I

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

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A BILL

To amend the Public Health Service Act 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 of

antimicrobials has also correlated with an increased rate in the development 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 antimicrobials are used, whether appropriately or inappropriately, the more this contributes to the development of antimicrobial resistance.

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

(4) Today, antimicrobial resistance poses a serious patient safety and public health threat throughout the United States.

(5) Tuberculosis is emerging as a virulent and growing threat to public health in the United States and throughout the world. Multidrug resistant tuberculosis (MDR–TB) was first documented in the early 1990s, and by 2004 there were approximately 424,000 new cases. Extensively drug resistant tuberculosis (XDR–TB) emerged in 2005 and has been called ''virtually untreatable'' by the World Health

Organization because this strain is resistant to nearly every approved tuberculosis drug.

(6) Nearly 70 percent of all hospital-acquired bacterial infections in the United States are resistant to at least one drug, and in some cases the situation is much worse. According to the Centers for Disease Control and Prevention, almost half of the identified methicillin-resistant Staphylococcus aureus (MRSA) strains in hospitals are resistant to all but a few antibiotics.

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

(8) The costs of antibiotic-resistant bacterial diseases are hard to quantify, but a 1995 report by the Office of Technology Assessment of Congress, which looked at 6 different antibiotic-resistant strains of bacteria, calculated that the minimum nationwide hospital costs of just these strains of bacteria accounted for $1,300,000,000 annually (1992 dollars).

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

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

(11) The Federal interagency Task Force on Antimicrobial Resistance was established in 1999, but the authorization of appropriations for the Task Force expired in 2006 and should be reauthorized to enable the continuation of the important coordinated Federal interagency effort to combat the adverse impacts of antimicrobial resistance on human health.

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

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 the end of the calendar year 2008, establish an Office of Antimicrobial Resistance in the Office of the Assistant Secretary for Health and appoint a director to that Office. The Secretary shall, not later than the end of the calendar year 2008, establish the Public Health Antimicrobial Advisory Board as a permanent 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 and budgetary allocations 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 de-

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

"(i) The Director of the Office of Antimicrobial Resistance.

"(ii) Representatives of such Federal agencies as the Secretary determines necessary, including at a minimum representatives of the following:

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

"(II) The Food and Drug Administration.

"(III) The National Institutes of Health.

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

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

"(VI) The Health Resources and Services Administration.

"(VII) The Department of Agriculture.

"(VIII) The Department of Defense.

''(IX) The Department of Veterans Affairs.

''(X) The Environmental Protection Agency.

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

''(i) IN GENERAL.—The Public Health Antimicrobial Advisory Board shall be composed of 19 voting members, appointed by the Secretary. Such members shall include representatives of the infectious diseases, medical (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 19 members first appointed—

''(I) 6 shall be appointed for a term of 1 year; and

''(II) 6 shall be appointed for a term of 2 years.

''(iii) CHAIR.—The Secretary shall appoint a Chair of the Public Health Anti-

microbial Advisory Board 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 1 year of the establishment of the Office and biennial updates thereafter. The updates shall include enhanced plans for addressing resistance in the United States and internationally. The Director of the Office shall

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

''(i) establish milestones 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 antimicrobials 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; and

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

''(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 less 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 on emerging antimicrobial resistance related to clinical outcomes in terms of how patients function, feel, or survive as well as data related to how antimicrobials may have been used inappropriately, obtained by government agencies including the Centers for Disease Control and Prevention, the Food and Drug Administration, the Department of Defense, the Department of Veterans Affairs, the Centers for Medi-

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

''(III) surveillance data and prevention and control activities regarding emerging antimicrobial resistance from reliable sources, including such data obtained by government agencies such as 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 possible from private sources and international bodies;

''(IV) data on the amount of antimicrobials used in humans, animals, and plants from reliable sources, including such data obtained by government agencies such as 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, and the Department of Agriculture, and as possible from private sources and international bodies;

''(V) the impact of antimicrobial resistance on human health resulting from the approval of antimicrobial drugs for use in humans or animals (including consideration of and recommendations on potential management plans to limit and reduce the negative impacts of such resistance on human health);

''(VI) reports of federally supported antimicrobial resistance research and antimicrobial drug development research activities (including clinical, epidemiological, prevention, and translational research) obtained from the National Institutes of Health, the Centers for Disease Control and Prevention, the Department of Veterans Affairs, the Department of Defense, the Environmental Protection Agency, and the Department of Agriculture, as well as reports of re-

search sponsored by other countries, industry, and non-governmental organizations;

''(VII) 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;

''(VIII) health plan employer data and information set (HEDIS) measures pertaining to appropriate use of antimicrobials; and

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

''(iii) PENDING APPLICATIONS.—The task force shall meet as necessary to provide input to the Secretary relevant to the pending application of any antimicrobial drug application submitted to the Secretary under the Federal Food, Drug, and Cosmetic Act or the Public Health Service

Act, including to provide the Secretary with recommendations regarding—

"(I) the potential impact of the approval of the drug on antimicrobial resistance and any potential benefits of the approval as measured by substantial evidence from adequate and well-controlled trials; and

"(II) suggestions for antimicrobial management strategies that could increase appropriate use and mitigate unnecessary increases in antimicrobial resistance predicted to result from approval of the drug application.

"(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 less 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) the establishment of uniform mechanisms and data sets for the reporting of resistance data;

''(V) the adequacy of existing surveillance systems to collect antimicrobial resistance and other infectious disease data, how best to improve the collection, reporting, and analysis of such data to help direct

prevention, control, and research initiatives;

''(VI) 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 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 made available to the public on the website described in subparagraph (A) shall be made public only to the extent not inconsistent with national security concerns and respectful of confidential business information.'';

(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, interventional, clinical, translational, and basic research efforts and funds directly or through the awards of grants or cooperative agreements to public or private entities the conduct of research, investigations, experiments, demonstrations, and studies that advance 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 antibiotic pressure for 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 antimicrobials;

''(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, the diagnosis, the 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 diseases 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.

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

(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) of this section,'';

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

(5) in subsection (e)—

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

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

(6) by amending subsection (g) to read as follows:

''(g) AUTHORIZATION OF APPROPRIATIONS.—

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

$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 $15,000,000 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 $5,000,000 shall be made available for the Centers for Disease Control and Prevention educational programs dedicated to the reduction of inappropriate antimicrobial use.

''(3) RATABLE REDUCTION.—If amounts appropriated under paragraph (1) for any fiscal year are less than the amounts required to comply with paragraph (2), the Secretary shall ratably reduce the amounts to be made available under paragraph (2) accordingly.''.

(b) ENSURE ACCESS TO ANTIMICROBIAL DATA AND RESEARCH.—The heads of government departments and agencies, including the Secretary of Health and Human Services, the Under Secretary for Health of the Department of Veterans Affairs, the Secretary of Defense, the Secretary of Agriculture, the Administrator of the Envi-

ronmental Protection Agency, the Administrator of the Centers for Medicare & Medicaid Services, the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, and the Commissioner of Food and Drugs, shall work with the Director of the Office of Antimicrobial Resistance and the Antimicrobial Resistance Task Force to identify relevant data and formats, and mechanisms for communicating these data to the Office of Antimicrobial Resistance, the Antimicrobial Resistance Task Force, and the Public Health Antimicrobial Advisory Board, including relevant data obtained by the agencies through contracts with other organizations, including—

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

(2) surveillance data regarding emerging antimicrobial resistance;

(3) susceptibility data related to antimicrobial drug use;

(4) data related to the amount of antimicrobials 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 prescribing practices.

In a manner not inconsistent with national security, summaries of such data (excluding any proprietary data) shall be made available to the public 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)).

(c) CONSULTATION BEFORE DRUG APPROVAL.—At least 90 days prior to granting approval to any antimicrobial drug application under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Public Health Service Act (42 U.S.C. 201 et seq.), the Secretary of Health and Human Services shall consult with the Antimicrobial Resistance Task Force regarding antimicrobial resistance issues associated with the drug for which the application was submitted, including the potential emergence of antimicrobial resistance.

(d) RELEVANT PORTIONS OF PENDING APPLICATIONS.—The Secretary of Health and Human Services shall make relevant portions of pending antimicrobial drug

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

(e) IMPROPER DISCLOSURE OF PROPRIETARY DATA.—The Secretary of Health and Human Services shall take appropriate steps to prevent the improper disclosure of proprietary data by the Antimicrobial Resistance Task Force, the Public Health Antimicrobial Advisory Board, or any of their members.

SEC. 4. COLLECTION OF ANTIMICROBIAL DRUG DATA.

(a) COLLECTION OF ANTIMICROBIAL PRODUCT AMOUNT DATA.—

(1) HUMAN ANTIMICROBIAL USE REPORTS.—Notwithstanding any other provision of law, starting in 2008 each sponsor of an antimicrobial drug product subject to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) which is sold or distributed in the United States shall, by March 31 of each calendar year, submit to the Office of Antimicrobial Resistance the amount of the antimicrobial drug product sold or distributed in the United States from January 1 to December 31 of the preceding calendar year to support epidemiologic

and microbiologic research on the impact of antimicrobial drug use and resistance development. To ensure uniform reporting standards, the Director of the Office of Antimicrobial Resistance shall establish the specific content and format of antimicrobial use data submissions.

(2) ANIMAL ANTIMICROBIAL USE REPORT.—Notwithstanding any other provision of law, starting in 2008 each sponsor of an antimicrobial drug product subject to section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) which is sold or distributed in the United States shall, by March 31 of each calendar year, submit to the Office of Antimicrobial Resistance the amount of the antimicrobial drug product sold or distributed in the United States from January 1 to December 31 of the preceding calendar year to support epidemiologic and microbiologic research on the impact of antimicrobial drug use in food-producing animals and resistance development. The data shall be reported as follows:

(A) By volume separately for use in poultry, cattle, aquaculture, and swine.

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

(C) Whatever additional standard criteria for reporting the Director of the Office of Antimicrobial Resistance may establish.

(3) PUBLIC AVAILABILITY OF SUMMARIES.—The Director of the Office of Antimicrobial Resistance shall make summaries of the data received under paragraphs (1) and (2) publicly available and ensure that such summaries are updated and published, in a manner not inconsistent with national security and respectful of confidential business information, 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 on the impact on human health of antimicrobial drug use in humans and food-producing animals.

(b) COLLECTION OF ANTIMICROBIAL PRESCRIPTION DATA.—

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

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

(2) ORGANIZATION.—The 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; and

(F) geographic region.

(3) COMPREHENSIVE ANNUAL REPORTS.—The Under Secretary for Health of the Department of Veterans Affairs and the Administrator of the Centers for Medicare & Medicaid Services shall submit comprehensive annual reports on such data, to be developed in coordination with the Director of the Centers for Disease Control and Prevention, to the Director of the Office of Antimicrobial Resistance. Such reports shall identify, where appropriate, interventions to prevent and control the development of

antimicrobial resistance and may include an analysis of the following:

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

(B) Where challenges to appropriate use remain.

(C) Trends and variations in rates of antimicrobial resistance.

(D) The relationship between drug use and resistance.

(4) DATA REVIEW.—The Under Secretary for Health of the Department of Veterans Affairs and the Administrator of the Centers for Medicare & Medicaid Services shall ensure that all of the data collected under paragraph (1), including all such data obtained through contracts with other organizations, are made accessible to the Office of Antimicrobial Resistance for review on an ongoing basis.

(5) PUBLIC AVAILABILITY OF REPORTS.—The Director of the Office of Antimicrobial Resistance shall make the reports received under paragraph (3) publicly available and ensure that it is updated and published, in a manner not inconsistent with national security, 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)).

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

(a) IN GENERAL.—The Secretary, through the Directors of the Centers for Disease Control and Prevention and 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 do the following:

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

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

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

(4) Serve as a clinical trials network for optimizing antimicrobial 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 persons employed at the sites established under subsection (a) shall—

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

(2) study the molecular epidemiology of these 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; and

(6) conduct basic antimicrobial resistance-related research.

(d) COORDINATION.—These sites established under subsection (a) shall be authorized to share data and cooperate with the Centers for Disease Control and Prevention and the National Institutes of Health.

(e) DATA ACCESS.—The Directors of the Centers for Disease Control and Prevention and 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. ANTIMICROBIAL RESISTANCE QUALITY MEASURES DEMONSTRATION PROJECTS.

Under section 319E(e) of the Public Health Service Act (42 U.S.C. 247d–5(e)), the Secretary of Health and Human Services, acting through the Director of the Office of Antimicrobial Resistance, shall award competitive grants to eligible entities 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. One goal of the demonstration projects shall be the validation of models that may lead to the development of quality measures for health care providers prescribing antimicrobials. These demonstration programs shall be developed and implemented through the direction of the Centers for Disease

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

SEC. 7. GAO REPORT.

Not later than January 1, 2012, the Comptroller General of the United States shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that examines whether and how this Act has affected the ability to monitor, prevent the spread of, and otherwise limit the impact of antimicrobial resistance on human health. The report shall include any recommendations of the Comptroller General for modifying this Act.

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