

113TH CONGRESS  
1ST SESSION

# S. 1256

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 SENATE OF THE UNITED STATES

JUNE 27, 2013

Mrs. FEINSTEIN (for herself, Ms. COLLINS, Mr. REED, Ms. CANTWELL, and Mrs. BOXER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## 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 “Preventing Antibiotic  
5 Resistance 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 foodborne ill-

1       ness 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.

18          (B) Such 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 such as an-  
23      thrax.

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; 114 Stat. 2315), but has not  
11 yet addressed antibiotic overuse in agriculture.

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

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

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

21           (C) cautioned that if current trends con-  
22 tinue, treatments for common infections will be-  
23 come increasingly limited and expensive, and, in  
24 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 the Food and Drug  
22                   Administration’s voluntary guidelines reducing  
23                   antibiotic use in food animals.

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) 13,500,000 kilograms of antibacterial  
21 drugs were sold for use on food animals in the  
22 United States in 2010;

23 (B) 3,300,000 kilograms of antibacterial  
24 drugs were used for human health in 2010; and



1           (C) 80 percent of antibacterial drugs dis-  
2           seminated in the United States in 2010 were  
3           sold for use on food animals, rather than being  
4           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 nontherapeutic antibiotic use  
12                   in food animals would preserve the use of such  
13                   antibiotics for medicine; and

14                   (C) a Danish ban on nontherapeutic anti-  
15                   biotics in food animals resulted in little change  
16                   in animal morbidity and mortality, and only a  
17                   modest increase in production cost.

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

1 controlling antibiotic resistance are needed, and are  
2 seeking voluntarily limits on antibiotic use.

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

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

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

1           (21) Many scientific studies confirm that the  
2 nontherapeutic use of antibiotics in agricultural ani-  
3 mals contribute to the development of antibiotic-re-  
4 sistant bacterial infections in people.

5           (22) Epidemiological research has shown that  
6 resistant Salmonella and Campylobacter infections  
7 are associated with increased numbers of ill patients  
8 and bloodstream infections, and increased death.

9           (23) The American Medical Association, the  
10 American Public Health Association, the National  
11 Association of County and City Health Officials, and  
12 the National Sustainable Agriculture Coalition are  
13 among the more than 400 organizations rep-  
14 resenting health, consumer, agricultural, environ-  
15 mental, humane, and other interests that have sup-  
16 ported enactment of legislation to phase out non-  
17 therapeutic use in farm animals of medically impor-  
18 tant antimicrobials.

19 **SEC. 3. PURPOSE.**

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

1 **SEC. 4. PROOF OF SAFETY OF MEDICALLY IMPORTANT**  
2 **ANTIMICROBIALS.**

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

7 (1) in the first sentence—

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

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

12 (C) by inserting after subparagraph (I) the  
13 following:

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

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

25 (b) PHASED ELIMINATION OF NONTHERAPEUTIC  
26 USE IN ANIMALS OF MEDICALLY IMPORTANT

1 ANTIMICROBIALS.—Section 512 of the Federal Food,  
2 Drug, and Cosmetic Act (21 U.S.C. 360b) is amended by  
3 adding at the end the following:

4 “(q) PHASED ELIMINATION OF NONTHERAPEUTIC  
5 USE IN ANIMALS OF MEDICALLY IMPORTANT  
6 ANTIMICROBIALS.—

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

10 “(A) that is a medically important anti-  
11 microbial;

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

15 “(C) that is otherwise marketed for human  
16 use.

17 “(2) WITHDRAWAL.—The Secretary shall with-  
18 draw the approval of a nontherapeutic use in food-  
19 producing animals of a drug described in paragraph  
20 (1) on the date that is 2 years after the date of en-  
21 actment of 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 medically  
19 important antimicrobial, the Secretary shall rescind  
20 each approval of a nontherapeutic use in a food-pro-  
21 ducing animal of the medically important anti-  
22 microbial, effective on the date that is 2 years after  
23 the date on which the Secretary grants the exemp-  
24 tion.

1           “(4) APPROVALS.—Except as provided in para-  
2           graph (5), if an application for a drug that is a  
3           medically important antimicrobial is submitted to  
4           the Secretary under section 505(b), the Secretary  
5           shall rescind each approval of a nontherapeutic use  
6           in a food-producing animal of the medically impor-  
7           tant antimicrobial, effective on the date that is 2  
8           years after the date on which the application is sub-  
9           mitted to the Secretary.

10           “(5) EXCEPTIONS.—Paragraph (3) or (4), as  
11           applicable, shall not apply if—

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

23                   “(B) before the date specified in subpara-  
24                   graph (A), the Secretary makes a final written  
25                   determination, with respect to a risk analysis of

1 the medically important antimicrobial conducted  
2 by the Secretary and any other relevant infor-  
3 mation, that there is a reasonable certainty of  
4 no harm to human health due to the develop-  
5 ment of antimicrobial resistance that is attrib-  
6 utable in whole or in part to the nontherapeutic  
7 use of the medically important antimicrobial.

8 “(6) DEFINITIONS.—In this subsection:

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

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

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

14 “(I) any kind of penicillin, tetra-  
15 cycline, macrolide, lincosamide,  
16 streptogramin, aminoglycoside, sul-  
17 fonamide, or cephalosporin; or

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



1           “(B) The term ‘therapeutic use’, with re-  
2           spect to a medically important antimicrobial,  
3           means the use of antimicrobials for the specific  
4           purpose of treating an animal with a docu-  
5           mented disease or infection. Such term does not  
6           include the continued use of such an anti-  
7           microbial in the animal after the disease or in-  
8           fection is resolved.

9           “(C) The term ‘nontherapeutic use’—

10           “(i) means administration of anti-  
11           biotics to an animal through feed or water  
12           (or, in poultry hatcheries, through any  
13           means) for purposes (such as growth pro-  
14           motion, feed efficiency, weight gain, or dis-  
15           ease prevention) other than therapeutic use  
16           or nonroutine disease control; and

17           “(ii) includes any repeated or regular  
18           pattern of use of medically important  
19           antimicrobials for purposes other than  
20           therapeutic use or nonroutine disease con-  
21           trol.

22           “(D) The term ‘noncustomary situation’  
23           does not include normal or standard practice  
24           and conditions on the premises that facilitate  
25           the transmission of disease.

1           “(E) The term ‘nonroutine disease control’  
2           means the use of antibiotics in the feed or  
3           water of an animal that is not sick, where it  
4           can be shown that a particular disease or infec-  
5           tion is, or is likely to be, present on the prem-  
6           ises because of a specific, non-customary situa-  
7           tion.”.

8 **SEC. 5. LIMITATIONS ON USE OF MEDICALLY IMPORTANT**  
9                           **ANTIMICROBIALS FOR NONROUTINE DISEASE**  
10                           **CONTROL.**

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

14           “(ccc) The administration of a medically important  
15 antimicrobial to a food-producing animal for nonroutine  
16 disease control in violation of the requirements of section  
17 512A.”.

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

1 **“SEC. 512A. LIMITATIONS ON USE OF MEDICALLY IMPOR-**  
2 **TANT ANTIMICROBIALS FOR NONROUTINE**  
3 **DISEASE CONTROL.**

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

8 “(1)(A) there is a significant risk that a disease  
9 or infection present on, or likely present on, the  
10 premises will be transmitted to the food-producing  
11 animal;

12 “(B) the administration of the medically impor-  
13 tant antimicrobial to the food-producing animal is  
14 necessary to prevent or reduce the risk of trans-  
15 mission of the disease or infection described in para-  
16 graph (1);

17 “(C) the medically important antimicrobial is  
18 administered to the food-producing animal for non-  
19 routine disease control for the shortest duration pos-  
20 sible to prevent or reduce the risk of transmission of  
21 the disease or infection described in paragraph (1)  
22 to the animal; and

23 “(D) the medically important antimicrobial is  
24 administered—

25 “(i) at a scale no greater than the barn,  
26 house, or pen level; and

1           “(ii) to the fewest animals possible to pre-  
 2           vent or reduce the risk of transmission of the  
 3           disease or infection described in paragraph (1);  
 4           or

5           “(2) the Secretary determines that there is a  
 6           reasonable certainty of no harm to human health  
 7           due to the development of antimicrobial resistance  
 8           that is attributable in whole or in part to such use  
 9           of the medically important antimicrobial and such  
 10          use does not threaten the public health.

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

12           “(1) The term ‘food-producing animal’ means a  
 13          food-producing animal intended for sale in interstate  
 14          commerce.

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

18          “(c) APPLICABILITY.—The amendments made by this  
 19          section apply beginning on the date that is 2 years after  
 20          the date of the enactment of this Act.

21          **SEC. 6. SENSE OF THE SENATE REGARDING VETERINARY**  
 22                                 **OVERSIGHT OF USE OF MEDICALLY IMPOR-**  
 23                                 **TANT ANTIMICROBIALS.**

24          “(a) IN GENERAL.—It is the sense of the Senate that  
 25          a valid veterinarian-client-patient relationship should exist

1 to ensure that medically important antimicrobials are used  
2 in a manner that is consistent with professionally accepted  
3 best practices.

4 (b) VETERINARIAN-CLIENT-PATIENT RELATION-  
5 SHIP.—In this section, the term “veterinarian-client-pa-  
6 tient relationship” means a relationship in which all of the  
7 following criteria are met:

8 (1) The veterinarian has assumed the responsi-  
9 bility for making medical judgments regarding the  
10 health of the patient and the client has agreed to  
11 follow the veterinarian’s instructions.

12 (2) The veterinarian has sufficient knowledge of  
13 the patient to initiate at least a general or prelimi-  
14 nary diagnosis of the medical condition of the pa-  
15 tient. This means that the veterinarian is personally  
16 acquainted with the keeping and care of the patient  
17 by virtue of—

18 (A) a timely examination of the patient by  
19 the veterinarian; or

20 (B) medically appropriate and timely visits  
21 by the veterinarian to the premises where the  
22 animal or animals are kept.

23 (3) The veterinarian is readily available for fol-  
24 low-up evaluation or has arranged for veterinary

1 emergency coverage and continuing care and treat-  
2 ment.

3 (4) The veterinarian provides oversight of treat-  
4 ment, compliance, and outcome.

5 (5) Patient records are maintained.

○