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106TH CONGRESS
1ST SESSION

H. R. 3266

To direct that essential antibiotic drugs not be used in livestock unless there is a reasonable certainty of no harm to human health.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 9, 1999

Mr. BROWN of Ohio (for himself, Mr. WAXMAN, and Ms. SLAUGHTER) introduced the following bill; which was referred to the Committee on Commerce

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A BILL

To direct that essential antibiotic drugs not be used in livestock unless there is a reasonable certainty of no harm to human health.

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 Essential Antibiotics for Human Diseases Act of 1999''.

SEC. 2. FINDINGS AND PURPOSE.

(a) FINDINGS.—The Congress finds the following:

(1) Several antibiotics, particularly penicillin, tetracycline, erythromycin, lincomycin, tylosin, baci-

tracin and virginiamycin, that either are used in or are related to antibiotics used in humans to treat infectious diseases are also used in animal feed in subtherapeutic amounts in order to promote the animals' growth.

(2) Mounting scientific evidence shows that using those antibiotics in livestock feed can lead to antibiotic-resistant bacteria that can be transferred to people, making it harder to treat certain infections.

(3) In 1969, the Swann Committee was formed in the United Kingdom to examine the public health effects of use of antimicrobial drugs in food-producing animals. The Committee recommended that antimicrobials be divided into ''feed'' and ''therapeutic'' classes of drugs and that the ''feed'' class not include drugs used therapeutically in humans or animals. All developed countries in the world, with the exception of the United States and Canada, currently follow such recommendations.

(4) In 1997, 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.

(5) 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''.

(6) In December 1998, health ministers for the European Union countries voted to ban the 4 remaining human-use antibiotics still in use at subtherapeutic levels to promote animal growth. The ban on using virginiamycin, tylosin, spiramycin, and bacitracin in animal feed became effective for the 15 member states of the European Union on July 1, 1999. 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.

(7) An April 1999 study by the General Accounting Office states that resistant strains of 3 specific organisms that cause illness or disease in humans—salmonella, campylobacter, and E. coli—are linked to the use of antibiotics in animals.

(8) Removing certain antibiotics from subtherapeutic use will not hinder the raising of livestock be-

cause non-antimicrobial growth promoters, alternative antibiotics, and alternative husbandry practices are available.

(b) PURPOSE.—The purpose of this Act is to insure that certain antimicrobial drugs essential to human health are not used subtherapeutically in food animals unless there is a reasonable certainty of no harm to human health due to the development of antimicrobial resistance as a result of such use.

SEC. 3. REQUIRING PROOF OF SAFETY.

(a) IN GENERAL.—Section 512(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(d)(1)) is amended by striking ''or'' at the end of subparagraph (H), by redesignating subparagraph (I) as subparagraph (J), and by adding after subparagraph (H) the following:

''(I) the Secretary is unable to determine, based on data submitted by the applicant, that there is a reasonable certainty of no harm to human health due to the development of antimicrobial resistance which is attributable to the subtherapeutic use of such drug; or''.

(b) WITHDRAWAL OF APPROVAL.—Section 512(e) of such Act (21 U.S.C. 360b(e)) is amended by redesignating paragraph (3) as paragraph (4) and by inserting after paragraph (2) the following:

"(3)(A) Except as provided in subparagraph (B), 2 years after the date of the enactment of this paragraph, approval pursuant to subsection (b) with respect to the subtherapeutic use of penicillin, tetracycline, erythromycin, lincomycin, tylosin, bacitracin, virginiamycin, or other antimicrobial new animal drugs in animals is deemed to be withdrawn and the use will be deemed unsafe for the purposes of section 501(a)(6) unless, based on data submitted by the applicant, the Secretary determines that there is a reasonable certainty of no harm to human health due to the development of antimicrobial resistance which is attributable to the subtherapeutic use of such drug.

"(B) If the Secretary determines that there is not a reasonable certainty of no harm to human health due to the development of antibiotic resistance that is attributable to the subtherapeutic use of such drug, the Secretary may issue an order withdrawing approval sooner than 2 years after the date of enactment of this paragraph.".

(c) DEFINITION.—Section 512 of such Act is amended by adding at the end the following:

"(q) For purposes of this section, the term 'subtherapeutic use' means any use of an antimicrobial drug in ani-

mals other than the high level, short term use to treat ill animals.''.

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