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1ST SESSION

S. 1211

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.

IN THE SENATE OF THE UNITED STATES

JUNE 15, 2011

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

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) 1,300,000 kilograms of antibacterial
16 drugs were sold for use on food animals in the
17 United States in 2009;

18 (B) 3,300,000 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;”; 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, with respect to a risk analysis of
9 the drug conducted by the Secretary and other
10 relevant information, that there is a reasonable
11 certainty of no harm to human health due to
12 the development of antimicrobial resistance that
13 is attributable in whole or in part to the non-
14 therapeutic use of the drug.

15 “(3) EXEMPTIONS.—Except as provided in
16 paragraph (5), if the Secretary grants an exemption
17 under section 505(i) for a drug that is a critical
18 antimicrobial animal drug, the Secretary shall re-
19 scind each approval of a nontherapeutic use in a
20 food-producing animal of the critical antimicrobial
21 animal drug, or of a drug in the same chemical class
22 as the critical antimicrobial animal drug, as of the
23 date that is 2 years after the date on which the Sec-
24 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, with respect to a risk analysis of
2 the critical antimicrobial animal drug conducted
3 by the Secretary and any other relevant infor-
4 mation, that there is a reasonable certainty of
5 no harm to human health due to the develop-
6 ment of antimicrobial resistance that is attrib-
7 utable in whole or in part to the nontherapeutic
8 use of the drug.”.

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

10 (a) **IN GENERAL.**—The Committee on Energy and
11 Commerce of the House of Representatives and the Com-
12 mittee on Health, Education, Labor, and Pensions of the
13 Senate shall each hold a hearing on the implementation
14 by the Commissioner of Food and Drugs of section 512(q)
15 of the Federal Food, Drug, and Cosmetic Act, as added
16 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 that House) at any
4 time, in the same manner, and to the same extent
5 as in the case of any other rule of that House.

○