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(Original Signature of Member)

113TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

To amend the Federal Food, Drug, and Cosmetic Act to preserve the effectiveness of medically important antimicrobials used in the treatment of human and animal diseases.

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IN THE HOUSE OF REPRESENTATIVES

Ms. SLAUGHTER introduced the following bill; which was referred to the Committee on \_\_\_\_\_

\_\_\_\_\_  
**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act to preserve the effectiveness of medically important antimicrobials 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 2013”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds the following:

1           (1)(A) In 1977, the Food and Drug Adminis-  
2           tration concluded that feeding livestock low doses of  
3           antibiotics used in human disease treatment could  
4           promote the development of antibiotic-resistance in  
5           bacteria. However, the Food and Drug Administra-  
6           tion did not act in response to these findings, despite  
7           laws requiring the agency to do so.

8           (B) In 2012, the Food and Drug Administra-  
9           tion was ordered by a Federal court to address the  
10          use of antibiotics in livestock, as the result of a law-  
11          suit filed against the agency citing the agency's fail-  
12          ure to act in response to the 1977 findings.

13          (2)(A) In 1998, the National Academy of  
14          Sciences noted that antibiotic-resistant bacteria gen-  
15          erate a minimum of \$4,000,000,000 to  
16          \$5,000,000,000 in costs to United States society  
17          and individuals yearly.

18          (B) In 2009, Cook County Hospital and the Al-  
19          liance for Prudent Use of Antibiotics estimated that  
20          the total health care cost of antibiotic resistant in-  
21          fections in the United States was between  
22          \$16,600,000,000 and \$26,000,000,000 annually.

23          (3) An April 1999 study by the Government  
24          Accountability Office concluded that resistant  
25          strains of 3 microorganisms that cause food-borne

1 illness or disease in humans (*Salmonella*,  
2 *Campylobacter*, and *E. coli*) are linked to the use of  
3 antibiotics in animals.

4 (4)(A) Large-scale, voluntary surveys by the  
5 Department of Agriculture's Animal and Plant  
6 Health Inspection Service in 1999, 2001, and 2006  
7 revealed that—

8 (i) 84 percent of grower-finisher swine  
9 farms, 83 percent of cattle feedlots, and 84 per-  
10 cent of sheep farms administer antimicrobials  
11 in the feed or water for health or growth pro-  
12 motion reasons; and

13 (ii) many of the antimicrobials identified  
14 are identical or closely related to drugs used in  
15 human medicine, including tetracyclines,  
16 macrolides, Bacitracin, penicillins, and  
17 sulfonamides; and

18 (B) these drugs are used in people to treat seri-  
19 ous diseases such as pneumonia, scarlet fever, rheu-  
20 matic fever, sexually transmitted infections, skin in-  
21 fections, and even pandemics like malaria and  
22 plague, as well as bioterrorism agents like smallpox  
23 and anthrax.

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

4           (B) Recognizing the public health threat caused  
5           by antibiotic resistance, Congress took several steps  
6           to curb antibiotic overuse in human medicine  
7           through amendments to the Public Health Service  
8           Act (42 U.S.C. 201 et seq.) made by section 102 of  
9           the Public Health Threats and Emergencies Act  
10          (Public Law 106–505, title I; 114 Stat. 2315), but  
11          has not yet addressed antibiotic overuse in agri-  
12          culture.

13          (6) In January 2001, a Federal interagency  
14          task force—

15                 (A) released an action plan to address the  
16                 continuing decline in effectiveness of antibiotics  
17                 against common bacterial infections, referred to  
18                 as antibiotic resistance;

19                 (B) determined that antibiotic resistance is  
20                 a growing menace to all people and poses a se-  
21                 rious threat to public health; and

22                 (C) cautioned that if current trends con-  
23                 tinue, treatments for common infections will be-  
24                 come increasingly limited and expensive, and, in  
25                 some cases, nonexistent.

1           (7) The United States Geological Survey re-  
2           ported in March 2002 that—

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

5                   (B) almost half of the tested streams were  
6                   downstream from agricultural operations.

7           (8) The peer-reviewed journal “Clinical Infec-  
8           tious Diseases” published a report in June 2002  
9           that—

10                   (A) was based on a 2-year review by ex-  
11                   perts in human and veterinary medicine, public  
12                   health, microbiology, biostatistics, and risk  
13                   analysis, of more than 500 scientific studies on  
14                   the human health impacts of antimicrobial use  
15                   in agriculture; and

16                   (B) recommended that antimicrobial  
17                   agents should no longer be used in agriculture  
18                   in the absence of disease, but should be limited  
19                   to therapy for diseased individual animals and  
20                   prophylaxis when disease is documented in a  
21                   herd or flock.

22           (9) In a March 2003 report, the National Acad-  
23           emy of Sciences stated that—

1 (A) a decrease in antimicrobial use in  
2 human medicine alone will have little effect on  
3 the current situation; and

4 (B) substantial efforts must be made to  
5 decrease inappropriate overuse in animals and  
6 agriculture.

7 (10) The Federal Food, Drug, and Cosmetic  
8 Act (21 U.S.C. 301 et seq.)—

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

11 (B) places the burden on manufacturers to  
12 account for health consequences and prove safe-  
13 ty.

14 (11)(A) In 2003, the Food and Drug Adminis-  
15 tration modified the drug approval process for anti-  
16 biotics to recognize the development of resistant bac-  
17 teria as an important aspect of safety, but most  
18 antibiotics currently used in animal production sys-  
19 tems for nontherapeutic purposes were approved be-  
20 fore the Food and Drug Administration began con-  
21 sidering resistance during the drug-approval process.

22 (B) The Food and Drug Administration has not  
23 established a schedule for reviewing those existing  
24 approvals.

1           (12)(A) In an April 2004 report, the Govern-  
2           ment Accountability Office—

3                   (i) concluded that Federal agencies do not  
4                   collect the critical data on antibiotic use in ani-  
5                   mals that they need to support research on  
6                   human health risks; and

7                   (ii) recommended that the Department of  
8                   Agriculture and the Department of Health and  
9                   Human Services develop and implement a plan  
10                  to collect data on antibiotic use in animals.

11           (B) In a September 2011 update to that report,  
12           the Government Accountability Office—

13                   (i) concluded that Federal agencies had  
14                   made limited progress in addressing antibiotic  
15                   use in animals;

16                   (ii) recommended that Federal agencies  
17                   fund research on alternatives to current anti-  
18                   biotic use practices; and

19                   (iii) recommended that Federal agencies  
20                   track the effectiveness of policies that curb anti-  
21                   biotic resistance, including FDA's voluntary  
22                   guidelines reducing antibiotic use in food ani-  
23                   mals.

24           (13) In 2009, the Congressional Research Serv-  
25           ice concluded that without restrictions on the use of

1 antimicrobial drugs in the production of livestock,  
2 export markets for livestock and poultry could be  
3 negatively impacted due to restrictions on the use of  
4 antibiotics in other nations.

5 (14) In 2010, the peer-reviewed journal “Molec-  
6 ular Cell” published a study demonstrating that low-  
7 dosage use of antibiotics causes a dramatic increase  
8 in genetic mutation, raising new concerns about the  
9 agricultural practice of using low-dosage antibiotics  
10 in order to stimulate growth promotion and rou-  
11 tinely prevent disease in unhealthy conditions.

12 (15) In 2010, the Danish Veterinary and Food  
13 Administration testified that the Danish ban of the  
14 nontherapeutic use of antibiotics in food animal pro-  
15 duction resulted in a marked reduction in anti-  
16 microbial resistance in multiple bacterial species, in-  
17 cluding *Campylobacter* and *Enterococci*.

18 (16) In 2011, the Food and Drug Administra-  
19 tion determined that—

20 (A) 13.5 million kilograms of antibacterial  
21 drugs were sold for use on food animals in the  
22 United States in 2010;

23 (B) 3.3 million kilograms of antibacterial  
24 drugs were used for human health in 2010; and

1 (C) therefore, 80 percent of antibacterial  
2 drugs disseminated in the United States in  
3 2010 were sold for use on food animals, rather  
4 than being used for human health.

5 (17) In 2011, a review of all scientific studies  
6 on antimicrobial use in farm animals, published in  
7 *Clinical Microbiology Reviews*, found that—

8 (A) use of antibiotics in food animals leads  
9 to development of reservoirs of antibiotic resist-  
10 ance;

11 (B) a ban on antibiotic use in food animals  
12 would preserve their use for medicine; and

13 (C) a Danish ban on antibiotics in food  
14 animals resulted in little change in animal mor-  
15 bidity and mortality, and only a modest in-  
16 crease in production cost.

17 (18) In April 2012, the Food and Drug Admin-  
18 istration issued voluntary guidance to industry on  
19 reducing antibiotic use in livestock and poultry. As  
20 part of that guidance, it summarized over 35 years  
21 of peer-reviewed scientific literature regarding use of  
22 antimicrobial drugs in livestock. As a result, FDA  
23 stated strategies for controlling antibiotic resistance  
24 are needed, and are seeking voluntarily limits on an-  
25 tibiotic use.

1           (19)(A) In January 2013, Consumer Reports  
2 published test results on pork products bought in  
3 grocery stores nationwide showing disturbingly high  
4 levels of *Salmonella* and *Yersinia enterocolitica* bac-  
5 teria that were resistant to the antibiotics used to  
6 treat food borne illnesses. A 2003 Consumer Report  
7 study showed similar results in poultry products.

8           (B) The Food and Drug Administration's Na-  
9 tional Antimicrobial Resistance Monitoring System  
10 routinely finds that retail meat products are con-  
11 taminated with bacteria (including the foodborne  
12 pathogens *Campylobacter* and *Salmonella*) that are  
13 resistant to antibiotics important in human medi-  
14 cine. The 2011 National Antimicrobial Resistance  
15 Monitoring System report found that the percentage  
16 of meat containing antibiotic resistant bacteria in-  
17 creases each year and that many of these bacteria  
18 exhibit multiple antibiotic resistance.

19           (20) Antibiotic resistance, resulting in a re-  
20 duced number of effective antibiotics, may signifi-  
21 cantly impair the ability of the United States to re-  
22 spond to terrorist attacks involving bacterial infec-  
23 tions or a large influx of hospitalized patients.

24           (21) Many scientific studies confirm that the  
25 nontherapeutic use of antibiotics in agricultural ani-

1       mals contribute to the development of antibiotic-re-  
2       sistant bacterial infections in people.

3           (22) 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           (23) The American Medical Association, the  
8       American Public Health Association, the National  
9       Association of County and City Health Officials, and  
10      the National Sustainable Agriculture Coalition are  
11      among the over 400 organizations representing  
12      health, consumer, agricultural, environmental, hu-  
13      mane, and other interests that have supported enact-  
14      ment of legislation to phase out nontherapeutic use  
15      in farm animals of medically important  
16      antimicrobials.

17 **SEC. 3. PURPOSE.**

18       The purpose of this Act is to preserve the effective-  
19      ness of medically important antimicrobials used in the  
20      treatment of human and animal diseases.

21 **SEC. 4. PROOF OF SAFETY OF MEDICALLY IMPORTANT**  
22 **ANTIMICROBIALS.**

23       (a) APPLICATIONS PENDING OR SUBMITTED AFTER  
24      ENACTMENT.—Section 512(d)(1) of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 360b(d)(1)) is amend-  
2 ed—

3 (1) in the first sentence—

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

6 (B) in subparagraph (I), by inserting “or”  
7 at the end; and

8 (C) by inserting after subparagraph (I) the  
9 following:

10 “(J) with respect to a medically important  
11 antimicrobial (as defined in subsection (q)), the  
12 applicant has failed to demonstrate that there  
13 is a reasonable certainty of no harm to human  
14 health due to the development of antimicrobial  
15 resistance that is attributable, in whole or in  
16 part, to the nontherapeutic use (as defined in  
17 subsection (q)) of the medically important anti-  
18 microbial or drug;” and

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

21 (b) PHASED ELIMINATION OF NONTHERAPEUTIC  
22 USE IN ANIMALS OF MEDICALLY IMPORTANT  
23 ANTIMICROBIALS.—Section 512 of the Federal Food,  
24 Drug, and Cosmetic Act (21 U.S.C. 360b) is amended by  
25 adding at the end the following:

1       “(q) PHASED ELIMINATION OF NONTHERAPEUTIC  
2 USE IN ANIMALS OF MEDICALLY IMPORTANT  
3 ANTIMICROBIALS.—

4           “(1) APPLICABILITY.—This paragraph applies  
5 to the nontherapeutic use in a food-producing ani-  
6 mal of a drug—

7           “(A) that is a medically important anti-  
8 microbial; or

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

12           “(ii) that is otherwise marketed for human  
13 use.

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

19           “(A) before the date that is 2 years after  
20 the date of the enactment of this subsection,  
21 the Secretary makes a final written determina-  
22 tion that the holder of the approved application  
23 has demonstrated that there is a reasonable  
24 certainty of no harm to human health due to  
25 the development of antimicrobial resistance that

1 is attributable in whole or in part to the non-  
2 therapeutic use of the 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 drug conducted  
7 by the Secretary and other relevant informa-  
8 tion, that there is a reasonable certainty of no  
9 harm to human health due to the development  
10 of antimicrobial resistance that is attributable  
11 in whole or in part to the nontherapeutic use of  
12 the drug.

13 “(3) EXEMPTIONS.—Except as provided in  
14 paragraph (5), if the Secretary grants an exemption  
15 under section 505(i) for a drug that is a medically  
16 important antimicrobial, the Secretary shall rescind  
17 each approval of a nontherapeutic use in a food-pro-  
18 ducing animal of the medically important anti-  
19 microbial, as of the date that is 2 years after the  
20 date on which the Secretary grants the exemption.

21 “(4) APPROVALS.—Except as provided in para-  
22 graph (5), if an application for a drug that is a  
23 medically important antimicrobial is submitted to  
24 the Secretary under section 505(b), the Secretary  
25 shall rescind each approval of a nontherapeutic use

1 in a food-producing animal of the medically impor-  
2 tant antimicrobial, as of the date that is 2 years  
3 after the date on which the application is submitted  
4 to the Secretary.

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

7 “(A) before the date on which approval  
8 would be rescinded under that paragraph, the  
9 Secretary makes a final written determination  
10 that the holder of the application for the ap-  
11 proved nontherapeutic use has demonstrated  
12 that there is a reasonable certainty of no harm  
13 to human health due to the development of  
14 antimicrobial resistance that is attributable in  
15 whole or in part to the nontherapeutic use in  
16 the food-producing animal of the medically im-  
17 portant antimicrobial; or

18 “(B) before the date specified in subpara-  
19 graph (A), the Secretary makes a final written  
20 determination, with respect to a risk analysis of  
21 the medically important antimicrobial conducted  
22 by the Secretary and any other relevant infor-  
23 mation, that there is a reasonable certainty of  
24 no harm to human health due to the develop-  
25 ment of antimicrobial resistance that is attrib-

1           utable in whole or in part to the nontherapeutic  
2           use of the medically important antimicrobial.

3           “(3) DEFINITION.—In this subsection:

4                   “(A) The term ‘medically important anti-  
5           microbial’ means a drug that—

6                           “(i) is intended for use in food-pro-  
7           ducing animals; and

8                           “(ii) is composed wholly or partly of—

9                                   “(I) any kind of penicillin, tetra-  
10           cycline,       macrolide,       lincosamide,  
11           streptogramin,   aminoglycoside,   sul-  
12           fonamide, or cephalosporin; or

13                                   “(II) a drug from an anti-  
14           microbial class that is listed as ‘highly  
15           important’, ‘critically important’, or  
16           ‘important’ by the World Health Or-  
17           ganization in the latest edition of its  
18           publication entitled ‘Critically Impor-  
19           tant Antimicrobials for Human Medi-  
20           cine’ (or a successor publication).

21                   “(B) The term ‘therapeutic use’, with re-  
22           spect to a medically important antimicrobial,  
23           means the use of antimicrobials for the specific  
24           purpose of treating an animal with a docu-  
25           mented disease or infection. Such term does not

1 include the continued use of such an anti-  
2 microbial in the animal after the disease or in-  
3 fection is resolved.

4 “(C) The term ‘nontherapeutic use’—

5 “(i) means administration of anti-  
6 biotics to an animal through feed and  
7 water (or, in poultry hatcheries, through  
8 any means) for purposes (such as growth  
9 promotion, feed efficiency, weight gain, or  
10 disease prevention) other than therapeutic  
11 use or nonroutine disease control; and

12 “(ii) includes any repeated or regular  
13 pattern of use of medically important  
14 antimicrobials for purposes other than  
15 therapeutic use or nonroutine disease con-  
16 trol.

17 “(D) The term ‘noncustomary situation’  
18 does not include normal or standard practice  
19 and conditions on the premises that facilitate  
20 the transmission of disease.

21 “(E) The term ‘nonroutine disease control’  
22 means the use of antibiotics on an animal that  
23 is not sick but where it can be shown that a  
24 particular disease or infection is present, or is  
25 likely to occur because of a specific, noncus-

1 tomary situation, on the premises at the barn,  
2 house, pen, or other level at which the animal  
3 is kept .”.

4 **SEC. 5. LIMITATIONS ON USE OF MEDICALLY IMPORTANT**  
5 **ANTIMICROBIALS FOR NONROUTINE DISEASE**  
6 **CONTROL.**

7 (a) PROHIBITED ACTS.—Section 301 of the Federal  
8 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-  
9 ed by adding at the end the following:

10 “(ccc) The administration of a medically important  
11 antimicrobial to a food-producing animal for nonroutine  
12 disease control in violation of the requirements of section  
13 512A.”.

14 (b) REQUIREMENTS.—Chapter V of the Federal  
15 Food, Drug, and Cosmetic Act is amended by inserting  
16 after section 512 of such Act (21 U.S.C. 360b) the fol-  
17 lowing:

18 **“SEC. 512A. LIMITATIONS ON USE OF MEDICALLY IMPOR-**  
19 **TANT ANTIMICROBIALS FOR NONROUTINE**  
20 **DISEASE CONTROL.**

21 “(a) PROHIBITION.—It shall be unlawful to admin-  
22 ister (including by means of animal feed) a medically im-  
23 portant antimicrobial to a food-producing animal for non-  
24 routine disease control unless—

1           “(1) there is a significant risk that a disease or  
2           infection present on the premises will be transmitted  
3           to the food-producing animal;

4           “(2) the administration of the medically impor-  
5           tant antimicrobial to the food-producing animal is  
6           necessary to prevent or reduce the risk of trans-  
7           mission of the disease or infection described in para-  
8           graph (1);

9           “(3) the medically important antimicrobial is  
10          administered to the food-producing animal for non-  
11          routine disease control for the shortest duration pos-  
12          sible to prevent or reduce the risk of transmission of  
13          the disease or infection described in paragraph (1)  
14          to the animal; and

15          “(4) the medically important antimicrobial is  
16          administered—

17                 “(A) at a scale no greater than the barn,  
18                 house, or pen level; and

19                 “(B) to the fewest animals possible to pre-  
20                 vent or reduce the risk of transmission of the  
21                 disease or infection described in paragraph (1).

22          “(b) DEFINITIONS.—In this section:

23                 “(1) The term ‘food-producing animal’ means a  
24                 food-producing animal intended for sale in interstate  
25                 commerce.

1           “(2) The terms ‘medically important anti-  
2           microbial’ and ‘nonroutine disease control’ have the  
3           meanings given to such terms in section 512(q).”.

4           (c) APPLICABILITY.—The amendments made by this  
5           section apply beginning on the date that is 6 months after  
6           the date of the enactment of this Act.