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, Mr. BINGAMAN, and Mr. INOUYE) 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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) Short Title.—This Act may be cited as the “Preservation of Antibiotics for Medical Treatment Act of 2003”.

(b) Table of Contents.—The table of contents of this Act is as follows:
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.

SEC. 2. FINDINGS.

Congress finds that—

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

(B) the task force determined that antibiotic resistance is a growing menace to all people and poses a serious threat to public health; and

(C) the task force 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; and

(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 (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)(A) an estimated 70 percent of the antibiotics and other antimicrobial used in the United States are fed to farm animals for nontherapeutic purposes, including—
(i) growth promotion; and

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

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

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

(B) the periodical entitled “Clinical Infectious
Diseases” published a report in June 2002, 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

(C) the report 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;
(7)(A) the United States Geological Survey reported in March 2002 that antibiotics were present in 48 percent of the streams tested nationwide; and (B) almost half of the tested streams were downstream from agricultural operations;

(8) 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;

(9)(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 antibiotics used to treat food-borne illnesses; and

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

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

(11)(A) in 1999, the European Union banned the practice of feeding medically important antibiotics to animals other than for disease treatment
or control, and prior to that, individual European
countries had banned the use of specific antibiotics
in animal feed; and

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

(12) 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;

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

(14) 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 rep-
resenting health, consumer, agricultural, environ-
mental, humane, and other interests that support
enactment of legislation to phase out nontherapeutic
use in farm animals of medically important anti-
biotics;
(15) 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 safe-
ty;

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

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

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

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

(B) that process—

(i) is a valuable contribution to public
health; and
(ii) may determine that there is a reasonable certainty of no harm from the use of certain antibiotics in animal agriculture; and

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

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 phasing out use of certain antibiotics for nontherapeutic purposes in food-producing animals.

TITLE I—SAFETY OF CRITICAL ANTIMICROBIAL ANIMAL DRUGS

SEC. 101. 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:

“(nn) 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, bacitracin, macrolide, lincomycin, streptogramin, aminoglycoside, 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.

“(oo) 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) NONTHERAPEUTIC USE.—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) by redesignating subparagraph (I) as subparagraph (J); and

(C) by inserting after subparagraph (H) the following:
“(I) 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; or”;

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

“(B) a drug—

“(i) for which, as of the day before the date of enactment of this subsection, there was in effect an approval of an application filed under subsection (b) or (j) of section 505; or

“(ii) that was 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 that date of enactment, the Secretary makes a 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 subpara-
graph (A), the Secretary makes a final written
determination under this subsection, with re-
spect to a risk analysis of the drug conducted
by the Secretary and other relevant informa-
tion, 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 re-
scind 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 Sec-
retary grants the exemption.

“(4) APPROVALS.—If an application for a drug
that is critical antimicrobial animal drug is sub-
mitted to the Secretary under section 505(b), the
Secretary shall rescind each approval of a nonthera-
peutic 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 Sec-
retary.

“(5) Exception.—Paragraph (3) or (4), as the
case may be, shall not apply if, before the date on
which approval would be rescinded under that sub-
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 re-
sistance that is attributable, in whole or in part, to
the nontherapeutic use in the food-producing animal
of the critical antimicrobial animal drug.”.

TITLE II—USE OF CRITICAL
ANTIMICROBIAL ANIMAL
DRUGS IN AGRICULTURE

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

(a) Definitions.—In this section, the terms “crit-
al antimicrobial animal drug” and “nontherapeutic use”
have the meanings given the terms in section 201 of the

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

(e) Priority for Family Farmers and Small
Farms.—In awarding payments under subsection (b), the
Secretary of Agriculture shall give priority to family-
owned and family-operated farms or ranches and to small
farms or ranches, as determined by the Secretary.

(d) Authorization of Appropriations.—There
are authorized to be appropriated such sums as are nec-
essary to carry out this section for fiscal year 2004 and
for each subsequent fiscal year.

SEC. 202. RESEARCH AND DEMONSTRATION PROGRAMS.
Subtitle D of title VII of the Farm Security and
Rural Investment Act of 2002 (116 Stat. 455) is amended
by adding at the end the following:

“SEC. 7413. PHASING OUT OF NONTHERAPEUTIC USE OF
CRITICAL ANTIMICROBIAL ANIMAL DRUGS.
“(a) Definitions.—In this section, the terms ‘crit-
ical antimicrobial animal drug’ and ‘nontherapeutic use’
have the meanings given the terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

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

“(1) phasing out the nontherapeutic use of critical antimicrobial animal drugs in livestock or poultry; and

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

“(c) EDUCATION.—The Secretary shall use the results of the research and demonstration programs and the experience of agricultural producers that have reduced or eliminated the nontherapeutic use of critical antimicrobial animal drugs to educate other agricultural producers, through the Cooperative Research, Education, and Extension Service, concerning how to successfully phase out such use in livestock or poultry.

“(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this section for fiscal years 2004 through 2007.”.
SEC. 203. COLLECTION OF DATA ON CRITICAL ANTI-

MICROBIAL ANIMAL DRUGS.

(a) IN GENERAL.—Chapter V of the Federal Food,

Drug, and Cosmetic Act is amended by inserting after sec-

tion 512 (21 U.S.C. 360b) the following:

“SEC. 512A. COLLECTION OF DATA ON CRITICAL ANTI-

MICROBIAL ANIMAL DRUGS.

“(a) IN GENERAL.—Not later than July 1 of each

year, a manufacturer of a critical antimicrobial animal

drug or an animal feed for food-producing animals bearing

or containing a critical antimicrobial animal drug shall

submit to the Secretary a report, in such form as the Sec-

retary shall require, containing information on the sales

during the previous calendar year of the critical anti-

microbial animal drug or animal feed.

“(b) INFORMATION TO BE INCLUDED.—A report

under subsection (a) shall—

“(1) state separately the quantity of the critical

antimicrobial animal drug, including in animal feed

bearing or containing the critical antimicrobial ani-

mal drug, sold for each kind of food-producing ani-

mal;

“(2) describe the claimed purpose of use for

each kind of food-producing animal as being for

growth promotion, weight gain, feed efficiency, dis-

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

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

“(c) PUBLICATION.—

“(1) IN GENERAL.—The Secretary shall—

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

“(B) publish the information at least annually.

“(2) PROTECTION OF CONFIDENTIALITY.—The Secretary shall aggregate information, if necessary, to avoid disclosure under paragraph (1) of confidential business information.”.

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

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