 per year.

(10) In January 2001, a Federal interagency task force on antibiotic resistance concluded that ''drug-resistant pathogens are a growing menace to all people, regardless of age, gender, or socioeconomic background. If we do not act to address the problem . . . [d]rug choices for the treatment of common infections will become increasingly lim-

ited and expensive—and, in some cases, nonexistent.''.

(11) Scientific studies published in major peer-reviewed research journals have shown that resistance traits can be transferred among unrelated species of bacteria, including from nonpathogens to pathogens.

(12) Development of resistance to antibiotics could significantly impair the ability of the United States to respond effectively to a bioterrorist attack and is likely to increase the casualties that result from such an attack.

SEC. 3. PRESERVING THE EFFECTIVENESS OF ANTIBIOTICS SUCH AS CIPRO.

(a) PROHIBITING THE USE OF DRUGS RELATED TO CIPRO IN POULTRY.—Section 512(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(a)(2)) is amended—

(1) in subparagraph (B), by striking ''and'' at the end;

(2) in subparagraph (C), by striking the period and inserting ''; and''; and

(3) by adding at the end the following:

''(D) such drug is not a member of the fluoroquinolone class of antimicrobial drugs, or if

such drug is a member of the fluoroquinolone class of antimicrobial drugs, the Secretary shall have found, based on information submitted to the Secretary by the sponsor of such drug, that there exists 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 use in animal feed of such drug.

''Nothing in subparagraph (D) shall be construed to affect an approval under this subsection for a drug of the fluoroquinolone class of antimicrobial drugs that is used in or for cattle.''.

(b) DEFINITION.—Section 201(w) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(w)) is amended—

(1) by striking ''(w) The term'' and inserting ''(w)(1) The term''; and

(2) by adding at the end the following:

''(2) With respect to subparagraph (D) of section 512(a)(2) (and in provisions of this Act that refer to such subparagraph), the term 'animal feed' shall include an article that is a fluid administered to animals other than man. Such term does not include fluids administered via hypodermic injection.''.

SEC. 4. REQUIRING PROOF OF SAFETY OF ANTIMICROBIAL NEW ANIMAL DRUGS.

(a) NONTHERAPEUTIC USE; APPLICATIONS PENDING ON 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 subparagraph (H), by striking ''or'' at the end;

(2) by redesignating subparagraph (I) as subparagraph (J);

(3) by inserting after subparagraph (H) the following subparagraph:

''(I) with respect to a critical antimicrobial drug or a drug of the same chemical class as a critical antimicrobial 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 such drug; or''; and

(4) in the matter after and below subparagraph (J) (as redesignated by paragraph (2)), by striking ''(A) through (I)'' and inserting ''(A) through (J)''.

(b) PHASED ELIMINATION OF NONTHERAPEUTIC USE IN ANIMALS OF ANTIBIOTICS 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) With respect to the nontherapeutic use in an animal of—

''(1) a drug that is a critical antimicrobial drug; or

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

for which, as of the day before the date of enactment of this subsection, there was in effect an approval of an application filed pursuant to subsection (b), the Secretary shall withdraw such approval on the date that is 2 years after the date of enactment of this subsection unless the Secretary, based on information submitted to the Secretary by the sponsor of such drug, has determined prior to the date that is 2 years after such date of enactment 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 such drug.

''(r)(1) If the Secretary grants an exemption under section 505(i) or under section 351 of the Public Health Service Act (42 U.S.C. 262) to a drug that is an antibiotic drug, the Secretary shall rescind each approval of a nontherapeutic use in an animal of such drug or of a drug

in the same chemical class as such drug upon the expiration of the 2-year period beginning on the date on which the Secretary grants the exemption, except as provided in paragraph (3).

''(2) If an application for an antibiotic drug is submitted to the Secretary under section 505(b) or under section 351 of the Public Health Service Act (42 U.S.C. 262), the Secretary shall rescind each approval of a nontherapeutic use in an animal of such drug or a drug in the same chemical class as such drug upon the expiration of the 2-year period beginning on the date on which the application is submitted to the Secretary, except as provided in paragraph (3).

''(3) Paragraph (1) or (2), as the case may be, applies unless, before the date on which approval would be rescinded under such paragraph, the Secretary determines 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 in an animal of such drug.''.

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

''(s) For purposes of this section, the term 'nontherapeutic use', with respect to a critical antimicrobial drug, means any use of such drug in an animal in the absence of disease in such animal, including use for growth promotion, feed efficiency, or routine disease prevention.

''(t) For purposes of this section, the term 'critical antimicrobial drug' means any drug that is—

''(1) intended for use in animals other than humans that are—

''(A) intended for use as, or to generate, food for humans; or

''(B) intended to breed or otherwise produce animals described in subparagraph (A); and

''(2)(A) composed wholly or partly of any kind of penicillin, tetracycline, bacitracin, macrolide, lincomycin, streptogramin, aminoglycoside, sulfonamide; or

''(B) any other drug or derivative thereof that is used in humans or intended for use in humans to inhibit or destroy micro-organisms.''.

SEC. 5. ASSISTANCE TO DEFRAY FARMERS' EXPENSES IN PHASING OUT NONTHERAPEUTIC USE OF MEDICALLY IMPORTANT ANTIBIOTICS; PREFERENCE FOR FAMILY FARMS.

(a) IN GENERAL.—The Secretary of Agriculture may make payments to producers of livestock or poultry who the Secretary determines are substantially reducing, or have substantially reduced, the nontherapeutic use of critical antimicrobial drugs in livestock or poultry in order to defray the costs of such reduction.

(b) DEFINITION.—In this section the terms ''critical antimicrobial drug'' and ''nontherapeutic use'' have the meanings given such terms in section 512(s) of the Federal Food, Drug, and Cosmetic Act (as amended by this Act).

(c) PRIORITY FOR FAMILY FARMERS.—In awarding payments under subsection (a), the Secretary of Agriculture shall give priority to family-owned and family-operated farms or ranches.

(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be necessary to carry out this section for fiscal year 2003 and for each subsequent fiscal year.

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