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H. R. 1587

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 16, 2017

Ms. SLAUGHTER (for herself, Ms. DELAURO, Mr. CICILLINE, Mr. CONNOLLY, Mr. DEFazio, Mr. DEUTCH, Mr. LANGEVIN, Mr. TED LIEU of California, Mr. LOWENTHAL, Ms. MCCOLLUM, Mr. MOULTON, Mrs. NAPOLITANO, Ms. NORTON, Ms. SPEIER, Ms. TSONGAS, Mr. YARMUTH, Mr. JEFFRIES, and Ms. SHEA-PORTER) 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 2017”.

1 **SEC. 2. FINDINGS.**

2 The Congress finds the following:

3 (1) All uses of antibiotics, including for food-
4 producing animals, have the potential to cause re-
5 sistance and contribute to the development of anti-
6 biotic-resistant bacterial infections in people.

7 (2) In 1977, the Food and Drug Administra-
8 tion (FDA) concluded that feeding livestock low
9 doses of antibiotics used in human disease treatment
10 could promote the development of antibiotic resist-
11 ance in bacteria. However, the Food and Drug Ad-
12 ministration did not act in response to these find-
13 ings, despite laws requiring the agency to do so.

14 (3) In 2012, the Food and Drug Administra-
15 tion Guidance for Industry #209 provided a sum-
16 mary of over 40 years of peer-reviewed scientific lit-
17 erature regarding use of antimicrobial drugs in live-
18 stock which reiterated that the use of antibiotics in
19 animals contributes to the resistance in human
20 pathogens and concludes that strategies for control-
21 ling antibiotic resistance, including limiting medi-
22 cally important antimicrobial drugs in food-pro-
23 ducing animals only to uses that are considered nec-
24 essary for assuring animal health are needed.

25 (4) The 2014 President's Council of Advisors
26 on Science and Technology Report to the President

1 on Combating Antibiotic-Resistant Bacteria also
2 concludes that substantial evidence exists that the
3 use of antibiotics in food animals promotes the de-
4 velopment and spread of antibiotic resistance in bac-
5 teria that can spread to people and that it is clear
6 that agricultural use of antibiotics can affect human
7 health.

8 (5) Recently published scientific studies have
9 shown that food-producing animals, and animal pro-
10 duction facilities, are a source of antibiotic-resistant
11 bacteria which have infected humans and present an
12 increased risk of acquiring and antibiotics resistant
13 infection.

14 (6) Antibiotic resistance is a crisis which
15 threatens public health, the economy, and national
16 security.

17 (7) In 2013, the Centers for Disease Control
18 and Prevention estimated that antibiotic-resistant
19 infections cause at least 2 million infections, 23,000
20 deaths, 8 million additional hospital days, and \$20
21 to \$35 billion in excess direct health care costs each
22 year in the United States.

23 (8) The 2014 World Health Organization re-
24 port, “Antimicrobial Resistance: Global Report on
25 Surveillance 2014”, concluded that antimicrobial re-

1 sistance is a current reality and the problem is so
2 serious that it threatens the achievements of modern
3 medicine.

4 (9) Without effective antibiotics—

5 (A) common infections could become un-
6 treatable—even fatal; and

7 (B) medical advances such as joint replace-
8 ments, Cesarean sections, organ transplants
9 and chemotherapy could become nonviable.

10 (10) Antibiotic resistance, resulting in a re-
11 duced number of effective antibiotics, may signifi-
12 cantly impair the ability of the United States to re-
13 spond to terrorist attacks involving bacterial infec-
14 tions, such as anthrax and smallpox, or to an event
15 resulting in a large influx of hospitalized patients.

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

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

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

23 (C) therefore, 80 percent of antibacterial
24 drugs disseminated in the United States in

1 2010 were sold for use on food animals, rather
2 than being used for human health.

3 (12) The “FDA Annual Summary Report on
4 Antimicrobials Sold or Distributed in 2012 for Use
5 in Food-Producing Animals” showed that the use of
6 medically important antibiotics in food-producing
7 animals increased 16 percent from 2009 to 2012.

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

16 (B) The Food and Drug Administration has not
17 established a schedule for reviewing those existing
18 approvals.

19 (14) A stated goal of FDA Guidance documents
20 209 and 213 is a reduction in the overall consump-
21 tion of antibiotics. The FDA policy continues to
22 allow the use of antibiotics for routine disease pre-
23 vention without requiring evidence of the presence of
24 a specific disease or requiring the mitigation of con-
25 ditions which elevate disease risk.

1 (15) There is inadequate distinction between
2 usage for disease prevention and production pur-
3 poses, such as growth promotion, on FDA approved
4 drug labels. A 2014 analysis of the approved animal
5 drugs affected by Guidance 213 by the Pew Chariti-
6 table Trusts found that numerous approved drug la-
7 bels contained overlapping indications for growth-
8 promotion and disease prevention.

9 (16) The European Union (EU) banned the use
10 of antibiotics for growth promotion in 2006, a full
11 decade before the FDA’s voluntary approach will go
12 into effect.

13 (17) Since the EU ban, antibiotic usage has de-
14 creased without affecting livestock production.

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

21 (19) The experience in the Netherlands has
22 shown that during the phaseout use indications for
23 growth promotion were completely supplanted by
24 disease prevention. Total antibiotic consumption re-
25 maind constant. After the implementation of man-

1 datory reduction targets and improved surveillance
2 of usage practices antibiotic consumption declined
3 ahead of target without impacting production levels.

4 (20) In 2009, the Congressional Research Serv-
5 ice concluded that without restrictions on the use of
6 antimicrobial drugs in the production of livestock,
7 export markets for livestock and poultry could be
8 negatively impacted due to restrictions on the use of
9 antibiotics in other nations.

10 (21) The American Medical Association, the In-
11 fectious Disease Society of America, the American
12 Public Health Association, the National Association
13 of County and City Health Officials, and the Na-
14 tional Sustainable Agriculture Coalition are among
15 the over 400 organizations representing health, con-
16 sumer, agricultural, environmental, humane, and
17 other interests that have supported enactment of
18 legislation to phaseout nontherapeutic use in farm
19 animals of medically important antimicrobials.

20 **SEC. 3. PURPOSE.**

21 The purpose of this Act is to preserve the effective-
22 ness of medically important antimicrobials used in the
23 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 paragraph 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; or

12 “(B)(i) 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 “(ii) 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 as of the date that is 2 years after the
23 date on which the Secretary grants the exemption.

24 “(4) APPROVALS.—Except as provided in para-
25 graph (5), if an application for a drug that is a

1 medically important antimicrobial is submitted to
2 the Secretary under section 505(b), the Secretary
3 shall rescind each approval of a nontherapeutic use
4 in a food-producing animal of the medically impor-
5 tant antimicrobial as of the date that is 2 years
6 after the date on which the application is submitted
7 to the Secretary.

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

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

21 “(B) before the date specified in subpara-
22 graph (A), the Secretary makes a final written
23 determination, with respect to a risk analysis of
24 the medically important antimicrobial conducted
25 by the Secretary and any other relevant infor-

1 mation, that there is a reasonable certainty of
2 no harm to human health due to the develop-
3 ment of antimicrobial resistance that is attrib-
4 utable in whole or in part to the nontherapeutic
5 use of the medically important antimicrobial.

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

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

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

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

12 “(I) any kind of penicillin, tetra-
13 cycline, macrolide, lincosamide, strep-
14 togramin, aminoglycoside, sulfona-
15 mide, or cephalosporin; or

16 “(II) a drug from an antimicrobi-
17 al class that is listed as ‘highly impor-
18 tant’, ‘critically important’, or ‘impor-
19 tant’ by the World Health Organiza-
20 tion in the latest edition of its publica-
21 tion entitled ‘Critically Important
22 Antimicrobials for Human Medicine’
23 (or a successor publication).

24 “(B) The term ‘therapeutic use’, with re-
25 spect to a medically important antimicrobial,

1 means the use of antimicrobials for the specific
2 purpose of treating an animal with a docu-
3 mented disease or infection. Such term does not
4 include the continued use of such an anti-
5 microbial in the animal after the disease or in-
6 fection is resolved.

7 “(C) The term ‘nontherapeutic use’—

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

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

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

24 “(E) The term ‘nonroutine disease control’
25 means the use of antibiotics on an animal that

1 is not sick but where it can be shown that a
2 particular disease or infection is present, or is
3 likely to occur because of a specific, noncus-
4 tomary situation, on the premises at the barn,
5 house, pen, or other level at which the animal
6 is kept.”.

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

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

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

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

21 **“SEC. 512A. LIMITATIONS ON USE OF MEDICALLY IMPOR-**
22 **TANT ANTIMICROBIALS FOR NONROUTINE**
23 **DISEASE CONTROL.**

24 “(a) PROHIBITION.—It shall be unlawful to admin-
25 ister (including by means of animal feed) a medically im-

1 portant antimicrobial to a food-producing animal for non-
2 routine disease control unless—

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

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

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

17 “(4) the medically important antimicrobial is
18 administered—

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

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

24 “(b) DEFINITIONS.—In this section:

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

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

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

○