

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.

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## 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

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## 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”;

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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