

113TH CONGRESS  
1ST SESSION

# S. 895

To improve the ability of the Food and Drug Administration to study the use of antimicrobial drugs in food-producing animals.

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IN THE SENATE OF THE UNITED STATES

MAY 8, 2013

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

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## A BILL

To improve the ability of the Food and Drug Administration to study the use of antimicrobial drugs in food-producing animals.

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 “Antimicrobial Data  
5 Collection Act”.

6 **SEC. 2. RESEARCH PROGRAMS TO STUDY ANTIMICROBIAL**  
7 **RESISTANCE.**

8 (a) DEFINITIONS.—In this Act—

1           (1) the term “Commissioner” means the Com-  
2           missioner of Food and Drugs; and

3           (2) the term “Secretary” means the Secretary  
4           of Health and Human Services.

5           (b) COMMENCEMENT OF PILOT DATA COLLECTION  
6           AND ANALYSIS PROGRAM.—The Secretary, acting through  
7           the Commissioner, shall develop a research program or  
8           programs to study the relationship between the sales, dis-  
9           tribution, end-use practices of animal drugs containing an  
10          antimicrobial active ingredient in food-producing animals  
11          and antimicrobial resistance trends. The Secretary may  
12          also consider any other available sound information,  
13          science, research, expertise, or program designs in car-  
14          rying out this subsection.

15          (c) PURPOSE OF PROGRAMS.—Any research program  
16          developed under subsection (b) shall be developed in order  
17          to better determine—

18               (1) the relationships between sales data, dis-  
19               tribution data, and end-usage data of animal drugs  
20               containing an antimicrobial active ingredient in food-  
21               producing animals to inform policies of Food and  
22               Drug Administration regarding data collection and  
23               regulation of antimicrobial products in agriculture,  
24               including consideration of the potential value and

1 feasibility of data from veterinary feed directives and  
2 other sources; and

3 (2) the relationships between the use of animal  
4 drugs containing an antimicrobial active ingredient  
5 in food-producing animals and trends in anti-  
6 microbial resistance, including by using the data col-  
7 lected through the National Antimicrobial Resistance  
8 Monitoring System or other studies regarding resist-  
9 ance levels in bacteria associated with food-pro-  
10 ducing animals.

11 (d) CONSULTATION.—Any research program devel-  
12 oped under subsection (b) shall be developed in consulta-  
13 tion with the Secretary of Agriculture, which shall include  
14 at a minimum consultation with the Under Secretary for  
15 Food Safety, the Under Secretary for Marketing and Reg-  
16 ulatory Programs, and the Under Secretary for Research,  
17 Education, and Economics at the Department of Agri-  
18 culture. To the extent practicable, such Under Secretaries  
19 shall provide assistance in developing and conducting such  
20 research programs.

21 (e) IMPLEMENTATION.—Not later than 180 days  
22 after the date of enactment of this Act, the Secretary shall  
23 implement the research program or programs developed  
24 under subsection (b). The Secretary shall analyze data  
25 from such program or programs to determine the con-

1 tribution of such data to studying antimicrobial resistance  
2 and establishing the antimicrobial data collection strategy  
3 as described in section 3(b)(1)(B).

4 **SEC. 3. REPORTS TO CONGRESS; DEVELOPMENT OF DATA**  
5 **COLLECTION STRATEGY.**

6 (a) INITIAL REPORT.—As soon as practicable after  
7 the date of enactment of this Act, the Secretary shall—

8 (1) submit to Congress a report that—

9 (A) describes the research design and goals  
10 for the research program or programs developed  
11 under section 2(b); and

12 (B) includes a needs assessment, consid-  
13 ering broad sources of data and models on anti-  
14 microbial use in food-producing animals that  
15 the Food and Drug Administration may need or  
16 from which the Food and Drug Administration  
17 could benefit, to improve the evaluation of Food  
18 and Drug Administration programs regarding  
19 antimicrobial resistance and how a systematic  
20 and valid data collection strategy will be de-  
21 signed to comply with subsection (b)(1)(B); and

22 (2) make such report publicly available.

23 (b) REPORT REGARDING RESULTS AND REC-  
24 OMMENDATIONS.—Not later than 2 years after the date  
25 of enactment of this Act, the Secretary shall—

1 (1) submit to Congress a report that—

2 (A) describes the comprehensive results of  
3 any research program or programs developed  
4 under section 2(b), including with respect to the  
5 determinations made pursuant to paragraphs  
6 (1) and (2) of section 2(c); and

7 (B) provides recommendations for devel-  
8 oping an antimicrobial data collection strategy  
9 based on the information contained in the com-  
10 ments to the Advanced Notice of Proposed  
11 Rulemaking entitled “Antimicrobial Animal  
12 Drug Distribution Reporting” (77 Fed. Reg.  
13 44177 (July 27, 2012)) and any relevant infor-  
14 mation obtained in the research pilot program  
15 carried out under section 2; and

16 (2) make such report publicly available.

17 **SEC. 4. ENHANCED REPORTING AND PUBLICATION OF**  
18 **SALES DATA.**

19 (a) IN GENERAL.—Section 512(l)(3)(E) of the Fed-  
20 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
21 360b(l)(3)(E)) is amended—

22 (1) by redesignating clauses (i) and (ii) as sub-  
23 clauses (I) and (II);

24 (2) by striking “The Secretary shall make sum-  
25 maries of the information reported under this para-

1 graph publicly available, except that—” and insert-  
2 ing “(i) Not later than a date established by the  
3 Secretary for 2014, and on such date in each year  
4 thereafter, the Secretary shall make publicly avail-  
5 able a summary of the information (including dosage  
6 form information, if practicable) reported under this  
7 paragraph for the previous year, except that—”; and

8 (3) by inserting after subclause (II), as redesign-  
9 nated by paragraph (1), the following:

10 “(ii) In making the summaries available under this  
11 subparagraph, the following shall apply:

12 “(I) The Secretary shall segregate the cat-  
13 egories of amounts reported into the following 2 sub-  
14 categories, after consultation with applicable classi-  
15 fications as determined by the Secretary, subject to  
16 subclause (IV):

17 “(aa) The volume of drugs of importance  
18 to human medicine.

19 “(bb) The volume of drugs not of impor-  
20 tance to human medicine.

21 “(II) As practicable, the Secretary shall seg-  
22 regate amounts reported into the following:

23 “(aa) Container size.

24 “(bb) Strength.

25 “(cc) Dosage form.

1 “(dd) Marketing status.

2 “(III) In any cross-tabulation of the amounts  
3 reported with any reporting category, the Secretary  
4 shall include the categories ‘Not Independently Re-  
5 ported’ and ‘Not Independently Reported Export’.

6 “(IV) Every 5 years, the Secretary shall re-  
7 evaluate the classifications consulted under sub-  
8 clause (I) after opportunity for public comment.

9 “(iii) The Secretary shall maximize the quality, accu-  
10 racy, detail, and specificity of data made publicly available  
11 in the summaries under this subparagraph, to the extent  
12 practicable, such as regarding the type, estimated level of  
13 exposure, and target animals of antimicrobial drugs. In  
14 carrying out the preceding sentence, the Secretary may  
15 provide additional information in such summaries.

16 “(iv) The Secretary shall conduct an annual evalua-  
17 tion of the effectiveness of and compliance with relevant  
18 policies and programs of the Food and Drug Administra-  
19 tion regarding antimicrobial drug sales for food-producing  
20 animals, and use of such drugs and antimicrobial resist-  
21 ance, using valid and robust performance metrics. Begin-  
22 ning in 2014, the Secretary shall include with each annual  
23 summary made publicly available under this subparagraph  
24 a report that describes the results of the evaluation con-

1 ducted under this clause with respect to the preceding  
2 year.”.

3 (b) REISSUANCE.—Not later than 3 years after the  
4 date of enactment of this Act, the Secretary shall reissue  
5 the summary reports issued before 2012 under section  
6 512(l)(3)(E) of the Federal Food, Drug, and Cosmetic Act  
7 (21 U.S.C. 360b(l)(3)(E)) using the format designed for  
8 the 2012 summary report. The Secretary shall publish the  
9 reissued reports in one combined publication.

10 **SEC. 5. ACTION TO PROTECT PUBLIC AND ANIMAL HEALTH.**

11 (a) PUBLICATION OF FINAL GUIDANCE.—

12 (1) IN GENERAL.—Not later than 180 days  
13 after the date of enactment of this Act, the Sec-  
14 retary shall publish a final version of the draft Vol-  
15 untary Guidance #213 of the Food and Drug Ad-  
16 ministration (entitled “New Animal Drugs and New  
17 Animal Drug Combination Products Administered in  
18 or on Medicated Feed or Drinking Water of Food-  
19 Producing Animals: Recommendations for Drug  
20 Sponsors for Voluntarily Aligning Product Use Con-  
21 ditions with GFI #209”).

22 (2) EFFECT OF SUBSECTION.—Nothing in this  
23 subsection shall be construed to affect any other ob-  
24 ligations of the Food and Drug Administration re-  
25 garding the authorities of such Administration to



1 regulate antimicrobial drugs and protect public  
2 health.

3 (b) REPORT BY GAO.—

4 (1) IN GENERAL.—Not later than 3 years after  
5 the conclusion of the research pilot program or pro-  
6 grams developed under section 2, the Comptroller  
7 General of the United States shall commence a  
8 study to evaluate—

9 (A) the approaches used by the Food and  
10 Drug Administration to eliminate injudicious  
11 use of antimicrobial drugs in food-producing  
12 animals; and

13 (B) the effectiveness of the data collection  
14 activities carried out by the Food and Drug Ad-  
15 ministration regarding antimicrobial resistance.

16 (2) REPORT.—Not later than 1 year after com-  
17 mencing the study described in paragraph (1), the  
18 Comptroller General of the United States shall sub-  
19 mit to the Committee on Health, Education, Labor,  
20 and Pensions of the Senate and the Committee on  
21 Energy and Commerce of the House of Representa-  
22 tives a report that describes the results of such  
23 study.

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