

114TH CONGRESS
2D SESSION

S. 3176

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

IN THE SENATE OF THE UNITED STATES

JULY 13, 2016

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 antibiotic 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 Antibiotic Resistance Act” or the “STAAR Act”.

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

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 antibiotic drugs have correlated with increased rates
2 of antibiotic resistance.

3 (2) Through mutation as well as other mecha-
4 nisms, bacteria develop resistance to antibiotic drugs
5 over time. Overuse and other inappropriate use of
6 antibiotics lessen their effectiveness and contribute
7 to the development of antibiotic resistance.

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

13 (4) Each year, nearly 2,000,000 people become
14 infected with bacteria that are resistant to anti-
15 biotics and at least 23,000 people die as a result of
16 such infections. Many more die from other condi-
17 tions that were complicated by an antibiotic-resistant
18 infection.

19 (5) According to a 2013 report from the Cen-
20 ters for Disease Control and Prevention,
21 carbapenem-resistant Enterobacteriaceae (CRE)
22 bacteria are on the rise among patients in medical
23 facilities. CRE bacteria have become resistant to all
24 or nearly all the antibiotics currently available.
25 Invasive infections, such as a bloodstream infection,

1 with CRE bacteria are associated with mortality
2 rates exceeding 40 percent.

3 (6) A 2012 study conducted at Columbia Uni-
4 versity (“Clinical Infectious Disease”, September
5 2012) found that each antibiotic-resistant infection
6 costs, on average, over \$15,000 more to treat than
7 antibiotic-susceptible infections.

8 (7) The costs of antibiotic-resistant infections
9 in terms of lives lost and the economy will only rise
10 as antibiotic resistance continues to spread.

11 (8) Antibiotic resistance is one of the greatest
12 threats to human health worldwide, calling for in-
13 creased prevention, antibiotic stewardship, surveil-
14 lance, and research and development for new anti-
15 biotics and rapid diagnostics.

16 (9) The President’s National Action Plan for
17 Combating Antibiotic-Resistant Bacteria, issued in
18 March 2015 (referred to in this section as the “Ac-
19 tion Plan”), which was developed in response to Ex-
20 ecutive Order 13676, dated September 18, 2014 (79
21 Fed. Reg. 56931; relating to combating antibiotic-
22 resistant bacteria), outlines specific steps to address
23 antibiotic resistance.

24 (10) The Action Plan includes the domestic and
25 international efforts of the United States to prevent,

1 detect, and control illness and death related to infec-
2 tions caused by antibiotic-resistant bacteria by im-
3 plementing measures to mitigate the emergence and
4 spread of antibiotic resistance and ensuring the con-
5 tinued availability of therapeutics for the treatment
6 of bacterial infections.

7 (11) Misuse and overuse of antibiotics has con-
8 tributed to antibiotic resistance. A recent study on
9 antibiotic prescribing practices found that 1 in 3 an-
10 tibiotic prescriptions were determined unnecessary or
11 inappropriate.

12 **SEC. 3. TASK FORCE FOR COMBATING ANTIBIOTIC-RESIST-**
13 **ANT BACTERIA; ADVISORY COUNCIL ON COM-**
14 **BATING ANTIBIOTIC-RESISTANT BACTERIA.**

15 (a) **TASK FORCE.**—Section 319E of the Public
16 Health Service Act (42 U.S.C. 247d–5) is amended—

17 (1) in subsection (a)—

18 (A) in paragraph (1), by striking “The
19 Secretary shall establish” and inserting “In ac-
20 cordance with the objectives of Executive Order
21 13676, dated September 18, 2014 (79 Fed.
22 Reg. 56931; relating to combating antibiotic-re-
23 sistant bacteria), the Secretary shall establish”;

24 (B) by amending paragraph (2) to read as
25 follows:

1 “(2) MEMBERS OF THE ANTIMICROBIAL RE-
2 SISTANCE TASK FORCE.—The task force described in
3 paragraph (1) shall be co-chaired by the Secretaries
4 of Health and Human Services, Agriculture, and De-
5 fense, and shall be composed of representatives of
6 relevant Federal agencies and such executive depart-
7 ments, agencies, or offices as the co-chairs may des-
8 ignate.”;

9 (C) by amending paragraph (4) to read as
10 follows:

11 “(4) MEETINGS.—At least twice a year, the
12 task force described in paragraph (1) shall have a
13 public meeting to assess progress and obstacles to
14 implementing the President’s National Action Plan
15 for Combating Antibiotic-Resistant Bacteria, issued
16 in March 2015 (referred to in this section as the
17 ‘Action Plan’). Among other issues, the task force
18 may discuss and review, based on need or concern—

19 “(A) Federal activities to slow the emer-
20 gence of resistant bacteria and prevention of
21 the spread of resistant infections, including pro-
22 motion of the optimal use of vaccines to prevent
23 infections, and implementation of health care
24 policies and antibiotic stewardship programs
25 that improve patient outcomes;

1 “(B) Federal activities to strengthen na-
2 tional One-Health surveillance efforts as de-
3 scribed in the Action Plan to combat resistance,
4 including enhancement and integration of data
5 from surveillance systems that monitor human
6 pathogens, including the National Healthcare
7 Safety Network, the Emerging Infections Pro-
8 gram, and the National Antimicrobial Resist-
9 ance Monitoring System, with data from sur-
10 veillance systems that monitor animal patho-
11 gens, including the National Animal Health
12 Monitoring System, the National Animal
13 Health Laboratory Network, and the Veterinary
14 Laboratory Investigation and Response Net-
15 work;

16 “(C) Federal efforts to advance the devel-
17 opment and use of rapid and innovative diag-
18 nostic tests for identification and characteriza-
19 tion of resistant bacteria;

20 “(D) Federal efforts to accelerate basic
21 and applied research and development for new
22 antibiotics, other therapeutics, and vaccines;
23 and

24 “(E) improvements in international col-
25 laboration and capacities for antibiotic-resist-

1 ance prevention, surveillance, control, and anti-
2 biotic research and development.”; and

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

4 “(5) AVAILABILITY OF INFORMATION.—The
5 task force, to the extent permitted by law, shall—

6 “(A) provide the Advisory Council de-
7 scribed in section 319E–1 with such informa-
8 tion as may be required for carrying out the
9 functions of such Advisory Council, including
10 information on progress in advancing the Ac-
11 tion Plan, meeting minutes, and other key in-
12 formation of the task force; and

13 “(B) ensure that all information described
14 in subparagraph (A) is made available on the
15 websites of the Department of Health and
16 Human Services, the Department of Agri-
17 culture, and the Department of Defense.”; and

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

19 “(h) ANNUAL PROGRESS REPORT TO CONGRESS ON
20 IMPLEMENTATION OF NATIONAL ACTION PLAN FOR COM-
21 BATING ANTIBIOTIC-RESISTANT BACTERIA.—Not later
22 than 1 year after the date of the enactment of the Strate-
23 gies to Address Antibiotic Resistance Act, and annually
24 thereafter, the Secretary, in cooperation with the Sec-
25 retary of Agriculture, the Secretary of Defense, and the

1 task force described in subsection (a) shall submit to the
2 Committee on Health, Education, Labor, and Pensions of
3 the Senate and the Committee on Energy and Commerce
4 of the House of Representatives, and make available on
5 the websites of the Department of Health and Human
6 Services, the Department of Agriculture, and the Depart-
7 ment of Defense, a report on the progress made in imple-
8 menting the goals of the Action Plan.”.

9 (b) ADVISORY COUNCIL.—Part B of title III of the
10 Public Health Service Act (42 U.S.C. 243 et seq.) is
11 amended by inserting after section 319E the following:

12 **“SEC. 319E-1. PRESIDENTIAL ADVISORY COUNCIL ON COM-**
13 **BATING ANTIBIOTIC-RESISTANT BACTERIA.**

14 “(a) IN GENERAL.—The Presidential Advisory Coun-
15 cil on Combating Antibiotic-Resistant Bacteria established
16 through Executive Order 13676, dated September 18,
17 2014 (79 Fed. Reg. 56931; relating to combating anti-
18 biotic-resistant bacteria) (referred to in this section as the
19 ‘Advisory Council’), shall provide advice, information, and
20 recommendations to the Secretary regarding programs
21 and policies intended to support and evaluate the imple-
22 mentation of such Executive Order 13676, including the
23 National Strategy for Combating Antibiotic-Resistant
24 Bacteria and the President’s National Action Plan for

1 Combating Antibiotic-Resistant Bacteria, issued in March
2 2015.

3 “(b) MEETINGS AND DUTIES.—

4 “(1) MEETINGS.—The Advisory Council shall
5 meet as the Chair determines to be appropriate but
6 not less than twice per year, and, to the extent prac-
7 ticable, in conjunction with meetings of the task
8 force described in section 319E.

9 “(2) RECOMMENDATIONS.—The Advisory Coun-
10 cil shall make recommendations to the Secretary, in
11 consultation with the Secretary of Agriculture and
12 the Secretary of Defense, regarding programs and
13 policies intended to—

14 “(A) preserve the effectiveness of anti-
15 biotics by optimizing their use;

16 “(B) advance research to develop improved
17 methods for combating antibiotic resistance and
18 conducting antibiotic stewardship;

19 “(C) strengthen surveillance of antibiotic-
20 resistant bacterial infections;

21 “(D) prevent the transmission of anti-
22 biotic-resistant bacterial infections;

23 “(E) advance the development of rapid
24 point-of-care and agricultural diagnostics;

1 “(F) further research on new treatments
2 for bacterial infections;

3 “(G) develop alternatives to antibiotics for
4 agricultural purposes;

5 “(H) maximize the dissemination of up-to-
6 date information on the appropriate and proper
7 use of antibiotics to the general public and
8 human and animal health care providers; and

9 “(I) improve international coordination of
10 efforts to combat antibiotic resistance.”.

11 **SEC. 4. SURVEILLANCE AND REPORTING OF ANTIBIOTIC**
12 **USE AND RESISTANCE.**

13 Part B of title III of the Public Health Service Act
14 (42 U.S.C. 243 et seq.), as amended by section 3(b), is
15 further amended by inserting after section 319E–1 the fol-
16 lowing:

17 **“SEC. 319E–2. SURVEILLANCE AND REPORTING OF ANTI-**
18 **BIOTIC USE AND RESISTANCE.**

19 “(a) IN GENERAL.—The Secretary, acting through
20 the Director of the Centers for Disease Control and Pre-
21 vention, shall use the National Healthcare Safety Network
22 and other appropriate surveillance systems to assess—

23 “(1) appropriate conditions, outcomes, and
24 measures causally related to antibacterial resistance,
25 including types of infections, the causes for infec-

1 tions, and whether infections are acquired in a com-
2 munity or hospital setting, increased lengths of hos-
3 pital stay, increased costs, and rates of mortality;
4 and

5 “(2) changes in bacterial resistance to drugs in
6 relation to patient outcomes, including changes in
7 percent resistance, prevalence of antibiotic-resistant
8 infections, and other such changes.

9 “(b) ANTIBIOTIC USE DATA.—The Director of the
10 Centers for Disease Control and Prevention shall work
11 with Federal agencies (including the Department of Vet-
12 erans Affairs and the Department of Defense), private
13 vendors, health care organizations, pharmacy benefit man-
14 agers, and other entities as appropriate to obtain reliable
15 and comparable human antibiotic drug consumption data
16 (including, as available and appropriate, volume antibiotic
17 distribution data and antibiotic use, including prescription
18 data) by State or metropolitan areas.

19 “(c) ANTIBIOTIC RESISTANCE TREND DATA.—The
20 Director of the Centers for Disease Control and Preven-
21 tion shall intensify and expand efforts to collect antibiotic
22 resistance data and encourage adoption of the antibiotic
23 resistance and use module within the National Healthcare
24 Safety Network among all health care facilities across the
25 continuum of care, including, as appropriate, acute care

1 hospitals, dialysis facilities, nursing homes, and ambula-
2 tory surgical centers. The Director shall seek to collect
3 data from electronic medication administration reports
4 and laboratory systems to produce regular reports on anti-
5 biotic resistance patterns and antibiotic use.

6 “(d) PUBLIC AVAILABILITY OF DATA.—The Sec-
7 retary, acting through the Director of the Centers for Dis-
8 ease Control and Prevention, shall, for the purposes of im-
9 proving the monitoring of important trends in patient out-
10 comes in relation to antibacterial resistance—

11 “(1) make the data derived from surveillance
12 under this section publicly available on a regular
13 basis that is not less than annually; and

14 “(2) examine opportunities to make such data
15 available in near real time.”.

16 **SEC. 5. DETECT NETWORK OF ANTIBIOTIC RESISTANCE RE-**
17 **GIONAL LABORATORIES.**

18 (a) IN GENERAL.—The Secretary of Health and
19 Human Services, acting through the Director of the Cen-
20 ters for Disease Control and Prevention, shall establish
21 not less than 7 Antibiotic Resistance Surveillance and
22 Laboratory Network sites, building upon the intramural
23 and extramural programs and laboratories of the Centers
24 for Disease Control and Prevention, to intensify, strength-
25 en, and expand the national capacity to—

- 1 (1) monitor the emergence and changes in the
2 patterns of antibiotic-resistant bacteria;
- 3 (2) describe, confirm, and, as necessary, facili-
4 tate a response to, local or regional outbreaks of re-
5 sistant bacteria;
- 6 (3) assess and describe antibiotic resistance
7 patterns to inform public health and improve preven-
8 tion practices;
- 9 (4) obtain isolates of pathogens, and in par-
10 ticular, bacteria that show new or atypical patterns
11 of resistance adversely affecting public health;
- 12 (5) assist in studying the epidemiology of infec-
13 tions from such pathogens;
- 14 (6) evaluate commonly used antibiotic suscepti-
15 bility testing methods to improve the accuracy of re-
16 sistance testing and reporting;
- 17 (7) as necessary, develop or evaluate novel diag-
18 nostic tests capable of detecting new or emerging re-
19 sistance in bacteria;
- 20 (8) link data generated by regional laboratory
21 networks under existing public health surveillance
22 networks and relevant government agencies; and
- 23 (9) provide laboratory assistance and reference
24 testing of antibiotic-resistant bacteria to enhance in-

1 fection control and facilitate outbreak detection and
2 response in health care and community settings.

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

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

10 **SEC. 6. CLINICAL TRIALS NETWORK ON ANTIBACTERIAL**
11 **RESISTANCE.**

12 (a) IN GENERAL.—The Secretary of Health and
13 Human Services, acting through the Director of the Na-
14 tional Institute of Allergy and Infectious Diseases, shall
15 maintain a Clinical Trials Network on Antibacterial Re-
16 sistance to enhance, strengthen, and expand research on
17 clinical science, antibacterial and diagnostic development,
18 and optimal usage strategies, and shall, at a minimum—

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

22 (2) link data generated by regional laboratory
23 networks under existing public health surveillance
24 networks and industry;

1 (3) advance clinical trial efforts to develop anti-
2 biotics diagnostics, and evaluate and optimize the
3 usage of such antibiotics;

4 (4) conduct clinical research to develop natural
5 histories of resistant infectious diseases;

6 (5) examine patient outcomes with currently
7 available antibiotic therapy and validate and improve
8 upon biomarkers and other surrogate endpoints; and

9 (6) study shorter treatment duration and early
10 cessation of antibiotic therapy for treatment efficacy
11 and effect on development of resistance.

12 (b) ANTIBIOTIC RESISTANCE LEADERSHIP GROUP.—

13 The Secretary of Health and Human Services, acting
14 through the Director of the National Institute of Allergy
15 and Infectious Diseases, shall maintain an antibiotic re-
16 sistance leadership group (referred to in this section as
17 the “leadership group”) to advance the development and
18 implementation of a comprehensive clinical research agen-
19 da to address antibacterial resistance that takes into con-
20 sideration the recommendations contained in the Presi-
21 dent’s National Action Plan for Combating Antibiotic-Re-
22 sistant Bacteria, issued in March 2015. The leadership
23 group shall provide support for the following compo-
24 nents—

25 (1) scientific leadership and operations;

- 1 (2) clinical studies design and implementation;
- 2 (3) network laboratories; and
- 3 (4) statistical and data management.

4 (c) APPROPRIATIONS.—There are authorized to be
5 appropriated to carry out this section such sums as may
6 be necessary for each of fiscal years 2017 through 2023.

7 **SEC. 7. REGIONAL PREVENTION COLLABORATIVE EF-**
8 **FORTS.**

9 The Secretary of Health and Human Services, acting
10 through the Director of the Centers for Disease Control
11 and Prevention, shall work with State and local health de-
12 partments to support the expansion of collaborative efforts
13 by groups of health care facilities that focus on preventing
14 the spread of antibiotic-resistant bacteria that pose a seri-
15 ous threat to public health, and that are designed to inter-
16 rupt and prevent the transmission of significant antibiotic-
17 resistant pathogens being transmitted across health care
18 settings in a geographic region. Such collaborative efforts
19 shall—

- 20 (1) identify significant drug resistant pathogens
21 being transmitted across health care settings locally;
- 22 (2) implement evidence-based interventions to
23 interrupt and prevent the transmission of infections
24 associated with health care and antibiotic-resistant
25 strains of bacteria, including evidence-based trans-

1 mission prevention guidelines, rigorous hand hygiene
2 protocols, and infection control and prevention meas-
3 ures;

4 (3) assess compliance and identify barriers to
5 adherence to such measures;

6 (4) evaluate the impact of such measures on
7 hospital readmissions, in health care facilities across
8 the continuum of care, rates of health care associ-
9 ated infections, or any other relevant measures that
10 characterize the health or economic impact of the
11 collaborative efforts; and

12 (5) provide recommendations for improved out-
13 comes and compliance with such measures.

14 **SEC. 8. PREVENTION EPICENTERS.**

15 (a) IN GENERAL.—To provide the regional preven-
16 tion collaborative efforts established under section 7 with
17 tools, strategies, and evidence-based interventions, the Di-
18 rector of the Centers for Disease Control and Prevention
19 may intensify and expand academic public health partner-
20 ships through the work of the Prevention Epicenters Pro-
21 gram of the Centers for Disease Control and Prevention.
22 The Centers for Disease Control and Prevention and the
23 epicenters participating in such program shall work with
24 entities, including the regional prevention collaborative ef-
25 forts, to—

1 (1) evaluate new and existing interventions to
2 prevent or limit infection rates in health care facili-
3 ties across the continuum of care and in community
4 settings;

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

7 (3) assess the feasibility, cost effectiveness, and
8 appropriateness of surveillance and prevention pro-
9 grams in differing health care and institutional set-
10 tings.

11 (b) EDUCATIONAL MATERIALS.—The Centers for
12 Disease Control and Prevention shall use the research and
13 evidence from the epicenters participating in the Preven-
14 tion Epicenters Program to create and disseminate edu-
15 cational materials focused on infection prevention and con-
16 trol for use in health care facilities across the continuum
17 of care and in community settings.

18 **SEC. 9. CONTINUATION OF CURRENT PROGRAMS.**

19 Subsection (g) of section 319E of the Public Health
20 Service Act (42 U.S.C. 247d–5) is amended by striking
21 “\$40,000,000” and all that follows through the period at
22 the end and inserting “such sums as may be necessary
23 for each of the fiscal years 2017 through 2021.”.

1 **SEC. 10. PROTECTION OF CONFIDENTIAL AND NATIONAL**
2 **SECURITY INFORMATION.**

3 Except as otherwise required by law, this Act (and
4 the amendments made by this Act) shall not be construed
5 to permit an otherwise-prohibited disclosure of trade se-
6 crets, confidential commercial information, or material in-
7 consistent with national security that is obtained by any
8 person under this Act (or any amendment made by this
9 Act).

○