

113TH CONGRESS
1ST SESSION

H. R. 1150

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 HOUSE OF REPRESENTATIVES

MARCH 14, 2013

Ms. SLAUGHTER introduced the following bill; which was referred to the Committee on Energy and Commerce

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 “(6) 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.

○