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1ST SESSION

S. 619

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.

IN THE SENATE OF THE UNITED STATES

MARCH 17, 2009

Mr. REID (for Mr. KENNEDY (for himself and Ms. SNOWE)) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Preservation of Antibiotics for Medical Treatment Act of
6 2009”.

7 (b) TABLE OF CONTENTS.—The table of contents of
8 this Act is as follows:

- Sec. 1. Short title; table of contents.
Sec. 2. Findings.
Sec. 3. Purpose.
Sec. 4. Proof of safety of critical antimicrobial animal drugs.

1 **SEC. 2. FINDINGS.**

2 The Congress finds that—

3 (1)(A) in January 2001, a Federal interagency
4 task force released an action plan to address the
5 continuing decline in effectiveness of antibiotics
6 against common bacterial infections, referred to as
7 antibiotic resistance;

8 (B) the task force determined that antibiotic re-
9 sistance is a growing menace to all people and poses
10 a serious threat to public health; and

11 (C) the task force cautioned that if current
12 trends continue, treatments for common infections
13 will become increasingly limited and expensive, and,
14 in some cases, nonexistent;

15 (2) antibiotic resistance, resulting in a reduced
16 number of effective antibiotics, may significantly im-
17 pair the ability of the United States to respond to
18 terrorist attacks involving bacterial infections or a
19 large influx of hospitalized patients;

20 (3)(A) any overuse or misuse of antibiotics con-
21 tributes to the spread of antibiotic resistance, wheth-
22 er in human medicine or in agriculture; and

1 (B) recognizing the public health threat caused
2 by antibiotic resistance, Congress took several steps
3 to curb antibiotic overuse in human medicine
4 through amendments to the Public Health Service
5 Act (42 U.S.C. 201 et seq.) made by section 102 of
6 the Public Health Threats and Emergencies Act
7 (Public Law 106–505, title I; 114 Stat. 2315), but
8 has not yet addressed antibiotic overuse in agri-
9 culture;

10 (4) in a March 2003 report, the National Acad-
11 emy of Sciences stated that—

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

15 (B) substantial efforts must be made to
16 decrease inappropriate overuse in animals and
17 agriculture;

18 (5)(A) an estimated 70 percent of the anti-
19 biotics and other antimicrobial drugs used in the
20 United States are fed to farm animals for nonthera-
21 peutic purposes, including—

22 (i) growth promotion; and

23 (ii) compensation for crowded, unsanitary,
24 and stressful farming and transportation condi-
25 tions; and

1 (B) unlike human use of antibiotics, these non-
2 therapeutic uses in animals typically do not require
3 a prescription;

4 (6)(A) large-scale, voluntary surveys by the De-
5 partment of Agriculture's Animal and Plant Health
6 Inspection Service in 1999, 2001, and 2006 revealed
7 that 84 percent of grower-finisher swine farms, 83
8 percent of cattle feedlots, and 84 percent of sheep
9 farms administer antimicrobials in the feed or water
10 for health or growth promotion reasons, and many
11 of the antimicrobials identified are identical or close-
12 ly related to drugs used in human medicine, includ-
13 ing tetracyclines, macrolides, Bacitracin, penicillins,
14 and sulfonamides; and

15 (B) these drugs are used in people to treat seri-
16 ous diseases such as pneumonia, scarlet fever, rheu-
17 matic fever, venereal disease, skin infections, and
18 even pandemics like plague, as well as bioterrorism
19 agents like anthrax;

20 (7) many scientific studies confirm that the
21 nontherapeutic use of antibiotics in agricultural ani-
22 mals contributes to the development of antibiotic-re-
23 sistant bacterial infections in people;

24 (8)(A) the periodical entitled "Clinical Infec-
25 tious Diseases" published a report in June 2002,

1 based on a 2-year review by experts in human and
2 veterinary medicine, public health, microbiology, bio-
3 statistics, and risk analysis, of more than 500 sci-
4 entific studies on the human health impacts of anti-
5 microbial use in agriculture; and

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

11 (9) the United States Geological Survey re-
12 ported in March 2002 that—

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

15 (B) almost half of the tested streams were
16 downstream from agricultural operations;

17 (10) an April 1999 study by the General Ac-
18 counting Office concluded that resistant strains of 3
19 microorganisms that cause food-borne illness or dis-
20 ease in humans—*Salmonella*, *Campylobacter*, and *E.*
21 *coli*—are linked to the use of antibiotics in animals;

22 (11) epidemiological research has shown that
23 resistant *Salmonella* and *Campylobacter* infections
24 are associated with increased numbers of ill patients
25 and bloodstream infections, and increased death;

1 (12)(A) in January 2003, Consumer Reports
2 published test results on poultry products bought in
3 grocery stores nationwide showing disturbingly high
4 levels of Campylobacter and Salmonella bacteria that
5 were resistant to antibiotics used to treat food-borne
6 illnesses;

7 (B) the Food and Drug Administration's Na-
8 tional Antimicrobial Resistance Monitoring System
9 routinely finds that retail meat products are con-
10 taminated with bacteria resistant to antibiotics im-
11 portant in human medicine including the foodborne
12 pathogens Campylobacter and Salmonella; and

13 (C) in December 2007, the USDA issued a fact
14 sheet on the recently recognized link between anti-
15 microbial drug use in animals and the Methicillin
16 Resistant Staphylococcus Aureas (MRSA) infections
17 in humans;

18 (13) in October 2001, the New England Jour-
19 nal of Medicine published an editorial urging a ban
20 on nontherapeutic use of medically important anti-
21 biotics in animals;

22 (14) in 1998, the National Academy of Sciences
23 noted that antibiotic-resistant bacteria generate a
24 minimum of \$4,000,000,000 to \$5,000,000,000 in
25 costs to United States society and individuals yearly;

1 (15) the American Medical Association, the
2 American Public Health Association, the National
3 Association of County and City Health Officials, and
4 the National Campaign for Sustainable Agriculture,
5 are among the more than 300 organizations rep-
6 resenting health, consumer, agricultural, environ-
7 mental, humane, and other interests that have sup-
8 ported enactment of legislation to phase out non-
9 therapeutic use in farm animals of medically impor-
10 tant antibiotics;

11 (16) the Federal Food, Drug, and Cosmetic Act
12 (21 U.S.C. 301 et seq.)—

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

15 (B) places the burden on manufacturers to
16 account for health consequences and prove safe-
17 ty;

18 (17)(A) the Food and Drug Administration re-
19 cently modified the drug approval process for anti-
20 biotics to recognize the development of resistant bac-
21 teria as an important aspect of safety;

22 (B) however, most antibiotics currently used in
23 animal production systems for nontherapeutic pur-
24 poses were approved before the Food and Drug Ad-

1 ministration began giving in-depth consideration to
2 resistance during the drug-approval process; and

3 (C) the Food and Drug Administration has not
4 established a schedule for reviewing those existing
5 approvals;

6 (18) certain non-routine uses of antibiotics in
7 animal agriculture are legitimate to prevent animal
8 disease; and

9 (19)(A) an April 2004 study by the General Ac-
10 counting Office concluded that Federal agencies do
11 not collect the critical data on antibiotic use in ani-
12 mals that they need to support research on human
13 health risks; and

14 (B) the report recommends that the Depart-
15 ment of Agriculture and the Department of Health
16 and Human Services develop and implement a plan
17 to collect data on antibiotic use in animals.

18 **SEC. 3. PURPOSE.**

19 The purpose of this Act is to preserve the effective-
20 ness of medically important antibiotics used in the treat-
21 ment of human and animal diseases by reviewing the safe-
22 ty of certain antibiotics for nontherapeutic purposes in
23 food-producing animals.

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

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

6 “(rr) CRITICAL ANTIMICROBIAL ANIMAL DRUG.—
7 The term ‘critical antimicrobial animal drug’ means a
8 drug that—

9 “(1) is intended for use in food-producing ani-
10 mals; and

11 “(2) is composed wholly or partly of—

12 “(A) any kind of penicillin, tetracycline,
13 macrolide, lincosamide, streptogramin, amino-
14 glycoside, or sulfonamide; or

15 “(B) any other drug or derivative of a
16 drug that is used in humans or intended for use
17 in humans to treat or prevent disease or infec-
18 tion caused by microorganisms.

19 “(ss) NONTHERAPEUTIC USE.—The term ‘nonthera-
20 peutic use’, with respect to a critical antimicrobial animal
21 drug, means any use of the drug as a feed or water addi-
22 tive for an animal in the absence of any clinical sign of
23 disease in the animal for growth promotion, feed effi-
24 ciency, weight gain, routine disease prevention, or other
25 routine purpose.”.

1 (b) APPLICATIONS PENDING OR SUBMITTED AFTER
2 ENACTMENT.—Section 512(d)(1) of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 360b(d)(1)) is amend-
4 ed—

5 (1) in the first sentence—

6 (A) in subparagraph (H), by striking “or”
7 at the end;

8 (B) by redesignating subparagraph (I) as
9 subparagraph (J); and

10 (C) by inserting after subparagraph (H)
11 the following:

12 “(I) with respect to a critical antimicrobial
13 animal drug or a drug of the same chemical
14 class as a critical antimicrobial animal drug,
15 the applicant has failed to demonstrate that
16 there is a reasonable certainty of no harm to
17 human health due to the development of anti-
18 microbial resistance that is attributable, in
19 whole or in part, to the nontherapeutic use of
20 the drug; or”; and

21 (2) in the second sentence, by striking “(A)
22 through (I)” and inserting “(A) through (J)”.

23 (c) PHASED ELIMINATION OF NONTHERAPEUTIC
24 USE IN ANIMALS OF CRITICAL ANTIMICROBIAL ANIMAL
25 DRUGS IMPORTANT FOR HUMAN HEALTH.—Section 512

1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
2 360b) is amended by adding at the end the following:

3 “(q) PHASED ELIMINATION OF NONTHERAPEUTIC
4 USE IN ANIMALS OF CRITICAL ANTIMICROBIAL ANIMAL
5 DRUGS IMPORTANT FOR HUMAN HEALTH.—

6 “(1) APPLICABILITY.—This subsection applies
7 to the nontherapeutic use in a food-producing ani-
8 mal of a drug—

9 “(A)(i) that is a critical antimicrobial ani-
10 mal drug; or

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

13 “(B)(i) for which there is in effect an ap-
14 proval of an application or an exemption under
15 subsection (b), (i), or (j) of section 505; or

16 “(ii) that is otherwise marketed for use.

17 “(2) WITHDRAWAL.—The Secretary shall with-
18 draw the approval of a nontherapeutic use in food-
19 producing animals described in paragraph (1) on the
20 date that is 2 years after the date of enactment of
21 this subsection unless—

22 “(A) before the date that is 2 years after
23 the date of the enactment of this subsection,
24 the Secretary makes a final written determina-
25 tion that the holder of the approved application

1 has demonstrated that there is a reasonable
2 certainty of no harm to human health due to
3 the development of antimicrobial resistance that
4 is attributable in whole or in part to the non-
5 therapeutic use of the drug; or

6 “(B) before the date specified in subpara-
7 graph (A), the Secretary makes a final written
8 determination, with respect to a risk analysis of
9 the drug conducted by the Secretary and other
10 relevant information, that there is a reasonable
11 certainty of no harm to human health due to
12 the development of antimicrobial resistance that
13 is attributable in whole or in part to the non-
14 therapeutic use of the drug.

15 “(3) EXEMPTIONS.—Except as provided in
16 paragraph (5), if the Secretary grants an exemption
17 under section 505(i) for a drug that is a critical
18 antimicrobial animal drug, the Secretary shall re-
19 scind each approval of a nontherapeutic use in a
20 food-producing animal of the critical antimicrobial
21 animal drug, or of a drug in the same chemical class
22 as the critical antimicrobial animal drug, as of the
23 date that is 2 years after the date on which the Sec-
24 retary grants the exemption.

1 “(4) APPROVALS.—Except as provided in para-
2 graph (5), if an application for a drug that is a crit-
3 ical antimicrobial animal drug is submitted to the
4 Secretary under section 505(b), the Secretary shall
5 rescind each approval of a nontherapeutic use in a
6 food-producing animal of the critical antimicrobial
7 animal drug, or of a drug in the same chemical class
8 as the critical antimicrobial animal drug, as of the
9 date that is 2 years after the date on which the ap-
10 plication is submitted to the Secretary.

11 “(5) EXCEPTION.—Paragraph (3) or (4), as the
12 case may be, shall not apply if—

13 “(A) before the date on which approval
14 would be rescinded under that paragraph, the
15 Secretary makes a final written determination
16 that the holder of the application for the ap-
17 proved nontherapeutic use has demonstrated
18 that there is a reasonable certainty of no harm
19 to human health due to the development of
20 antimicrobial resistance that is attributable in
21 whole or in part to the nontherapeutic use in
22 the food-producing animal of the critical anti-
23 microbial animal drug; or

24 “(B) before the date specified in subpara-
25 graph (A), the Secretary makes a final written

1 determination, with respect to a risk analysis of
2 the critical antimicrobial animal drug conducted
3 by the Secretary and any other relevant infor-
4 mation, that there is a reasonable certainty of
5 no harm to human health due to the develop-
6 ment of antimicrobial resistance that is attrib-
7 utable in whole or in part to the nontherapeutic
8 use of the drug.”.

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