

108TH CONGRESS
1ST SESSION

S. 1460

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

JULY 25 (legislative day, JULY 21), 2003

Mr. KENNEDY (for himself, Ms. SNOWE, Mr. REED, and Mr. BINGAMAN) 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 2003”.

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.

TITLE I—SAFETY OF CRITICAL ANTIMICROBIAL ANIMAL DRUGS

- Sec. 101. Proof of safety of critical antimicrobial animal drugs.

TITLE II—USE OF CRITICAL ANTIMICROBIAL ANIMAL DRUGS IN
 AGRICULTURE

- Sec. 201. Assistance to defray expenses of livestock or poultry producers in phasing out nontherapeutic use of critical antimicrobial animal drugs.
 Sec. 202. Research and demonstration programs.
 Sec. 203. Collection of data on critical antimicrobial animal drugs.

1 **SEC. 2. FINDINGS.**

2 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

1 terrorist attacks involving bacterial infections or a
2 large influx of hospitalized patients;

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

6 (B) recognizing the public health threat caused
7 by antibiotic resistance, Congress took several steps
8 to curb antibiotic overuse in human medicine
9 through amendments to the Public Health Service
10 Act (42 U.S.C. 201 et seq.) made by section 102 of
11 the Public Health Threats and Emergencies Act
12 (114 Stat. 2315), but has not yet addressed anti-
13 biotic overuse in agriculture;

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

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

19 (B) substantial efforts must be made to
20 decrease inappropriate overuse in animals and
21 agriculture;

22 (5)(A) an estimated 70 percent of the anti-
23 biotics and other antimicrobial used in the United
24 States are fed to farm animals for nontherapeutic
25 purposes, including—

1 (i) growth promotion; and

2 (ii) compensation for crowded, unsanitary,
3 and stressful farming and transportation condi-
4 tions; and

5 (B) unlike human use of antibiotics, these non-
6 therapeutic uses in animals typically do not require
7 a prescription;

8 (6)(A) many scientific studies confirm that the
9 nontherapeutic use of antibiotics in agricultural ani-
10 mals contributes to the development of antibiotic-re-
11 sistant bacterial infections in people;

12 (B) the periodical entitled “Clinical Infectious
13 Diseases” published a report in June 2002, based on
14 a 2-year review by experts in human and veterinary
15 medicine, public health, microbiology, biostatistics,
16 and risk analysis, of more than 500 scientific studies
17 on the human health impacts of antimicrobial use in
18 agriculture; and

19 (C) the report recommended that antimicrobial
20 agents should no longer be used in agriculture in the
21 absence of disease, but should be limited to therapy
22 for diseased individual animals and prophylaxis
23 when disease is documented in a herd or flock;

1 (7)(A) the United States Geological Survey re-
2 ported in March 2002 that antibiotics were present
3 in 48 percent of the streams tested nationwide; and

4 (B) almost half of the tested streams were
5 downstream from agricultural operations;

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

11 (9)(A) in January 2003, Consumer Reports
12 published test results on poultry products bought in
13 grocery stores nationwide showing disturbingly high
14 levels of Campylobacter and Salmonella bacteria that
15 were resistant to antibiotics used to treat food-borne
16 illnesses; and

17 (B) further studies showed similar results in
18 other meat products;

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

23 (11)(A) in 1999, the European Union banned
24 the practice of feeding medically important anti-
25 biotics to animals other than for disease treatment

1 or control, and prior to that, individual European
2 countries had banned the use of specific antibiotics
3 in animal feed; and

4 (B) those countries have experienced no signifi-
5 cant impact on animal health or productivity, food
6 safety, or meat prices, and more importantly, levels
7 of resistant bacteria have declined sharply;

8 (12) in 1998, the National Academy of Sciences
9 noted that antibiotic-resistant bacteria generate a
10 minimum of \$4,000,000,000 to \$5,000,000,000 in
11 costs to United States society and individuals yearly;

12 (13) a year later, the National Academy of
13 Sciences estimated that eliminating the use of all
14 antibiotics as feed additives would cost each Amer-
15 ican consumer less than \$5 to \$10 per year;

16 (14) the American Medical Association, the
17 American Public Health Association, the National
18 Association of County and City Health Officials, and
19 the National Campaign for Sustainable Agriculture,
20 are among the more than 300 organizations rep-
21 resenting health, consumer, agricultural, environ-
22 mental, humane, and other interests that support
23 enactment of legislation to phase out nontherapeutic
24 use in farm animals of medically important anti-
25 biotics;

1 (15) the Federal Food, Drug, and Cosmetic Act
2 (21 U.S.C. 301 et seq.)—

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

5 (B) places the burden on manufacturers to
6 account for health consequences and prove safe-
7 ty;

8 (16)(A) the Food and Drug Administration re-
9 cently modified the drug approval process for anti-
10 biotics to recognize the development of resistant bac-
11 teria as an important aspect of safety;

12 (B) however, most antibiotics currently used in
13 animal production systems for nontherapeutic pur-
14 poses were approved before the Food and Drug Ad-
15 ministration began giving in-depth consideration to
16 resistance during the drug-approval process; and

17 (C) the Food and Drug Administration has not
18 established a schedule for reviewing those existing
19 approvals;

20 (17)(A) the Food and Drug Administration has
21 begun a process of evaluating the safety of anti-
22 biotics used in animal agriculture; and

23 (B) that process—

24 (i) is a valuable contribution to public
25 health; and

1 (ii) may determine that there is a rea-
 2 sonable certainty of no harm from the use
 3 of certain antibiotics in animal agriculture;
 4 and

5 (18) certain nonroutine uses of antibiotics in
 6 animal agriculture to prevent disease are legitimate.

7 **SEC. 3. PURPOSE.**

8 The purpose of this Act is to preserve the effective-
 9 ness of medically important antibiotics used in the treat-
 10 ment of human and animal diseases by phasing out use
 11 of certain antibiotics for nontherapeutic purposes in food-
 12 producing animals.

13 **TITLE I—SAFETY OF CRITICAL**
 14 **ANTIMICROBIAL ANIMAL DRUGS**

15 **SEC. 101. PROOF OF SAFETY OF CRITICAL ANTIMICROBIAL**
 16 **ANIMAL DRUGS.**

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

20 “(nn) CRITICAL ANTIMICROBIAL ANIMAL DRUG.—

21 The term ‘critical antimicrobial animal drug’ means a
 22 drug that—

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

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

1 “(A) any kind of penicillin, tetracycline,
2 bacitracin, macrolide, lincomycin,
3 streptogramin, aminoglycoside, sulfonamide; or

4 “(B) any other drug or derivative of a
5 drug that is used in humans or intended for use
6 in humans to treat or prevent disease or infec-
7 tion caused by microorganisms.

8 “(oo) NONTHERAPEUTIC USE.—The term ‘nonthera-
9 peutic use’, with respect to a critical antimicrobial animal
10 drug, means any use of the drug as a feed or water addi-
11 tive for an animal in the absence of any clinical sign of
12 disease in the animal for growth promotion, feed effi-
13 ciency, weight gain, routine disease prevention, or other
14 routine purpose.”.

15 (b) NONTHERAPEUTIC USE.—Section 512(d)(1) of
16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 360b(d)(1)) is amended—

18 (1) in the first sentence—

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

21 (B) by redesignating subparagraph (I) as
22 subparagraph (J); and

23 (C) by inserting after subparagraph (H)
24 the following:

1 “(I) with respect to a critical antimicrobial
2 animal drug or a drug of the same chemical
3 class as a critical antimicrobial animal drug,
4 the applicant has failed to demonstrate that
5 there is a reasonable certainty of no harm to
6 human health due to the development of anti-
7 microbial resistance that is attributable, in
8 whole or in part, to the nontherapeutic use of
9 the drug; or”;

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

12 (c) PHASED ELIMINATION OF NONTHERAPEUTIC
13 USE IN ANIMALS OF CRITICAL ANTIMICROBIAL ANIMAL
14 DRUGS IMPORTANT FOR HUMAN HEALTH.—Section 512
15 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 360b) is amended by adding at the end the following:

17 “(q) PHASED ELIMINATION OF NONTHERAPEUTIC
18 USE IN ANIMALS OF CRITICAL ANTIMICROBIAL ANIMAL
19 DRUGS IMPORTANT FOR HUMAN HEALTH.—

20 “(1) APPLICABILITY.—This subsection applies
21 to the nontherapeutic use in a food-producing ani-
22 mal of—

23 “(A)(i) a drug that is a critical anti-
24 microbial animal drug; or

1 “(ii) a drug that is of the same chemical
2 class as a critical antimicrobial animal drug;
3 and

4 “(B) a drug—

5 “(i) for which, as of the day before
6 the date of enactment of this subsection,
7 there was in effect an approval of an appli-
8 cation filed under subsection (b) or (j) of
9 section 505; or

10 “(ii) that was otherwise marketed for
11 use.

12 “(2) WITHDRAWAL.—The Secretary shall with-
13 draw the approval of a nontherapeutic use in food-
14 producing animals described in paragraph (1) on the
15 date that is 2 years after the date of enactment of
16 this subsection unless—

17 “(A) before the date that is 2 years after
18 that date of enactment, the Secretary makes a
19 written determination that the holder of the ap-
20 proved application has demonstrated that there
21 is a reasonable certainty of no harm to human
22 health due to the development of antimicrobial
23 resistance that is attributable in whole or in
24 part to the nontherapeutic use of the drug; or

1 “(B) before the date specified in subpara-
2 graph (A), the Secretary makes a final written
3 determination under this subsection, with re-
4 spect to a risk analysis of the drug conducted
5 by the Secretary and other relevant informa-
6 tion, that there is a reasonable certainty of no
7 harm to human health due to the development
8 of antimicrobial resistance that is attributable
9 in whole or in part to the nontherapeutic use of
10 the drug.

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

21 “(4) APPROVALS.—If an application for a drug
22 that is critical antimicrobial animal drug is sub-
23 mitted to the Secretary under section 505(b), the
24 Secretary shall rescind each approval of a nonthera-
25 peutic use in a food-producing animal of the critical

1 antimicrobial animal drug, or of a drug in the same
 2 chemical class as the critical antimicrobial animal
 3 drug, as of the date that is 2 years after the date
 4 on which the application is submitted to the Sec-
 5 retary.

6 “(5) EXCEPTION.—Paragraph (3) or (4), as the
 7 case may be, shall not apply if, before the date on
 8 which approval would be rescinded under that sub-
 9 paragraph, the Secretary determines that the holder
 10 of the approved application has demonstrated that
 11 there is a reasonable certainty of no harm to human
 12 health due to the development of antimicrobial re-
 13 sistance that is attributable, in whole or in part, to
 14 the nontherapeutic use in the food-producing animal
 15 of the critical antimicrobial animal drug.”.

16 **TITLE II—USE OF CRITICAL**
 17 **ANTIMICROBIAL ANIMAL**
 18 **DRUGS IN AGRICULTURE**

19 **SEC. 201. ASSISTANCE TO DEFRAY EXPENSES OF LIVE-**
 20 **STOCK OR POULTRY PRODUCERS IN PHAS-**
 21 **ING OUT NONTHERAPEUTIC USE OF CRIT-**
 22 **ICAL ANTIMICROBIAL ANIMAL DRUGS.**

23 (a) DEFINITIONS.—In this section, the terms “crit-
 24 ical antimicrobial animal drug” and “nontherapeutic use”

1 have the meanings given the terms in section 201 of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

3 (b) PAYMENTS.—The Secretary of Agriculture may
4 make payments to producers of livestock or poultry that
5 the Secretary determines are substantially reducing, or
6 have substantially reduced, the nontherapeutic use of crit-
7 ical antimicrobial animal drugs in livestock or poultry in
8 order to defray the costs of such reduction.

9 (c) PRIORITY FOR FAMILY FARMERS AND SMALL
10 FARMS.—In awarding payments under subsection (b), the
11 Secretary of Agriculture shall give priority to family-
12 owned and family-operated farms or ranches and to small
13 farms or ranches, as determined by the Secretary.

14 (d) AUTHORIZATION OF APPROPRIATIONS.—There
15 are authorized to be appropriated such sums as are nec-
16 essary to carry out this section for fiscal year 2004 and
17 for each subsequent fiscal year.

18 **SEC. 202. RESEARCH AND DEMONSTRATION PROGRAMS.**

19 Subtitle D of title VII of the Farm Security and
20 Rural Investment Act of 2002 (116 Stat. 455) is amended
21 by adding at the end the following:

22 **“SEC. 7413. PHASING OUT OF NONTHERAPEUTIC USE OF**
23 **CRITICAL ANTIMICROBIAL ANIMAL DRUGS.**

24 “(a) DEFINITIONS.—In this section, the terms ‘crit-
25 ical antimicrobial animal drug’ and ‘nontherapeutic use’

1 have the meanings given the terms in section 201 of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

3 “(b) GRANTS.—The Secretary, in consultation with
4 the Secretary of Health and Human Services, shall award
5 grants to colleges and universities to establish research
6 and demonstration programs for—

7 “(1) phasing out the nontherapeutic use of crit-
8 ical antimicrobial animal drugs in livestock or poul-
9 try; and

10 “(2) informing livestock and poultry producers
11 of methods for accomplishing the objective described
12 in paragraph (1).

13 “(c) EDUCATION.—The Secretary shall use the re-
14 sults of the research and demonstration programs and the
15 experience of agricultural producers that have reduced or
16 eliminated the nontherapeutic use of critical antimicrobial
17 animal drugs to educate other agricultural producers,
18 through the Cooperative Research, Education, and Exten-
19 sion Service, concerning how to successfully phase out
20 such use in livestock or poultry.

21 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
22 are authorized to be appropriated such sums as are nec-
23 essary to carry out this section for fiscal years 2004
24 through 2007.”.

1 **SEC. 203. COLLECTION OF DATA ON CRITICAL ANTI-**
2 **MICROBIAL ANIMAL DRUGS.**

3 (a) IN GENERAL.—Chapter V of the Federal Food,
4 Drug, and Cosmetic Act is amended by inserting after sec-
5 tion 512 (21 U.S.C. 360b) the following:

6 **“SEC. 512A. COLLECTION OF DATA ON CRITICAL ANTI-**
7 **MICROBIAL ANIMAL DRUGS.**

8 “(a) IN GENERAL.—Not later than July 1 of each
9 year, a manufacturer of a critical antimicrobial animal
10 drug or an animal feed for food-producing animals bearing
11 or containing a critical antimicrobial animal drug shall
12 submit to the Secretary a report, in such form as the Sec-
13 retary shall require, containing information on the sales
14 during the previous calendar year of the critical anti-
15 microbial animal drug or animal feed.

16 “(b) INFORMATION TO BE INCLUDED.—A report
17 under subsection (a) shall—

18 “(1) state separately the quantity of the critical
19 antimicrobial animal drug, including in animal feed
20 bearing or containing the critical antimicrobial ani-
21 mal drug, sold for each kind of food-producing ani-
22 mal;

23 “(2) describe the claimed purpose of use for
24 each kind of food-producing animal as being for
25 growth promotion, weight gain, feed efficiency, dis-

1 ease prevention, disease control, disease treatment,
2 or another purpose; and

3 “(3) describe the dosage form of the drug.

4 “(c) PUBLICATION.—

5 “(1) IN GENERAL.—The Secretary shall—

6 “(A) make the information submitted
7 under subsection (a) available to the public; and

8 “(B) publish the information at least an-
9 nually.

10 “(2) PROTECTION OF CONFIDENTIALITY.—The
11 Secretary shall aggregate information, if necessary,
12 to avoid disclosure under paragraph (1) of confiden-
13 tial business information.”.

14 (b) PROHIBITED ACTS.—Section 301(e) of the Fed-
15 eral Food, Drug, and Cosmetic Act (21 U.S.C. 331(e))
16 is amended by striking “515(f)” and inserting “512A,
17 515(f),”.

18 (c) EFFECTIVE DATE.—The amendments made by
19 this section take effect on January 1, 2005.

○