

113TH CONGRESS
2D SESSION

S. 2236

To amend the Public Health Service Act to enhance efforts to address antimicrobial resistance, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 10, 2014

Mr. BROWN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to enhance efforts to address antimicrobial resistance, and for other purposes.

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 and overuse of

1 antimicrobial drugs have correlated with increased
2 rates 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 antimicrobial drugs are used, whether appro-
8 priately or inappropriately, the more this contributes
9 to the development of antimicrobial resistance.

10 (3) Scientific evidence suggests that the devel-
11 opment of antimicrobial resistance in humans is not
12 due only to use of antimicrobial drugs in humans,
13 but also may be caused by the use of antimicrobial
14 drugs in food-producing animals.

15 (4) A study estimates that in 2005 more than
16 94,000 invasive methicillin-resistant *Staphylococcus*
17 *aureus* (MRSA) bacterial infections occurred in the
18 United States and more than 18,500 of these infec-
19 tions resulted in death—7 times more than a decade
20 earlier.

21 (5) The 2009 Influenza A: H1N1 virus out-
22 break, and the yearly seasonal influenza outbreaks,
23 exacerbate concerns about antiviral resistance given
24 that so few antivirals are available to treat influenza
25 as well as secondary bacterial infections due to

1 MRSA, antibiotic-resistant Streptococcus pneu-
 2 monia, and other bacteria that cause respiratory dis-
 3 eases. Given that, during the 1918 influenza pan-
 4 demic, many thousands of deaths were caused by
 5 complications due to secondary bacterial infections
 6 and not by the influenza virus itself.

7 (6) Each year, nearly 2,000,000 people contract
 8 bacterial infections in hospitals and approximately
 9 90,000 of these people die from these infections.
 10 Many of these infections are resistant to one or
 11 more commonly used antibiotics.

12 (7) A 2012 study conducted at Columbia Uni-
 13 versity (“Clinical Infectious Disease”, September
 14 2012) found that each antibiotic-resistant infection
 15 costs, on average, over \$15,000 more to treat than
 16 susceptible infections.

17 (8) The costs of antimicrobial-resistant infec-
 18 tions in terms of lives lost and the economy will only
 19 rise as antimicrobial resistance continues to spread.

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

21 Section 319E of the Public Health Service Act (42
 22 U.S.C. 247d–5) is amended—

23 (1) in subsection (a)—

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

1 “ANTIMICROBIAL RESISTANCE OFFICE, TASK
2 FORCE, AND ADVISORY BOARD”;

3 (B) in paragraph (1)—

4 (i) by striking “as of the date of the
5 enactment of this section” and inserting
6 “as of September 30, 2006”; and

7 (ii) by adding at the end the fol-
8 lowing: “The Secretary shall, not later
9 than 1 year after the date of enactment of
10 the Strategies to Address Antimicrobial
11 Resistance Act, direct the Assistant Sec-
12 retary of Health to establish an Anti-
13 microbial Resistance Office and appoint a
14 director to that Office. The Secretary shall,
15 not later than 1 year after the date of en-
16 actment of such Act, establish the Public
17 Health Antimicrobial Advisory Board as an
18 advisory board to the Director of the Anti-
19 microbial Resistance Office. The Director
20 of the Antimicrobial Resistance Office shall
21 serve as the Director of the Antimicrobial
22 Resistance Task Force. To avoid duplica-
23 tion and ensure that Federal resources are
24 used efficiently and effectively, the Direc-
25 tor shall work in conjunction with the Fed-

1 eral agencies represented on the Task
2 Force to coordinate all antimicrobial resist-
3 ance activities undertaken and supported
4 by the Federal Government, including the
5 activities and budgetary allocations of the
6 Office, Task Force, and Public Health
7 Antimicrobial Advisory Board.”;

8 (C) by amending paragraph (2) to read as
9 follows:

10 “(2) MEMBERS.—

11 “(A) MEMBERS OF THE ANTIMICROBIAL
12 RESISTANCE TASK FORCE.—The task force de-
13 scribed in paragraph (1) shall be composed of
14 representatives of such Federal agencies as the
15 Secretary determines necessary, including rep-
16 resentation of the following:

17 “(i) The Antimicrobial Resistance Of-
18 fice.

19 “(ii) The Assistant Secretary for Pre-
20 paredness and Response.

21 “(iii) The Biomedical Advanced Re-
22 search and Development Authority.

23 “(iv) The Centers for Disease Control
24 and Prevention.

1 “(v) The Food and Drug Administra-
2 tion.

3 “(vi) The National Institutes of
4 Health.

5 “(vii) The Agency for Healthcare Re-
6 search and Quality.

7 “(viii) The Centers for Medicare &
8 Medicaid Services.

9 “(ix) The Health Resources and Serv-
10 ices Administration.

11 “(x) The Department of Agriculture.

12 “(xi) The Department of Education.

13 “(xii) The Department of Defense.

14 “(xiii) The Department of Veterans
15 Affairs.

16 “(xiv) The Environmental Protection
17 Agency.

18 “(xv) The Department of Homeland
19 Security.

20 “(xvi) The United States Agency for
21 International Development.

22 “(B) MEMBERS OF THE PUBLIC HEALTH
23 ANTIMICROBIAL ADVISORY BOARD.—

24 “(i) IN GENERAL.—The Public Health
25 Antimicrobial Advisory Board shall be

1 composed of 19 voting members, appointed
 2 by the Secretary. Such members shall in-
 3 clude experts from the medical professions
 4 (including hospital and community-based
 5 physicians), pharmacy, public health, vet-
 6 erinary, research, and international health
 7 communities, as well as one representative
 8 from a public interest group.

9 “(ii) TERMS.—Each member ap-
 10 pointed under clause (i) shall be appointed
 11 for a term of 3 years, except that of the
 12 19 members first appointed—

13 “(I) 6 shall be appointed for a
 14 term of 12 months; and

15 “(II) 6 shall be appointed for a
 16 term of 2 years.

17 “(iii) CHAIR.—The Secretary shall ap-
 18 point a Chair of the Public Health Anti-
 19 microbial Advisory Board from among its
 20 members to lead and supervise the activi-
 21 ties of the Advisory Board.

22 “(iv) DISCLOSURE OF FINANCIAL IN-
 23 TERESTS.—Prior to a meeting of the Pub-
 24 lic Health Antimicrobial Advisory Board,
 25 each member of the Advisory Board shall

1 disclose to the Secretary any potential, rel-
2 evant financial interests as defined under
3 section 208(a) of title 18, United States
4 Code.”;

5 (D) in paragraph (3)(B), by striking “in
6 consultation with the task force described in
7 paragraph (1) and” and inserting “acting
8 through the Director of the Antimicrobial Re-
9 sistance Office and the Director of the Centers
10 for Disease Control and Prevention, and in con-
11 sultation with”; and

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

14 “(4) MEETINGS AND DUTIES.—

15 “(A) ANTIMICROBIAL RESISTANCE OFFICE
16 DUTIES.—The Director of the Antimicrobial
17 Resistance Office, working in conjunction with
18 the Federal agencies that are represented on
19 the task force described in paragraph (1), shall
20 issue an update to the Public Health Action
21 Plan to Combat Antimicrobial Resistance within
22 1 year of the establishment of the Office and
23 annually thereafter. The updates shall include
24 enhanced plans for addressing antimicrobial re-
25 sistance in the United States and internation-

1 ally. The Director of the Office shall post on a
2 website these updates as well as summaries of
3 all non-proprietary data the Task Force makes
4 available. The Director of the Antimicrobial Re-
5 sistance Office shall work in conjunction with
6 the Federal agencies that are represented on
7 the task force described in paragraph (1), and
8 in consultation with the Public Health Anti-
9 microbial Advisory Board, to—

10 “(i) establish benchmarks for achiev-
11 ing the goals set forth in the action plan;

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

17 “(iii) assess how antimicrobial prod-
18 ucts are being used in humans, animals,
19 plants, and the environment and the risks
20 and benefits of those uses in furthering the
21 development of resistance and the implica-
22 tions thereof for patient safety and public
23 health;

24 “(iv) establish a priority list of human
25 infectious diseases with the greatest need

1 for development of new point-of-care and
2 other diagnostics, antimicrobial drugs, and
3 vaccines, and in particular serious and life-
4 threatening resistant infections, for which
5 there are few or no diagnostic, treatment,
6 or prevention options;

7 “(v) recommend basic, clinical, epide-
8 miological, prevention, and translational
9 research where additional federally sup-
10 ported studies may be beneficial;

11 “(vi) recommend how to support anti-
12 microbial development through Food and
13 Drug Administration activities, including
14 through the agency’s Critical Path Initia-
15 tive and the Reagan-Udall Foundation;

16 “(vii) recommend how best to
17 strengthen and link antimicrobial resist-
18 ance-related surveillance and prevention
19 and control activities; and

20 “(viii) collaborate with the Assistant
21 Secretary for Preparedness and Response
22 to ensure that strategies to address anti-
23 microbial-resistance are coordinated with
24 initiatives aimed at pandemic influenza, se-

1 vere acute respiratory syndrome, and bio-
2 terrorism.

3 “(B) ANTIMICROBIAL RESISTANCE TASK
4 FORCE MEETINGS AND DUTIES.—

5 “(i) MEETINGS.—The Antimicrobial
6 Resistance Task Force shall convene peri-
7 odically as the Director of the Anti-
8 microbial Resistance Task Force deter-
9 mines to be appropriate, but not fewer
10 than twice a year, to consider issues relat-
11 ing to antimicrobial resistance.

12 “(ii) PUBLIC HEALTH ACTION
13 PLAN.—At least twice a year, the task
14 force described in paragraph (1) shall have
15 a meeting to review, discuss, and further
16 develop the Public Health Action Plan to
17 Combat Antimicrobial Resistance first
18 issued by the interagency task force on
19 antimicrobial resistance in 2001. Among
20 other issues, the task force may discuss
21 and review, based on current need or con-
22 cern—

23 “(I) antimicrobial clinical suscep-
24 tibility concentrations proposed, estab-

lished, or updated by the Food and Drug Administration;

“(II) data obtained by government agencies and, as possible, by private sources on emerging antimicrobial resistance related to clinical outcomes as well as data related to how antimicrobial drugs may have been used inappropriately;

“(III) surveillance data and prevention and control activities regarding emerging antimicrobial resistance from reliable sources including the Centers for Disease Control and Prevention, the Food and Drug Administration, the Department of Defense, the Department of Veterans Affairs, the Department of Agriculture, the Environmental Protection Agency, and as feasible from private sources and international bodies;

“(IV) data on the amount of antimicrobial products used in humans, animals, plants, and the environment from reliable sources, includ-

1 ing data from the Centers for Disease
2 Control and Prevention, the Food and
3 Drug Administration, the Environ-
4 mental Protection Agency, the De-
5 partment of Veterans Affairs, the
6 Centers for Medicare & Medicaid
7 Services, the Department of Home-
8 land Security, and the Department of
9 Agriculture, and as feasible from pri-
10 vate sources and international bodies;

11 “(V) the impact of antimicrobial
12 resistance on human health resulting
13 from the approval of antimicrobial
14 drugs for use in humans, animals, or
15 plants (including consideration of and
16 recommendations on potential man-
17 agement plans to limit and reduce the
18 negative impacts of such resistance on
19 human health and consideration of
20 the benefits to animal health and food
21 safety);

22 “(VI) reports of federally sup-
23 ported antimicrobial resistance re-
24 search and antimicrobial drug, related
25 diagnostics, and vaccine development

1 for antimicrobial resistant infections
2 (such as methicillin-resistant *Staphy-*
3 *lococcus aureus* (MRSA)) and other
4 research activities (including clinical,
5 epidemiological, prevention, and trans-
6 lational research) obtained from Fed-
7 eral agencies, as well as reports of re-
8 search sponsored by other countries,
9 industry, and non-governmental orga-
10 nizations;

11 “(VII) reports on efforts by the
12 Food and Drug Administration to de-
13 velop policies and guidance which en-
14 courage antimicrobial drug, related
15 diagnostics, and vaccine development
16 and appropriate use while maintaining
17 high standards for safety and effec-
18 tiveness;

19 “(VIII) quality measures, which
20 may include health plan employer
21 data and information set (HEDIS)
22 measures, pertaining to appropriate
23 use of antimicrobial drugs; and

24 “(IX) other data and issues the
25 task force described in paragraph (1)

1 identifies as relevant to the issue of
2 antimicrobial resistance.

3 “(iii) PENDING APPLICATIONS.—The
4 Food and Drug Administration may con-
5 sult with the Director of the Antimicrobial
6 Resistance Office concerning the pending
7 application of any antimicrobial drug appli-
8 cation submitted to the Secretary under
9 section 505 or 512 of the Federal Food,
10 Drug, and Cosmetic Act or the Public
11 Health Service Act.

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

14 “(i) MEETINGS.—The Public Health
15 Antimicrobial Advisory Board shall meet
16 as the Chair of the Public Health Anti-
17 microbial Advisory Board determines to be
18 appropriate, preferably in conjunction with
19 meetings of the Antimicrobial Resistance
20 Task Force, but not fewer than 2 times
21 each year.

22 “(ii) RECOMMENDATIONS.—The Pub-
23 lic Health Antimicrobial Advisory Board
24 shall make recommendations to the Sec-

retary, and the Antimicrobial Resistance
Office, regarding—

“(I) ways to encourage the availability of an adequate supply of safe and effective antimicrobial products, related diagnostics, and vaccines;

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

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

“(IV) incentives necessary to establish uniform mechanisms (which could include electronic surveillance systems) and data sets for State and local reporting of resistance;

“(V) the adequacy of existing United States antimicrobial resistance and use surveillance;

“(VI) the development of a national plan for the collection and anal-

1 ysis of isolates of resistant pathogens,
 2 including establishing priorities as to
 3 which isolates should be collected; and
 4 “(VII) areas for government,
 5 nongovernment, and international co-
 6 operation to strengthen implementa-
 7 tion of the Public Health Action Plan
 8 to Combat Antimicrobial Resistance.

9 “(D) AVAILABILITY OF INFORMATION.—

10 The Antimicrobial Resistance Office shall en-
 11 sure that all information shall be made avail-
 12 able to the public on the website described in
 13 subparagraph (A) consistent with section 9 of
 14 the Strategies to Address Antimicrobial Resist-
 15 ance Act.”;

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

18 “(b) ANTIMICROBIAL RESISTANCE STRATEGIC RE-
 19 SEARCH PLAN.—The Secretary, acting through the Direc-
 20 tor of the National Institutes of Health, working in con-
 21 sultation with the Director of the Centers for Disease Con-
 22 trol and Prevention, the Assistant Secretary for Prepared-
 23 ness and Response, the Director of the Biomedical Ad-
 24 vanced Research and Development Authority, the Director
 25 of the Antimicrobial Resistance Office, the Public Health

1 Antimicrobial Advisory Board, and other non-government
2 experts, including representatives from professional soci-
3 eties and the pharmaceutical, vaccine, and medical device
4 industries, and other Federal agencies shall develop a
5 blue-ribbon antimicrobial resistance strategic research
6 plan that strengthens existing epidemiological, inter-
7 ventional, clinical, behavioral, translational, and basic re-
8 search efforts to advance the understanding of—

9 “(1) the development, implementation, and effi-
10 cacy of interventions to prevent and control the
11 emergence and transmission of antimicrobial resist-
12 ance;

13 “(2) how best to optimize antimicrobial effec-
14 tiveness while limiting the emergence of resistance,
15 including addressing issues related to duration of
16 therapy, effectiveness of therapy in self-resolving dis-
17 eases, and determining populations most likely to
18 benefit from antimicrobial drugs;

19 “(3) the extent to which specific uses of anti-
20 microbial products in humans, animals, plants, and
21 other uses accelerate development and transmission
22 of antimicrobial resistance;

23 “(4) the natural histories of infectious diseases
24 (including defining the disease, diagnosis, severity,
25 and the time course of illness);

1 “(5) the development of new therapeutics, in-
 2 cluding antimicrobial drugs, biologics, and devices
 3 against resistant pathogens, and in particular dis-
 4 eases for which few or no therapeutics are in devel-
 5 opment;

6 “(6) the development and testing of medical
 7 diagnostics to identify patients with infectious dis-
 8 ease and identify the exact cause of infectious dis-
 9 eases syndromes, particularly with respect to the de-
 10 tection of pathogens resistant to antimicrobial drugs;

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

13 “(8) the sequencing of the genomes, or other
 14 DNA analysis, or other comparative analysis of pri-
 15 ority pathogens (as determined by the Public Health
 16 Antimicrobial Advisory Board), in collaboration with
 17 the Department of Defense and the Joint Genome
 18 Institute of the Department of Energy.”;

19 (3) in subsection (c)—

20 (A) by inserting “acting through the Di-
 21 rector of the Antimicrobial Resistance Office,”
 22 after “The Secretary,”; and

23 (B) by striking “members of the task force
 24 described in subsection (a),”;

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

(5) in subsection (e)—

(A) by amending the subsection heading to read as follows: “IMPROVING UPTAKE AND MEASUREMENT OF ANTIMICROBIAL STEWARDSHIP”;

(B) in paragraph (1)—

(i) by inserting “, acting through the Director of the Antimicrobial Resistance Office,” after “The Secretary”; and

(ii) by striking “judicious use of antimicrobial drugs or control the spread of antimicrobial-resistant pathogens” and inserting “the uptake and measurement of antimicrobial stewardship programs in the Nation’s health care facilities”;

(C) in paragraph (2), by striking “laboratory”;

(D) in paragraph (3), by inserting “, acting through the Antimicrobial Resistance Office,” after “The Secretary”; and

(E) by adding at the end the following new paragraphs:

1 “(4) DEFINITION OF ANTIMICROBIAL STEWARD-
2 SHIP.—For purposes of this subsection and Act,
3 ‘antimicrobial stewardship’ means coordinated inter-
4 ventions designed to improve and measure the ap-
5 propriate use of antimicrobial agents, including pro-
6 moting the use of antimicrobials only when clinically
7 indicated, and, when antimicrobials are indicated,
8 promoting the selection of the optimal antimicrobial
9 drug regimen including dosing, duration of therapy,
10 and route of administration.

11 “(5) PREFERENCE IN MAKING AWARDS.—In
12 making awards under paragraph (1), the Secretary
13 shall give preference to eligible entities that will use
14 grant funds to establish demonstration projects that
15 lead to the development of quality measures for
16 health care providers prescribing antimicrobial
17 drugs.”;

18 (6) by redesignating subsections (f) and (g) as
19 subsections (i) and (j), respectively; and

20 (7) by inserting after subsection (e) the fol-
21 lowing new subsections:

22 “(f) APPROPRIATE ANTIMICROBIAL USE.—The Sec-
23 retary, acting through the Director of the Centers for Dis-
24 ease Control and Prevention, shall take such additional ac-
25 tions as follows:

1 “(1) To pilot and test health care quality meas-
 2 ures to help providers, facilities, and health systems
 3 measure and benchmark appropriate antimicrobial
 4 use. As appropriate, the Director shall work with
 5 standard setting organizations (such as the National
 6 Quality Forum, the Joint Commission, and the Na-
 7 tional Committee for Quality Assurance) to deter-
 8 mine if any such measure is suitable for national
 9 quality reporting efforts.

10 “(2) To develop methods to help providers, fa-
 11 cilities, and health systems measure and improve ap-
 12 propriate antimicrobial use, including methods and
 13 tools to assess the change in antimicrobial use, the
 14 impact on antibiotic resistance and adverse effects
 15 (such as *Clostridium difficile* infections), and the
 16 economic impact and cost savings of antimicrobial
 17 stewardship programs.

18 “(g) COLLECTION OF HUMAN ANTIMICROBIAL CON-
 19 SUMPTION AND RESISTANCE TREND DATA.—

20 “(1) ANTIMICROBIAL USE DATA.—The Director
 21 of the Centers for Disease Control and Prevention
 22 shall work with private vendors, health care organi-
 23 zations, pharmacy benefit managers, and other enti-
 24 ties to obtain reliable and comparable human anti-
 25 microbial drug consumption data (including volume

1 antimicrobial distribution data and antimicrobial
2 use, including prescription data) by State or metro-
3 politan area.

4 “(2) ANTIMICROBIAL RESISTANCE TREND
5 DATA.—The Director of the Centers for Disease
6 Control and Prevention shall intensify and expand
7 their efforts to collect antimicrobial resistance data
8 including through the establishment of an Anti-
9 microbial Resistance Surveillance and Laboratory
10 Network, established in section 4 of the Strategies
11 to Address Antimicrobial Resistance Act, and devel-
12 opment of a fully automated antimicrobial resistance
13 and use module within the National Healthcare
14 Safety Network. The Director shall seek to collect
15 data from electronic medication administration re-
16 ports (eMAR) and laboratory systems to produce
17 regular reports on antimicrobial resistance patterns
18 and antimicrobial use.

19 “(3) MEANINGFUL USE REPORTING.—The Of-
20 fice of the National Coordinator for Health Informa-
21 tion Technology shall work with the Director of the
22 Centers for Disease Control and Prevention to deter-
23 mine how best antimicrobial use, susceptibility, and
24 resistance data can be incorporated into meaningful
25 use reporting.

1 “(4) REPORT.—Not later than 2 years after the
2 date of the enactment of the Strategies to Address
3 Antimicrobial Resistance Act, and every two years
4 thereafter, the Director of the Centers for Disease
5 Control and Prevention shall submit to the Com-
6 mittee on Energy and Commerce of the House of
7 Representatives and the Committee on Health, Edu-
8 cation, Labor, and Pensions of the Senate and make
9 available on the agency’s website a report summa-
10 rizing key trends and major issues related to anti-
11 microbial resistance and use in the United States.
12 Each such report shall include the most relevant and
13 up-to-date data available from the infectious diseases
14 and surveillance programs of the Centers for Disease
15 Control and Prevention. Each such report shall—

16 “(A) outline major issues and threats in
17 antimicrobial resistance facing the United
18 States;

19 “(B) provide data on the incidence, preva-
20 lence, morbidity, mortality, and general societal
21 burden, including economic, of antimicrobial re-
22 sistant pathogens;

23 “(C) provide updates on resistance pat-
24 terns and antimicrobials use data and potential
25 impacts on human health and patient safety;

1 “(D) articulate activities of the Centers for
2 Disease Control and Prevention targeted toward
3 measuring and preventing the spread of drug
4 resistant pathogens;

5 “(E) describe any international develop-
6 ments that may impact antimicrobial resistance
7 in the United States; and

8 “(F) identify the major gaps that the Na-
9 tion faces in the areas of antimicrobial resist-
10 ance surveillance, prevention, use, and anti-
11 microbial stewardship.

12 “(h) ENSURE ACCESS TO ANTIMICROBIAL RESIST-
13 ANCE DATA AND RESEARCH.—The Director of the Anti-
14 microbial Resistance Office shall work with the Federal
15 agencies represented on the Antimicrobial Resistance
16 Task Force to identify relevant data and formats, and
17 mechanisms for communicating such data to the Anti-
18 microbial Resistance Office and Antimicrobial Resistance
19 Task Force and, in a manner consistent with section 9
20 of the Strategies to Address Antimicrobial Resistance Act,
21 with the Public Health Antimicrobial Advisory Board and
22 the public, including relevant data obtained by the agen-
23 cies through contracts with other organizations, includ-
24 ing—

1 “(1) use and clinical outcomes data on patients
2 receiving antimicrobial drugs for the treatment, pre-
3 vention, or diagnosis of infection or infectious dis-
4 eases;

5 “(2) surveillance data regarding emerging anti-
6 microbial drug resistance and existing resistance
7 patterns;

8 “(3) susceptibility data related to antimicrobial
9 drug use;

10 “(4) data related to the amount of anti-
11 microbial products used in humans, animals, plants,
12 and the environment;

13 “(5) data from federally funded research in-
14 tended to support antimicrobial drug, vaccine, and
15 related diagnostics development;

16 “(6) data demonstrating the impact of research,
17 surveillance, and prevention and control initiatives in
18 understanding and controlling antimicrobial resist-
19 ance; and

20 “(7) data regarding implementation and evalua-
21 tion of interventions to improve antimicrobial drug
22 prescribing practices.”.

1 **SEC. 4. ANTIMICROBIAL RESISTANCE SURVEILLANCE AND**
2 **LABORATORY NETWORK.**

3 (a) IN GENERAL.—The Secretary of Health and
4 Human Services, acting through the Director of the Cen-
5 ters for Disease Control and Prevention, shall establish
6 at least 10 Antimicrobial Resistance Surveillance and Lab-
7 oratory Network sites, building upon the intramural and
8 extramural programs and laboratories of the Centers for
9 Disease Control and Prevention, to intensify, strengthen,
10 and expand the national capacity to—

11 (1) monitor the emergence and changes in the
12 patterns of antimicrobial resistant pathogens;

13 (2) describe, confirm, and as necessary facili-
14 tate a response to local or regional outbreaks of re-
15 sistant pathogens;

16 (3) assess and describe antimicrobial resistance
17 patterns to inform public health and improve preven-
18 tion practices;

19 (4) obtain isolates of pathogens, and in par-
20 ticular, pathogens that show new or atypical pat-
21 terns of resistance adversely affecting public health;

22 (5) study the epidemiology of infections from
23 such pathogens;

24 (6) evaluate commonly used antimicrobial sus-
25 ceptibility testing methods to improve the accuracy
26 of resistance testing and reporting; and

1 (7) as necessary, develop novel diagnostic tests
 2 capable of detecting new or emerging resistance in
 3 pathogens.

4 (b) GEOGRAPHIC DISTRIBUTION.—The sites estab-
 5 lished under subsection (a) shall be geographically distrib-
 6 uted across the United States.

7 (c) NONDUPLICATION OF CURRENT NATIONAL CA-
 8 PACITY.—The sites established under subsection (a) may
 9 be based in academic centers, health departments, and ex-
 10 isting surveillance and laboratory sites.

11 **SEC. 5. CLINICAL TRIALS NETWORK ON ANTIBACTERIAL**
 12 **RESISTANCE.**

13 (a) IN GENERAL.—The Secretary, acting through the
 14 Director of the National Institute of Allergy and Infec-
 15 tious Diseases, shall establish a Clinical Trials Network
 16 on Antibacterial Resistance to enhance, strengthen, and
 17 expand research on clinical science, antibacterial and diag-
 18 nostic development, and optimal usage strategies, and
 19 shall, at a minimum—

20 (1) facilitate research to better understand re-
 21 sistance mechanisms and how to prevent, control,
 22 and treat resistant organisms;

23 (2) advance clinical trial efforts to develop anti-
 24 microbial therapies, vaccines and diagnostics, and
 25 evaluate and optimize their usage;

1 (3) conduct clinical research to develop natural
2 histories of resistant infectious diseases;

3 (4) examine patient outcomes with currently
4 available antimicrobial therapy and validate and im-
5 prove upon biomarkers and other surrogate end-
6 points; and

7 (5) study shorter treatment duration and early
8 cessation of antimicrobial therapy for treatment effi-
9 cacy and effect on development of resistance.

10 (b) LEADERSHIP GROUP FOR A CLINICAL RESEARCH
11 NETWORK ON ANTIBACTERIAL RESISTANCE.—The Sec-
12 retary, acting through the Director of the National Insti-
13 tute of Allergy and Infectious Diseases, shall establish a
14 Leadership Group for the Clinical Research Network on
15 Antibacterial Resistance described in subsection (a) to de-
16 velop and implement a comprehensive clinical research
17 agenda to address antibacterial resistance that takes into
18 consideration the recommendations contained in the Stra-
19 tegic Research Plan on Antimicrobial Resistance devel-
20 oped in accordance with section 319E of the Public Health
21 Service Act. The Leadership Group shall provide support
22 for the following components—

23 (1) scientific leadership and operations;

24 (2) network laboratories; and

25 (3) statistical and data management.

1 (c) APPROPRIATIONS.—There are authorized to be
 2 appropriated from the existing budget of the National In-
 3 stitute of Allergy and Infectious Diseases, \$100,000,000
 4 annually for each of fiscal years 2015 through 2021 to
 5 carry out this section.

6 **SEC. 6. REGIONAL PREVENTION COLLABORATIVES.**

7 The Secretary, acting through the Director of the
 8 Centers for Disease Control and Prevention, shall work
 9 with State health departments to support regional preven-
 10 tion collaboratives designed to interrupt and prevent the
 11 transmission of significant antibiotic resistant pathogens
 12 being transmitted across health care settings in a geo-
 13 graphic region. Such regional prevention collaboratives
 14 shall work to—

- 15 (1) identify significant drug resistant pathogens
 16 being transmitted across health care settings locally;
- 17 (2) implement evidence-based interventions to
 18 interrupt and prevent the transmission of such
 19 pathogens; and
- 20 (3) evaluate the impact of such measures on
 21 hospital readmissions, transitions of care, rates of
 22 health care associated infections, or any other rel-
 23 evant measures that characterize the health or eco-
 24 nomic impact of the collaboratives.

1 **SEC. 7. PREVENTION EPICENTERS.**

2 To provide the regional prevention collaboratives es-
3 tablished under section 6 with tools, strategies, and evi-
4 dence-based interventions, the Director of the Centers for
5 Disease Control and Prevention may intensify and expand
6 academic public health partnerships through the work of
7 the Prevention Epicenters Program of the Centers for Dis-
8 ease Control and Prevention. The Centers for Disease
9 Control and Prevention and the epicenters participating
10 in such program shall work with the regional prevention
11 collaboratives to—

12 (1) evaluate new and existing interventions to
13 prevent or limit the emergence of antimicrobial re-
14 sistance throughout the geographic region of the
15 collaboratives;

16 (2) facilitate public health research on the pre-
17 vention and control of resistant organisms; and

18 (3) assess the feasibility, cost-effectiveness, and
19 appropriateness of surveillance and prevention pro-
20 grams in differing health care and institutional set-
21 tings.

22 **SEC. 8. CONTINUATION OF CURRENT PROGRAMS.**

23 Subsection (j) of section 319E of the Public Health
24 Service Act (42 U.S.C. 247d–5), as redesignated by sec-
25 tion 3(6), is amended by inserting “and for each of the
26 fiscal years 2015 through 2019” after “2006”.

1 **SEC. 9. PROTECTION OF CONFIDENTIAL AND NATIONAL SE-**
2 **CURITY INFORMATION.**

3 Except as otherwise required by law, this Act (and
4 the amendments made by this Act) shall not permit public
5 disclosure of trade secrets, confidential commercial infor-
6 mation, or material inconsistent with national security
7 that is obtained by any person under this Act (or amend-
8 ments made by this Act).

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