AMENDMENTS

2002—Subsec. (b). Pub. L. 107–188, § 109(1)(A), in introductory provisions, substituted ''shall directly or through awards of grants or cooperative agreements to public or private entities provide for the conduct of'' for ''shall conduct and support''.

Subsec. (b)(4). Pub. L. 107–188, § 109(1)(B), amended par. (4) generally. Prior to amendment, par. (4) read as follows: ''the sequencing of the genomes of priority pathogens as determined by the Director of the National Institutes of Health in consultation with the task force established under subsection (a) of this section; and''.

Subsec. (e)(2). Pub. L. 107–188, § 109(2), inserted ''schools or programs that train medical laboratory personnel,'' after ''professional medical societies,''.

Subsec. (g). Pub. L. 107–188, § 109(3), substituted ''$25,000,000 for each of the fiscal years 2002 and 2003, and such sums as may be necessary for each of the fiscal years 2004 through 2006'' for ''and such sums as may be necessary for each subsequent fiscal year through 2006''.

§ 247d–5a. Identification of clinically susceptible concentrations of antimicrobials

(a) Definition

In this section, the term ''clinically susceptible concentrations'' means specific values which characterize bacteria as clinically susceptible, intermediate, or resistant to the drug (or drugs) tested.

(b) Identification

The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), through the Commissioner of Food and Drugs, shall identify (where such information is reasonably available) and periodically update clinically susceptible concentrations.

(c) Public availability

The Secretary, through the Commissioner of Food and Drugs, shall make such clinically susceptible concentrations publicly available, such as by posting on the Internet, not later than 30 days after the date of identification and any update under this section.

(d) Effect

Nothing in this section shall be construed to restrict, in any manner, the prescribing of antibiotics by physicians, or to limit the practice of medicine, including for diseases such as Lyme and tick-borne diseases.

(Pub. L. 110–85, title XI, § 1111, Sept. 27, 2007, 121 Stat. 975.)

CODIFICATION

Section was enacted as part of the Food and Drug Administration Amendments Act of 2007, and not as part of the Public Health Service Act which comprises this chapter.

§ 247d–6. Public health countermeasures to a bioterrorist attack

(a) All-hazards public health and medical response curricula and training

(1) In general

The Secretary, in collaboration with the Secretary of Defense, and in consultation with relevant public and private entities, shall develop core health and medical response curricula and trainings by adapting applicable existing curricula and training programs to improve responses to public health emergencies.

(2) Curriculum

The public health and medical response training program may include course work related to—

(A) medical management of casualties, taking into account the needs of at-risk individuals;

(B) public health aspects of public health emergencies;

(C) mental health aspects of public health emergencies;

(D) national incident management, including coordination among Federal, State, local, tribal, international agencies, and other entities; and

(E) protecting health care workers and health care first responders from workplace exposures during a public health emergency.

(3) Peer review

On a periodic basis, products prepared as part of the program shall be rigorously tested and peer-reviewed by experts in the relevant fields.

(4) Credit

The Secretary and the Secretary of Defense shall—

(A) take into account continuing professional education requirements of public health and healthcare professions; and

(B) cooperate with State, local, and tribal accrediting agencies and with professional associations in arranging for students enrolled in the program to obtain continuing professional education credit for program courses.

(5) Dissemination and training

(A) In general

The Secretary may provide for the dissemination and teaching of the materials described in paragraphs (1) and (2) by appropriate means, as determined by the Secretary.

(B) Certain entities

The education and training activities described in subparagraph (A) may be carried out by Federal public health or medical entities, appropriate educational entities, professional organizations and societies, private accrediting organizations, and other nonprofit institutions or entities meeting criteria established by the Secretary.

(C) Grants and contracts

In carrying out this subsection, the Secretary may carry out activities directly or through the award of grants and contracts, and may enter into interagency agreements with other Federal agencies.

(b) Advice to the Federal Government

(1) Required advisory committees

In coordination with the working group under subsection (a) of this section, the Secretary shall establish advisory committees in accordance with paragraphs (2) and (3) to pro-

vide expert recommendations to assist such working groups in carrying out their respective responsibilities under subsections (a) and (b) of this section.

(2) National Advisory Committee on At-Risk Individuals and Public Health Emergencies

(A) In general

For purposes of paragraph (1), the Secretary shall establish an advisory committee to be known as the National Advisory Committee on At-Risk Individuals and Public Health Emergencies (referred to in this paragraph as the ''Advisory Committee'').

(B) Duties

The Advisory Committee shall provide recommendations regarding—

(i) the preparedness of the health care (including mental health care) system to respond to public health emergencies as they relate to at-risk individuals;

(ii) needed changes to the health care and emergency medical service systems and emergency medical services protocols to meet the special needs of at-risk individuals; and

(iii) changes, if necessary, to the national stockpile under section 300hh–12 of this title to meet the emergency health security of at-risk individuals.

(C) Composition

The Advisory Committee shall be composed of such Federal officials as may be appropriate to address the special needs of the diverse population groups of at-risk populations.

(D) Termination

The Advisory Committee terminates six years after June 12, 2002.

(3) Emergency Public Information and Communications Advisory Committee

(A) In general

For purposes of paragraph (1), the Secretary shall establish an advisory committee to be known as the Emergency Public Information and Communications Advisory Committee (referred to in this paragraph as the ''EPIC Advisory Committee'').

(B) Duties

The EPIC Advisory Committee shall make recommendations to the Secretary and report on appropriate ways to communicate public health information regarding bioterrorism and other public health emergencies to the public.

(C) Composition

The EPIC Advisory Committee shall be composed of individuals representing a diverse group of experts in public health, medicine, communications, behavioral psychology, and other areas determined appropriate by the Secretary.

(D) Dissemination

The Secretary shall review the recommendations of the EPIC Advisory Committee and ensure that appropriate information is disseminated to the public.

(E) Termination

The EPIC Advisory Committee terminates one year after June 12, 2002.

(c) Expansion of Epidemic Intelligence Service Program

The Secretary may establish 20 officer positions in the Epidemic Intelligence Service Program, in addition to the number of the officer positions offered under such Program in 2006, for individuals who agree to participate, for a period of not less than 2 years, in the Career Epidemiology Field Officer program in a State, local, or tribal health department that serves a health professional shortage area (as defined under section 254e(a) of this title), a medically underserved population (as defined under section 254b(b)(3) of this title), or a medically underserved area or area at high risk of a public health emergency as designated by the Secretary.

(d) Centers for Public Health Preparedness; core curricula and training

(1) In general

The Secretary may establish at accredited schools of public health, Centers for Public Health Preparedness (hereafter referred to in this section as the ''Centers'').

(2) Eligibility

To be eligible to receive an award under this subsection to establish a Center, an accredited school of public health shall agree to conduct activities consistent with the requirements of this subsection.

(3) Core curricula

The Secretary, in collaboration with the Centers and other public or private entities shall establish core curricula based on established competencies leading to a 4-year bachelor's degree, a graduate degree, a combined bachelor and master's degree, or a certificate program, for use by each Center. The Secretary shall disseminate such curricula to other accredited schools of public health and other health professions schools determined appropriate by the Secretary, for voluntary use by such schools.

(4) Core competency-based training program

The Secretary, in collaboration with the Centers and other public or private entities shall facilitate the development of a competency-based training program to train public health practitioners. The Centers shall use such training program to train public health practitioners. The Secretary shall disseminate such training program to other accredited schools of public health, health professions schools, and other public or private entities as determined by the Secretary, for voluntary use by such entities.

(5) Content of core curricula and training program

The Secretary shall ensure that the core curricula and training program established pursuant to this subsection respond to the needs of State, local, and tribal public health authorities and integrate and emphasize es-

sential public health security capabilities consistent with section 300hh–1(b)(2) of this title.

(6) Academic-workforce communication

As a condition of receiving funding from the Secretary under this subsection, a Center shall collaborate with a State, local, or tribal public health department to—

(A) define the public health preparedness and response needs of the community involved;

(B) assess the extent to which such needs are fulfilled by existing preparedness and response activities of such school or health department, and how such activities may be improved;

(C) prior to developing new materials or trainings, evaluate and utilize relevant materials and trainings developed by others Centers; and

(D) evaluate community impact and the effectiveness of any newly developed materials or trainings.

(7) Public health systems research

In consultation with relevant public and private entities, the Secretary shall define the existing knowledge base for public health preparedness and response systems, and establish a research agenda based on Federal, State, local, and tribal public health preparedness priorities. As a condition of receiving funding from the Secretary under this subsection, a Center shall conduct public health systems research that is consistent with the agenda described under this paragraph.

(e) Accelerated research and development on priority pathogens and countermeasures

(1) In general

With respect to pathogens of potential use in a bioterrorist attack, and other agents that may cause a public health emergency, the Secretary, taking into consideration any recommendations of the working group under subsection (a) of this section, shall conduct, and award grants, contracts, or cooperative agreements for, research, investigations, experiments, demonstrations, and studies in the health sciences relating to—

(A) the epidemiology and pathogenesis of such pathogens;

(B) the sequencing of the genomes, or other DNA analysis, or other comparative analysis, of priority pathogens (as determined by the Director of the National Institutes of Health in consultation with the working group established in subsection (a) of this section), in collaboration and coordination with the activities of the Department of Defense and the Joint Genome Institute of the Department of Energy;

(C) the development of priority countermeasures; and

(D) other relevant areas of research;

with consideration given to the needs of children and other vulnerable populations.

(2) Priority

The Secretary shall give priority under this section to the funding of research and other studies related to priority countermeasures.

(3) Role of Department of Veterans Affairs

In carrying out paragraph (1), the Secretary shall consider using the biomedical research and development capabilities of the Department of Veterans Affairs, in conjunction with that Department's affiliations with health-professions universities. When advantageous to the Government in furtherance of the purposes of such paragraph, the Secretary may enter into cooperative agreements with the Secretary of Veterans Affairs to achieve such purposes.

(4) Priority countermeasures

For purposes of this section, the term ''priority countermeasure'' means a drug, biological product, device, vaccine, vaccine adjuvant, antiviral, or diagnostic test that the Secretary determines to be—

(A) a priority to treat, identify, or prevent infection by a biological agent or toxin listed pursuant to section 262a(a)(1) of this title, or harm from any other agent that may cause a public health emergency; or

(B) a priority to treat, identify, or prevent conditions that may result in adverse health consequences or death and may be caused by the administering of a drug, biological product, device, vaccine, vaccine adjuvant, antiviral, or diagnostic test that is a priority under subparagraph (A).

(f) Authorization of appropriations

(1) Fiscal year 2007

There are authorized to be appropriated to carry out this section for fiscal year 2007—

(A) to carry out subsection (a)—

(i) $5,000,000 to carry out paragraphs (1) through (4); and

(ii) $7,000,000 to carry out paragraph (5);

(B) to carry out subsection (c), $3,000,000; and

(C) to carry out subsection (d), $31,000,000, of which $5,000,000 shall be used to carry out paragraphs (3) through (5) of such subsection.

(2) Subsequent fiscal years

There are authorized to be appropriated such sums as may be necessary to carry out this section for fiscal year 2008 and each subsequent fiscal year.

(July 1, 1944, ch. 373, title III, § 319F, as added Pub. L. 106–505, title I, § 102, Nov. 13, 2000, 114 Stat. 2321; amended Pub. L. 107–188, title I, §§ 104(a) 105, 108, 111(3), 125, June 12, 2002, 116 Stat. 605, 606, 609, 611, 614; Pub. L. 108–276, § 2(d), July 21, 2004, 118 Stat. 842; Pub. L. 109–417, title III, §§ 301(d), (e), 304, Dec. 19, 2006, 120 Stat. 2854, 2855, 2859.)

AMENDMENTS

2006—Subsec. (a). Pub. L. 109–417, § 304(1), added subsec. (a) and struck out heading and text of former subsec. (a) which established a working group on bioterrorism and other public health emergencies.

Subsec. (b)(2). Pub. L. 109–417, § 301(d)(1), substituted ''At-Risk Individuals and Public Health Emergencies'' for ''Children and Terrorism'' in heading.

Subsec. (b)(2)(A). Pub. L. 109–417, § 301(d)(2), substituted ''At-Risk Individuals and Public Health Emergencies'' for ''Children and Terrorism''.

Subsec. (b)(2)(B)(i). Pub. L. 109–417, § 301(d)(3)(A), substituted ''public health emergencies as they relate to at-risk individuals'' for ''bioterrorism as it relates to children''.

Subsec. (b)(2)(B)(ii), (iii). Pub. L. 109–417, § 301(d)(3)(B), (C), substituted ''at-risk individuals'' for ''children''.

Subsec. (b)(2)(C). Pub. L. 109–417, § 301(d)(4), substituted ''at-risk populations'' for ''children, and child health experts on infectious disease, environmental health, toxicology, and other relevant professional disciplines''.

Subsec. (b)(2)(D). Pub. L. 109–417, § 301(d)(5), substituted ''six years'' for ''one year''.

Subsec. (b)(3)(B). Pub. L. 109–417, § 301(e), struck out ''and the working group under subsection (a) of this section'' after ''Secretary''.

Subsecs. (c) to (h). Pub. L. 109–417, § 304(2)–(4), added subsecs. (c), (d), and (f), redesignated subsec. (h) as (e), and struck out former subsecs. (c) to (g), which related to: in subsec. (c), development of communication strategy; in subsec. (d), Federal Internet site on bioterrorism; in subsec. (e), grants to increase capacity to detect, diagnose, and respond to acts of bioterrorism; in subsec. (f), assistance to State and local health agencies to enable effective response to attacks; and, in subsec. (g), education and training activities.

Subsecs. (i), (j). Pub. L. 109–417, § 304(5), struck out subsecs. (i) and (j) which related to report to congressional committees on public health and medical consequences of a bioterrorist attack and the supplementary nature of funds appropriated under this section, respectively.

2004—Subsec. (a)(1). Pub. L. 108–276, § 2(d)(1), inserted ''the Secretary of Homeland Security,'' after ''Management Agency,'' in introductory provisions.

Subsec. (h)(4)(B). Pub. L. 108–276, § 2(d)(2), substituted ''to treat, identify, or prevent conditions'' for ''to diagnose conditions''.

2002—Subsec. (a). Pub. L. 107–188, § 108, added subsec. (a) and struck out heading and text of former subsec. (a). Text read as follows: ''The Secretary, in coordination with the Secretary of Defense, shall establish a joint interdepartmental working group on preparedness and readiness for the medical and public health effects of a bioterrorist attack on the civilian population. Such joint working group shall—

''(1) coordinate research on pathogens likely to be used in a bioterrorist attack on the civilian population as well as therapies to treat such pathogens;

''(2) coordinate research and development into equipment to detect pathogens likely to be used in a bioterrorist attack on the civilian population and protect against infection from such pathogens;

''(3) develop shared standards for equipment to detect and to protect against infection from pathogens likely to be used in a bioterrorist attack on the civilian population; and

''(4) coordinate the development, maintenance, and procedures for the release of, strategic reserves of vaccines, drugs, and medical supplies which may be needed rapidly after a bioterrorist attack upon the civilian population.''

Subsec. (b). Pub. L. 107–188, § 104(a)(1), (3), added subsec. (b) and struck out former subsec. (b) which related to establishment, functions, membership, and coordination of a working group on the public health and medical consequences of bioterrorism.

Subsecs. (c), (d). Pub. L. 107–188, § 104(a)(3), added subsecs. (c) and (d). Former subsecs. (c) and (d) redesignated (e) and (f), respectively.

Subsec. (e). Pub. L. 107–188, § 104(a)(2), redesignated subsec. (c) as (e). Former subsec. (e) redesignated (g).

Subsec. (e)(2). Pub. L. 107–188, § 111(3), which directed the amendment of section 391F(e)(2) of the Public Health Service Act by striking out ''or'' after ''clinic,'' and inserting before period '', professional organization or society, school or program that trains medical laboratory personnel, private accrediting organization, or other nonprofit private institution or entity meeting criteria established by the Secretary'', was executed to subsec. (e)(2) of this section, which is section 319F(e)(2) of the Act, to reflect the probable intent of Congress.

Subsec. (f). Pub. L. 107–188, § 104(a)(2), redesignated subsec. (d) as (f). Former subsec. (f) redesignated (h).

Subsec. (g). Pub. L. 107–188, § 105, amended heading and text of subsec. (g) generally. Prior to amendment, text read as follows: ''The Secretary, in collaboration with members of the working group described in subsection (b) of this section, and professional organizations and societies, shall—

''(1) develop and implement educational programs to instruct public health officials, medical professionals, and other personnel working in health care facilities in the recognition and care of victims of a bioterrorist attack; and

''(2) develop and implement programs to train laboratory personnel in the recognition and identification of a potential bioweapon.''

Pub. L. 107–188, § 104(a)(2), redesignated subsec. (e) as (g). Former subsec. (g) redesignated (i).

Subsec. (h). Pub. L. 107–188, § 125, amended heading and text of subsec. (h) generally. Prior to amendment, text read as follows: ''The Secretary shall consult with the working group described in subsection (a) of this section, to develop priorities for and conduct research, investigations, experiments, demonstrations, and studies in the health sciences related to—

''(1) the epidemiology and pathogenesis of potential bioweapons;

''(2) the development of new vaccines or other therapeutics against pathogens likely to be used in a bioterrorist attack;

''(3) the development of medical diagnostics to detect potential bioweapons; and

''(4) other relevant research areas.''

Pub. L. 107–188, § 104(a)(2), redesignated subsec. (f) as (h). Former subsec. (h) redesignated (j).

Subsec. (i). Pub. L. 107–188, § 104(a)(1), (2), redesignated subsec. (g) as (i) and struck out heading and text of former subsec. (i). Text read as follows: ''There are authorized to be appropriated to carry out this section $215,000,000 for fiscal year 2001, and such sums as may be necessary for each subsequent fiscal year through 2006.''

Subsec. (j). Pub. L. 107–188, § 104(a)(2), redesignated subsec. (h) as (j).

OTHER REPORTS

Pub. L. 107–188, title I, § 101(b)(1), June 12, 2002, 116 Stat. 598, provided that:

''(1) IN GENERAL.—Not later than one year after the date of the enactment of this Act [June 12, 2002], the Secretary of Health and Human Services (referred to in this subsection as the 'Secretary') shall submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report concerning—

''(A) the recommendations and findings of the National Advisory Committee on Children and Terrorism under section 319F(c)(2) of the Public Health Service Act [probably means subsec. (b)(2) of this section];

''(B) the recommendations and findings of the EPIC Advisory Committee under section 319F(c)(3) of such Act [probably means subsec. (b)(3) of this section];

''(C) the characteristics that may render a rural community uniquely vulnerable to a biological attack, including distance, lack of emergency transport, hospital or laboratory capacity, lack of integration of Federal or State public health networks, workforce deficits, or other relevant characteristics;

''(D) the characteristics that may render areas or populations designated as medically underserved populations (as defined in section 330 of such Act [section 254b of this title]) uniquely vulnerable to a biological attack, including significant numbers of low-income or uninsured individuals, lack of affordable and accessible health care services, insufficient public and primary health care resources, lack of integration of

Federal or State public health networks, workforce deficits, or other relevant characteristics;

''(E) the recommendations of the Secretary with respect to additional legislative authority that the Secretary determines is necessary to effectively strengthen rural communities, or medically underserved populations (as defined in section 330 of such Act); and

''(F) the need for and benefits of a National Disaster Response Medical Volunteer Service that would be a private-sector, community-based rapid response corps of medical volunteers.''

STUDY REGARDING COMMUNICATIONS ABILITIES OF PUBLIC HEALTH AGENCIES

Pub. L. 107–188, title I, § 104(b), June 12, 2002, 116 Stat. 606, provided that: ''The Secretary of Health and Human Services, in consultation with the Federal Communications Commission, the National Telecommunications and Information Administration, and other appropriate Federal agencies, shall conduct a study to determine whether local public health entities have the ability to maintain communications in the event of a bioterrorist attack or other public health emergency. The study shall examine whether redundancies are required in the telecommunications system, particularly with respect to mobile communications, for public health entities to maintain systems operability and connectivity during such emergencies. The study shall also include recommendations to industry and public health entities about how to implement such redundancies if necessary.''

§ 247d–6a. Authority for use of certain procedures regarding qualified countermeasure research and development activities

(a) In general

(1) Authority

In conducting and supporting research and development activities regarding countermeasures under section 247d–6(h) of this title, the Secretary may conduct and support such activities in accordance with this section and, in consultation with the Director of the National Institutes of Health, as part of the program under section 285f of this title, if the activities concern qualified countermeasures.

(2) Definitions

In this section:

(A) Qualified countermeasure

The term ''qualified countermeasure'' means a drug (as that term is defined by section 321(g)(1) of title 21), biological product (as that term is defined by section 262(i) of this title), or device (as that term is defined by section 321(h) of title 21), that the Secretary determines to be a priority (consistent with sections 182(2) and 184(a) of title 6) to—

(i) diagnose, mitigate, prevent, or treat harm from any biological agent (including organisms that cause an infectious disease) or toxin, chemical, radiological, or nuclear agent that may cause a public health emergency affecting national security; or

(ii) diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device that is used as described in this subparagraph.

(B) Infectious disease

The term ''infectious disease'' means a disease potentially caused by a pathogenic organism (including a bacteria, virus, fungus, or parasite) that is acquired by a person and that reproduces in that person.

(3) Interagency cooperation

(A) In general

In carrying out activities under this section, the Secretary is authorized, subject to subparagraph (B), to enter into interagency agreements and other collaborative undertakings with other agencies of the United States Government.

(B) Limitation

An agreement or undertaking under this paragraph shall not authorize another agency to exercise the authorities provided by this section.

(4) Availability of facilities to the Secretary

In any grant, contract, or cooperative agreement entered into under the authority provided in this section with respect to a biocontainment laboratory or other related or ancillary specialized research facility that the Secretary determines necessary for the purpose of performing, administering, or supporting qualified countermeasure research and development, the Secretary may provide that the facility that is the object of such grant, contract, or cooperative agreement shall be available as needed to the Secretary to respond to public health emergencies affecting national security.

(5) Transfers of qualified countermeasures

Each agreement for an award of a grant, contract, or cooperative agreement under section 247d–6(h) of this title for the development of a qualified countermeasure shall provide that the recipient of the award will comply with all applicable export-related controls with respect to such countermeasure.

(b) Expedited procurement authority

(1) Increased simplified acquisition threshold for qualified countermeasure procurements

(A) In general

For any procurement by the Secretary of property or services for use (as determined by the Secretary) in performing, administering, or supporting qualified countermeasure research or development activities under this section that the Secretary determines necessary to respond to pressing research and development needs under this section, the amount specified in section 134 of title 41, as applicable pursuant to section 3101(b)(1)(A) of title 41, shall be deemed to be $25,000,000 in the administration, with respect to such procurement, of—

(i) section 3305(a)(1) of title 41 and its implementing regulations; and

(ii) section 3101(b)(1)(B) of title 41 and its implementing regulations.

(B) Application of certain provisions

Notwithstanding subparagraph (A) and the provision of law and regulations referred to