I

110TH CONGRESS
1ST SESSION

S. 2313

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

IN THE SENATE OF THE UNITED STATES

NOVEMBER 6, 2007

Mr. BROWN (for himself and Mr. HATCH) 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 amend the Public Health Service Act to enhance efforts to address antimicrobial resistance.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Strategies to Address Antimicrobial Resistance Act''.

SEC. 2. FINDINGS.

The Congress finds as follows:

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

antimicrobial drugs have correlated with increased rates of antimicrobial resistance.

(2) Through mutation as well as other mechanisms, bacteria and other infectious disease-causing organisms—viruses, fungi, and parasites—develop resistance to antimicrobial drugs over time. The more antimicrobial drugs are used, whether appropriately or inappropriately, the more this contributes to the development of antimicrobial resistance.

(3) Scientific evidence suggests that the source of antimicrobial resistance in humans is not just limited to use of antimicrobial drugs in humans, but may in fact also be from food-producing animals which are exposed to antimicrobial drugs.

(4) A study estimates that in 2005 more than 94,000 invasive methicillin-resistant Staphylococcus aureus (MRSA) infections occurred in the United States and more than 18,500 of these infections resulted in death.

(5) Each year, nearly 2,000,000 people contract bacterial infections in hospitals and approximately 90,000 of these people die from these infections.

(6) The costs of antimicrobial-resistant bacterial diseases are hard to quantify, but a 1995 report by the Office of Technology Assessment of and

agency of Congress, which looked at 6 different antimicrobial-resistant strains of bacteria, calculated that the minimum nationwide hospital costs of just these strains of bacteria accounted for $1,300,000,000 annually in 1992 dollars ($1,870,000,000 in 2006 dollars).

(7) The cost to society of antimicrobial-resistant infections will only rise as antimicrobial resistance continues to spread.

SEC. 3. ANTIMICROBIAL RESISTANCE TASK FORCE.

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

(1) in subsection (a)—

(A) in the subsection heading, by striking ''TASK FORCE'' and inserting the following: ''OFFICE OF ANTIMICROBIAL RESISTANCE, TASK FORCE, AND ADVISORY BOARD'';

(B) in paragraph (1)—

(i) by striking ''as of the date of the enactment of this section'' and inserting ''September 30, 2006''; and

(ii) by adding at the end the following: ''The Secretary shall, not later than 1 year after the date of enactment of the Strategies to Address Antimicrobial

Resistance Act, establish an Office of Antimicrobial Resistance in the Office of the Secretary and appoint a director to that Office. The Secretary shall, not later than 1 year after the date of enactment of such Act, establish the Public Health Antimicrobial Advisory Board as an advisory board to the Director of the Office of Antimicrobial Resistance. The Director of the Office of Antimicrobial Resistance shall serve as the Director of the task force and supervise the activities of the Office, task force, and advisory board.'';

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

''(2) MEMBERS.—

''(A) MEMBERS OF THE ANTIMICROBIAL RESISTANCE TASK FORCE.—The task force described in paragraph (1) shall be composed of representatives of such Federal agencies as the Secretary determines necessary, including representation of the following:

''(i) The Office of Antimicrobial Resistance.

"(ii) The Assistant Secretary of Preparedness and Response.

"(iii) The Centers for Disease Control and Prevention.

"(iv) The Food and Drug Administration.

"(v) The National Institutes of Health.

"(vi) The Agency for Healthcare Research and Quality.

"(vii) The Centers for Medicare & Medicaid Services.

"(viii) The Health Resources and Services Administration.

"(ix) The Department of Agriculture.

"(x) The Department of Education.

"(xi) The Department of Defense.

"(xii) The Department of Veterans Affairs.

"(xiii) The Environmental Protection Agency.

"(xiv) The Department of Homeland Security.

"(B) MEMBERS OF THE PUBLIC HEALTH ANTIMICROBIAL ADVISORY BOARD.—

''(i) IN GENERAL.—The Public Health Antimicrobial Advisory Board shall be composed of 13 voting members, appointed by the Secretary. Such members shall include experts from the medical professions (including hospital and community-based physicians), public health, veterinary, research, and international health communities.

''(ii) TERMS.—Each member appointed under clause (i) shall be appointed for a term of 3 years, except that of the 13 members first appointed—

''(I) 4 shall be appointed for a term of 12 months; and

''(II) 4 shall be appointed for a term of 2 years.

''(iii) CHAIR.—The Secretary shall appoint a Chair of the Public Health Antimicrobial Advisory Board from among its members to lead and supervise the activities of the advisory board.'';

(D) in paragraph (3)(B), by striking ''in consultation with the task force described in paragraph (1) and'' and inserting ''acting

through the Director of the Office of Antimicrobial Resistance and the Director of the Centers for Disease Control and Prevention, and in consultation with''; and

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

''(4) MEETINGS AND DUTIES.—

''(A) OFFICE OF ANTIMICROBIAL RESISTANCE DUTIES.—The Director of the Office of Antimicrobial Resistance, working in conjunction with the Federal agencies that are represented on the task force described in paragraph (1), shall issue an update to the Public Health Action Plan to Combat Antimicrobial Resistance within 18 months of the establishment of the Office and biennial updates thereafter. The updates shall include enhanced plans for addressing antimicrobial resistance in the United States and internationally. The Director of the Office shall post on a website these updates as well as summaries of all non-proprietary data the Task Force makes available. The Director of the Office of Antimicrobial Resistance shall, as appropriate—

''(i) establish benchmarks for achieving the goals set forth in the action plan;

''(ii) assess the ongoing, observed patterns of emergence of antimicrobial resistance, and their impact on clinical outcomes in terms of how patients feel, function, or survive;

''(iii) assess how antimicrobial products are being used in humans, animals, and plants, and the impact of such use in furthering the development of resistance and the implications thereof for patient safety and public health;

''(iv) establish a priority list of human infectious diseases with the greatest need for development of new point-of-care and other diagnostics, antimicrobial drugs, and vaccines, and in particular serious and life-threatening bacterial diseases, for which there are few or no diagnostic or treatment options;

''(v) recommend basic, clinical, epidemiological, prevention, and translational research where additional federally supported studies may be beneficial;

"(vi) recommend how to support antimicrobial development through the Food and Drug Administration's Critical Path Initiative;

"(vii) recommend how best to strengthen and link antimicrobial resistance-related surveillance and prevention and control activities; and

"(viii) collaborate with the Assistant Secretary for Preparedness and Response to ensure that strategies to address antimicrobial-resistance are coordinated with initiatives aimed at Severe Acute Respiratory Syndrome, bioterrorism, and other emerging health threats.

"(B) ANTIMICROBIAL RESISTANCE TASK FORCE MEETINGS AND DUTIES.—

"(i) MEETINGS.—The Antimicrobial Resistance Task Force shall convene periodically as the Director of the Antimicrobial Resistance Task Force determines to be appropriate, but not fewer than twice a year, to consider issues relating to antimicrobial resistance.

"(ii) PUBLIC HEALTH ACTION PLAN.—At least twice a year, the task force shall have a meeting to review, discuss, and further develop the Public Health Action Plan to Combat Antimicrobial Resistance issued by the interagency task force on antimicrobial resistance in 2001. Among other issues, the task force may discuss and review, based on current need or concern—

"(I) antimicrobial clinical susceptibility concentrations proposed, established, 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 in terms of how patients function, feel, or survive as well as data related to how antimicrobial drugs may have been used inappropriately;

"(III) surveillance data and prevention and control activities regard-

ing 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, and plants from reliable sources including data from the Centers for Disease Control and Prevention, the Food and Drug Administration, the Environmental Protection Agency, the Department of Veterans Affairs, the Centers for Medicare & Medicaid Services, the Department of Homeland Security, and the Department of Agriculture, and as feasible from private sources and international bodies;

''(V) reports of federally supported antimicrobial resistance research and antimicrobial drug development research activities (including clinical, epidemiological, prevention, and translational research) obtained from Federal agencies, as well as reports of research sponsored by other countries, industry, and non-governmental organizations;

''(VI) reports on efforts by the Food and Drug Administration to develop policies and guidances which encourage antimicrobial drug development and appropriate use while maintaining high standards for safety and effectiveness;

''(VII) health plan employer data and information set (HEDIS) measures pertaining to appropriate use of antimicrobial drugs; and

''(VIII) other data and issues the task force identifies as relevant to the issue of antimicrobial resistance.

"(iii) PENDING APPLICATIONS.—The Food and Drug Administration may consult with the Director of the Office of Antimicrobial Resistance concerning the pending application of any antimicrobial drug application submitted to the Secretary under section 505 or 512 of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act.

"(C) PUBLIC HEALTH ANTIMICROBIAL ADVISORY BOARD MEETINGS AND DUTIES.—

"(i) MEETINGS.—The Public Health Antimicrobial Advisory Board shall meet as the Chair of the Public Health Antimicrobial Advisory Board determines to be appropriate, but not fewer than 2 times each year.

"(ii) RECOMMENDATIONS.—The Public Health Antimicrobial Advisory Board shall make recommendations to the Secretary, and the Office of Antimicrobial Resistance, regarding—

"(I) ways to encourage the availability of an adequate supply of safe and effective antimicrobial products;

"(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 and data sets for State reporting of resistance data;

"(V) the adequacy of existing surveillance systems to collect antimicrobial resistance data and how best to improve the collection, reporting, and analysis of such data;

"(VI) the development of a national plan for the collection and analysis of isolates of resistant pathogens, including establishing priorities as to which isolates should be collected;

"(VII) the implementation and evaluation of interventions to promote

appropriate antimicrobial drug use in both inpatient and outpatient settings; and

"(VIII) areas for government, nongovernment, and international cooperation to strengthen implementation of the Public Health Action Plan to Combat Antimicrobial Resistance.

"(D) AVAILABILITY OF INFORMATION.—The Office of Antimicrobial Resistance shall ensure that all information shall be made available to the public on the website described in subparagraph (A) consistent with section 7 of the Strategies to Address Antimicrobial Resistance Act.";

(2) by amending subsection (b) to read as follows:

"(b) ANTIMICROBIAL RESISTANCE RESEARCH AND PRODUCT DEVELOPMENT.—The Secretary, acting through the Director of the Office of Antimicrobial Resistance, the Director of the Centers for Disease Control and Prevention, and the Director of the National Institutes of Health, and in consultation with other Federal agencies, shall develop an antimicrobial resistance strategic research plan that strengthens existing epidemiological, inter-

ventional, clinical, behavioral, translational, and basic research efforts to advance the understanding of—

''(1) the development, implementation, and efficacy of interventions to prevent and control the emergence and transmission of antimicrobial resistance;

''(2) how best to optimize antimicrobial effectiveness while limiting the emergence of resistance, including addressing issues related to duration of therapy, effectiveness of therapy in self-resolving diseases, and determining populations most likely to benefit from antimicrobial drugs;

''(3) the extent to which the use of antimicrobial products in humans, animals, plants, and other uses accelerates development and transmission of antimicrobial resistance;

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

''(5) the development of new therapeutics, including antimicrobial drugs, biologics, and devices against resistant pathogens, and in particular diseases for which few or no therapeutics are in development;

''(6) the development and testing of medical diagnostics to identify patients with infectious disease and identify the exact cause of infectious diseases syndromes, particularly with respect to the detection of pathogens resistant to antimicrobial drugs;

''(7) the epidemiology, pathogenesis, mechanisms, and genetics of antimicrobial resistance; and

''(8) the sequencing of the genomes, or other DNA analysis, or other comparative analysis of priority pathogens (as determined by the advisory board), in collaboration with the Department of Defense and the Joint Genome Institute of the Department of Energy.''; and

(3) in subsection (c)—

(A) by inserting ''acting through the Director of the Office of Antimicrobial Resistance,'' after ''The Secretary,''; and

(B) by striking ''members of the task force described in subsection (a),'';

(4) in subsection (d)(1), by inserting '', through the Office of Antimicrobial Resistance,'' after ''The Secretary''; and

(5) in subsection (e)—

(A) in paragraph (1), by inserting ", acting through the Director of the Office of Antimicrobial Resistance," after "The Secretary";

(B) in paragraph (3), by inserting ", acting through the Office of Antimicrobial Resistance," after "The Secretary"; and

(C) by adding at the end the following:

"(4) PREFERENCE IN MAKING AWARDS.—In making awards under paragraph (1), the Secretary shall give preference to eligible entities that will use grant funds to establish demonstration projects to assess the scope of the antimicrobial resistance problem and the level of appropriate and inappropriate use of antimicrobial drugs especially related to acute bacterial otitis media and upper respiratory infections, and in particular acute exacerbation of chronic bronchitis, including the validation of models that may lead to the development of quality measures for health care providers prescribing antimicrobial drugs.".

(b) ENSURE ACCESS TO ANTIMICROBIAL DATA AND RESEARCH.—The Director of the Office of Antimicrobial Resistance shall work with the agencies represented on the Antimicrobial Resistance Task Force to identify relevant data and formats, and mechanisms for communicating

such data to the Office of Antimicrobial Resistance and the Antimicrobial Resistance Task Force, including relevant data obtained by the agencies through contracts with other organizations, including—

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

(2) surveillance data regarding emerging antimicrobial drug resistance;

(3) susceptibility data related to antimicrobial drug use;

(4) data related to the amount of antimicrobial products used in humans, animals, and plants;

(5) data from federally funded research intended to support antimicrobial drug development;

(6) data demonstrating the impact of research, surveillance, and prevention and control initiatives in understanding and controlling antimicrobial resistance; and

(7) data regarding implementation and evaluation of interventions to improve antimicrobial drug prescribing practices.

SEC. 4. COLLECTION OF ANTIMICROBIAL DRUG DATA.

(a) SUBMISSION OF HUMAN AND ANIMAL DRUG DISTRIBUTION DATA.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 512 the following:

"SEC. 512A. SUBMISSION OF HUMAN AND ANIMAL DRUG DISTRIBUTION DATA.

"(a) IN GENERAL.—Notwithstanding any other provision of law, the Secretary shall require that human drug distribution data required to be submitted for each calendar year under section 314.81(b)(ii) of title 21, Code of Federal Regulations (or any successor regulation) and the animal drug distribution data required to be submitted for each such calendar year under section 514.80(b)(4)(i) of title 21, Code of Federal Regulations (or any successor regulation) be—

"(1) submitted not later than 60 days after the beginning of the subsequent calendar year; and

"(2) made available to the Office of Antimicrobial Resistance, the Antimicrobial Resistance Task Force, and the Public Health Antimicrobial Advisory Board.

"(b) CONFIDENTIALITY.—The Office of Antimicrobial Resistance, the Antimicrobial Resistance Task Force, and the Public Health Antimicrobial Advisory Board shall sign a confidentiality agreement to protect

proprietary information made available under subsection (a)(2).''.

(b) COMPARABLE DATA.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Office of Antimicrobial Resistance, shall explore opportunities to secure from private vendors reliable and comparable animal and human antimicrobial drug consumption data (volume antimicrobial distribution data and antimicrobial use, including prescription data) by State or metropolitan area, as necessary, to supplement the antimicrobial drug consumption data to be collected under this section for the purpose of demonstrating how the consumption of antimicrobial drugs for human and animal uses may affect the development of resistance over time and within geographic locations and to institute preventive interventions.

(2) NEGOTIATIONS.—The Director of the Office of Antimicrobial Resistance may enter into negotiations with private vendors to determine acceptable formats for making summaries of antimicrobial drug consumption data that is collected under this section publicly available for research purposes while main-

taining the confidentiality of any proprietary commercial data.

(3) OTHER MEANS TO SECURE DATA.—If the Director of the Office of Antimicrobial Resistance is not able to secure sufficient supplemental antimicrobial drug consumption data for human and animal uses through private vendors as provided for in this section, the Secretary shall consider other means to secure such consumption data, including through the conduct of surveys about how antimicrobial drugs are used in various settings and make such data available to the public consistent with section 7.

(c) COLLECTION OF ANTIMICROBIAL PRESCRIPTION DATA.—

(1) CLINICAL OUTCOMES DATA.—The Director of the Office of Antimicrobial Resistance shall work with the Under Secretary for Health of the Department of Veterans Affairs and the Administrator of the Centers for Medicare & Medicaid Services to collect relevant drug utilization data and clinical outcomes data, as determined relevant by the Director of the Office of Antimicrobial Resistance, on patients who receive services funded by such agencies and who are receiving prescription antimicrobial

agents for the treatment, prevention, or diagnosis of infection or infectious diseases.

(2) ORGANIZATION.—Any data collected under paragraph (1) shall be organized by—

(A) indication (including results of diagnostic studies when available);

(B) dosage;

(C) route of administration;

(D) duration;

(E) age of the patient; and

(F) geographic region.

(d) PUBLIC AVAILABILITY OF SUMMARIES.—The Director of the Office of Antimicrobial Resistance shall make summaries of the data received under this section publicly available by antimicrobial drug class and ensure that such summaries are updated and published, in a manner consistent with section 7, at least once annually on the website described in section 319E(a)(4)(A) of the Public Health Service Act (42 U.S.C. 247d–5(a)(4)(A)) in order to support epidemiologic and microbiologic research. In the case of an antimicrobial drug class where only one antimicrobial drug has been approved, such summary data shall not be made public.

SEC. 5. ANTIMICROBIAL RESISTANCE CLINICAL RESEARCH AND PUBLIC HEALTH NETWORK.

(a) IN GENERAL.—The Secretary, through the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health, shall establish at least 10 Antimicrobial Resistance Clinical Research and Public Health Network sites to strengthen the national capacity to—

(1) describe and confirm regional outbreaks through surveillance of locally available clinical specimens;

(2) assess, integrate, and address local and national antimicrobial resistance patterns;

(3) facilitate research on prevention, control, and treatment of resistant organisms; and

(4) serve as a clinical trials network for optimizing antimicrobial drug effectiveness.

(b) GEOGRAPHIC DISTRIBUTION.—The sites established under subsection (a) shall be geographically distributed across the United States, based in academic centers, health departments, and existing surveillance sites.

(c) RESPONSIBILITIES.—The sites established under subsection (a) shall—

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

(2) study the molecular epidemiology of such pathogens;

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

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

(5) conduct clinical research to develop natural histories of infectious disease and to study duration of antimicrobial use related to resistance development, among other things;

(6) assess the feasibility, cost-effectiveness, and appropriateness of surveillance and screening programs in differing health care and institutional settings, such as schools; and

(7) evaluate current treatment protocols and make appropriate recommendations on best practices for treating drug resistant infections.

(d) COORDINATION.—The sites established under subsection (a) may share data and cooperate with the Cen-

ters for Disease Control and Prevention and the National Institutes of Health.

(e) DATA ACCESS.—The Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health shall ensure that summary reports of data obtained by the Antimicrobial Resistance Clinical Research and Public Health Network sites are made accessible to the Antimicrobial Task Force for review on an ongoing basis.

SEC. 6. AUTHORIZATION OF APPROPRIATIONS.

Section 319E(g) of the Public Health Service Act (42 U.S.C. 247d–5(g)) is amended to read as follows:

''(g) AUTHORIZATION OF APPROPRIATIONS.—

''(1) AUTHORIZATION.—There are authorized to be appropriated to carry out this section (other than subsection (b)) $45,000,000 for fiscal year 2008, $65,000,000 for fiscal year 2009, $120,000,000 for fiscal year 2010, and such sums as may be necessary for each subsequent fiscal year.

''(2) ALLOCATION.—Of the amount appropriated to carry out this section for a fiscal year, not less than one-third of such amount shall be made available for activities of the Centers for Disease Control and Prevention under subsections (a)(3)(B) and (c), of which at least one-third of such amount

shall be made available for the Centers for Disease Control and Prevention educational programs dedicated to the reduction of inappropriate antimicrobial use.''.

SEC. 7. PROTECTION OF CONFIDENTIAL AND NATIONAL SECURITY INFORMATION.

Except as otherwise required by law, this Act (and the amendments made by this Act) shall not permit public disclosure of trade secrets, confidential commercial information, or material inconsistent with national security that is obtained by any person under this Act.

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