

111TH CONGRESS
1ST SESSION

H. R. 1549

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 HOUSE OF REPRESENTATIVES

MARCH 17, 2009

Ms. SLAUGHTER (for herself, Mr. TIERNEY, Mr. HONDA, Mr. VAN HOLLEN, Mr. HINCHEY, Mr. GRIJALVA, Ms. HIRONO, Ms. ZOE LOFGREN of California, Mr. KUCINICH, Ms. LEE of California, Mr. DEFazio, Mr. WEXLER, Mr. GEORGE MILLER of California, Mr. FRANK of Massachusetts, Mr. FARR, Ms. DELAURO, Mr. SHERMAN, Mr. CONNOLLY of Virginia, Mr. STARK, Mrs. MALONEY, Mr. JACKSON of Illinois, Mr. BRADY of Pennsylvania, and Ms. KILROY) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Rules, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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,*

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

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

5 (b) TABLE OF CONTENTS.—The table of contents of
6 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.
- Sec. 5. Committee hearings on implementation.

7 **SEC. 2. FINDINGS.**

8 The Congress finds that—

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

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

17 (C) the task force cautioned that if current
18 trends continue, treatments for common infections
19 will become increasingly limited and expensive, and,
20 in some cases, nonexistent;

21 (2) antibiotic resistance, resulting in a reduced
22 number of effective antibiotics, may significantly im-
23 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 (Public Law 106–505, title I; 114 Stat. 2315), but
13 has not yet addressed antibiotic overuse in agri-
14 culture;

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

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

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

23 (5)(A) an estimated 70 percent of the anti-
24 biotics and other antimicrobial drugs used in the

1 United States are fed to farm animals for nonthera-
2 peutic purposes, including—

3 (i) growth promotion; and

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

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

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

21 (B) these drugs are used in people to treat seri-
22 ous diseases such as pneumonia, scarlet fever, rheu-
23 matic fever, venereal disease, skin infections, and
24 even pandemics like malaria and plague, as well as
25 bioterrorism agents like smallpox and anthrax;

1 (7) many scientific studies confirm that the
2 nontherapeutic use of antibiotics in agricultural ani-
3 mals contributes to the development of antibiotic-re-
4 sistant bacterial infections in people;

5 (8)(A) the periodical entitled “Clinical Infec-
6 tious Diseases” published a report in June 2002,
7 based on a 2-year review by experts in human and
8 veterinary medicine, public health, microbiology, bio-
9 statistics, and risk analysis, of more than 500 sci-
10 entific studies on the human health impacts of anti-
11 microbial use in agriculture; and

12 (B) the report recommended that antimicrobial
13 agents should no longer be used in agriculture in the
14 absence of disease, but should be limited to therapy
15 for diseased individual animals and prophylaxis
16 when disease is documented in a herd or flock;

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

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

21 (B) almost half of the tested streams were
22 downstream from agricultural operations;

23 (10) an April 1999 study by the General Ac-
24 counting Office concluded that resistant strains of 3
25 microorganisms that cause food-borne illness or dis-

1 ease in humans—Salmonella, Campylobacter, and E.
2 coli—are linked to the use of antibiotics in animals;

3 (11) epidemiological research has shown that
4 resistant Salmonella and Campylobacter infections
5 are associated with increased numbers of ill patients
6 and bloodstream infections, and increased death;

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

13 (B) the Food and Drug Administration’s Na-
14 tional Antimicrobial Resistance Monitoring System
15 routinely finds that retail meat products are con-
16 taminated with bacteria resistant to antibiotics im-
17 portant in human medicine including the foodborne
18 pathogens Campylobacter and Salmonella; and

19 (C) in December 2007, the USDA issued a fact
20 sheet on the recently recognized link between anti-
21 microbial drug use in animals and the Methicillin
22 Resistant Staphylococcus Aureas (MRSA) infections
23 in humans;

24 (13) in October 2001, the New England Jour-
25 nal of Medicine published an editorial urging a ban

1 on nontherapeutic use of medically important anti-
2 biotics in animals;

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

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

17 (16) the Federal Food, Drug, and Cosmetic Act
18 (21 U.S.C. 301 et seq.)—

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

21 (B) places the burden on manufacturers to
22 account for health consequences and prove safe-
23 ty;

24 (17)(A) the Food and Drug Administration re-
25 cently modified the drug approval process for anti-

1 biotics to recognize the development of resistant bac-
2 teria as an important aspect of safety;

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

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

11 (18) certain non-routine uses of antibiotics in
12 animal agriculture are legitimate to prevent animal
13 disease; and

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

19 (B) the report recommends that the Depart-
20 ment of Agriculture and the Department of Health
21 and Human Services develop and implement a plan
22 to collect data on antibiotic use in animals.

23 **SEC. 3. PURPOSE.**

24 The purpose of this Act is to preserve the effective-
25 ness of medically important antibiotics used in the treat-

1 ment of human and animal diseases by reviewing the safe-
 2 ty of certain antibiotics for nontherapeutic purposes in
 3 food-producing animals.

4 **SEC. 4. PROOF OF SAFETY OF CRITICAL ANTIMICROBIAL**
 5 **ANIMAL DRUGS.**

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

9 “(rr) CRITICAL ANTIMICROBIAL ANIMAL DRUG.—
 10 The term ‘critical antimicrobial animal drug’ means a
 11 drug that—

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

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

15 “(A) any kind of penicillin, tetracycline,
 16 macrolide, lincosamide, streptogramin, amino-
 17 glycoside, or sulfonamide; or

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

22 “(ss) NONTHERAPEUTIC USE.—The term ‘nonthera-
 23 peutic use’, with respect to a critical antimicrobial animal
 24 drug, means any use of the drug as a feed or water addi-
 25 tive for an animal in the absence of any clinical sign of

1 disease in the animal for growth promotion, feed effi-
2 ciency, weight gain, routine disease prevention, or other
3 routine purpose.”.

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

8 (1) in the first sentence—

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

11 (B) by redesignating subparagraph (I) as
12 subparagraph (J); and

13 (C) by inserting after subparagraph (H)
14 the following:

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

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

1 (c) PHASED ELIMINATION OF NONTHERAPEUTIC
2 USE IN ANIMALS OF CRITICAL ANTIMICROBIAL ANIMAL
3 DRUGS IMPORTANT FOR HUMAN HEALTH.—Section 512
4 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
5 360b) is amended by adding at the end the following:

6 “(q) PHASED ELIMINATION OF NONTHERAPEUTIC
7 USE IN ANIMALS OF CRITICAL ANTIMICROBIAL ANIMAL
8 DRUGS IMPORTANT FOR HUMAN HEALTH.—

9 “(1) APPLICABILITY.—This subsection applies
10 to the nontherapeutic use in a food-producing ani-
11 mal of a drug—

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

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

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

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

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

1 “(A) before the date that is 2 years after
2 the date of the enactment of this subsection,
3 the Secretary makes a final written determina-
4 tion that the holder of the approved application
5 has demonstrated that there is a reasonable
6 certainty of no harm to human health due to
7 the development of antimicrobial resistance that
8 is attributable in whole or in part to the non-
9 therapeutic use of the drug; or

10 “(B) before the date specified in subpara-
11 graph (A), the Secretary makes a final written
12 determination under this subsection, with re-
13 spect to a risk analysis of the drug conducted
14 by the Secretary and other relevant informa-
15 tion, that there is a reasonable certainty of no
16 harm to human health due to the development
17 of antimicrobial resistance that is attributable
18 in whole or in part to the nontherapeutic use of
19 the drug.

20 “(3) EXEMPTIONS.—Except as provided in
21 paragraph (5), if the Secretary grants an exemption
22 under section 505(i) for a drug that is a critical
23 antimicrobial animal drug, the Secretary shall re-
24 scind each approval of a nontherapeutic use in a
25 food-producing animal of the critical antimicrobial

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

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

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

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

1 the food-producing animal of the critical anti-
2 microbial animal drug; or

3 “(B) before the date specified in subpara-
4 graph (A), the Secretary makes a final written
5 determination under this subsection, with re-
6 spect to a risk analysis of the critical anti-
7 microbial animal drug conducted by the Sec-
8 retary and any other relevant information, that
9 there is a reasonable certainty of no harm to
10 human health due to the development of anti-
11 microbial resistance that is attributable in
12 whole or in part to the nontherapeutic use of
13 the drug.”.

14 **SEC. 5. COMMITTEE HEARINGS ON IMPLEMENTATION.**

15 (a) IN GENERAL.—The Committee on Energy and
16 Commerce of the House of Representatives and the Com-
17 mittee on Energy of the Senate shall each hold a hearing
18 on the implementation by the Commissioner of Food and
19 Drugs of section 512(q) of the Federal Food, Drug, and
20 Cosmetic Act, as added by section 4 of this Act.

21 (b) EXERCISE OF RULEMAKING AUTHORITY.—Sub-
22 section (a) is enacted—

23 (1) as an exercise of the rulemaking power of
24 the House of Representatives and Senate, and, as
25 such, they shall be considered as part of the rules

1 of the House or Senate (as the case may be), and
2 such rules shall supersede any other rule of the
3 House or Senate only to the extent that rule is in-
4 consistent therewith; and

5 (2) with full recognition of the constitutional
6 right of either House to change such rules (so far
7 as relating to the procedure in such House) at any
8 time, in the same manner, and to the same extent
9 as in the case of any other rule of the House or Sen-
10 ate.

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