

107<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# S. 2508

To preserve the effectiveness of medically important antibiotics by restricting their use as additives to animal feed.

---

## IN THE SENATE OF THE UNITED STATES

MAY 13 (legislative day, MAY 9), 2002

Mr. KENNEDY (for himself, Mr. REED, and Mr. BINGAMAN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

## A BILL

To preserve the effectiveness of medically important antibiotics by restricting their use as additives to animal feed.

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 Human Treatment Act of 2002”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

8 (1) Several antibiotics and classes of antibiotics  
9 either are used in or are related to antibiotics used

1 in humans to treat infectious diseases and are also  
2 routinely administered to healthy agricultural ani-  
3 mals, generally via feed or water, in order to pro-  
4 mote the animals' growth or to prevent disease.  
5 Such uses do not require a veterinarian's prescrip-  
6 tion.

7 (2) Mounting scientific evidence shows that this  
8 nontherapeutic use of antibiotics in agricultural ani-  
9 mals can lead to development of antibiotic-resistant  
10 bacteria that can be transferred to people, making it  
11 harder to treat certain infections.

12 (3) In 1997 and in 2000, the World Health Or-  
13 ganization recommended that antibiotics used to  
14 treat humans should not also be used to promote  
15 animal growth, although such antibiotics could still  
16 be used to treat ill animals. Most developed coun-  
17 tries in the world, with the exception of the United  
18 States and Canada, restrict the use of antimicrobials  
19 in animal production systems for growth promotion.

20 (4) In July 1998, the National Academy of  
21 Sciences, in a report prepared at the request of the  
22 United States Department of Agriculture and the  
23 Food and Drug Administration, concluded "there is  
24 a link between the use of antibiotics in food animals,

1 the development of bacterial resistance to these  
2 drugs, and human disease”.

3 (5) In July 1999, the European Union banned  
4 the use for animal growth promotion of remaining  
5 human-use antibiotics still in use to promote animal  
6 growth. Prior to that action, individual European  
7 countries, including the United Kingdom, Denmark,  
8 Finland, and Sweden, had banned the use in animal  
9 feed of specific antibiotics.

10 (6) In October 2000, the Food and Drug Ad-  
11 ministration issued a notice announcing its intention  
12 to withdraw approvals for use of fluoroquinolone  
13 antibiotics in poultry, in light of the fact that in-  
14 creased resistance to fluoroquinolones in certain bac-  
15 teria followed approval of those antibiotics for such  
16 use in the mid-1990s. The Food and Drug Adminis-  
17 tration concluded that “the use of fluoroquinolones  
18 in poultry is a significant cause of fluoroquinolone  
19 resistant infections in humans.” One manufacturer  
20 of such drugs is contesting FDA’s proposed with-  
21 drawal and continues to market its product. Pre-  
22 vious proceedings by FDA to withdraw approval of  
23 animal drugs have taken substantial amounts of  
24 time following initiation of formal action by FDA,  
25 including 6 years in one instance and 20 in another.

1           (7) In June 2001, the American Medical Asso-  
2           ciation adopted a resolution opposing nontherapeutic  
3           use of antimicrobials in animal agriculture. Medical  
4           professional organizations that have taken a similar  
5           position include the American College of Preventive  
6           Medicine, the American Public Health Association,  
7           and the Council of State and Territorial Epidemiolo-  
8           gists.

9           (8) In October 2001, the New England Journal  
10          of Medicine published a guest editorial titled  
11          “Antimicrobials in Animal Feed—Time to Stop”.  
12          The editorial urged a ban on nontherapeutic use in  
13          animals of medically important antibiotics.

14          (9) The National Academy of Sciences has  
15          found that eliminating the use of antibiotics as feed  
16          additives would cost each American consumer not  
17          more than \$5 to \$10 per year.

18          (10) In January 2001, a Federal interagency  
19          task force on antibiotic resistance concluded that  
20          “drug-resistant pathogens are a growing menace to  
21          all people, regardless of age, gender, or socio-  
22          economic background. If we do not act to address  
23          the problem . . . [d]rug choices for the treatment  
24          of common infections will become increasingly lim-

1 ited and expensive—and, in some cases, non-  
2 existent.”.

3 (11) Scientific studies published in major peer-  
4 reviewed research journals have shown that resist-  
5 ance traits can be transferred among unrelated spe-  
6 cies of bacteria, including from nonpathogens to  
7 pathogens.

8 (12) Development of resistance to antibiotics  
9 could significantly impair the ability of the United  
10 States to respond effectively to a bioterrorist attack  
11 and is likely to increase the casualties that result  
12 from such an attack.

13 **SEC. 3. PRESERVING THE EFFECTIVENESS OF ANTIBIOTICS**  
14 **SUCH AS CIPRO.**

15 (a) PROHIBITING THE USE OF DRUGS RELATED TO  
16 CIPRO IN POULTRY.—Section 512(a)(2) of the Federal  
17 Food, Drug, and Cosmetic Act (21 U.S.C. 360b(a)(2)) is  
18 amended—

19 (1) in subparagraph (B), by striking “and” at  
20 the end;

21 (2) in subparagraph (C), by striking the period  
22 and inserting “; and”; and

23 (3) by adding at the end the following:

24 “(D) such drug is not a member of the  
25 fluoroquinolone class of antimicrobial drugs, or if

1 such drug is a member of the fluoroquinolone class  
2 of antimicrobial drugs, the Secretary shall have  
3 found, based on information submitted to the Sec-  
4 retary by the sponsor of such drug, that there exists  
5 a reasonable certainty of no harm to human health  
6 due to the development of antimicrobial resistance  
7 that is attributable in whole or in part to the use in  
8 animal feed of such drug.

9 “Nothing in subparagraph (D) shall be construed to affect  
10 an approval under this subsection for a drug of the  
11 fluoroquinolone class of antimicrobial drugs that is used  
12 in or for cattle.”.

13 (b) DEFINITION.—Section 201(w) of the Federal  
14 Food, Drug, and Cosmetic Act (21 U.S.C. 321(w)) is  
15 amended—

16 (1) by striking “(w) The term” and inserting  
17 “(w)(1) The term”; and

18 (2) by adding at the end the following:

19 “(2) With respect to subparagraph (D) of section  
20 512(a)(2) (and in provisions of this Act that refer to such  
21 subparagraph), the term ‘animal feed’ shall include an ar-  
22 ticle that is a fluid administered to animals other than  
23 man. Such term does not include fluids administered via  
24 hypodermic injection.”.

1 **SEC. 4. REQUIRING PROOF OF SAFETY OF ANTIMICROBIAL**  
2 **NEW ANIMAL DRUGS.**

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

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

9 (2) by redesignating subparagraph (I) as sub-  
10 paragraph (J);

11 (3) by inserting after subparagraph (H) the fol-  
12 lowing subparagraph:

13 “(I) with respect to a critical antimicrobial drug  
14 or a drug of the same chemical class as a critical  
15 antimicrobial drug, the applicant has failed to dem-  
16 onstrate that there is a reasonable certainty of no  
17 harm to human health due to the development of  
18 antimicrobial resistance that is attributable, in whole  
19 or in part, to the nontherapeutic use of such drug;  
20 or”; and

21 (4) in the matter after and below subparagraph  
22 (J) (as redesignated by paragraph (2)), by striking  
23 “(A) through (I)” and inserting “(A) through (J)”.

24 (b) PHASED ELIMINATION OF NONTHERAPEUTIC  
25 USE IN ANIMALS OF ANTIBIOTICS IMPORTANT FOR  
26 HUMAN HEALTH.—Section 512 of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 360b) is amended by  
2 adding at the end the following:

3 “(q) With respect to the nontherapeutic use in an  
4 animal of—

5 “(1) a drug that is a critical antimicrobial drug;

6 or

7 “(2) a drug that is of the same chemical class  
8 as a critical antimicrobial drug;

9 for which, as of the day before the date of enactment of  
10 this subsection, there was in effect an approval of an appli-  
11 cation filed pursuant to subsection (b), the Secretary shall  
12 withdraw such approval on the date that is 2 years after  
13 the date of enactment of this subsection unless the Sec-  
14 retary, based on information submitted to the Secretary  
15 by the sponsor of such drug, has determined prior to the  
16 date that is 2 years after such date of enactment that  
17 there is a reasonable certainty of no harm to human health  
18 due to the development of antimicrobial resistance that is  
19 attributable in whole or in part to the nontherapeutic use  
20 of such drug.

21 “(r)(1) If the Secretary grants an exemption under  
22 section 505(i) or under section 351 of the Public Health  
23 Service Act (42 U.S.C. 262) to a drug that is an antibiotic  
24 drug, the Secretary shall rescind each approval of a non-  
25 therapeutic use in an animal of such drug or of a drug

1 in the same chemical class as such drug upon the expira-  
2 tion of the 2-year period beginning on the date on which  
3 the Secretary grants the exemption, except as provided in  
4 paragraph (3).

5 “(2) If an application for an antibiotic drug is sub-  
6 mitted to the Secretary under section 505(b) or under sec-  
7 tion 351 of the Public Health Service Act (42 U.S.C. 262),  
8 the Secretary shall rescind each approval of a nonthera-  
9 peutic use in an animal of such drug or a drug in the  
10 same chemical class as such drug upon the expiration of  
11 the 2-year period beginning on the date on which the ap-  
12 plication is submitted to the Secretary, except as provided  
13 in paragraph (3).

14 “(3) Paragraph (1) or (2), as the case may be, ap-  
15 plies unless, before the date on which approval would be  
16 rescinded under such paragraph, the Secretary determines  
17 that the holder of the approved application has dem-  
18 onstrated that there is a reasonable certainty of no harm  
19 to human health due to the development of antimicrobial  
20 resistance that is attributable, in whole or in part, to the  
21 nontherapeutic use in an animal of such drug.”.

22 (c) DEFINITIONS.—Section 512 of the Federal Food,  
23 Drug, and Cosmetic Act (21 U.S.C. 360b), as amended  
24 by subsection (b), is further amended by adding at the  
25 end the following:

1       “(s) For purposes of this section, the term ‘nonthera-  
2       peutic use’, with respect to a critical antimicrobial drug,  
3       means any use of such drug in an animal in the absence  
4       of disease in such animal, including use for growth pro-  
5       motion, feed efficiency, or routine disease prevention.

6       “(t) For purposes of this section, the term ‘critical  
7       antimicrobial drug’ means any drug that is—

8               “(1) intended for use in animals other than hu-  
9       mans that are—

10                   “(A) intended for use as, or to generate,  
11       food for humans; or

12                   “(B) intended to breed or otherwise  
13       produce animals described in subparagraph (A);  
14       and

15               “(2)(A) composed wholly or partly of any kind  
16       of penicillin, tetracycline, bacitracin, macrolide, lin-  
17       comycin, streptogramin, aminoglycoside, sul-  
18       fonamide; or

19               “(B) any other drug or derivative thereof that  
20       is used in humans or intended for use in humans to  
21       inhibit or destroy micro-organisms.”.

1 **SEC. 5. ASSISTANCE TO DEFRAY FARMERS' EXPENSES IN**  
2 **PHASING OUT NONTHERAPEUTIC USE OF**  
3 **MEDICALLY IMPORTANT ANTIBIOTICS; PREF-**  
4 **ERENCE FOR FAMILY FARMS.**

5 (a) **IN GENERAL.**—The Secretary of Agriculture may  
6 make payments to producers of livestock or poultry who  
7 the Secretary determines are substantially reducing, or  
8 have substantially reduced, the nontherapeutic use of crit-  
9 ical antimicrobial drugs in livestock or poultry in order  
10 to defray the costs of such reduction.

11 (b) **DEFINITION.**—In this section the terms “critical  
12 antimicrobial drug” and “nontherapeutic use” have the  
13 meanings given such terms in section 512(s) of the Fed-  
14 eral Food, Drug, and Cosmetic Act (as amended by this  
15 Act).

16 (c) **PRIORITY FOR FAMILY FARMERS.**—In awarding  
17 payments under subsection (a), the Secretary of Agri-  
18 culture shall give priority to family-owned and family-op-  
19 erated farms or ranches.

20 (d) **AUTHORIZATION OF APPROPRIATIONS.**—There is  
21 authorized to be appropriated such sums as may be nec-  
22 essary to carry out this section for fiscal year 2003 and  
23 for each subsequent fiscal year.

○