

110TH CONGRESS
1ST SESSION

H. R. 3697

To amend the Public Health Service Act to address antimicrobial resistance.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 27, 2007

Mr. MATHESON (for himself, Mr. FERGUSON, Mr. WAXMAN, and Ms. BALDWIN) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to address antimicrobial resistance.

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 “Strategies to Address
5 Antimicrobial Resistance Act”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

8 (1) The advent of the antibiotic era has saved
9 millions of lives and allowed for incredible medical
10 progress; however, the increased use of

1 antimicrobials has also correlated with an increased
2 rate in the development of antimicrobial resistance.

3 (2) Through mutation as well as other mecha-
4 nisms, bacteria and other infectious disease-causing
5 organisms—viruses, fungi, and parasites—develop
6 resistance to antimicrobial drugs over time. The
7 more antimicrobials are used, whether appropriately
8 or inappropriately, the more this contributes to the
9 development of antimicrobial resistance.

10 (3) Scientific evidence suggests that the source
11 of antibiotic resistance in humans is not just limited
12 to use of antibiotics in humans, but may in fact also
13 be passed to humans from food-producing animals
14 which are exposed to antibiotics.

15 (4) Today, antimicrobial resistance poses a seri-
16 ous patient safety and public health threat through-
17 out the United States.

18 (5) Tuberculosis is emerging as a virulent and
19 growing threat to public health in the United States
20 and throughout the world. Multidrug resistant tu-
21 berculosis (MDR-TB) was first documented in the
22 early 1990s, and by 2004 there were approximately
23 424,000 new cases. Extensively drug resistant tuber-
24 culosis (XDR-TB) emerged in 2005 and has been
25 called “virtually untreatable” by the World Health

1 Organization because this strain is resistant to near-
2 ly every approved tuberculosis drug.

3 (6) Nearly 70 percent of all hospital-acquired
4 bacterial infections in the United States are resist-
5 ant to at least one drug, and in some cases the situ-
6 ation is much worse. According to the Centers for
7 Disease Control and Prevention, almost half of the
8 identified methicillin-resistant *Staphylococcus aureus*
9 (MRSA) strains in hospitals are resistant to all but
10 a few antibiotics.

11 (7) Each year, nearly 2,000,000 people contract
12 bacterial infections in hospitals, and approximately
13 90,000 of these people die from these infections —
14 7 times more than a decade earlier.

15 (8) The costs of antibiotic-resistant bacterial
16 diseases are hard to quantify, but a 1995 report by
17 the Office of Technology Assessment of Congress,
18 which looked at 6 different antibiotic-resistant
19 strains of bacteria, calculated that the minimum na-
20 tionwide hospital costs of just these strains of bac-
21 teria accounted for \$1,300,000,000 annually (1992
22 dollars).

23 (9) A 1989-published study has estimated that
24 the total societal cost of all antibiotic-resistant bac-
25 teria was up to \$30,000,000,000 annually.

1 (10) The cost to society of antimicrobial-resist-
2 ant infections will only rise as antimicrobial resist-
3 ance continues to spread.

4 (11) The Federal interagency Task Force on
5 Antimicrobial Resistance was established in 1999,
6 but the authorization of appropriations for the Task
7 Force expired in 2006 and should be reauthorized to
8 enable the continuation of the important coordinated
9 Federal interagency effort to combat the adverse im-
10 pacts of antimicrobial resistance on human health.

11 (12) The Congress should strengthen the Task
12 Force and give it the tools necessary to carry out the
13 Public Health Action Plan to Combat Antimicrobial
14 Resistance.

15 **SEC. 3. ANTIMICROBIAL RESISTANCE TASK FORCE.**

16 (a) IN GENERAL.—Section 319E of the Public
17 Health Service Act (42 U.S.C. 247d–5) is amended—

18 (1) in subsection (a)—

19 (A) in the subsection heading, by striking
20 “TASK FORCE” and inserting the following:

21 “OFFICE OF ANTIMICROBIAL RESISTANCE,
22 TASK FORCE, AND ADVISORY BOARD”;

23 (B) in paragraph (1)—

1 (i) by striking “as of the date of the
2 enactment of this section” and inserting
3 “September 30, 2006”; and

4 (ii) by adding at the end the fol-
5 lowing: “The Secretary shall, not later
6 than the end of the calendar year 2008, es-
7 tablish an Office of Antimicrobial Resist-
8 ance in the Office of the Assistant Sec-
9 retary for Health and appoint a director to
10 that Office. The Secretary shall, not later
11 than the end of the calendar year 2008, es-
12 tablish the Public Health Antimicrobial
13 Advisory Board as a permanent advisory
14 board to the Director of the Office of Anti-
15 microbial Resistance. The Director of the
16 Office of Antimicrobial Resistance shall
17 serve as the Director of the task force and
18 supervise the activities and budgetary allo-
19 cations of the Office, task force, and advi-
20 sory board.”;

21 (C) by amending paragraph (2) to read as
22 follows:

23 “(2) MEMBERS.—

24 “(A) MEMBERS OF THE ANTIMICROBIAL
25 RESISTANCE TASK FORCE.—The task force de-

1 scribed in paragraph (1) shall be composed of
2 the following members:

3 “(i) The Director of the Office of
4 Antimicrobial Resistance.

5 “(ii) Representatives of such Federal
6 agencies as the Secretary determines nec-
7 essary, including at a minimum represent-
8 atives of the following:

9 “(I) The Centers for Disease
10 Control and Prevention.

11 “(II) The Food and Drug Ad-
12 ministration.

13 “(III) The National Institutes of
14 Health.

15 “(IV) The Agency for Healthcare
16 Research and Quality.

17 “(V) The Centers for Medicare &
18 Medicaid Services.

19 “(VI) The Health Resources and
20 Services Administration.

21 “(VII) The Department of Agri-
22 culture.

23 “(VIII) The Department of De-
24 fense.

1 “(IX) The Department of Vet-
2 erans Affairs.

3 “(X) The Environmental Protec-
4 tion Agency.

5 “(B) MEMBERS OF THE PUBLIC HEALTH
6 ANTIMICROBIAL ADVISORY BOARD.—

7 “(i) IN GENERAL.—The Public Health
8 Antimicrobial Advisory Board shall be
9 composed of 19 voting members, appointed
10 by the Secretary. Such members shall in-
11 clude representatives of the infectious dis-
12 eases, medical (including hospital and com-
13 munity-based physicians), public health,
14 veterinary, research, and international
15 health communities.

16 “(ii) TERMS.—Each member ap-
17 pointed under clause (i) shall be appointed
18 for a term of 3 years, except that of the
19 19 members first appointed—

20 “(I) 6 shall be appointed for a
21 term of 1 year; and

22 “(II) 6 shall be appointed for a
23 term of 2 years.

24 “(iii) CHAIR.—The Secretary shall ap-
25 point a Chair of the Public Health Anti-

1 microbial Advisory Board to lead and su-
2 pervise the activities of the advisory
3 board.”;

4 (D) in paragraph (3)(B), by striking “in
5 consultation with the task force described in
6 paragraph (1) and” and inserting “acting
7 through the Director of the Office of Anti-
8 microbial Resistance and the Director of the
9 Centers for Disease Control and Prevention,
10 and in consultation with”; and

11 (E) by amending paragraph (4) to read as
12 follows:

13 “(4) MEETINGS AND DUTIES.—

14 “(A) OFFICE OF ANTIMICROBIAL RESIST-
15 ANCE DUTIES.—The Director of the Office of
16 Antimicrobial Resistance, working in conjunc-
17 tion with the Federal agencies that are rep-
18 resented on the task force described in para-
19 graph (1), shall issue an update to the Public
20 Health Action Plan to Combat Antimicrobial
21 Resistance within 1 year of the establishment of
22 the Office and biennial updates thereafter. The
23 updates shall include enhanced plans for ad-
24 dressing resistance in the United States and
25 internationally. The Director of the Office shall

1 establish and maintain a website for posting
2 these updates as well as summaries of all non-
3 proprietary data made available to the task
4 force. The Director of the Office of Anti-
5 microbial Resistance shall, as appropriate—

6 “(i) establish milestones for achieving
7 the goals set forth in the action plan;

8 “(ii) assess the ongoing observed pat-
9 terns of emergence of antimicrobial resist-
10 ance, and their impact on clinical outcomes
11 in terms of how patients feel, function, or
12 survive;

13 “(iii) assess how antimicrobials are
14 being used in humans, animals, and plants,
15 and the impact of such use in furthering
16 the development of resistance and the im-
17 plications thereof for patient safety and
18 public health;

19 “(iv) establish a priority list of human
20 infectious diseases with the greatest need
21 for development of new point-of-care and
22 other diagnostics, antimicrobial drugs, and
23 vaccines, and in particular serious and life-
24 threatening bacterial diseases, for which

1 there are few or no diagnostic or treatment
2 options;

3 “(v) recommend basic, clinical, epide-
4 miological, prevention, and translational
5 research where additional federally sup-
6 ported studies may be beneficial;

7 “(vi) recommend how to support anti-
8 microbial development through the Food
9 and Drug Administration’s Critical Path
10 Initiative; and

11 “(vii) recommend how best to
12 strengthen and link antimicrobial resist-
13 ance-related surveillance and prevention
14 and control activities.

15 “(B) ANTIMICROBIAL RESISTANCE TASK
16 FORCE MEETINGS AND DUTIES.—

17 “(i) MEETINGS.—The Antimicrobial
18 Resistance Task Force shall convene peri-
19 odically as the Director of the Anti-
20 microbial Resistance Task Force deter-
21 mines to be appropriate, but not less than
22 twice a year, to consider issues relating to
23 antimicrobial resistance.

24 “(ii) PUBLIC HEALTH ACTION
25 PLAN.—At least twice a year, the task

1 force shall have a meeting to review, dis-
2 cuss, and further develop the Public
3 Health Action Plan to Combat Anti-
4 microbial Resistance issued by the inter-
5 agency task force on antimicrobial resist-
6 ance in 2001. Among other issues, the task
7 force may discuss and review, based on
8 current need or concern—

9 “(I) antimicrobial clinical suscep-
10 tibility concentrations proposed, estab-
11 lished, or updated by the Food and
12 Drug Administration;

13 “(II) data on emerging anti-
14 microbial resistance related to clinical
15 outcomes in terms of how patients
16 function, feel, or survive as well as
17 data related to how antimicrobials
18 may have been used inappropriately,
19 obtained by government agencies in-
20 cluding the Centers for Disease Con-
21 trol and Prevention, the Food and
22 Drug Administration, the Department
23 of Defense, the Department of Vet-
24 erans Affairs, the Centers for Medi-

1 care & Medicaid Services, and as possible from private sources;

2
3 “(III) surveillance data and prevention and control activities regarding emerging antimicrobial resistance
4 from reliable sources, including such
5 data obtained by government agencies
6 such as the Centers for Disease Control and Prevention, the Food and
7 Drug Administration, the Department
8 of Defense, the Department of Veterans Affairs, the Department of Agriculture, the Environmental Protection Agency, and as possible from private sources and international bodies;

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16 “(IV) data on the amount of antimicrobials used in humans, animals, and plants from reliable sources,
17 including such data obtained by government agencies such as the Centers
18 for Disease Control and Prevention,
19 the Food and Drug Administration,
20 the Environmental Protection Agency,
21 the Department of Veterans Affairs,
22 the Centers for Medicare & Medicaid

1 Services, and the Department of Agri-
2 culture, and as possible from private
3 sources and international bodies;

4 “(V) the impact of antimicrobial
5 resistance on human health resulting
6 from the approval of antimicrobial
7 drugs for use in humans or animals
8 (including consideration of and rec-
9 ommendations on potential manage-
10 ment plans to limit and reduce the
11 negative impacts of such resistance on
12 human health);

13 “(VI) reports of federally sup-
14 ported antimicrobial resistance re-
15 search and antimicrobial drug devel-
16 opment research activities (including
17 clinical, epidemiological, prevention,
18 and translational research) obtained
19 from the National Institutes of
20 Health, the Centers for Disease Con-
21 trol and Prevention, the Department
22 of Veterans Affairs, the Department
23 of Defense, the Environmental Protec-
24 tion Agency, and the Department of
25 Agriculture, as well as reports of re-

1 search sponsored by other countries,
2 industry, and non-governmental orga-
3 nizations;

4 “(VII) reports on efforts by the
5 Food and Drug Administration to de-
6 velop policies and guidances which en-
7 courage antimicrobial drug develop-
8 ment and appropriate use while main-
9 taining high standards for safety and
10 effectiveness;

11 “(VIII) health plan employer
12 data and information set (HEDIS)
13 measures pertaining to appropriate
14 use of antimicrobials; and

15 “(IX) other data and issues the
16 task force identifies as relevant to the
17 issue of antimicrobial resistance.

18 “(iii) PENDING APPLICATIONS.—The
19 task force shall meet as necessary to pro-
20 vide input to the Secretary relevant to the
21 pending application of any antimicrobial
22 drug application submitted to the Sec-
23 retary under the Federal Food, Drug, and
24 Cosmetic Act or the Public Health Service

1 Act, including to provide the Secretary
2 with recommendations regarding—

3 “(I) the potential impact of the
4 approval of the drug on antimicrobial
5 resistance and any potential benefits
6 of the approval as measured by sub-
7 stantial evidence from adequate and
8 well-controlled trials; and

9 “(II) suggestions for anti-
10 microbial management strategies that
11 could increase appropriate use and
12 mitigate unnecessary increases in
13 antimicrobial resistance predicted to
14 result from approval of the drug ap-
15 plication.

16 “(C) PUBLIC HEALTH ANTIMICROBIAL AD-
17 VISORY BOARD MEETINGS AND DUTIES.—

18 “(i) MEETINGS.—The Public Health
19 Antimicrobial Advisory Board shall meet
20 as the Chair of the Public Health Anti-
21 microbial Advisory Board determines to be
22 appropriate, but not less than 2 times each
23 year.

24 “(ii) RECOMMENDATIONS.—The Pub-
25 lic Health Antimicrobial Advisory Board

1 shall make recommendations to the Sec-
2 retary, and the Office of Antimicrobial Re-
3 sistance, regarding—

4 “(I) ways to encourage the avail-
5 ability of an adequate supply of safe
6 and effective antimicrobial products;

7 “(II) research priorities and
8 other measures (such as antimicrobial
9 drug resistance management plans) to
10 enhance the safety and efficacy of
11 antimicrobial products;

12 “(III) how best to implement and
13 update the goals of the Public Health
14 Action Plan to Combat Antimicrobial
15 Resistance;

16 “(IV) the establishment of uni-
17 form mechanisms and data sets for
18 the reporting of resistance data;

19 “(V) the adequacy of existing
20 surveillance systems to collect anti-
21 microbial resistance and other infec-
22 tious disease data, how best to im-
23 prove the collection, reporting, and
24 analysis of such data to help direct

1 prevention, control, and research ini-
2 tiatives;

3 “(VI) development of a national
4 plan for the collection and analysis of
5 isolates of resistant pathogens, includ-
6 ing establishing priorities as to which
7 isolates should be collected;

8 “(VII) the implementation and
9 evaluation of interventions to promote
10 appropriate antimicrobial use in both
11 inpatient and outpatient settings; and

12 “(VIII) areas for government,
13 nongovernment, and international co-
14 operation to strengthen implementa-
15 tion of the Public Health Action Plan
16 to Combat Antimicrobial Resistance.

17 “(D) AVAILABILITY OF INFORMATION.—

18 The Office of Antimicrobial Resistance shall en-
19 sure that all information made available to the
20 public on the website described in subparagraph
21 (A) shall be made public only to the extent not
22 inconsistent with national security concerns and
23 respectful of confidential business informa-
24 tion.”;

1 (2) by amending subsection (b) to read as fol-
2 lows:

3 “(b) **ANTIMICROBIAL RESISTANCE RESEARCH AND**
4 **PRODUCT DEVELOPMENT.**—The Secretary, acting
5 through the Director of the Office of Antimicrobial Resist-
6 ance, the Director of the Centers for Disease Control and
7 Prevention, and the Director of the National Institutes of
8 Health, and in consultation with other Federal agencies,
9 shall develop an antimicrobial resistance strategic research
10 plan that strengthens existing epidemiological, inter-
11 ventional, clinical, translational, and basic research efforts
12 and funds directly or through the awards of grants or co-
13 operative agreements to public or private entities the con-
14 duct of research, investigations, experiments, demonstra-
15 tions, and studies that advance understanding of—

16 “(1) the development, implementation, and effi-
17 cacy of interventions to prevent and control the
18 emergence and transmission of antimicrobial resist-
19 ance;

20 “(2) how best to optimize antimicrobial effec-
21 tiveness while limiting antibiotic pressure for the
22 emergence of resistance, including addressing issues
23 related to duration of therapy, effectiveness of ther-
24 apy in self-resolving diseases, and determining popu-
25 lations most likely to benefit from antimicrobials;

1 “(3) the extent to which the use of anti-
2 microbial products in humans, animals, plants, and
3 other uses accelerates development and transmission
4 of antimicrobial resistance;

5 “(4) the natural histories of infectious diseases
6 (including defining the disease, the diagnosis, the se-
7 verity, and the time course of illness);

8 “(5) the development of new therapeutics, in-
9 cluding antimicrobial drugs, biologics, and devices
10 against resistant pathogens, and in particular dis-
11 eases for which few or no therapeutics are in devel-
12 opment;

13 “(6) the development and testing of medical
14 diagnostics to identify patients with infectious dis-
15 eases and identify the exact cause of infectious dis-
16 eases syndromes, particularly with respect to the de-
17 tection of pathogens resistant to antimicrobial drugs;

18 “(7) the epidemiology, pathogenesis, mecha-
19 nisms, and genetics of antimicrobial resistance; and

20 “(8) the sequencing of the genomes, or other
21 DNA analysis, or other comparative analysis of pri-
22 ority pathogens (as determined by the advisory
23 board), in collaboration with the Department of De-
24 fense and the Joint Genome Institute of the Depart-
25 ment of Energy.

1 To the extent practical, such research shall be conducted
2 in conjunction with the Antimicrobial Resistance Clinical
3 Research and Public Health Network.”;

4 (3) in subsection (c)—

5 (A) by inserting “acting through the Di-
6 rector of the Office of Antimicrobial Resist-
7 ance” after “The Secretary,”; and

8 (B) by striking “members of the task force
9 described in subsection (a) of this section,”;

10 (4) in subsection (d)(1), by inserting “, through
11 the Office of Antimicrobial Resistance,” after “The
12 Secretary”;

13 (5) in subsection (e)—

14 (A) in paragraph (1), by inserting “, act-
15 ing through the Director of the Office of Anti-
16 microbial Resistance,” after “The Secretary”;
17 and

18 (B) in paragraph (3), by inserting “, act-
19 ing through the Office of Antimicrobial Resist-
20 ance,” after “The Secretary”; and

21 (6) by amending subsection (g) to read as fol-
22 lows:

23 “(g) AUTHORIZATION OF APPROPRIATIONS.—

24 “(1) AUTHORIZATION.—There are authorized to
25 be appropriated to carry out this section

1 \$45,000,000 for fiscal year 2008, \$65,000,000 for
2 fiscal year 2009, \$120,000,000 for fiscal year 2010,
3 and such sums as may be necessary for each subse-
4 quent fiscal year.

5 “(2) ALLOCATION.—Of the amount appro-
6 priated to carry out this section for a fiscal year, not
7 less than \$15,000,000 shall be made available for
8 activities of the Centers for Disease Control and
9 Prevention under subsections (a)(3)(B) and (c), of
10 which at least \$5,000,000 shall be made available
11 for the Centers for Disease Control and Prevention
12 educational programs dedicated to the reduction of
13 inappropriate antimicrobial use.

14 “(3) RATABLE REDUCTION.—If amounts appro-
15 priated under paragraph (1) for any fiscal year are
16 less than the amounts required to comply with para-
17 graph (2), the Secretary shall ratably reduce the
18 amounts to be made available under paragraph (2)
19 accordingly.”.

20 (b) ENSURE ACCESS TO ANTIMICROBIAL DATA AND
21 RESEARCH.—The heads of government departments and
22 agencies, including the Secretary of Health and Human
23 Services, the Under Secretary for Health of the Depart-
24 ment of Veterans Affairs, the Secretary of Defense, the
25 Secretary of Agriculture, the Administrator of the Envi-

1 ronmental Protection Agency, the Administrator of the
2 Centers for Medicare & Medicaid Services, the Director
3 of the Centers for Disease Control and Prevention, the Di-
4 rector of the National Institutes of Health, and the Com-
5 missioner of Food and Drugs, shall work with the Director
6 of the Office of Antimicrobial Resistance and the Anti-
7 microbial Resistance Task Force to identify relevant data
8 and formats, and mechanisms for communicating these
9 data to the Office of Antimicrobial Resistance, the Anti-
10 microbial Resistance Task Force, and the Public Health
11 Antimicrobial Advisory Board, including relevant data ob-
12 tained by the agencies through contracts with other orga-
13 nizations, including—

14 (1) use and clinical outcomes data on patients
15 receiving antimicrobial agents for the treatment,
16 prevention, or diagnosis of infection or infectious
17 diseases;

18 (2) surveillance data regarding emerging anti-
19 microbial resistance;

20 (3) susceptibility data related to antimicrobial
21 drug use;

22 (4) data related to the amount of antimicrobials
23 used in humans, animals, and plants;

24 (5) data from federally funded research in-
25 tended to support antimicrobial drug development;

1 (6) data demonstrating the impact of research,
2 surveillance, and prevention and control initiatives in
3 understanding and controlling antimicrobial resist-
4 ance; and

5 (7) data regarding implementation and evalua-
6 tion of interventions to improve antimicrobial pre-
7 scribing practices.

8 In a manner not inconsistent with national security, sum-
9 maries of such data (excluding any proprietary data) shall
10 be made available to the public on the website described
11 in section 319E(a)(4)(A) of the Public Health Service Act
12 (42 U.S.C. 247d–5(a)(4)(A)).

13 (c) CONSULTATION BEFORE DRUG APPROVAL.—At
14 least 90 days prior to granting approval to any anti-
15 microbial drug application under the Federal Food, Drug,
16 and Cosmetic Act (21 U.S.C. 301 et seq.) or the Public
17 Health Service Act (42 U.S.C. 201 et seq.), the Secretary
18 of Health and Human Services shall consult with the Anti-
19 microbial Resistance Task Force regarding antimicrobial
20 resistance issues associated with the drug for which the
21 application was submitted, including the potential emer-
22 gence of antimicrobial resistance.

23 (d) RELEVANT PORTIONS OF PENDING APPLICA-
24 TIONS.—The Secretary of Health and Human Services
25 shall make relevant portions of pending antimicrobial drug

1 applications submitted under the Federal Food, Drug, and
2 Cosmetic Act (21 U.S.C. 301 et seq.) or the Public Health
3 Service Act (42 U.S.C. 201 et seq.) available to the Anti-
4 microbial Resistance Task Force for the purposes of this
5 Act and the amendments made by this Act.

6 (e) IMPROPER DISCLOSURE OF PROPRIETARY
7 DATA.—The Secretary of Health and Human Services
8 shall take appropriate steps to prevent the improper dis-
9 closure of proprietary data by the Antimicrobial Resist-
10 ance Task Force, the Public Health Antimicrobial Advi-
11 sory Board, or any of their members.

12 **SEC. 4. COLLECTION OF ANTIMICROBIAL DRUG DATA.**

13 (a) COLLECTION OF ANTIMICROBIAL PRODUCT
14 AMOUNT DATA.—

15 (1) HUMAN ANTIMICROBIAL USE REPORTS.—

16 Notwithstanding any other provision of law, starting
17 in 2008 each sponsor of an antimicrobial drug prod-
18 uct subject to section 505 of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C. 355) which is
20 sold or distributed in the United States shall, by
21 March 31 of each calendar year, submit to the Of-
22 fice of Antimicrobial Resistance the amount of the
23 antimicrobial drug product sold or distributed in the
24 United States from January 1 to December 31 of
25 the preceding calendar year to support epidemiologic

1 and microbiologic research on the impact of anti-
2 microbial drug use and resistance development. To
3 ensure uniform reporting standards, the Director of
4 the Office of Antimicrobial Resistance shall establish
5 the specific content and format of antimicrobial use
6 data submissions.

7 (2) ANIMAL ANTIMICROBIAL USE REPORT.—

8 Notwithstanding any other provision of law, starting
9 in 2008 each sponsor of an antimicrobial drug prod-
10 uct subject to section 512 of the Federal Food,
11 Drug, and Cosmetic Act (21 U.S.C. 360b) which is
12 sold or distributed in the United States shall, by
13 March 31 of each calendar year, submit to the Of-
14 fice of Antimicrobial Resistance the amount of the
15 antimicrobial drug product sold or distributed in the
16 United States from January 1 to December 31 of
17 the preceding calendar year to support epidemiologic
18 and microbiologic research on the impact of anti-
19 microbial drug use in food-producing animals and
20 resistance development. The data shall be reported
21 as follows:

22 (A) By volume separately for use in poul-
23 try, cattle, aquaculture, and swine.

24 (B) By total volume sold for use in all
25 food-producing animals.

1 (C) Whatever additional standard criteria
2 for reporting the Director of the Office of Anti-
3 microbial Resistance may establish.

4 (3) PUBLIC AVAILABILITY OF SUMMARIES.—
5 The Director of the Office of Antimicrobial Resist-
6 ance shall make summaries of the data received
7 under paragraphs (1) and (2) publicly available and
8 ensure that such summaries are updated and pub-
9 lished, in a manner not inconsistent with national
10 security and respectful of confidential business infor-
11 mation, at least once annually on the website de-
12 scribed in section 319E(a)(4)(A) of the Public
13 Health Service Act (42 U.S.C. 247d–5(a)(4)(A)) in
14 order to support epidemiologic and microbiologic re-
15 search on the impact on human health of anti-
16 microbial drug use in humans and food-producing
17 animals.

18 (b) COLLECTION OF ANTIMICROBIAL PRESCRIPTION
19 DATA.—

20 (1) CLINICAL OUTCOMES DATA.—The Under
21 Secretary for Health of the Department of Veterans
22 Affairs and the Administrator of the Centers for
23 Medicare & Medicaid Services shall, as determined
24 to be relevant by the Director of the Office of Anti-
25 microbial Resistance, collect drug utilization data

1 and clinical outcomes data on patients within the
2 Department of Veterans Affairs and the Medicare
3 and Medicaid service systems, respectively, who are
4 receiving prescription antimicrobial agents for the
5 treatment, prevention, or diagnosis of infection or
6 infectious diseases.

7 (2) ORGANIZATION.—The data collected under
8 paragraph (1) shall be organized by—

9 (A) indication (including results of diag-
10 nostic studies when available);

11 (B) dosage;

12 (C) route of administration;

13 (D) duration;

14 (E) age; and

15 (F) geographic region.

16 (3) COMPREHENSIVE ANNUAL REPORTS.—The
17 Under Secretary for Health of the Department of
18 Veterans Affairs and the Administrator of the Cen-
19 ters for Medicare & Medicaid Services shall submit
20 comprehensive annual reports on such data, to be
21 developed in coordination with the Director of the
22 Centers for Disease Control and Prevention, to the
23 Director of the Office of Antimicrobial Resistance.
24 Such reports shall identify, where appropriate, inter-
25 ventions to prevent and control the development of

1 antimicrobial resistance and may include an analysis
2 of the following:

3 (A) Intra- and extra-label antimicrobial
4 use.

5 (B) Where challenges to appropriate use
6 remain.

7 (C) Trends and variations in rates of anti-
8 microbial resistance.

9 (D) The relationship between drug use and
10 resistance.

11 (4) DATA REVIEW.—The Under Secretary for
12 Health of the Department of Veterans Affairs and
13 the Administrator of the Centers for Medicare &
14 Medicaid Services shall ensure that all of the data
15 collected under paragraph (1), including all such
16 data obtained through contracts with other organiza-
17 tions, are made accessible to the Office of Anti-
18 microbial Resistance for review on an ongoing basis.

19 (5) PUBLIC AVAILABILITY OF REPORTS.—The
20 Director of the Office of Antimicrobial Resistance
21 shall make the reports received under paragraph (3)
22 publicly available and ensure that it is updated and
23 published, in a manner not inconsistent with na-
24 tional security, at least once annually on the website

1 described in section 319E(a)(4)(A) of the Public
2 Health Service Act (42 U.S.C. 247d–5(a)(4)(A)).

3 **SEC. 5. ANTIMICROBIAL RESISTANCE CLINICAL RESEARCH**
4 **AND PUBLIC HEALTH NETWORK.**

5 (a) IN GENERAL.—The Secretary, through the Direc-
6 tors of the Centers for Disease Control and Prevention
7 and the National Institutes of Health, shall establish at
8 least 10 Antimicrobial Resistance Clinical Research and
9 Public Health Network sites to strengthen the national ca-
10 pacity to do the following:

11 (1) Describe and confirm regional outbreaks
12 through surveillance of locally available clinical
13 specimens.

14 (2) Rapidly assess, integrate, and address local
15 and national antimicrobial resistance patterns.

16 (3) Facilitate research concerning prevention,
17 control, and treatment of resistant organisms.

18 (4) Serve as a clinical trials network for opti-
19 mizing antimicrobial effectiveness.

20 (b) GEOGRAPHIC DISTRIBUTION.—The sites estab-
21 lished under subsection (a) shall be geographically distrib-
22 uted across the United States, based in academic centers,
23 health departments, and existing surveillance sites.

24 (c) RESPONSIBILITIES.—The persons employed at
25 the sites established under subsection (a) shall—

1 (1) monitor the emergence and changes in the
2 patterns of antimicrobial resistant pathogens in peo-
3 ple;

4 (2) study the molecular epidemiology of these
5 pathogens;

6 (3) evaluate the efficacy of new and existing
7 interventions to prevent or limit the emergence of
8 antimicrobial resistance throughout the geographic
9 region of the site;

10 (4) provide to the Centers for Disease Control
11 and Prevention isolates of resistant pathogens, and
12 in particular, pathogens that show new or atypical
13 patterns of resistance adversely affecting public
14 health;

15 (5) conduct clinical research to develop natural
16 histories of infectious disease and to study duration
17 of antimicrobial use related to resistance develop-
18 ment, among other things; and

19 (6) conduct basic antimicrobial resistance-re-
20 lated research.

21 (d) COORDINATION.—These sites established under
22 subsection (a) shall be authorized to share data and co-
23 operate with the Centers for Disease Control and Preven-
24 tion and the National Institutes of Health.

1 (e) DATA ACCESS.—The Directors of the Centers for
2 Disease Control and Prevention and the National Insti-
3 tutes of Health shall ensure that summary reports of data
4 obtained by the Antimicrobial Resistance Clinical Re-
5 search and Public Health Network sites are made acces-
6 sible to the Antimicrobial Task Force for review on an
7 ongoing basis.

8 **SEC. 6. ANTIMICROBIAL RESISTANCE QUALITY MEASURES**
9 **DEMONSTRATION PROJECTS.**

10 Under section 319E(e) of the Public Health Service
11 Act (42 U.S.C. 247d–5(e)), the Secretary of Health and
12 Human Services, acting through the Director of the Office
13 of Antimicrobial Resistance, shall award competitive
14 grants to eligible entities to establish demonstration
15 projects to assess the scope of the antimicrobial resistance
16 problem and the level of appropriate and inappropriate use
17 of antimicrobial drugs especially related to acute bacterial
18 otitis media and upper respiratory infections, and in par-
19 ticular acute exacerbation of chronic bronchitis. One goal
20 of the demonstration projects shall be the validation of
21 models that may lead to the development of quality meas-
22 ures for health care providers prescribing antimicrobials.
23 These demonstration programs shall be developed and im-
24 plemented through the direction of the Centers for Disease

1 Control and Prevention educational programs dedicated to
2 the reduction of inappropriate antimicrobial use.

3 **SEC. 7. GAO REPORT.**

4 Not later than January 1, 2012, the Comptroller
5 General of the United States shall submit a report to the
6 Committee on Health, Education, Labor, and Pensions of
7 the Senate and the Committee on Energy and Commerce
8 of the House of Representatives that examines whether
9 and how this Act has affected the ability to monitor, pre-
10 vent the spread of, and otherwise limit the impact of anti-
11 microbial resistance on human health. The report shall in-
12 clude any recommendations of the Comptroller General for
13 modifying this Act.

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