

112TH CONGRESS  
1ST SESSION

# H. R. 965

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 9, 2011

Ms. SLAUGHTER 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Preservation of Anti-  
5 biotics for Medical Treatment Act of 2011”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds the following:

1           (1) In January 2001, a Federal interagency  
2 task force—

3           (A) released an action plan to address the  
4 continuing decline in effectiveness of antibiotics  
5 against common bacterial infections, referred to  
6 as antibiotic resistance;

7           (B) determined that antibiotic resistance is  
8 a growing menace to all people and poses a se-  
9 rious threat to public health; and

10          (C) cautioned that if current trends con-  
11 tinue, treatments for common infections will be-  
12 come increasingly limited and expensive, and, in  
13 some cases, nonexistent.

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

19          (3)(A) Any overuse or misuse of antibiotics con-  
20 tributes to the spread of antibiotic resistance, wheth-  
21 er in human medicine or in agriculture.

22          (B) Recognizing the public health threat caused  
23 by antibiotic resistance, Congress took several steps  
24 to curb antibiotic overuse in human medicine  
25 through amendments to the Public Health Service

1 Act (42 U.S.C. 201 et seq.) made by section 102 of  
2 the Public Health Threats and Emergencies Act  
3 (Public Law 106–505, title I; 114 Stat. 2315), but  
4 has not yet addressed antibiotic overuse in agri-  
5 culture.

6 (4) In a March 2003 report, the National Acad-  
7 emy of Sciences stated that—

8 (A) a decrease in antimicrobial use in  
9 human medicine alone will have little effect on  
10 the current situation; and

11 (B) substantial efforts must be made to  
12 decrease inappropriate overuse in animals and  
13 agriculture.

14 (5) In 2010, the FDA determined that—

15 (A) 13.1 million kilograms of antibacterial  
16 drugs were sold for use on food animals in the  
17 United States in 2009;

18 (B) 3.3 million kilograms of antibacterial  
19 drugs were used for human health in 2009; and

20 (C) therefore, 80 percent of antibacterial  
21 drugs disseminated in the United States in  
22 2009 were sold for use on food animals, rather  
23 than being used for human health.

24 (6)(A) Large-scale, voluntary surveys by the  
25 Department of Agriculture’s Animal and Plant

1 Health Inspection Service in 1999, 2001, and 2006  
2 revealed that—

3 (i) 84 percent of grower-finisher swine  
4 farms, 83 percent of cattle feedlots, and 84 per-  
5 cent of sheep farms administer antimicrobials  
6 in the feed or water for health or growth pro-  
7 motion reasons; and

8 (ii) many of the antimicrobials identified  
9 are identical or closely related to drugs used in  
10 human medicine, including tetracyclines,  
11 macrolides, Bacitracin, penicillins, and  
12 sulfonamides; and

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

18 (7) Many scientific studies confirm that the  
19 nontherapeutic use of antibiotics in agricultural ani-  
20 mals contributes to the development of antibiotic-re-  
21 sistant bacterial infections in people.

22 (8) The periodical entitled “Clinical Infectious  
23 Diseases” published a report in June 2002, that—

24 (A) was based on a 2-year review by ex-  
25 perts in human and veterinary medicine, public

1 health, microbiology, biostatistics, and risk  
2 analysis, of more than 500 scientific studies on  
3 the human health impacts of antimicrobial use  
4 in agriculture; and

5 (B) recommended that antimicrobial  
6 agents should no longer be used in agriculture  
7 in the absence of disease, but should be limited  
8 to therapy for diseased individual animals and  
9 prophylaxis when disease is documented in a  
10 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) In 2010, the peer-reviewed journal Molec-  
2           ular Cell published a study demonstrating that low-  
3           dosage use of antibiotics causes a dramatic increase  
4           in genetic mutation, raising new concerns about the  
5           agricultural practice of using low-dosage antibiotics  
6           in order to stimulate growth promotion and rou-  
7           tinely prevent disease in unhealthy conditions.

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

14          (B) The Food and Drug Administration's Na-  
15          tional Antimicrobial Resistance Monitoring System  
16          routinely finds that retail meat products are con-  
17          taminated with bacteria (including the foodborne  
18          pathogens Campylobacter and Salmonella) that are  
19          resistant to antibiotics important in human medi-  
20          cine.

21          (C) In December 2007, the USDA issued a fact  
22          sheet on the recently recognized link between anti-  
23          microbial drug use in animals and Methicillin Resist-  
24          ant Staphylococcus Aureas (MRSA) infections in hu-  
25          mans.

1           (14) In October 2001, the New England Jour-  
2           nal of Medicine published an editorial urging a ban  
3           on nontherapeutic use of medically important anti-  
4           biotics in animals.

5           (15)(A) In 1998, the National Academy of  
6           Sciences noted that antibiotic-resistant bacteria gen-  
7           erate a minimum of \$4,000,000,000 to  
8           \$5,000,000,000 in costs to United States society  
9           and individuals yearly.

10          (B) In 2009, Cook County Hospital and the Al-  
11          liance for Prudent Use of Antibiotics estimated that  
12          the total health care cost of antibiotic resistant in-  
13          fections in the United States was between  
14          \$16,600,000,000 and \$26,000,000,000 annually.

15          (16) The American Medical Association, the  
16          American Public Health Association, the National  
17          Association of County and City Health Officials, and  
18          the National Campaign for Sustainable Agriculture  
19          are among the more than 300 organizations rep-  
20          resenting health, consumer, agricultural, environ-  
21          mental, humane, and other interests that have sup-  
22          ported enactment of legislation to phase out non-  
23          therapeutic use in farm animals of medically impor-  
24          tant antibiotics.

1           (17) In 2010, the Danish Veterinary and Food  
2 Administration testified that the Danish ban of the  
3 non-therapeutic use of antibiotics in food animal  
4 production resulted in a marked reduction in anti-  
5 microbial resistance in multiple bacterial species, in-  
6 cluding *Campylobacter* and *Enterococci*.

7           (18) In 2009, the Congressional Research Serv-  
8 ice concluded that restrictions overseas on the use of  
9 antimicrobial drugs in the production of livestock  
10 could impact U.S. export markets for livestock and  
11 poultry.

12           (19) The Federal Food, Drug, and Cosmetic  
13 Act (21 U.S.C. 301 et seq.)—

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

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

19           (20)(A) The Food and Drug Administration re-  
20 cently modified the drug approval process for anti-  
21 biotics to recognize the development of resistant bac-  
22 teria as an important aspect of safety, but most  
23 antibiotics currently used in animal production sys-  
24 tems for nontherapeutic purposes were approved be-



1 fore the Food and Drug Administration began con-  
2 sidering resistance during the drug-approval process.

3 (B) The Food and Drug Administration has not  
4 established a schedule for reviewing those existing  
5 approvals.

6 (21) Certain non-routine uses of antibiotics in  
7 animal agriculture are legitimate to prevent animal  
8 disease.

9 (22) An April 2004 study by the General Ac-  
10 counting Office—

11 (A) concluded that Federal agencies do not  
12 collect the critical data on antibiotic use in ani-  
13 mals that they need to support research on  
14 human health risks; and

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

19 **SEC. 3. PURPOSE.**

20 The purpose of this Act is to preserve the effective-  
21 ness of medically important antibiotics used in the treat-  
22 ment of human and animal diseases by reviewing the safe-  
23 ty of certain antibiotics for nontherapeutic purposes in  
24 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 “(ss) 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,  
14 aminoglycoside, 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 “(tt) 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) in subparagraph (I), by inserting “or”  
9 at the end; and

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

12 “(J) 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 under this subsection, with re-  
9                     spect to a risk analysis of the drug conducted  
10                    by the Secretary and other relevant informa-  
11                    tion, that there is a reasonable certainty of no  
12                    harm to human health due to the development  
13                    of antimicrobial resistance that is attributable  
14                    in whole or in part to the nontherapeutic use of  
15                    the drug.

16                   “(3) EXEMPTIONS.—Except as provided in  
17                    paragraph (5), if the Secretary grants an exemption  
18                    under section 505(i) for a drug that is a critical  
19                    antimicrobial animal drug, the Secretary shall re-  
20                    scind each approval of a nontherapeutic use in a  
21                    food-producing animal of the critical antimicrobial  
22                    animal drug, or of a drug in the same chemical class  
23                    as the critical antimicrobial animal drug, as of the  
24                    date that is 2 years after the date on which the Sec-  
25                    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 under this subsection, with re-  
2 spect to a risk analysis of the critical anti-  
3 microbial animal drug conducted by the Sec-  
4 retary and any other relevant information, 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.”.

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

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

17 (b) EXERCISE OF RULEMAKING AUTHORITY.—Sub-  
18 section (a) is enacted—

19 (1) as an exercise of the rulemaking power of  
20 the House of Representatives and Senate, and, as  
21 such, they shall be considered as part of the rules  
22 of the House or Senate (as the case may be), and  
23 such rules shall supersede any other rule of the  
24 House or Senate only to the extent that rule is in-  
25 consistent therewith; and

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

○