

113TH CONGRESS
1ST SESSION

S. _____

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.

IN THE SENATE OF THE UNITED STATES

Mrs. FEINSTEIN introduced the following bill; which was read twice and 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 “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 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.