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111TH CONGRESS
2^D SESSION

H. R. 5498

[Report No. 111-659, Part I]

To enhance homeland security by improving efforts to prevent, deter, prepare for, detect, attribute, respond to, and recover from an attack with a weapon of mass destruction, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 10, 2010

Mr. PASCRELL (for himself, Mr. KING of New York, Mr. THOMPSON of Mississippi, Ms. CLARKE, and Mr. DANIEL E. LUNGREN of California) introduced the following bill; which was referred to the Committee on Homeland Security, and in addition to the Committees on Energy and Commerce, Agriculture, Transportation and Infrastructure, Foreign Affairs, and Select Intelligence (Permanent Select), for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

NOVEMBER 18, 2010

Reported from the Committee on Homeland Security with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

NOVEMBER 18, 2010

The Committees on Agriculture, Foreign Affairs, Transportation and Infrastructure, and the Permanent Select Committee on Intelligence discharged

NOVEMBER 18, 2010

Referral to the Committee on Energy and Commerce extended for a period ending not later than December 3, 2010

DECEMBER 3, 2010

Referral to the Committee on Energy and Commerce extended for a period ending not later than December 17, 2010

DECEMBER 17, 2010

Referral to the Committee on Energy and Commerce extended for a period ending not later than December 21, 2010

DECEMBER 21, 2010

Referral to the Committee on Energy and Commerce extended for a period ending not later than December 22, 2010

DECEMBER 22, 2010

Additional sponsors: Ms. RICHARDSON, Mrs. MILLER of Michigan, Ms. JACKSON LEE of Texas, Mr. CARNEY, Ms. NORTON, Mr. AL GREEN of Texas, and Mr. DENT

DECEMBER 22, 2010

The Committee on Energy and Commerce discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

[For text of introduced bill, see copy of bill as introduced on June 10, 2010]

A BILL

To enhance homeland security by improving efforts to prevent, deter, prepare for, detect, attribute, respond to, and recover from an attack with a weapon of mass destruction, 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; TABLE OF CONTENTS.**

4 (a) *SHORT TITLE.*—*This Act may be cited as the*
 5 *“WMD Prevention and Preparedness Act of 2010”.*

6 (b) *TABLE OF CONTENTS.*—*The table of contents for*
 7 *this Act is as follows:*

Sec. 1. Short title; table of contents.

Sec. 2. Definitions.

TITLE I—INTELLIGENCE MATTERS

Sec. 101. National intelligence strategy for countering the threat from weapons of mass destruction.

Sec. 102. National intelligence strategy for countering biological threats.

TITLE II—HOMELAND SECURITY MATTERS

Sec. 201. Weapons of mass destruction prevention and preparedness.

Sec. 202. Definitions.

Sec. 203. Dual-use terrorist risks from synthetic genomics.

Sec. 204. Dissemination of information analyzed by the Department to State, local, tribal, and private entities with responsibilities relating to homeland security.

Sec. 205. National Biosurveillance Integration Center (NBIC).

Sec. 206. Report on establishment of the system assessment and validation for emergency responders (SAVER) program.

Sec. 207. National Academy of Sciences study of forensic science in homeland security.

Sec. 208. Harmonization of regulations.

Sec. 209. Communications planning for weapons of mass destruction information dissemination.

Sec. 210. Environmental recovery from chemical, biological, radiological, and nuclear attacks.

TITLE III—PUBLIC HEALTH MATTERS

Sec. 301. National medical countermeasure dispensing strategy.

Sec. 302. Material threat assessments and determinations.

Sec. 303. National pre-event vaccination and antimicrobial dispensing policy review.

Sec. 304. Designation of tier 1 material threat agents.

Sec. 305. Background checks.

Sec. 306. Biotechnology research, development, and procurement.

TITLE IV—FOREIGN RELATIONS MATTERS

Sec. 401. International collaboration and information sharing relating to biosecurity.

Sec. 402. International engagement to enhance biodefense and biosecurity.
Sec. 403. Interagency task force on best practices for global biopreparedness.
Sec. 404. Biological and Toxin Weapons Convention.

1 **SEC. 2. DEFINITIONS.**

2 *In this Act:*

3 (1) *The term “appropriate congressional com-*
4 *mittees” means the Committee on Homeland Security*
5 *of the House of Representatives and any committee of*
6 *the House of Representatives or the Senate having leg-*
7 *islative jurisdiction under the rules of the House of*
8 *Representatives or Senate, respectively, over the mat-*
9 *ter concerned.*

10 (2) *The term “weapon of mass destruction” has*
11 *the meaning given that term in section 1403(1) fo the*
12 *Defense Against Weapons of Mass Destruction Act of*
13 *1996 (50 U.S.C. 2302).*

14 (3) *The term “Intelligence Community” has the*
15 *meaning given that term in section 3(4) of the Na-*
16 *tional Security Act of 1947 (50 U.S.C. 401a(4)).*

17 (4) *The term “national biosecurity and bio-*
18 *defense stakeholders” means officials from the Federal,*
19 *State, local, and tribal authorities and individuals*
20 *from the private sector who are involved in efforts to*
21 *prevent, deter, prepare for, detect, attribute, respond,*
22 *and recover from a biological attack or other phe-*
23 *nomena that may have serious health consequences for*

1 *the United States, including wide-scale fatalities or*
2 *infectious disease outbreaks.*

3 **TITLE I—INTELLIGENCE**
4 **MATTERS**

5 **SEC. 101. NATIONAL INTELLIGENCE STRATEGY FOR COUN-**
6 **TERING THE THREAT FROM WEAPONS OF**
7 **MASS DESTRUCTION.**

8 *(a) STRATEGY.—*

9 *(1) DEVELOPMENT.—The Director of National*
10 *Intelligence, in consultation with the Secretary of*
11 *Homeland Security and the heads of other appro-*
12 *priate Federal departments and agencies, shall de-*
13 *velop and implement—*

14 *(A) a strategy designed to improve the ca-*
15 *pabilities of the United States to collect, analyze,*
16 *and disseminate intelligence related to weapons*
17 *of mass destruction; and*

18 *(B) a plan to implement such strategy.*

19 *(2) TITLE.—The strategy required under para-*
20 *graph (1) shall be known as the “National Intel-*
21 *ligence Strategy for Countering the Threat from*
22 *Weapons of Mass Destruction”.*

23 *(b) CONTENTS.—The strategy required under sub-*
24 *section (a) shall—*

1 (1) *include methods for the recruitment, train-*
2 *ing, and retention of a workforce with expertise in the*
3 *collection, analysis, and dissemination of intelligence*
4 *related to all types of weapons of mass destruction*
5 *and science and technology related to weapons of*
6 *mass destruction, as well as expertise in science and*
7 *technology relating to threats posed by weapons of*
8 *mass destruction;*

9 (2) *include methods for collaboration, as appro-*
10 *priate, with individuals with the expertise described*
11 *in paragraph (1) who are not employed by the Fed-*
12 *eral Government;*

13 (3) *identify and address domestic needs for anal-*
14 *ysis and collection including the development of inno-*
15 *vative human and technical intelligence collection ca-*
16 *pabilities and techniques; and*

17 (4) *address each type of weapon of mass destruc-*
18 *tion as necessary and appropriate.*

19 (c) *IMPLEMENTATION PLAN.—The plan for imple-*
20 *menting the strategy required under subsection (a) shall in-*
21 *clude—*

22 (1) *actions necessary to increase the effectiveness*
23 *and efficiency of the sharing of intelligence on weap-*
24 *ons of mass destruction throughout the Intelligence*
25 *Community, including a description of statutory, reg-*

1 *ulatory, policy, technical, security, or other barriers*
2 *that prevent such sharing, and, as appropriate, the*
3 *development of uniform standards across the Intel-*
4 *ligence Community for such sharing;*

5 *(2) methods to disseminate intelligence products*
6 *to national biosecurity and biodefense stakeholders in*
7 *unclassified formats to increase the effectiveness and*
8 *efficiency of the sharing of information;*

9 *(3) actions necessary to provide open-source in-*
10 *telligence relating to weapons of mass destruction*
11 *to—*

12 *(A) appropriate Federal departments and*
13 *agencies;*

14 *(B) State, local, and tribal authorities; and*

15 *(C) private entities;*

16 *(4) specific objectives to be accomplished, with*
17 *corresponding schedule, for each year of the five-year*
18 *period that begins on the date on which the strategy*
19 *is submitted to the appropriate congressional commit-*
20 *tees under subsection (e) and tasks to accomplish such*
21 *objectives, including—*

22 *(A) a list prioritizing such objectives and*
23 *such tasks; and*

24 *(B) a schedule for meeting such objectives*
25 *and carrying out such tasks;*

1 (5) *assignments of roles and responsibilities to*
2 *elements of the Intelligence Community to implement*
3 *the strategy; and*

4 (6) *a schedule for assessment of the effectiveness*
5 *and efficiency of the strategy, including metrics.*

6 (d) *COORDINATION.—The Director of National Intel-*
7 *ligence shall, as the Director considers appropriate, coordi-*
8 *nate with State, local, and tribal government authorities,*
9 *private sector, and nongovernmental organizations in the*
10 *development of the National Intelligence Strategy for Coun-*
11 *tering the Threat from Weapons of Mass Destruction.*

12 (e) *REPORT.—Not later than one year after the date*
13 *of the enactment of this Act, the Director of National Intel-*
14 *ligence, in consultation with the Secretary of Homeland Se-*
15 *curity, shall submit to the appropriate congressional com-*
16 *mittees the strategy and plan required under subsection (a).*
17 *The report shall be in unclassified form but with a classified*
18 *annex, as appropriate.*

19 **SEC. 102. NATIONAL INTELLIGENCE STRATEGY FOR COUN-**
20 **TERING BIOLOGICAL THREATS.**

21 (a) *STRATEGY.—*

22 (1) *DEVELOPMENT.—The Director of National*
23 *Intelligence, in consultation with the Secretary of*
24 *Homeland Security and the heads of other appro-*
25 *priate Federal departments and agencies, shall de-*

1 *velop and implement a strategy and a plan for imple-*
2 *menting the strategy that is integrated into the Na-*
3 *tional Intelligence Strategy for Countering the Threat*
4 *from Weapons of Mass Destruction, as required under*
5 *this title.*

6 (2) *TITLE.—The strategy required under para-*
7 *graph (1) shall be known as the “National Intel-*
8 *ligence Strategy for Countering Biological Threats”.*

9 (b) *CONTENTS.—The strategy required under sub-*
10 *section (a) shall—*

11 (1) *include a for plan for establishing in the In-*
12 *telligence Community a cadre of—*

13 (A) *collectors and analysts in all agencies*
14 *in the Intelligence Community that are familiar*
15 *with biological threats, biological science, and*
16 *biotechnology;*

17 (B) *biological scientists;*

18 (C) *biotechologists; and*

19 (D) *experts with knowledge of the current*
20 *state of technologies that could be used to develop*
21 *a weapon of mass destruction;*

22 (2) *include a plan for defining the functions, ca-*
23 *pabilities, and gaps with respect to addressing the*
24 *risk of a weapon of mass destruction attack in the in-*
25 *telligence workforce;*

1 (3) *identify strategies to recruit, retain, and pro-*
2 *tect such workforce from workplace exposures to bio-*
3 *logical agents in the conduct of the duties of such*
4 *workforce;*

5 (4) *include methods for collaboration, as appro-*
6 *priate, with individuals with expertise described in*
7 *paragraph (1) who are not employed by the Federal*
8 *Government;*

9 (5) *address domestic and international needs for*
10 *analysis and collection;*

11 (6) *include a plan for defining, integrating, fo-*
12 *cusing, and enhancing existing capabilities in the In-*
13 *telligence Community dedicated to current tactical*
14 *and strategic biological threats; and*

15 (7) *include a plan for ensuring the prioritization*
16 *and sustained commitment of intelligence personnel*
17 *and resources to address biological threats.*

18 (c) *IMPLEMENTATION PLAN.—The implementation*
19 *plan for the strategy required under subsection (a) shall—*

20 (1) *include actions necessary to increase the ef-*
21 *fectiveness and efficiency of the sharing of intelligence*
22 *throughout the Intelligence Community on biological*
23 *weapons and organisms that could be used for biologi-*
24 *cal terrorism, including a description of statutory,*
25 *regulatory, policy, technical, security, or other bar-*

1 *riers that prevent such sharing, and, as appropriate,*
2 *the development of uniform standards across the In-*
3 *telligence Community for such sharing;*

4 *(2) address strategic and tactical human intel-*
5 *ligence, measurement and signature intelligence, tech-*
6 *nical intelligence, medical intelligence, and open-*
7 *source intelligence activities necessary to implement*
8 *the strategy;*

9 *(3) identify specific objectives to be accomplished*
10 *during each year of the five-year period that begins*
11 *on the date on which the strategy is submitted to the*
12 *appropriate congressional committees under sub-*
13 *section (d) and tasks to accomplish such objectives, in-*
14 *cluding—*

15 *(A) a list prioritizing such objectives and*
16 *such tasks; and*

17 *(B) a schedule for meeting such objectives*
18 *and carrying out such tasks;*

19 *(4) assign roles and responsibilities to elements*
20 *of the Intelligence Community to implement the strat-*
21 *egy;*

22 *(5) a schedule for assessment of the effectiveness*
23 *and efficiency of the strategy, including metrics; and*

1 **“TITLE XXI—WEAPONS OF MASS**
2 **DESTRUCTION PREVENTION**
3 **AND PREPAREDNESS**

4 **“Subtitle A—Prevention and**
5 **Deterrence**

6 **“SEC. 2101. WEAPONS OF MASS DESTRUCTION INTEL-**
7 **LIGENCE AND INFORMATION SHARING UNIT.**

8 *“(a) IN GENERAL.—There is established in the Office*
9 *of Intelligence and Analysis of the Department a unit for*
10 *weapons of mass destruction intelligence and information*
11 *sharing. The unit shall conduct intelligence and informa-*
12 *tion sharing activities consistent with the National Intel-*
13 *ligence Strategy for Countering the Threat from Weapons*
14 *of Mass Destruction under section 101 of the WMD Preven-*
15 *tion and Preparedness Act of 2010 and the National Intel-*
16 *ligence Strategy for Countering Biological Threats under*
17 *section 102 of that Act and shall—*

18 *“(1) evaluate and establish a baseline of terrorist*
19 *actors, their claims, and their plans to conduct at-*
20 *tacks involving chemical, biological, radiological, and*
21 *nuclear materials against the Nation;*

22 *“(2) support homeland security-focused intel-*
23 *ligence analysis of global infectious disease, public*
24 *health, food, agricultural, and veterinary issues;*

1 “(3) *provide tailored analytical support on these*
2 *threats to State, local, and tribal authorities as well*
3 *as members of the public health, scientific, and re-*
4 *sponse communities; and*

5 “(4) *perform other responsibilities, as assigned*
6 *by the Secretary.*

7 “(b) *COORDINATION.—Where appropriate, the unit*
8 *shall coordinate with others in the Intelligence Community,*
9 *including the National Counter Proliferation Center.*

10 “(c) *REPORT.—Not later than one year after the date*
11 *of the enactment of this section and annually thereafter, the*
12 *Secretary shall report to the appropriate congressional com-*
13 *mittees on the intelligence and information sharing activi-*
14 *ties of the unit for weapons of mass destruction intelligence*
15 *and information sharing established under subsection (a)*
16 *and all relevant entities within the Department to counter*
17 *the threat from weapons of mass destruction and how the*
18 *Department acted in accordance with relevant intelligence*
19 *strategies, including the National Intelligence Strategy for*
20 *Countering the Threat from Weapons of Mass Destruction*
21 *and the National Intelligence Strategy for Countering Bio-*
22 *logical Threats.*

1 **“SEC. 2102. INFORMATION SHARING AND COLLABORATION**
2 **FOR BIOSECURITY AND BIODEFENSE.**

3 *“(a) RESPONSIBILITIES OF SECRETARY OF HOMELAND*
4 *SECURITY.—To increase situational awareness, the Sec-*
5 *retary, acting through the Under Secretary for Intelligence*
6 *and Analysis, shall—*

7 *“(1) to the greatest extent practicable, integrate*
8 *into the homeland security, intelligence, and informa-*
9 *tion sharing process national biosecurity and bio-*
10 *defense stakeholders;*

11 *“(2) develop an information sharing framework*
12 *for homeland security intelligence and information*
13 *sharing with the national biosecurity and biodefense*
14 *stakeholders;*

15 *“(3) enable national biosecurity and biodefense*
16 *stakeholders to provide recommendations with respect*
17 *to the development of mechanisms and protocols to in-*
18 *tegrate information from national biosecurity and*
19 *biodefense stakeholders;*

20 *“(4) leverage existing and emerging homeland se-*
21 *curity capabilities and structures, including fusion*
22 *centers established pursuant to section 210A, to en-*
23 *hance prevention, detection, preparedness, and collec-*
24 *tive response, attribution, and recovery efforts of from*
25 *a biological attack or other phenomena that may have*
26 *serious health consequences for the United States, in-*

1 *cluding wide-scale fatalities or infectious disease out-*
2 *breaks; and*

3 *“(5) advance partnerships between the Depart-*
4 *ment and other Federal departments and agencies in*
5 *assessing potential threats and the risks from the in-*
6 *tentional use of biological agents by terrorists or other*
7 *actors.*

8 *“(b) COORDINATION WITH OTHER DEPARTMENTS AND*
9 *AGENCIES.—The Secretary shall work in coordination with*
10 *the Secretary of State, the Secretary of Agriculture, the Sec-*
11 *retary of Health and Human Services, and the heads of*
12 *other appropriate Federal agencies.*

13 **“SEC. 2103. BIOTERRORISM RISK ASSESSMENTS.**

14 *“(a) RISK ASSESSMENT.—The Secretary, in coordina-*
15 *tion with the heads of other appropriate Federal depart-*
16 *ments and agencies, shall produce biennial integrated risk*
17 *assessments, to be known as ‘Bioterrorism Risk Assessments’*
18 *to identify and assess the evolving terrorist risk of a biologi-*
19 *cal attack or other phenomena that may have serious health*
20 *consequences for the United States, including wide-scale fa-*
21 *talities or infectious disease outbreaks. These assessments*
22 *shall—*

23 *“(1) identify the threat, vulnerability, and con-*
24 *sequences of a biological terrorist attack against the*
25 *United States;*

1 “(2) take into account intelligence and informa-
2 tion regarding terrorist intentions, capabilities, plans,
3 and actions;

4 “(3) be used to inform and guide threat assess-
5 ments and determinations made by the Secretary re-
6 garding agents and toxins pursuant to section 302(9),
7 and to guide prioritization of other homeland security
8 activities, as appropriate;

9 “(4) provide the basis for risk-informed invest-
10 ments in national strategic biodefense research, devel-
11 opment, planning, preparedness, and collective re-
12 sponse to biological attacks;

13 “(5) identify key knowledge and data gaps;

14 “(6) define critical biodefense vulnerabilities;

15 “(7) provide risk-based prioritization of agents
16 for bioterrorism; and

17 “(8) evaluate progress in implementing national
18 biopreparedness policy.

19 “(b) *REQUIREMENT.*—*The Secretary shall—*

20 “(1) convene an interagency task force of subject
21 matter experts to provide recommendations to the
22 Under Secretary for Science and Technology as to the
23 adequacy of the methodology used in the Assessments
24 and to establish requirements and standards for the
25 Assessments;

1 “(2) engage with national biosecurity and bio-
2 defense stakeholders to obtain their input regarding
3 the Assessments, as appropriate; and

4 “(3) ensure, to the greatest extent practicable,
5 that the Assessments inform the risk management de-
6 cisions of the Department and can be made available
7 to national biosecurity and biodefense stakeholders, as
8 appropriate.

9 **“SEC. 2104. RADIOLOGICAL MATERIALS SECURITY.**

10 “(a) *RISK ASSESSMENT.*—The Secretary shall enhance
11 domestic preparedness for and collective response to ter-
12 rorism by conducting annual risk assessments regarding the
13 threat, vulnerability, and consequences of theft or other pro-
14 curement of radiological materials that could be used by
15 a terrorist in a radiological dispersion device, including
16 any specific threat information pertinent to the use of radi-
17 ological materials in a possible terrorist attack using a ra-
18 diological dispersion device.

19 “(b) *CONSIDERATIONS.*—In conducting the terrorism
20 risk assessments under subsection (a), the Secretary shall—

21 “(1) consult with Secretary of Energy, Secretary
22 of Health and Human Services, and the Nuclear Reg-
23 ulatory Commission;

1 “(2) consider relevant studies previously pre-
2 pared by other Federal agencies, or other reputable
3 sources;

4 “(3) focus on those radiological materials that
5 constitute the greatest risk, and designate those mate-
6 rials as high-risk radiological materials for purposes
7 of this section;

8 “(4) consider the potential radiological disper-
9 sion device value of different radiological materials
10 including availability, dispersability, and ease of
11 handling of such materials;

12 “(5) consider the vulnerability for theft or other
13 procurement that different facilities represent; and

14 “(6) consider the consequences of a successful ra-
15 diological dispersion device attack, including risk of
16 death or injury and economic losses.

17 “(c) CONSULTATION.—In conducting the terrorism risk
18 assessments under subsection (a), the Secretary shall consult
19 with the Intelligence Community, the Secretary of Energy
20 and the Field Intelligence Elements of the National Labora-
21 tories, and the Nuclear Regulatory Commission, the Sec-
22 retary of Health and Human Services, and other appro-
23 priate experts to integrate and analyze information needed
24 to develop the risk assessment.

1 “(d) *DISSEMINATION OF FINDINGS.*—*The Secretary*
2 *shall disseminate the findings of the risk assessments and*
3 *any specific risk information developed in the assessment*
4 *to all participating agencies including those described in*
5 *subsection (c), as well State and local agencies, and the fa-*
6 *cilities containing radiological source material and regu-*
7 *lated by the Nuclear Regulatory Commission.*

8 “(e) *CLASSIFICATION.*—*The Secretary shall, as appro-*
9 *priate, share the terrorism risk assessments with law en-*
10 *forcement and critical infrastructure operators with appro-*
11 *priate security clearances. The Secretary shall also make*
12 *available an unclassified version to each agency with which*
13 *the Secretary is required to consult under subsection (c),*
14 *as well as State and local law enforcement and public*
15 *health authorities, and facilities possessing radiological ma-*
16 *terials with the support of the Department of Energy.*

17 **“SEC. 2105. ENHANCED BIOSECURITY MEASURES.**

18 “(a) *REGULATIONS.*—*At the request of the Secretary,*
19 *the Secretary, in consultation with the Secretary of Agri-*
20 *culture, the Secretary of Health and Human Services, and*
21 *the heads of other appropriate Federal agencies, shall,*
22 *through a negotiated rulemaking committee under sub-*
23 *chapter III of chapter 5 of title 5, United States Code, estab-*
24 *lish enhanced biosecurity measures for persons or labora-*

1 *ories that possess, use, or transfer Tier I Material Threat*
2 *Agents. Such measures shall include—*

3 “(1) *standards for personnel surety programs;*

4 “(2) *standards for biosecurity practices and*
5 *training of responsible officials, laboratory personnel,*
6 *and support personnel;*

7 “(3) *standards for performing laboratory vulner-*
8 *ability assessments in collaboration with each facility;*

9 “(4) *risk-based laboratory security performance*
10 *standards;*

11 “(5) *penalties (including civil money penalties*
12 *and intermediate sanctions), in addition to any other*
13 *penalties that may apply under provisions of law;*
14 *and*

15 “(6) *any other security standards determined*
16 *necessary by the Secretary, the Secretary of Agri-*
17 *culture, Secretary of Health and Human Services,*
18 *and other agencies as appropriate.*

19 “(b) *NEGOTIATED RULEMAKING COMMITTEE.—The*
20 *Secretary shall establish a negotiated rulemaking committee*
21 *for purposes of subsection (a). Such committee shall include*
22 *a representative from each of the following:*

23 “(1) *The Department.*

24 “(2) *The Department of Health and Human*
25 *Services.*

1 “(3) *The Department of Agriculture.*

2 “(4) *The Department of Defense.*

3 “(5) *The Department of Energy.*

4 “(6) *The Department of Justice.*

5 “(7) *For-profit research institutions.*

6 “(8) *Academic research institutions.*

7 “(9) *Nonprofit research institutions*

8 “(10) *Other stakeholders, as the Secretary deter-*
9 *mines appropriate.*

10 “(c) *TIME REQUIREMENT.—The procedures for the ne-*
11 *gotiated rulemaking referred to in subsection (a) shall be*
12 *conducted in a timely manner to ensure that—*

13 “(1) *any recommendations with respect to pro-*
14 *posed regulations are provided to the Secretary and*
15 *the heads of the other appropriate Federal agencies*
16 *not later than one year after the date of the enact-*
17 *ment of this section; and*

18 “(2) *a final rule is promulgated not later than*
19 *two years after the date of the enactment of this sec-*
20 *tion.*

21 “(d) *FACTORS TO BE CONSIDERED.—In developing*
22 *proposed and final standards pursuant to the negotiated*
23 *rulemaking referred to in subsection (a), the negotiated*
24 *rulemaking committee shall consider—*

1 “(1) *the Commission on the Prevention of Weap-*
2 *ons of Mass Destruction Proliferation and Terrorism*
3 *(established under section 1851 of the Implementing*
4 *Recommendations of the 9/11 Commission Act of 2007*
5 *(Public Law 110–53; 121 Stat. 501));*

6 “(2) *the National Science Advisory Board for*
7 *Biosecurity (established under section 217a of title 42,*
8 *United States Code, section 222 of the Public Health*
9 *Service Act, and section 205 of the Pandemic and All-*
10 *Hazards Preparedness Act);*

11 “(3) *any working group established under Exec-*
12 *utive Order 13486 (74 Fed. Reg. 2289) relating to*
13 *strengthening laboratory biosecurity;*

14 “(4) *the Chemical Facility Anti-Terrorism Act of*
15 *2009; and*

16 “(5) *views from representatives of biosecurity*
17 *and biodefense stakeholders for methods to minimize*
18 *any disincentives to biological research arising from*
19 *enhanced biosecurity measures.*

20 “(e) *IMPLEMENTATION OF ENHANCED BIOSECURITY*
21 *MEASURES.—*

22 “(1) *ENFORCEMENT.—The Secretary of Agri-*
23 *culture and the Secretary of Health and Human*
24 *Services, in consultation with the Secretary, as ap-*
25 *propriate, shall enforce the measures established under*

1 *subsection (a) and any standards promulgated pursu-*
2 *ant to such section.*

3 “(2) *TRAINING PROGRAMS.—The Secretary of*
4 *Agriculture and the Secretary of Health and Human*
5 *Services, in coordination with the Secretary and the*
6 *heads of other Federal agencies, as appropriate, shall*
7 *develop training programs that comply with such*
8 *measures and standards.*

9 “(3) *PROCEDURES.—The Secretary of Agri-*
10 *culture and the Secretary of Health and Human*
11 *Services, in consultation with the Secretary and the*
12 *heads of other Federal agencies, as appropriate, shall*
13 *develop and implement procedures with respect to*
14 *when and how penalties and intermediate sanctions*
15 *may be imposed. Such procedures shall provide for*
16 *notice, a reasonable opportunity to respond to the*
17 *proposed penalty or intermediate sanction, and ap-*
18 *propriate procedures for appealing determinations re-*
19 *lating to the imposition of a penalty or intermediate*
20 *sanction.*

21 “(4) *SIMULTANEOUS LABORATORY INSPEC-*
22 *TIONS.—*

23 “(A) *INSPECTION DATA SHARING AND EN-*
24 *FORCEMENT UNIFORMITY.—The Secretary of Ag-*
25 *riculture and the Secretary of Health and*

1 *Human Services shall periodically provide the*
2 *Secretary with all data concerning inspections of*
3 *laboratories that handle Tier 1 Material Threat*
4 *Agents to ensure uniformity in enforcement of*
5 *the regulations enacted under subsection (a) and*
6 *to identify areas where the Secretary can provide*
7 *guidance to the Secretary of Agriculture or the*
8 *Secretary of Health and Human Services about*
9 *approaches to enhance security at specific lab-*
10 *oratories.*

11 “(B) *SIMULTANEOUS INSPECTIONS.—Any*
12 *inspections of the same laboratory conducted by*
13 *the Secretary of Agriculture pursuant to section*
14 *212(a)(1) of the Agricultural Bioterrorism Pro-*
15 *tection Act of 2002 and the Secretary of Health*
16 *and Human Services for compliance with regu-*
17 *lations promulgated under the Select Agent Pro-*
18 *gram under section 351A(a)(1) of the Public*
19 *Health Service Act, shall be conducted simulta-*
20 *nously to the extent practicable.*

21 “(C) *COMMON INSPECTION PROCEDURES.—*
22 *Departments conducting simultaneous inspec-*
23 *tions of a laboratory under this subsection shall*
24 *ensure, to the maximum extent practicable, that*
25 *such inspections are conducted using a common*

1 *set of inspection procedures across such depart-*
2 *ments in order to minimize the administrative*
3 *burden on such laboratory.*

4 “(D) *INSPECTION REPORTS.*—*Inspection re-*
5 *ports generated under this paragraph shall be*
6 *made available to each Federal agency that sup-*
7 *ports select agent laboratory activities at the in-*
8 *stitution that is the subject of the inspection re-*
9 *port, and to the institutions that are the object*
10 *of inspections.*

11 **“SEC. 2106. TIER I MATERIAL THREAT AGENT LOCATIONS.**

12 *“The Secretary of Agriculture and the Secretary of*
13 *Health and Human Services shall provide to the Secretary*
14 *a list of laboratories and other locations where Tier I Mate-*
15 *rial Threat Agents are present in the United States and*
16 *its territories.*

17 **“SEC. 2107. HIGH CONTAINMENT BIOLOGICAL LABORATORY**
18 **SECURITY GRANTS.**

19 “(a) *GRANTS AUTHORIZED.*—*The Secretary, acting*
20 *through the Administrator of the Federal Emergency Man-*
21 *agement Agency, may award grants based on risk to aca-*
22 *demic and nonprofit organizations and to State, local, and*
23 *tribal authorities that possess, use, or transfer Tier I Mate-*
24 *rial Threat Agents, to enhance security at laboratories of*
25 *such organizations and authorities.*

1 “(b) *AUTHORIZATION OF APPROPRIATIONS.*—*There is*
2 *authorized to be appropriated to the Department of Home-*
3 *land Security to carry out this subsection \$50,000,000 for*
4 *each of fiscal years 2011 through 2013.*

5 “**SEC. 2108. LABORATORY BIOSECURITY INFORMATION**
6 **SHARING.**

7 “(a) *IN GENERAL.*—*Consistent with the responsibil-*
8 *ities of the Secretary under section 201(d), the Secretary*
9 *shall establish procedures, with appropriate controls on ac-*
10 *cess, for the sharing of homeland security information, in-*
11 *cluding vulnerability assessments, security plans, best prac-*
12 *tices and other laboratory biosecurity-related information,*
13 *as the Secretary determines appropriate, with State, local,*
14 *and tribal government authorities, including law enforce-*
15 *ment authorities and emergency response providers.*

16 “(b) *ACCESS TO INFORMATION IN DATABASES.*—*In*
17 *carrying out this section, the Secretary shall have access*
18 *to and may use information from the national databases*
19 *established under section 212(d)(2) of the Agricultural Bio-*
20 *terrorism Protection Act of 2002 (7 U.S.C. 8401(d)(2)) and*
21 *subsections (d)(2) and (f)(3) of section 351A of the Public*
22 *Health Service Act (42 U.S.C. 262a).*

23 “(c) *CLASSIFIED AND SENSITIVE INFORMATION.*—*The*
24 *Secretary shall ensure that any information disseminated*
25 *under this section is handled consistent with—*

1 “(1) the authority of the Director of National In-
2 telligence to protect intelligence sources and methods
3 under the National Security Act of 1947 (50 U.S.C.
4 401 et seq.) and related procedures or similar au-
5 thorities of the Attorney General concerning sensitive
6 law enforcement information;

7 “(2) section 552a of title 5, United States Code
8 (commonly referred to as the Privacy Act of 1974);
9 and

10 “(3) other relevant laws.

11 **“SEC. 2109. PERIODIC HOMELAND SECURITY REVIEW OF**
12 **CRIMINAL STATUTES.**

13 “(a) *IN GENERAL.*—The Secretary, in coordination
14 with the Attorney General and the heads of other Federal
15 departments and agencies, as appropriate, shall, for pur-
16 poses of enhancing homeland security—

17 “(1) periodically review and recommend updates
18 to criminal laws to ensure that such laws are well
19 suited to the evolving risks of misuse of life sciences
20 by terrorists and others; and

21 “(2) ensure that national biosecurity and bio-
22 defense stakeholders at unique risk of exploitation
23 have access to guidance regarding actions that can re-
24 duce the risk of misuse of life sciences by terrorists
25 and others.

1 “(b) *REPORT.*—Not later than one year after the date
 2 of the enactment of this section, and biannually thereafter,
 3 the Secretary, in coordination with the Attorney General,
 4 shall submit to the appropriate congressional committees
 5 the recommended updates to criminal laws, as described in
 6 subsection (a)(1).

7 “**SEC. 2110. EXPORT ENFORCEMENT FOR COUNTER-PRO-**
 8 **LIFERATION.**

9 “(a) *IN GENERAL.*—The Secretary, in coordination
 10 with the Secretary of Commerce, the Secretary of Defense,
 11 the Attorney General, the Secretary of State, the Director
 12 of National Intelligence, and the heads of other appropriate
 13 Federal agencies shall—

14 “(1) *conduct homeland security investigations*
 15 *and enforce criminal violations of customs and export*
 16 *laws of the United States related to military items,*
 17 *controlled commodities, and sanctioned or embargoed*
 18 *countries to prevent individuals, terrorist groups, for-*
 19 *foreign adversaries, and hostile nations from—*

20 “(A) *illegally obtaining sensitive United*
 21 *States technology and munitions; and*

22 “(B) *obtaining weapons of mass destruction*
 23 *components, precursors, and delivery systems, in-*
 24 *cluding—*

1 “(i) *United States military technical*
2 *data, hardware, small arms and defense*
3 *services;*

4 “(ii) *dual-use technical data/source*
5 *code and commodities; and*

6 “(iii) *deemed exports; and*

7 “(2) *conduct industry outreach with manufac-*
8 *turers and exporters of strategic commodities that*
9 *may be targeted for procurement by terrorist organi-*
10 *zations and the countries that support them as well*
11 *as countries identified as weapons proliferators, in a*
12 *manner that acknowledges commerce and trade, by—*

13 “(A) *educating companies and individuals*
14 *on the export laws of the United States;*

15 “(B) *discussing export licensing issues and*
16 *requirements;*

17 “(C) *identifying red flag indicators used in*
18 *illegal procurement;*

19 “(D) *identifying the government agencies*
20 *responsible for the licensing of export-controlled*
21 *commodities and technology; and*

22 “(E) *establishing and fostering relationships*
23 *whereby companies and individuals can report*
24 *suspicious contacts or attempts to violate the ex-*
25 *port laws of the United States.*

1 “(b) *NATIONAL EXPORT ENFORCEMENT COORDINA-*
2 *TION.—*

3 “(1) *ESTABLISHMENT; MEMBERSHIP.—There is*
4 *established in the Department a unit responsible for*
5 *national export enforcement coordination that is*
6 *managed by the Secretary. The unit shall be composed*
7 *of members who are representatives from the Depart-*
8 *ment, the Department of Commerce, the Department*
9 *of Defense, the Department of Energy, the Depart-*
10 *ment of Justice, the Department of State, the Intel-*
11 *ligence Community, and other Federal agencies as ap-*
12 *propriate.*

13 “(2) *RESPONSIBILITIES.—The unit shall carry*
14 *out the following responsibilities:*

15 “(A) *Coordinating law enforcement counter-*
16 *proliferation investigations and intelligence*
17 *counter-proliferation activities.*

18 “(B) *Addressing licensing inquiries, re-*
19 *views, requests, checks, and verifications.*

20 “(C) *Conducting outreach and providing*
21 *training to the export trade community.*

1 **“Subtitle B—Preparedness**

2 **“SEC. 2121. COMMUNICATION OF THREAT INFORMATION**
3 **AND ALERTS.**

4 “(a) *FINDINGS.*—Congress makes the following find-
5 *ings:*

6 “(1) *The Commission on the Prevention of*
7 *Weapons of Mass Destruction Proliferation and Ter-*
8 *rorism recommended that ‘the Federal Government*
9 *should practice greater openness of public information*
10 *so that citizens better understand the threat and the*
11 *risk this threat poses to them’.*

12 “(2) *There are unique challenges for community*
13 *preparedness for attacks from weapons of mass de-*
14 *struction and their agents.*

15 “(b) *TERRORISM THREAT AWARENESS.*—

16 “(1) *TERRORISM THREAT AWARENESS.*—*The*
17 *Secretary, in coordination with the heads of appro-*
18 *priate Federal agencies, shall ensure that homeland*
19 *security information concerning terrorist threats is*
20 *provided to State, local, and tribal authorities and*
21 *the public within the United States, as appropriate,*
22 *for purposes of preparedness and collective response to*
23 *terrorism and for other purposes.*

24 “(2) *THREAT BULLETINS.*—

1 “(A) *IN GENERAL.*—Consistent with the re-
2 quirements of paragraph (1), the Secretary shall,
3 on a timely basis, prepare unclassified ter-
4 rorism-related threat and risk assessments.

5 “(B) *REQUIREMENTS.*—Each assessment re-
6 quired under subparagraph (A) shall—

7 “(i) include guidance to the public for
8 preventing and responding to acts of ter-
9 rorism; and

10 “(ii) be made available on the Internet
11 website of the Department and other pub-
12 licly accessible Internet websites, commu-
13 nication systems, and information net-
14 works.

15 “(3) *GUIDANCE TO STATE, LOCAL, AND TRIBAL*
16 *AUTHORITIES.*—The Secretary—

17 “(A) acting through the Administrator of
18 the Federal Emergency Management Agency,
19 shall provide to State, local, and tribal authori-
20 ties written guidance on communicating ter-
21 rorism-related threats and risks to the public
22 within their jurisdictions; and

23 “(B) shall identify and articulate the gov-
24 ernmental rationale for identifying particular

1 *communities as being at heightened risk of ex-*
2 *ploitation.*

3 “(4) *USE OF EXISTING RESOURCES.*—*The Sec-*
4 *retary shall use Internet websites, communication sys-*
5 *tems, and information networks in operation on the*
6 *date of an assessment under this subsection to satisfy*
7 *the requirements of paragraph (2)(B)(ii). The Sec-*
8 *retary shall provide guidance on how State, local,*
9 *tribal, and private entities can partner with public*
10 *television stations to disseminate information pro-*
11 *vided by the Department and shall provide informa-*
12 *tion on best practices on disseminating information*
13 *to residents of local communities, including*
14 *leveraging public television stations.*

15 **“SEC. 2122. INDIVIDUAL AND COMMUNITY PREPAREDNESS**
16 **FOR WEAPONS OF MASS DESTRUCTION.**

17 “(a) *IN GENERAL.*—*The Secretary, acting through the*
18 *Administrator for the Federal Emergency Management*
19 *Agency, shall assist State, local, and tribal authorities in*
20 *improving and promoting individual and community pre-*
21 *paredness and collective response to weapons of mass de-*
22 *struction and terrorist attacks involving chemical, biologi-*
23 *cal, radiological, and nuclear materials against the United*
24 *States by—*

1 “(1) developing guidance and checklists of rec-
2 ommended actions for individual and community
3 prevention and preparedness efforts and dissemi-
4 nating such guidance and checklists to communities
5 and individuals;

6 “(2) disseminating the guidance developed under
7 section 2151 to communities and individuals, as ap-
8 propriate;

9 “(3) providing information and training mate-
10 rials in support of individual and community pre-
11 paredness efforts;

12 “(4) conducting individual and community pre-
13 paredness outreach efforts; and

14 “(5) such other actions as the Secretary deter-
15 mines appropriate.

16 “(b) *COORDINATION*.—Where appropriate, the Sec-
17 retary shall coordinate with private sector and nongovern-
18 mental organizations to promote individual and commu-
19 nity preparedness and collective response to weapons of
20 mass destruction and terrorist attacks involving chemical,
21 biological, radiological, and nuclear materials against the
22 United States.

23 “(c) *BEST PRACTICES*.—In compiling guidance for in-
24 dividual and community preparedness in order to carry out
25 subsection (a)(3), the Secretary shall give due regard to best

1 *practices based on the experience of other countries and*
2 *agencies and th expertise of academic institutions and non-*
3 *governmental organizations.*

4 **“Subtitle C—Detection**

5 **“SEC. 2131. NATIONAL BIOSURVEILLANCE STRATEGY.**

6 *“(a) CURRENT STATE OF BIOSURVEILLANCE.—The*
7 *Secretary shall examine of the state of domestic and global*
8 *biosurveillance.*

9 *“(b) STRATEGY FOR BIOSURVEILLANCE.—The Sec-*
10 *retary shall submit to the appropriate congressional com-*
11 *mittees a national strategy for biosurveillance.*

12 *“(c) MATTERS FOR INCLUSION.—*

13 *“(1) IN GENERAL.—In developing the strategy*
14 *required under subsection (b), the Secretary shall take*
15 *into consideration—*

16 *“(A) the state of biosurveillance domesti-*
17 *cally and internationally;*

18 *“(B) material threat assessments and deter-*
19 *minations developed by the Secretary in accord-*
20 *ance with the Project BioShield Act of 2004*
21 *(Public Law 108–276) and the amendments*
22 *made by that Act;*

23 *“(C) reports on global trends produced by*
24 *the Office of the Director of National Intelligence*
25 *regarding the biological threat;*

1 “(D) information available in biosurveil-
2 lance systems and changes to information tech-
3 nology to allow for the incorporation and inte-
4 gration of this information;

5 “(E) Intelligence Community needs as ar-
6 ticulated in relevant intelligence strategies; and

7 “(F) costs associated with establishing and
8 maintaining the necessary infrastructure to inte-
9 grate biosurveillance systems.

10 “(2) *ADDITIONAL REQUIREMENTS.*—*This strat-*
11 *egy required under subsection (b) shall—*

12 “(A) include a plan for advancing situa-
13 tional awareness;

14 “(B) identify key elements of information to
15 be shared, critical sensitivities to be protected,
16 and a framework for enabling information ex-
17 change;

18 “(C) include a plan for fostering informa-
19 tion sharing between law enforcement, security,
20 intelligence, and national biosecurity and bio-
21 defense stakeholders to identify potential threats,
22 reduce vulnerabilities and improve collective re-
23 sponse activities to and investigations of sus-
24 pected biological attacks; and

1 “(D) include strategic and implementation
2 plans for the National Biosurveillance Integra-
3 tion Center under section 316.

4 **“SEC. 2132. DETECTION OF BIOLOGICAL ATTACKS.**

5 “(a) PROGRAM.—The Secretary shall carry out a pro-
6 gram in the Department to detect a biological attack or
7 event. Through such program, the Secretary shall—

8 “(1) deploy detectors to areas, based on risk, to
9 indicate the presence of biological agents;

10 “(2) provide information to participating lab-
11 oratories for their use in monitoring public health,
12 and biological material from these detectors to par-
13 ticipating laboratories for testing;

14 “(3) provide information about the presence of
15 biological agents to public health and law enforcement
16 personnel at all levels of government; and

17 “(4) provide advanced planning tools, concepts of
18 operations (including alarm resolution protocols), and
19 training exercises for collective response to and recov-
20 ery from biological attacks.

21 “(b) PROGRAM REQUIREMENTS.—Under the program
22 required under subsection (a), the Secretary shall—

23 “(1) enter into memoranda of agreement or
24 interagency agreements under the Economy Act of
25 1933 (31 U.S.C. 1535 et seq.) with the Director of the

1 *Centers of Disease Control and Prevention and the*
2 *Administrator of the Environmental Protection Agen-*
3 *cy, and the heads of other Federal departments and*
4 *agencies, setting forth roles and responsibilities, in-*
5 *cluding with respect to filter testing protocols for par-*
6 *ticipating laboratories and coordination with appro-*
7 *priate State, local, and tribal agencies;*

8 *“(2) determine, on an annual basis, whether*
9 *plans for biological detector capabilities and coverage*
10 *sufficiently protect the United States population; and*

11 *“(3) acting through the Under Secretary for*
12 *Science and Technology, and in consultation with the*
13 *Director for the Centers for Disease Control and Pre-*
14 *vention, implement an assay equivalency program for*
15 *biological threat assays that—*

16 *“(A) may evaluate biological threat detec-*
17 *tion assays, their protocols for use, and their as-*
18 *sociated response algorithms for confirmation of*
19 *biological threat agents, taking performance*
20 *measures and concepts of operation into consid-*
21 *eration;*

22 *“(B) may develop assay equivalency stand-*
23 *ards based on the findings of the evaluation*
24 *under subparagraph (A);*

25 *“(C) will be updated as necessary;*

1 “(D) shall require implementation of the
2 standards developed under subparagraph (B) for
3 all Department biological detection programs;
4 and

5 “(E) shall make such standards available to
6 support all other Federal biological detection
7 programs.

8 “(c) *CONTRACT AUTHORITY.*—The Secretary is author-
9 ized to enter into contracts with participating laboratories
10 for—

11 “(1) the provision of laboratory services to test
12 detector filters on a fee-for-service basis or on a pre-
13 payment or other similar basis; and

14 “(2) administrative and other costs related to
15 hosting program personnel and equipment in these
16 laboratories.

17 “(d) *DEFINITIONS.*—In this section:

18 “(1) The term ‘participating laboratory’ means
19 a laboratory that has been accepted as a member of
20 the Laboratory Response Network for Bioterrorism
21 that—

22 “(A) is fully equipped to detect and respond
23 quickly to acts of biological terrorism;

24 “(B) provides biocontainment and micro-
25 biological analysis in support of the Department,

1 *the Federal Bureau of Investigation and other*
2 *law enforcement agencies with responsibilities for*
3 *investigating biological incidents; and*

4 “(C) *supports threat agent characterization*
5 *studies and assay evaluation, research and devel-*
6 *opment.*

7 “(2) *The term ‘assay’ means any scientific test*
8 *that is designed to detect the presence of a biological*
9 *threat agent that is of a type selected under criteria*
10 *established by the Secretary.*

11 **“SEC. 2133. RAPID BIOLOGICAL THREAT DETECTION AND**
12 **IDENTIFICATION.**

13 “(a) *IN GENERAL.—Notwithstanding section 302(4)*
14 *the Secretary shall require the Under Secretary for Science*
15 *and Technology, in consultation with the heads of other rel-*
16 *evant operational components of the Department, assess*
17 *whether the development of screening capabilities for bio-*
18 *logical agents, pandemic influenza, and other infectious dis-*
19 *eases should be undertaken by the Science and Technology*
20 *Directorate to support entry and exit screening at ports of*
21 *entry and for other purposes.*

22 “(b) *DEVELOPMENT OF METHODS.—If the Under Sec-*
23 *retary determines that the development of such screening*
24 *capabilities should be undertaken, the Secretary shall, to the*
25 *extent possible, initiate development of safe and effective*

1 *methods to rapidly screen incoming travelers at ports of*
2 *entry for biological agents, pandemic influenza, and other*
3 *infectious diseases.*

4 “(c) *COLLABORATION.*—*In developing methods under*
5 *subsection (b), the Secretary may collaborate with the heads*
6 *of other Federal agencies, as needed.*

7 **“SEC. 2134. ESTABLISHMENT OF THE SYSTEM ASSESSMENT**
8 **AND VALIDATION FOR EMERGENCY RE-**
9 **SPONDERS (SAVER) PROGRAM.**

10 *“The Secretary, acting through the Under Secretary*
11 *for Science and Technology, shall carry out a program for*
12 *system assessment and validation of emergency response*
13 *equipment at the Department, to be known as the ‘SAVER*
14 *Program’.* *The Secretary shall ensure that such program—*

15 “(1) *conducts objective, impartial, practitioner-*
16 *relevant, and operationally-oriented assessments and*
17 *validations of commercial emergency responder equip-*
18 *ment and systems, including hand-held detectors for*
19 *agents used in weapons of mass destruction;*

20 “(2) *is supported by a network of scientists who*
21 *perform the assessment and validation activities;*

22 “(3) *provides results along with other relevant*
23 *equipment information to the emergency response*
24 *provider community in an operationally useful form;*

1 “(4) provides information on equipment that
2 falls within the categories listed in the Department’s
3 authorized equipment list;

4 “(5) provides information that enables decision-
5 makers and responders to better select, procure, use
6 and maintain emergency responder equipment; and

7 “(6) shares such information nationally with the
8 emergency response provider community.

9 **“SEC. 2135. PAYMENT FOR BIOTERRORISM LABORATORY**
10 **SERVICES.**

11 *“In carrying out their functions, responsibilities, au-*
12 *thorities, and duties to counter biological terrorism, the Sec-*
13 *retary, the Attorney General, and the heads of other partici-*
14 *pating Federal agencies are authorized to enter into con-*
15 *tracts with the State and local public health laboratories*
16 *that compose the Laboratory Response Network for Bioter-*
17 *rorism, and any other qualified laboratories, for the provi-*
18 *sion of laboratory testing services on a fee-for-service basis*
19 *or on a prepayment or other similar basis.*

20 **“SEC. 2136. ESTABLISHMENT OF THE INTEGRATED CONSOR-**
21 **TIUM OF LABORATORY NETWORKS.**

22 *“(a) ESTABLISHMENT.—There is established in the De-*
23 *partment an Integrated Consortium of Laboratory Net-*
24 *works that is managed by the Secretary.*

1 “(b) *REQUIREMENTS.—The Integrated Consortium of*
2 *Laboratory Networks shall—*

3 “(1) *be composed of networks of laboratories ca-*
4 *pable of integrated and coordinated response to and*
5 *consequence management of attacks from weapons of*
6 *mass destruction, acts of terrorism, and other inci-*
7 *dents requiring laboratory response capabilities;*

8 “(2) *be a coordinated and operational system of*
9 *laboratory networks that provide timely, high quality*
10 *results for early detection and effective consequence*
11 *management of attacks from weapons of mass destruc-*
12 *tion, acts of terrorism, and other events requiring an*
13 *integrated laboratory response;*

14 “(3) *serve as a system of laboratory networks*
15 *that are equipped to detect and respond quickly to at-*
16 *tacks from weapons of mass destruction and acts of*
17 *terrorism;*

18 “(4) *provide limited containment and analysis*
19 *in support of the Department, the Federal Bureau of*
20 *Investigation, and other law enforcement agencies*
21 *with responsibilities for investigating incidents in-*
22 *volving weapons of mass destruction or their agents;*
23 *and*

24 “(5) *support threat agent characterization stud-*
25 *ies and assay evaluation, research and development.*

1 **“Subtitle D—Attribution**

2 **“SEC. 2141. BIOFORENSICS CAPABILITIES AND STRATEGY.**

3 “(a) *NATIONAL BIOFORENSICS ANALYSIS CENTER.—*

4 *There is established in the Department a National*
5 *Bioforensics Analysis Center which shall serve as the lead*
6 *Federal facility to—*

7 “(1) *provide definitive forensic examination of*
8 *biothreat agents and related evidence;*

9 “(2) *provide necessary biocontainment;*

10 “(3) *integrate bioforensics requirements for law*
11 *enforcement, national security, and homeland secu-*
12 *rity;*

13 “(4) *provide bioforensics analysis in support of*
14 *the executive agencies with primary responsibilities*
15 *for preventing, deterring, responding to, attributing,*
16 *and recovering from biological attacks;*

17 “(5) *develop national bioforensics standards;*

18 “(6) *maintain the national bioforensics reposi-*
19 *tory collection as a reference collection of biological*
20 *agents and toxins for bioforensics comparisons and*
21 *identifications; and*

22 “(7) *support threat agent characterization stud-*
23 *ies and bioforensics assay evaluation research and de-*
24 *velopment.*

1 “(b) *NATIONAL BIOFORENSICS REPOSITORY COLLEC-*
2 *TION.—*

3 “(1) *IN GENERAL.—The National Bioforensics*
4 *Analysis Center shall maintain a distributed national*
5 *bioforensics repository collection.*

6 “(2) *ACTIVITIES.—The national bioforensics re-*
7 *pository collection shall—*

8 “(A) *receive, store, and distribute biological*
9 *threat agents and toxins;*

10 “(B) *serve as a distributed reference collec-*
11 *tion for comparative bioforensics identifications*
12 *and characterizations; and*

13 “(C) *support threat agent characterization*
14 *studies and the development of bioforensics as-*
15 *says, genomic analyses, organic and inorganic*
16 *chemical analyses, electron microscopy analyses,*
17 *and other relevant assays, analyses, and tests.*

18 “(3) *PARTICIPATION.—*

19 “(A) *IN GENERAL.—The Secretary, the At-*
20 *torney General, the Secretary of Agriculture, the*
21 *Secretary of Defense, the Secretary of Energy,*
22 *the Secretary of Health and Human Services, the*
23 *Director of National Intelligence, and the head of*
24 *any other appropriate executive agency with a*
25 *biological agent or toxin collection that is useful*

1 *for the bioforensics analysis of biological attacks,*
2 *performance of biological threat agent identifica-*
3 *tion and characterization studies, or evaluation*
4 *and development of bioforensics assays and meth-*
5 *ods shall provide to the distributed national*
6 *bioforensics repository collection authenticated*
7 *replicate samples of, or information on, all rel-*
8 *evant biological strains and toxins, as deter-*
9 *mined by the Secretary, in consultation with the*
10 *head of the executive agency possessing the agent*
11 *or toxin.*

12 “(B) *OTHER BIOLOGICAL AGENTS AND TOX-*
13 *INS.—The Secretary shall require the contribu-*
14 *tion to the national bioforensics repository collec-*
15 *tion of authenticated replicate samples of, or in-*
16 *formation on, all relevant biological strains and*
17 *toxins, as determined by the Secretary, from*
18 *public and private biological agent and toxin*
19 *collections that were collected or created with*
20 *support from a Federal grant or contract and*
21 *that support the functions described in para-*
22 *graph (2).*

23 “(4) *ACCESS.—The Secretary shall—*

24 “(A) *provide any executive agency that sub-*
25 *mits a biological agent or toxin, or information*

1 *on a biological agent or toxin, to the national*
2 *bioforensics repository collection with access to*
3 *the collection; and*

4 “(B) *establish a mechanism to provide pub-*
5 *lic and private entities with access to agents or*
6 *toxins in, or information regarding, the national*
7 *bioforensics repository collection, as determined*
8 *appropriate by the Secretary, with appropriate*
9 *protection of classified or law enforcement sen-*
10 *sitive information and intellectual property*
11 *rights.*

12 “(5) *REPORT.—*

13 “(A) *IN GENERAL.—Not later than one year*
14 *after the date of the enactment of this section,*
15 *and annually thereafter, the Secretary, in con-*
16 *sultation with the Attorney General, the Sec-*
17 *retary of Agriculture, the Secretary of Defense,*
18 *the Secretary of Energy, the Secretary of Health*
19 *and Human Services, the Director of National*
20 *Intelligence, and the head of any other appro-*
21 *priate executive agency that participates in or*
22 *contributes agents, or toxins, or information to*
23 *the national bioforensics repository collection,*
24 *shall submit to the appropriate committees of*

1 Congress a report regarding the national
2 bioforensics repository collection.

3 “(B) CONTENTS.—The report submitted
4 under subparagraph (A) shall—

5 “(i) discuss the status of the establish-
6 ment of the distributed national bioforensics
7 repository collection;

8 “(ii) identify domestic and inter-
9 national biological agent and toxin collec-
10 tions that would prove useful in carrying
11 out the functions of the distributed national
12 bioforensics repository collection;

13 “(iii) examine any access or participa-
14 tion issues affecting the establishment of the
15 distributed national bioforensics repository
16 collection or the ability to support
17 bioforensics analysis, threat agent charac-
18 terization studies, or bioforensics assay eval-
19 uation, research, and development, includ-
20 ing—

21 “(I) intellectual property con-
22 cerns;

23 “(II) access to collected or created
24 biological agent or toxin collections
25 funded by a Federal grant or contract;

1 “(III) costs incurred by domestic
2 and international biological agent and
3 toxin collections to access or contribute
4 biological agents or toxins to the na-
5 tional bioforensics repository collection;
6 and

7 “(IV) access to the national
8 bioforensics repository collection by
9 public and private researchers to sup-
10 port threat agent characterization
11 studies, bioforensics assay evaluation,
12 research, and development, and bio-
13 security research and development; and

14 “(iv) other issues determined appro-
15 priate.

16 “(c) NATIONAL BIOFORENSICS STRATEGY.—

17 “(1) IN GENERAL.—The Secretary, in coordina-
18 tion with the Attorney General, the Secretary of Agri-
19 culture, the Secretary of Defense, the Secretary of
20 Health and Human Services, the Director of National
21 Intelligence, and the head of any other appropriate
22 executive agency, as determined by the Secretary,
23 shall develop, coordinate, and maintain a national
24 bioforensics strategy.

1 “(2) CONTENTS.—*The national bioforensics*
2 *strategy shall—*

3 “(A) *provide for a coordinated approach*
4 *across all executive agencies with responsibilities*
5 *for—*

6 “(i) *conducting bioforensics examina-*
7 *tion of biological threat agents and related*
8 *evidence; and*

9 “(ii) *generating bioforensics require-*
10 *ments for law enforcement, national secu-*
11 *rity, and homeland security;*

12 “(B) *describe the roles and responsibilities*
13 *of all relevant executive agencies, including—*

14 “(i) *research to characterize threat*
15 *agents;*

16 “(ii) *assay evaluation, research, and*
17 *development; and*

18 “(iii) *funding;*

19 “(C) *establish mechanisms, in coordination*
20 *with State, local, and tribal authorities, for co-*
21 *ordinating with public health, homeland secu-*
22 *rity, and law enforcement agencies for the collec-*
23 *tion or receipt, transfer, or submission of*
24 *bioforensics evidence for analysis and its use;*
25 *and*

1 “(D) include—

2 “(i) guidance for collecting, processing,
3 and analyzing samples;

4 “(ii) requirements for reporting
5 bioforensics information to appropriate
6 agencies; and

7 “(iii) requirements for the distributed
8 national bioforensics repository collection.

9 “(3) REPORT.—Not later than one year after the
10 date of the enactment of this section, and biennially
11 thereafter, the Secretary, in consultation with the At-
12 torney General, the Secretary of Agriculture, the Sec-
13 retary of Defense, the Secretary of Health and
14 Human Services, the Director of National Intel-
15 ligence, and the heads of other appropriate agencies,
16 as determined by the Secretary, shall submit to the
17 appropriate committees of Congress the national
18 bioforensics strategy.

19 “(d) CONCEPT OF OPERATIONS.—The Secretary, in co-
20 ordination with the Attorney General and the heads of any
21 other appropriate Federal agencies shall ensure the avail-
22 ability of a detailed concept of operations for information
23 sharing and all-source analysis to support timely attribu-
24 tion of biological attacks.

1 “(e) *DETAILEE PROGRAM.*—Subject to the availability
2 of appropriations, the Secretary may implement a detailee
3 program to detail from governmental entities national bio-
4 security and biodefense stakeholders with appropriate clear-
5 ances, on a reimbursable basis, to the National Bioforensics
6 Analysis Center for the purpose of—

7 “(1) providing training and other educational
8 benefits for such stakeholders to help them to better
9 understand the policies, procedures, and laws gov-
10 erning national bioforensics activities; and

11 “(2) bolstering the capabilities and information
12 sharing activities of the National Bioforensics Anal-
13 ysis Center with national biosecurity and biodefense
14 stakeholders.

15 “(f) *RESEARCH AND DEVELOPMENT.*—The Secretary,
16 in coordination with the Attorney General and the heads
17 of any other appropriate Federal agencies, shall establish
18 a national-level research and development strategy and im-
19 plementation plan to advance the field of bioforensics.

20 “(g) *DEFINITION OF BIOFORENSICS.*—In this section,
21 the term ‘bioforensics’ means the scientific discipline dedi-
22 cated to analyzing evidence from an attack with a biological
23 weapon of mass destruction, an act of bioterrorism, a bio-
24 logical agent- or toxin-based criminal act, or the inad-

1 *vertent release of a biological agent or toxin for attribution*
2 *purposes.*

3 **“SEC. 2142. FEDERAL LAW ENFORCEMENT TRAINING TO IN-**
4 **VESTIGATE BIOLOGICAL THREATS.**

5 *“The Secretary, in coordination with the Attorney*
6 *General, the Secretary of Agriculture, the Secretary of*
7 *Health and Human Services, and the heads of other appro-*
8 *priate Federal departments and agencies, shall make avail-*
9 *able to law enforcement, public health, and security per-*
10 *sonnel at the Federal Law Enforcement Training Center*
11 *training on recognizing and responding to situations in-*
12 *volving potential biological threats, including performing*
13 *joint criminal and epidemiological investigations, and*
14 *shall—*

15 *“(1) ensure that tailored tactics, techniques, and*
16 *procedures are made available to law enforcement and*
17 *security personnel, including access to the tools needed*
18 *to respond to biological threats;*

19 *“(2) promote the use of simulation among Fed-*
20 *eral partners to exercise capabilities, refine oper-*
21 *ational concepts, and strengthen relationships across*
22 *the Government; and*

23 *“(3) make training available that will ensure*
24 *that law enforcement, public health, and agricultural*
25 *investigations of biological threats are coordinated.*

1 **“Subtitle E—Response**

2 **“SEC. 2151. FIRST RESPONDER GUIDANCE CONCERNING**
3 **WEAPONS OF MASS DESTRUCTION ATTACKS.**

4 “(a) *ESTABLISHMENT OF VOLUNTARY GUIDANCE.—*
5 *Not later than one year after the date of the enactment of*
6 *this section, the Secretary shall—*

7 “(1) *develop for police, fire, emergency medical*
8 *services, emergency management, and public health*
9 *personnel, voluntary guidance for responding to a re-*
10 *lease of chemical, biological, radiological, or nuclear*
11 *material;*

12 “(2) *in developing the guidance under paragraph*
13 *(1), review the experiences of other countries and the*
14 *expertise of academic institutions and non-govern-*
15 *mental organizations; and*

16 “(3) *make such guidance available to State,*
17 *local, and tribal authorities, nongovernmental organi-*
18 *zations, the private sector, and the public.*

19 “(b) *CONTENTS.—The guidance developed under sub-*
20 *section (a)(1) shall include—*

21 “(1) *protective action guidance for ensuring the*
22 *security, health, and safety of emergency response*
23 *providers;*

1 “(2) *specific information regarding the effects of*
2 *the chemical, biological, radiological, or nuclear mate-*
3 *rial on those exposed to the agent; and*

4 “(3) *best practices for emergency response pro-*
5 *viders to effectively deal with individuals affected by*
6 *an incident involving chemical, biological, radio-*
7 *logical, or nuclear material.*

8 “(c) *REVIEW AND REVISION OF GUIDANCE.—The Sec-*
9 *retary shall—*

10 “(1) *review the guidance developed under sub-*
11 *section (a)(1) at least once every 2 years,*

12 “(2) *make revisions to the guidance as appro-*
13 *priate; and*

14 “(3) *make any revised guidance available to*
15 *State, local, and tribal authorities, nongovernmental*
16 *organizations, the private sector, and the public.*

17 “(d) *PROCEDURES FOR DEVELOPING AND REVISING*
18 *GUIDANCE.—In carrying out the requirements of this sec-*
19 *tion, the Secretary shall establish procedures to—*

20 “(1) *inventory existing relevant hazardous mate-*
21 *rial response guidance;*

22 “(2) *enable members of the first responder and*
23 *first provider community to submit recommendations*
24 *of areas in which guidance is needed and could be de-*
25 *veloped under subsection (a)(1);*

1 “(3) *determine which entities should be consulted*
2 *in developing or revising the guidance;*

3 “(4) *prioritize, on a regular basis, guidance that*
4 *should be developed or revised; and*

5 “(5) *develop and disseminate the guidance in ac-*
6 *cordance with the prioritization under paragraph (4).*

7 “(e) *CONSULTATIONS.—The Secretary shall develop*
8 *and revise the guidance developed under subsection (a)(1),*
9 *and the procedures required under subsection (d), in con-*
10 *sultation with—*

11 “(1) *the heads of other Federal departments and*
12 *agencies, as appropriate;*

13 “(2) *the National Advisory Council established*
14 *under section 508;*

15 “(3) *the National Domestic Preparedness Consor-*
16 *tium;*

17 “(4) *State, local, and tribal authorities; and*

18 “(5) *nongovernmental organizations and private*
19 *industry.*

20 “(f) *REPORTING REQUIREMENTS.—Not later than 18*
21 *months after the date of the enactment of this section and*
22 *annually thereafter, the Secretary shall submit to the ap-*
23 *propriate congressional committees—*

24 “(1) *a description of the procedures established*
25 *under subsection (d);*

1 “(2) any guidance in effect on the date of the re-
2 port;

3 “(3) a list of entities to which the guidance de-
4 scribed in paragraph (2) was disseminated;

5 “(4) a plan for reviewing the guidance described
6 in paragraph (2), in accordance with subsection (e);

7 “(5) guidance required under subsection (d)(4),
8 and the methodology used by the Secretary for such
9 prioritization; and

10 “(6) a plan for developing, revising, and dis-
11 seminating the guidance.

12 **“SEC. 2152. INTEGRATED PLUME MODELING FOR COLLEC-**
13 **TIVE RESPONSE.**

14 “(a) *DEVELOPMENT.*—

15 “(1) *IN GENERAL.*—The Secretary shall acquire,
16 use, and disseminate integrated plume models to en-
17 able rapid response activities following a chemical,
18 biological, nuclear, or radiological attack or event.

19 “(2) *SCOPE.*—The Secretary shall—

20 “(A) ensure the rapid development and dis-
21 tribution of integrated plume models to appro-
22 priate officials of the Federal Government and
23 State, local, and tribal authorities to enable im-
24 mediate response to a chemical, biological, or ra-
25 diological attack or event;

1 “(B) establish mechanisms for dissemina-
2 tion by appropriate emergency response officials
3 of the integrated plume models described in
4 paragraph (1) to nongovernmental organizations
5 and the public to enable appropriate collective
6 response activities;

7 “(C) ensure that the development and dis-
8 semination of integrated plume models are as-
9 sessed during exercises administered by the De-
10 partment; and

11 “(D) ensure that lessons learned from as-
12 sessing the development and dissemination of in-
13 tegrated plume models during exercises adminis-
14 tered by the Department are put into the De-
15 partment of Homeland Security Lessons Learned
16 Information Sharing system.

17 “(b) REPORT.—Not later than one year after the date
18 of enactment of this section, and annually thereafter, the
19 Secretary shall submit to the appropriate congressional
20 committees a report regarding—

21 “(1) the acquisition, use, and dissemination of
22 integrated plume models under this section;

23 “(2) lessons learned from assessing the develop-
24 ment and dissemination of integrated plume models
25 during exercises administered by the Department; and

1 “(3) recommendations for improving integrated
2 plume models, as appropriate.

3 “(c) *DEFINITIONS.*—For purposes of this section:

4 “(1) The term ‘plume model’ means the assess-
5 ment of the location and prediction of the spread of
6 agents following a chemical, biological, radiological,
7 or nuclear attack or event.

8 “(2) The term ‘integrated plume model’ means a
9 plume model that integrates protective action guid-
10 ance and other information as the Secretary deter-
11 mines appropriate.

12 **“Subtitle F—Recovery**

13 **“SEC. 2161. RECOVERY AND RESTORATION FROM A BIO-**
14 **LOGICAL ATTACK OR INCIDENT GUIDANCE.**

15 “(a) *ESTABLISHMENT OF GUIDANCE.*—Not later than
16 one year after the date of the enactment of this section, the
17 Secretary, in coordination with the Administrator of the
18 Environmental Protection Agency and in consultation with
19 the Director of the Occupational Safety and Health Agency,
20 and the Director of the National Institute for Occupational
21 Safety and Health, shall develop and issue guidance for
22 clean-up and restoration of indoor and outdoor areas, in-
23 cluding subways and other mass transportation facilities,
24 that have been affected by a biological attack or event.

1 “(b) *CONTENTS.*—*The guidance developed under sub-*
2 *section (a) shall include—*

3 “(1) *acceptable levels of growth of the organism*
4 *in post-remediation area samples from affected sites;*

5 “(2) *standards for effective clean-up of affected*
6 *sites;*

7 “(3) *standards for safe post-event occupancy of*
8 *affected sites;*

9 “(4) *requirements to ensure that the decon-*
10 *tamination procedures for responding organizations*
11 *do not conflict;*

12 “(5) *requirements that each responding organi-*
13 *zation uses a uniform system for tracking costs and*
14 *performance of clean-up contractors;*

15 “(6) *levels of personal protection equipment;*

16 “(7) *maintenance of negative air pressure in*
17 *buildings;*

18 “(8) *standards for proper selection and use of*
19 *personal protective equipment;*

20 “(9) *air sampling procedures; and*

21 “(10) *how to develop occupational health and*
22 *safety plans that are appropriate for the specific risk*
23 *to responder health.*

24 “(c) *REVIEW AND REVISION OF GUIDANCE.*—*The Sec-*
25 *retary shall—*

1 “(1) not less frequently than once every 2 years,
2 review the guidance developed under subsection (a);

3 “(2) make revisions to the guidance as appro-
4 priate; and

5 “(3) make the revised guidance available to the
6 Federal government, State, local, and tribal authori-
7 ties, nongovernmental organizations, the private sec-
8 tor, and the public.

9 “(d) *PROCEDURES FOR DEVELOPING AND REVISING*
10 *GUIDANCE.*—In carrying out the requirements of this sec-
11 tion, the Secretary shall establish procedures to—

12 “(1) inventory existing relevant guidance;

13 “(2) enable the public to submit recommenda-
14 tions of areas in which guidance is needed;

15 “(3) determine which entities should be consulted
16 in developing or revising the guidance;

17 “(4) prioritize, on a regular basis, guidance that
18 should be developed or revised; and

19 “(5) develop and disseminate the guidance in ac-
20 cordance with the prioritization under paragraph (4).

21 “(e) *CONSULTATIONS.*—The Secretary shall develop
22 and revise the guidance developed under subsection (a), and
23 the procedures required under subsection (d), in consulta-
24 tion with—

1 “(1) the heads of other Federal departments and
2 agencies, as appropriate;

3 “(2) State, local, and tribal authorities; and

4 “(3) nongovernmental organizations and private
5 industry.

6 “(f) *REPORT*.—Not later than one year after the date
7 of the enactment of this section, and annually thereafter,
8 the Secretary shall provide appropriate congressional com-
9 mittees with—

10 “(1) a description of the procedures established
11 under subsection (d);

12 “(2) any guidance in effect on the date of the re-
13 port;

14 “(3) a list of entities to which the guidance de-
15 scribed in paragraph (2) were disseminated;

16 “(4) a plan for reviewing the guidance described
17 in paragraph (2), in accordance with subsection (e);

18 “(5) the prioritized list of the guidance required
19 under subsection (d)(4), and the methodology used by
20 the Secretary for such prioritization; and

21 “(6) a plan for developing, revising, and dis-
22 seminating the guidance.”.

23 “(b) *CLERICAL AMENDMENTS*.—The table of contents in
24 section 1(b) of such Act is amended by adding at the end
25 the following new items:

“TITLE XXI—WEAPONS OF MASS DESTRUCTION PREVENTION AND
PREPAREDNESS

“Subtitle A—Prevention and Deterrence

- “Sec. 2101. Weapons of Mass Destruction Intelligence and Information Sharing Unit.
- “Sec. 2102. Information sharing and collaboration for biosecurity and bio-defense.
- “Sec. 2103. Bioterrorism risk assessments.
- “Sec. 2104. Radiological materials security.
- “Sec. 2105. Enhanced biosecurity measures.
- “Sec. 2106. Tier I Material Threat Agent locations.
- “Sec. 2107. High containment biological laboratory security grants.
- “Sec. 2108. Laboratory biosecurity information sharing.
- “Sec. 2109. Periodic homeland security review of criminal statutes.
- “Sec. 2110. Export enforcement for counter-proliferation.

“Subtitle B—Preparedness

- “Sec. 2121. Communication of threat information and alerts.
- “Sec. 2122. Individual and community preparedness for weapons of mass destruction.

“Subtitle C—Detection

- “Sec. 2131. National biosurveillance strategy.
- “Sec. 2132. Detection of biological attacks.
- “Sec. 2133. Rapid biological threat detection and identification.
- “Sec. 2134. Establishment of the system assessment and validation for emergency responders (SAVER) program.
- “Sec. 2135. Payment for bioterrorism laboratory services.
- “Sec. 2136. Establishment of the integrated consortium of laboratory networks.

“Subtitle D—Attribution

- “Sec. 2141. Bioforensics capabilities and strategy.
- “Sec. 2142. Federal law enforcement training to investigate biological threats.

“Subtitle E—Response

- “Sec. 2151. First responder guidance concerning weapons of mass destruction attacks.
- “Sec. 2152. Integrated plume modeling for collective response.

“Subtitle F—Recovery

- “Sec. 2161. Recovery and restoration from a biological attack or incident guidance.

1 **SEC. 202. DEFINITIONS.**

2 *Section 2 of the Homeland Security Act of 2002 (6*
3 *U.S.C. 101) is amended by adding at the end the following*
4 *new paragraphs:*

5 *“(19) The term ‘weapon of mass destruction’ has*
6 *the meaning given that term in section 1403(1) fo the*
7 *Defense Against Weapons of Mass Destruction Act of*
8 *1996 (50 U.S.C. 2302).*

9 *“(20) The term ‘Intelligence Community’ has the*
10 *meaning given that term in section 3(4) of the Na-*
11 *tional Security Act of 1947 (50 U.S.C. 401a(4)).*

12 *“(21) The term ‘national biosecurity and bio-*
13 *defense stakeholders’ means officials from the Federal,*
14 *State, local, and tribal authorities and individuals*
15 *from the private sector who are involved in efforts to*
16 *prevent, deter, prepare for, detect, attribute, respond,*
17 *and recover from a biological attack or other phe-*
18 *nomena that may have serious health consequences for*
19 *the United States, including wide-scale fatalities or*
20 *infectious disease outbreaks.*

21 *“(22) The term ‘Tier I Material Threat Agent’*
22 *means a substance so designated under section*
23 *351A(a)(2) of the Public Health Service Act or section*
24 *212(a)(2) of the Agricultural Bioterrorism Protection*
25 *Act of 2002.”.*

1 **SEC. 203. DUAL-USE TERRORIST RISKS FROM SYNTHETIC**
2 **GENOMICS.**

3 (a) *SENSE OF CONGRESS.*—*It is the sense of Congress*
4 *that the field of synthetic genomics has the potential to fa-*
5 *cilitate enormous gains in fundamental discovery and bio-*
6 *technological applications, but it also has inherent dual-*
7 *use homeland security risks that must be managed.*

8 (b) *REQUIREMENT.*—*Not later than one year after the*
9 *date of enactment of this Act, the Secretary of Homeland*
10 *Security, acting through the Under Secretary of Homeland*
11 *Security for Science and Technology, shall examine and re-*
12 *port to the appropriate congressional committees on the*
13 *homeland security implications of the dual-use nature of*
14 *synthetic genomics, and if the Under Secretary determines*
15 *that such research is appropriate, may conduct research in*
16 *that area, including—*

17 (1) *determining the current capability of syn-*
18 *thetic nucleic acid providers to effectively differentiate*
19 *a legitimate customer from a potential terrorist or*
20 *other malicious actor;*

21 (2) *determining the current capability of syn-*
22 *thetic nucleic acid providers to effectively screen or-*
23 *ders for sequences of homeland security concern; and*

24 (3) *making recommendations regarding screen-*
25 *ing software, protocols, and other remaining capa-*
26 *bility gaps uncovered by the study.*

1 **SEC. 204. DISSEMINATION OF INFORMATION ANALYZED BY**
2 **THE DEPARTMENT TO STATE, LOCAL, TRIBAL,**
3 **AND PRIVATE ENTITIES WITH RESPONSIBIL-**
4 **ITIES RELATING TO HOMELAND SECURITY.**

5 (a) *RESPONSIBILITIES OF THE SECRETARY.*—Section
6 201(d)(8) of the Homeland Security Act of 2002 (6 U.S.C.
7 121(d)(8)) is amended by striking “and to agencies of
8 State” and all that follows and inserting “to State, local,
9 tribal, and private entities with such responsibilities, and,
10 as appropriate, to the public, in order to assist in pre-
11 venting, deterring, or responding to acts of terrorism
12 against the United States.”.

13 (b) *REPORT.*—Not later than one year after the date
14 of the enactment of this Act, the Secretary of Homeland Se-
15 curity shall submit to the appropriate congressional com-
16 mittees a report on the implementation of this section.

17 **SEC. 205. NATIONAL BIOSURVEILLANCE INTEGRATION CEN-**
18 **TER (NBIC).**

19 Section 316 of the Homeland Security Act of 2002 (6
20 U.S.C. 195b) is amended—

21 (1) in subsection (a), by striking “an office or
22 directorate of the Department” and all that follows
23 through the period at the end and inserting the fol-
24 lowing: “the Office of Intelligence and Analysis.”;

25 (2) in subsection (d)(2)(B)—

1 (A) by inserting “and disseminate” after
2 “integrate”; and

3 (B) by inserting “, including information
4 and intelligence generated elsewhere within the
5 Office of Intelligence and Analysis and the De-
6 partment,” after “information” ;

7 (3) in subsection (e)(1), by striking subpara-
8 graph (A) and inserting the following new subpara-
9 graph (A):

10 “(A) integrate biosurveillance information
11 into the NBIC, with the goal of promoting infor-
12 mation sharing between Federal, State, local,
13 and tribal authorities to detect biological attacks
14 and events of homeland concern;”;

15 (4) by amending paragraph (2) of subsection (f)
16 to read as follows:

17 “(2) *DETAIL OF PERSONNEL.*—The head of a
18 participating Federal department or agency shall de-
19 tail, on a reimbursable basis, any of the personnel of
20 that department or agency to the Department to as-
21 sist the NBIC in carrying out this section.”; and

22 (5) by redesignating subsection (j) as subsection
23 (k) and inserting after subsection (i) the following
24 new subsection (j):

1 “(j) *ANNUAL REPORT.*—Not later than one year after
2 the date of the enactment of the WMD Prevention and Pre-
3 paredness Act of 2010 and annually thereafter, the Sec-
4 retary shall submit to the appropriate congressional com-
5 mittees a report on—

6 “(1) the status of operations at the National Bio-
7 surveillance Integration Center of the Department
8 under section 316;

9 “(2) efforts by the Office of Intelligence and
10 Analysis to take responsibility for the National Bio-
11 surveillance Integration Center; and

12 “(3) efforts to integrate the biosurveillance efforts
13 of Federal, State, local, and tribal authorities.”.

14 **SEC. 206. REPORT ON ESTABLISHMENT OF THE SYSTEM AS-**
15 **SESSMENT AND VALIDATION FOR EMER-**
16 **GENCY RESPONDERS (SAVER) PROGRAM.**

17 *Not later than one year after the date of the enactment*
18 *of this Act, the Secretary of Homeland Security shall sub-*
19 *mit to the appropriate congressional committees a report*
20 *on the SAVER Program under section 2134 of the Home-*
21 *land Security Act of 2002, as added by section 201.*

22 **SEC. 207. NATIONAL ACADEMY OF SCIENCES STUDY OF FO-**
23 **RENSIC SCIENCE IN HOMELAND SECURITY.**

24 “(a) *STUDY.*—Not later than 90 days after the date of
25 the enactment of this Act, the Secretary of Homeland Secu-

1 rity, acting through the Under Secretary of Homeland Se-
2 curity for Science and Technology, shall seek to enter into
3 an agreement with the National Academy of Sciences to—

4 (1) conduct a study, building on previous studies
5 conducted by the National Academy of Sciences, on
6 the role of forensic science in homeland security; and

7 (2) issue recommendations to enhance this home-
8 land security capability to investigate attacks from
9 weapons of mass destruction, terrorist incidents, and
10 other crimes investigated by the Department.

11 (b) *REPORT.*—Not later than two years after the date
12 of the enactment of this Act, the Secretary shall submit to
13 the appropriate congressional committees a report con-
14 taining the results of the National Academy of Sciences
15 study required under subsection (a), together with any rec-
16 ommendations of the Secretary related thereto.

17 (c) *AUTHORIZATION OF APPROPRIATIONS.*—There is
18 authorized to be appropriated to the Department, for fiscal
19 year 2011, \$1,000,000 to carry out this section.

20 **SEC. 208. HARMONIZATION OF REGULATIONS.**

21 (a) *REGULATIONS UNDER PUBLIC HEALTH SERVICE*
22 *ACT.*—Not later than one year after the Secretary of Home-
23 land Security promulgates regulations or amendments
24 thereto to carry out section 2104 of the Homeland Security
25 Act of 2002, as added by section 201, the Secretary of

1 *Health and Human Services shall amend regulations pro-*
2 *mulgated under the Select Agent Program under section*
3 *351A(b)(1) of the Public Health Service Act (42 U.S.C.*
4 *262a(b)(1)) to ensure that such regulations are not redun-*
5 *dant or are not in conflict with the regulations promulgated*
6 *by the Secretary under such section 2104.*

7 **(b) REGULATIONS UNDER AGRICULTURE BIOTER-**
8 *RORISM PROTECTION ACT OF 2002.—Not later than one*
9 *year after the Secretary of Homeland Security promulgates*
10 *regulations or amendments thereto pursuant to such section*
11 *2104, the Secretary of Agriculture shall amend regulations*
12 *promulgated under the Select Agent Program under section*
13 *212(b)(1) of the Agricultural Bioterrorism Protection Act*
14 *of 2002 (7 U.S.C. 8401(b)(1)) to ensure that such regula-*
15 *tions are not redundant or are not in conflict with the regu-*
16 *lations promulgated by the Secretary under such section*
17 *2104.*

18 **SEC. 209. COMMUNICATIONS PLANNING FOR WEAPONS OF**
19 **MASS DESTRUCTION INFORMATION DISSEMI-**
20 **NATION.**

21 **(a) COMMUNICATIONS PLANS REQUIRED.—Section**
22 *653 of the Post-Katrina Emergency Management Reform*
23 *Act of 2006 (6 U.S.C. 753) is amended—*

1 (1) *in subsection (a)(4), by inserting after “man-*
2 *made disasters” the following “, and a communica-*
3 *tions plan described in subsection (f)”;* and

4 (2) *by adding at the end the following new sub-*
5 *section:*

6 “(f) *COMMUNICATIONS PLAN.—*

7 “(1) *IN GENERAL.—A communications plan de-*
8 *veloped under subsection (a)(4) shall be designed to*
9 *provide information to the public related to pre-*
10 *venting, preparing for, and responding to attacks*
11 *from weapons of mass destruction and acts of ter-*
12 *rorism;*

13 “(2) *CONSULTATION.—As appropriate, the Ad-*
14 *ministrator shall consult with State, local, and tribal*
15 *authorities and coordinate with other Federal depart-*
16 *ments and agencies in developing communications*
17 *plans under paragraph (1).*

18 “(3) *PRE-SCRIPTED MESSAGES AND MESSAGE*
19 *TEMPLATES.—*

20 “(A) *IN GENERAL.—The Administrator*
21 *shall develop and disseminate pre-scripted mes-*
22 *sages and message templates to be provided to*
23 *State, local, and tribal authorities so that those*
24 *authorities can quickly and rapidly disseminate*
25 *critical information to the public in anticipation*

1 *of, during, or in the immediate aftermath of an*
2 *attack from a weapon of mass destruction or ter-*
3 *rorist incident, and to be included in the Depart-*
4 *ment of Homeland Security’s Lessons Learned*
5 *Information Sharing system.*

6 “(B) *DEVELOPMENT AND DESIGN.—The*
7 *pre-scripted messages or message templates*
8 *shall—*

9 “(i) *be developed in consultation with*
10 *State, local, and tribal authorities and in*
11 *coordination with other appropriate Federal*
12 *departments and agencies;*

13 “(ii) *be designed to provide accurate,*
14 *essential, and appropriate information and*
15 *instructions to the population directly af-*
16 *ected by an incident, including informa-*
17 *tion regarding an evacuation, sheltering in*
18 *place, hospital surge operations, health, and*
19 *safety; and*

20 “(iii) *be designed to provide accurate,*
21 *essential, and appropriate information and*
22 *instructions to emergency response pro-*
23 *viders and medical personnel responding to*
24 *an incident.*

1 “(C) *COMMUNICATIONS FORMATS.*—*The Ad-*
2 *ministrator shall develop pre-scripted messages*
3 *or message templates under this paragraph in*
4 *multiple formats to ensure delivery—*

5 “(i) *in cases where the usual commu-*
6 *nications infrastructure is unusable; and*

7 “(ii) *to individuals with disabilities or*
8 *other special needs and individuals with*
9 *limited English proficiency.*

10 “(D) *DISSEMINATION AND TECHNICAL AS-*
11 *SISTANCE.*—*The Administrator shall ensure that*
12 *all pre-scripted messages and message templates*
13 *developed under this paragraph are made avail-*
14 *able to State, local, and tribal authorities so that*
15 *those authorities may incorporate them, as ap-*
16 *propriate, into their emergency plans. The Ad-*
17 *ministrator shall also make available relevant*
18 *technical assistance to those authorities to sup-*
19 *port communications planning.*

20 “(E) *EXERCISES.*—*To ensure that the pre-*
21 *scripted messages or message templates developed*
22 *under this paragraph can be effectively utilized*
23 *in a disaster or incident, the Administrator shall*
24 *incorporate such pre-scripted messages or mes-*
25 *sage templates into exercises conducted under the*

1 *National Exercise Program described in section*
2 *648 of the Post-Katrina Emergency Management*
3 *Reform Act of 2006 (6 U.S.C. 748).”.*

4 **(b) REPORT.**—*Not later than one year after the date*
5 *of the enactment of this Act, the Administrator shall submit*
6 *to the appropriate congressional committees the commu-*
7 *nications plans required to be developed under the amend-*
8 *ments made by subsection (a), including pre-scripted mes-*
9 *sages or message templates developed in conjunction with*
10 *the plans and a description of the means that will be used*
11 *to deliver these messages during such incidents.*

12 **SEC. 210. ENVIRONMENTAL RECOVERY FROM CHEMICAL, BI-**
13 **OLOGICAL, RADIOLOGICAL, AND NUCLEAR**
14 **ATTACKS.**

15 **(a) IN GENERAL.**—*To facilitate environmental recov-*
16 *ery from a chemical, biological, radiological, or nuclear at-*
17 *tack or other incident involving chemical, biological, radio-*
18 *logical, or nuclear materials and to foster collective response*
19 *to terrorism, the Administrator of the Environmental Pro-*
20 *tection Agency, in coordination with the Administrator of*
21 *the Federal Emergency Management Agency, shall assess*
22 *capability gaps in environmental recovery preparedness*
23 *and provide guidance to State, local, and tribal authorities.*

1 (b) *REQUIREMENTS.*—*In carrying out subsection (a),*
2 *the Administrator of the Environmental Protection Agency*
3 *shall—*

4 (1) *assess capability gaps in the Nation’s ability*
5 *to recover from chemical, biological, radiological, and*
6 *nuclear attacks or incidents, with specific attention*
7 *to—*

8 (A) *decontamination standards, gaps in*
9 *such standards, and recommendations for re-*
10 *search to minimize these gaps;*

11 (B) *environmental remediation methods;*
12 *and*

13 (C) *such other components as determined by*
14 *the Secretary;*

15 (2) *disseminate guidance to State, local, and*
16 *tribal authorities that conforms to the goals of the Na-*
17 *tional Disaster Recovery Strategy as required in Sec-*
18 *tion 682 of the Department of Homeland Security*
19 *Appropriations Act, 2007 (Public Law 109–295; 6*
20 *U.S.C. 771) regarding how to conduct environmental*
21 *remediation of contaminated areas, including—*

22 (A) *clarification of Federal roles and re-*
23 *sponsibilities for assisting State, local, and tribal*
24 *authorities; and*

1 (B) such other guidance as determined by
2 the Secretary; and

3 (3) develop exercises in consultation with State,
4 local, and tribal authorities and other appropriate
5 Federal agencies, to enhance collective response to and
6 recovery from chemical, biological, radiological and
7 nuclear attacks and incidents, including exercises that
8 address analysis, environmental cleanup methods,
9 and decontamination standards.

10 (c) *REPORT.*—Not later than one year after the date
11 of the enactment of this Act, the Administrator of the Envi-
12 ronmental Protection Agency shall submit to the appro-
13 priate congressional committees a report on the Adminis-
14 trator’s assessment under section 2162 of the Homeland Se-
15 curity Act of 2002, as added by section 201.

16 **SEC. 211. UNIVERSITY-BASED CENTERS FOR HOMELAND SE-**
17 **CURITY CRITERIA FOR DESIGNATION.**

18 Section 308(b)(2)(B)(iii) of the Homeland Security
19 Act of 2002 (6 U.S.C. 188(b)(2)(B)(iii)) is amended by in-
20 serting before the period at the end the following “, includ-
21 ing medical readiness training and research, and commu-
22 nity resiliency for public health and healthcare critical in-
23 frastructure”.

1 **TITLE III—PUBLIC HEALTH**
2 **MATTERS**

3 **SEC. 301. NATIONAL MEDICAL COUNTERMEASURE DIS-**
4 **PENSING STRATEGY.**

5 *Title III of the Public Health Service Act is amended*
6 *by inserting after section 319F-4 (42 U.S.C. 247d-6e) the*
7 *following:*

8 **“SEC. 319F-5. NATIONAL MEDICAL COUNTERMEASURE DIS-**
9 **PENSING STRATEGY.**

10 “(a) *DEFINITIONS.—In this section—*

11 “(1) *the term ‘dispense’ means to provide med-*
12 *ical countermeasures to an affected population in re-*
13 *sponse to a threat or incident; and*

14 “(2) *the term ‘medical countermeasure’ means a*
15 *qualified countermeasure (as defined in section 319F-*
16 *1(a)(2)).*

17 “(b) *STRATEGY.—The Secretary, in coordination with*
18 *the Secretary of Homeland Security, the Secretary of Agri-*
19 *culture, and other appropriate Federal agencies, shall de-*
20 *velop, implement, and, as appropriate, periodically update*
21 *a National Medical Countermeasure Dispensing Strategy to*
22 *enhance preparedness and collective response to a terrorist*
23 *attack on humans or animals with any chemical, biological,*
24 *radiological, or nuclear material.*

1 **SEC. 303. NATIONAL PRE-EVENT VACCINATION AND ANTI-**
2 **MICROBIAL DISPENSING POLICY REVIEW.**

3 (a) *REQUIREMENT.*—*The Secretary of Health and*
4 *Human Services, in coordination with the Secretary of*
5 *Homeland Security, shall review the adequacy of domestic*
6 *vaccination and antimicrobial dispensing policy, guidance,*
7 *and information provided to the public in light of any*
8 *known terrorist risk of a biological attack or other phe-*
9 *nomena that may have serious health consequences for the*
10 *United States, including wide-scale fatalities or infectious*
11 *disease outbreaks. In carrying out the review under this sec-*
12 *tion, the Secretary shall consider—*

13 (1) *material threat assessments and determina-*
14 *tions conducted by the Department of Homeland Se-*
15 *curity;*

16 (2) *reports on global trends and intelligence pro-*
17 *duced by the Office of the Director of National Intel-*
18 *ligence and the Intelligence Community regarding bi-*
19 *ological threats;*

20 (3) *the availability of domestic vaccine and*
21 *antimicrobials to dispense to the public, on a vol-*
22 *untary basis, in anticipation of a biological attack;*
23 *and*

24 (4) *making surplus or expiring domestic vaccine*
25 *and antimicrobials available to State, local, and trib-*

1 *as appropriate, shall by regulation designate as*
2 *‘Tier I Material Threat Agents’ those agents and*
3 *toxins—*

4 “(i) *that—*

5 “(I) *are determined by the Sec-*
6 *retary of Homeland Security under*
7 *section 319F-2(c)(2) to present a mate-*
8 *rial threat against the United States*
9 *population sufficient to affect national*
10 *security; and*

11 “(II) *are determined to warrant*
12 *designation after applying the criteria*
13 *in subparagraph (B); or*

14 “(ii) *that clearly present a material*
15 *threat to the Nation as otherwise deter-*
16 *mined by the Secretary or the Secretary of*
17 *Homeland Security.*

18 “(B) *CRITERIA.—In determining whether to*
19 *designate an agent or toxin as a Tier I Material*
20 *Threat Agent under subparagraph (A)(i), the*
21 *Secretary, in coordination with the Secretary of*
22 *Homeland Security, shall consider—*

23 “(i) *whether the agent or toxin can be*
24 *used effectively in a biological attack;*

1 “(ii) information available from any
2 biological or bioterrorism risk assessments
3 conducted by the Department of Homeland
4 Security and relevant assessments by other
5 agencies; and

6 “(iii) such other criteria and informa-
7 tion as the Secretary, in coordination with
8 the Secretary of Homeland Security, deter-
9 mines appropriate and relevant.

10 “(C) *INCLUSION OF AGENTS AND TOXINS*
11 *NOT PREVIOUSLY LISTED.*—All agents or toxins
12 designated by the Secretary as Tier I Material
13 Threat Agents shall be included on the list main-
14 tained by the Secretary pursuant to paragraph
15 (1).

16 “(D) *EVALUATION OF TIER I MATERIAL*
17 *THREAT AGENTS.*—The Secretary, in coordina-
18 tion with the Secretary of Homeland Security,
19 shall—

20 “(i) on an ongoing basis, consider the
21 inclusion of additional agents or toxins on
22 the list of Tier I Material Threat Agents, as
23 appropriate; and

24 “(ii) at least biennially, review the list
25 of Tier I Material Threat agents to deter-

1 *mine whether any agents or toxins should*
2 *be removed from the list.”; and*

3 *(3) in paragraph (3), as so redesignated—*

4 *(A) by striking “list under paragraph (1)”*
5 *and inserting “lists under paragraphs (1) and*
6 *(2)”;* and

7 *(B) by striking “revise the list” and insert-*
8 *ing “revise the lists”.*

9 ***(b) AGRICULTURAL BIOTERRORISM PROTECTION ACT***
10 ***OF 2002.—Section 212(a) of the Agricultural Bioterrorism***
11 ***Protection Act of 2002 (7 U.S.C. 8401(a)) is amended—***

12 *(1) by redesignating paragraph (2) as para-*
13 *graph (3);*

14 *(2) by inserting after paragraph (1) the fol-*
15 *lowing:*

16 ***“(2) TIER I MATERIAL THREAT AGENTS.—***

17 ***“(A) DESIGNATION OF TIER I: MATERIAL***
18 ***THREAT AGENTS.—Not later than one year after***
19 ***the date of the enactment of this paragraph, the***
20 ***Secretary, in coordination with the Secretary of***
21 ***Homeland Security, the Secretary of Health and***
22 ***Human Services, and other Federal officials as***
23 ***appropriate, shall by regulation designate as***
24 ***‘Tier I Material Threat Agents’ those agents and***
25 ***toxins—***

1 “(i) that—

2 “(I) are determined by the Sec-
3 retary of Homeland Security under
4 section 319F-2(c)(2) of the Public
5 Health Service Act to present a mate-
6 rial threat against the United States
7 population sufficient to affect national
8 security; and

9 “(II) are determined to warrant
10 designation after applying the criteria
11 in subparagraph (B); or

12 “(ii) that clearly present a material
13 threat to the Nation as otherwise deter-
14 mined by the Secretary or the Secretary of
15 Homeland Security.

16 “(B) CRITERIA.—In determining whether to
17 designate an agent or toxin as a Tier I Material
18 Threat Agent under subparagraph (A)(i), the
19 Secretary, in coordination with the Secretary of
20 Homeland Security, shall consider—

21 “(i) whether the agent or toxin can be
22 used effectively in a biological attack;

23 “(ii) information available from any
24 biological or bioterrorism risk assessments
25 conducted by the Department of Homeland

1 *Security and relevant assessments by other*
2 *agencies; and*

3 “(iii) *such other criteria and informa-*
4 *tion that the Secretary, in coordination*
5 *with the Secretary of Homeland Security,*
6 *determines appropriate and relevant.*

7 “(C) *INCLUSION OF AGENTS AND TOXINS*
8 *NOT PREVIOUSLY LISTED.—All agents or toxins*
9 *designated by the Secretary as Tier 1 Material*
10 *Threat Agents shall be included on the list main-*
11 *tained by the Secretary pursuant to paragraph*
12 *(1).*

13 “(D) *EVALUATION OF TIER I MATERIAL*
14 *THREAT AGENTS.—The Secretary, in coordina-*
15 *tion with the Secretary of Homeland Security,*
16 *shall—*

17 “(i) *on an ongoing basis, consider the*
18 *inclusion of additional agents or toxins on*
19 *the list of Tier I Material Threat Agents, as*
20 *appropriate; and*

21 “(ii) *at least biennially, review the list*
22 *of Tier I Material Threat agents to deter-*
23 *mine whether any agents or toxins should*
24 *be removed from the list.”; and*

25 *(3) in paragraph (3), as so redesignated—*

1 *functions, capabilities, authorities, and responsibilities of*
2 *NIH, BARDA, and Project BioShield. The process shall—*

3 “(1) *assign NIH responsibility for research and*
4 *development of technologies that range in development*
5 *from basic principles observed and reported up to*
6 *model or prototype demonstration in a relevant envi-*
7 *ronment;*

8 “(2) *assign BARDA responsibility for research*
9 *and development of technologies that range in devel-*
10 *opment from model or prototype demonstration in a*
11 *relevant environment up to a system qualified for ap-*
12 *plication through successful test and demonstration;*

13 “(3) *assign Project BioShield responsibility for*
14 *procurement of technologies that—*

15 “(A) *are qualified for application through*
16 *successful test and demonstration; and*

17 “(B) *meet the minimum statutory require-*
18 *ments for emergency use authorization in section*
19 *564 of the Federal Food, Drug, and Cosmetic*
20 *Act; and*

21 “(4) *include a formal agreement among NIH,*
22 *BARDA, and Project BioShield that—*

23 “(A) *identifies the need for any specific bio-*
24 *logical countermeasure, derived from information*
25 *developed under section 319F-2;*

1 “(B) identifies the current technology readi-
2 ness level of the countermeasure; and

3 “(C) requires the development of the biologi-
4 cal countermeasure from the current technology
5 readiness level through the procurement of the
6 countermeasure in accordance with paragraph
7 (3).

8 “(b) *RESPONSIBILITY OF NIH.*—For countermeasures
9 identified under subsection (a)(4)(A) that have a level of
10 development from basic principles observed and reported up
11 to model or prototype demonstration in a relevant environ-
12 ment, the Director of NIH shall conduct research and devel-
13 opment until the Director certifies to the Secretary of
14 Health and Human Services that—

15 “(1) the countermeasure has completed model or
16 prototype demonstration in a relevant environment;
17 or

18 “(2) the Director does not believe that completion
19 of model or prototype demonstration in a relevant en-
20 vironment is reasonably achievable.

21 “(c) *RESPONSIBILITY OF BARDA.*—For counter-
22 measures identified under subsection (a)(4)(A) that have a
23 level of development of model or prototype demonstration
24 in a relevant environment, including but not limited to
25 those countermeasures certified to have that level of develop-

1 *ment by the Director of NIH, the Director of BARDA shall*
2 *conduct research and development until the Director of*
3 *BARDA certifies to the Secretary of Health and Human*
4 *Services that—*

5 “(1) *the countermeasure has qualified for appli-*
6 *cation through successful test and demonstration; or*

7 “(2) *the Director does not believe that qualifica-*
8 *tion for application through successful test and dem-*
9 *onstration is reasonably achievable.*

10 “(d) *RESPONSIBILITY OF PROJECT BIOSHIELD.—For*
11 *countermeasures identified under subsection (a)(4)(A) that*
12 *are qualified for application through successful test and*
13 *demonstration, including but not limited to those counter-*
14 *measures certified to have qualified for application through*
15 *successful test and demonstration by the Director of*
16 *BARDA, the Assistant Secretary of Health and Human*
17 *Services for Preparedness and Response shall use the Project*
18 *BioShield special reserve fund to may procure the counter-*
19 *measure if the countermeasure meets the requirements for*
20 *emergency use authorization described in subsection*
21 *(a)(3)(B).*

22 “(e) *NO REQUIREMENT FOR FOOD AND DRUG ADMIN-*
23 *ISTRATION GENERAL USE APPROVAL.—The Secretary shall*
24 *ensure that the Directors of NIH and BARDA and the As-*
25 *stant Secretary of Health and Human Services for Pre-*

1 *paredness and Response do not discontinue any research,*
2 *development, or procurement of a countermeasure identified*
3 *under subsection (a)(4)(A) because the Food and Drug Ad-*
4 *ministration has not, or decides against, approving or li-*
5 *censing the countermeasure for general use under chapter*
6 *V of the Federal Food, Drug, and Cosmetic Act or section*
7 *351 of this Act, as applicable.*

8 “(f) *INNOVATION.*—*The Secretary shall require the Di-*
9 *rectors of NIH and BARDA and the Assistant Secretary*
10 *of Health and Human Services for Preparedness and Re-*
11 *sponse to aggressively pursue innovative research, develop-*
12 *ment, and procurement of each countermeasure identified*
13 *under subsection (a)(4)(A).*

14 “(g) *DEFINITIONS.*—*In this section:*

15 “(1) *The term ‘BARDA’ means the he Bio-*
16 *medical Advanced Research and Development Author-*
17 *ity established under section 319L(c).*

18 “(2) *The term ‘NIH’ means the National Insti-*
19 *tutes of Health.*

20 “(3) *The term ‘Project Bioshield’ means the Fed-*
21 *eral medical countermeasure procurement program es-*
22 *tablished by Public Law 108–276.’’.*

1 **TITLE IV—FOREIGN RELATIONS**
2 **MATTERS**

3 **SEC. 401. INTERNATIONAL COLLABORATION AND INFORMA-**
4 **TION SHARING RELATING TO BIOSECURITY.**

5 *The Secretary of State, in coordination with the Sec-*
6 *retary of Homeland Security, the Secretary of Agriculture,*
7 *the Secretary of Health and Human Services, and the heads*
8 *of other appropriate Federal agencies, shall—*

9 (1) *support efforts in other countries and regions*
10 *to develop mechanisms and capabilities for reporting*
11 *to United Nations organizations validated data on bi-*
12 *ological attacks or other phenomena that may have se-*
13 *rious health consequences for the United States, in-*
14 *cluding wide-scale fatalities or infectious disease out-*
15 *breaks;*

16 (2) *engage other Federal and nongovernmental*
17 *entities and other countries to advance awareness and*
18 *understanding of the risk posed by information de-*
19 *derived from the life sciences that has the potential for*
20 *misuse to cause harm, and advance recommendations*
21 *on how best to address such risk;*

22 (3) *engage such entities and countries to promote*
23 *greater awareness and understanding of the global*
24 *availability of and access to life science technologies*
25 *and materials; and*

1 (4) *promote the development and use of mecha-*
2 *nisms for reporting, preserving, and sharing data on*
3 *Federal programs and investments in international*
4 *scientific, agricultural, medical, and public health*
5 *collaborations in support of efforts to enhance global*
6 *biosecurity.*

7 **SEC. 402. INTERNATIONAL ENGAGEMENT TO ENHANCE BIO-**
8 **DEFENSE AND BIOSECURITY.**

9 *The Secretary of State, in coordination and consulta-*
10 *tion with the Secretary of Homeland Security, and the*
11 *heads other appropriate Federal agencies, shall, as appro-*
12 *priate—*

13 (1) *support efforts of other countries to establish*
14 *and build capacity to effectively implement legislation*
15 *criminalizing the development or use of biological*
16 *weapons or acts of bioterrorism;*

17 (2) *engage other countries and international*
18 *nongovernmental entities to develop and establish*
19 *common standards, guidance, and best practices for*
20 *actions relevant to preventing acts of bioterrorism*
21 *and the illicit use of life sciences;*

22 (3) *support the efforts of other countries to en-*
23 *hance biosecurity and safety practices at laboratories*
24 *and other facilities with materials that could be used*
25 *in biological weapons or in an act of bioterrorism;*

1 (4) *promote the development and adoption of*
2 *international guidance for the safety and security of*
3 *high-risk pathogens and toxins; and*

4 (5) *promote information sharing relating to*
5 *threats and best practices between the intelligence*
6 *community, Federal law enforcement, and inter-*
7 *national law enforcement and security officials.*

8 **SEC. 403. INTERAGENCY TASK FORCE ON BEST PRACTICES**
9 **FOR GLOBAL BIOPREPAREDNESS.**

10 (a) *SENSE OF CONGRESS.—It is the sense of Congress*
11 *that preparedness for a chemical, biological, radiological,*
12 *or nuclear incident must be undertaken not only domesti-*
13 *cally but also internationally. Specifically, there is a need*
14 *for a global preparedness architecture for such an event.*
15 *Congress supports efforts to provide an international forum*
16 *for discussion of key health security policies with inter-*
17 *national dimensions, and the establishment of a formal*
18 *United States interagency task force to develop best prac-*
19 *tices and recommendations for implementation of a global*
20 *preparedness architecture could enhance global prepared-*
21 *ness.*

22 (b) *ESTABLISHMENT OF TASK FORCE.—The Secretary*
23 *of State shall convene and lead an interagency task force*
24 *to examine—*

1 (1) *the state of global biopreparedness for a*
2 *major biological event;*

3 (2) *necessary components of a global bio-*
4 *preparedness architecture that would advance inter-*
5 *national health security, including considerations*
6 *of—*

7 (A) *risk assessments;*

8 (B) *prevention and deterrence;*

9 (C) *detection;*

10 (D) *regional stockpiling of medical counter-*
11 *measures, including considerations of—*

12 (i) *security of the stockpile;*

13 (ii) *delivery planning; and*

14 (iii) *legal dimensions of and obstacles*
15 *to implementing such an architecture;*

16 (E) *attribution;*

17 (F) *response;*

18 (G) *other elements that should be a compo-*
19 *nent of such an architecture; and*

20 (H) *obstacles to implementing such an ar-*
21 *chitecture;*

22 (3) *best practices for preparedness based on les-*
23 *sons learned from domestic efforts to address the above*
24 *issues, and that may be applicable internationally;*

1 (4) activities undertaken through the National
2 Strategy for Countering Biological Threats and the
3 International Health Regulations 2005, as well as
4 other activities deemed relevant by the task force; and

5 (5) the utility of working through existing inter-
6 national forums as a mechanism for distributing this
7 information to the international community.

8 (c) *MEMBERSHIP*.—Members of the task force shall in-
9 clude representatives from—

10 (1) the Department of Homeland Security;

11 (2) the Department of Health and Human Serv-
12 ices, including the Centers for Disease Control and
13 Prevention;

14 (3) the Department of Agriculture;

15 (4) the Department of Defense;

16 (5) the Department of Justice;

17 (6) the Department of State;

18 (7) the United States Agency for International
19 Development;

20 (8) the Director of National Intelligence;

21 (9) other Federal Departments and agencies, as
22 determined appropriate by the Secretary; and

23 (10) other national biosecurity and biodefense
24 stakeholders, including private sector, including the
25 pharmaceutical industry and the biological laboratory

1 *community, as determined appropriate by the Sec-*
2 *retary.*

3 *(d) REPORT.—Not later than 18 months after the date*
4 *of the enactment of this Act, the Secretary shall submit to*
5 *the appropriate congressional committees a report on the*
6 *findings of the task force established under this section.*

7 **SEC. 404. BIOLOGICAL AND TOXIN WEAPONS CONVENTION.**

8 *The Secretary of State shall—*

9 *(1) promote confidence in effective implementa-*
10 *tion of and compliance with the Convention on the*
11 *Prohibition of the Development, Production and*
12 *Stockpiling of Bacteriological (Biological) and Toxin*
13 *Weapons and on their Destruction (commonly re-*
14 *ferred to as the “Biological and Toxin Weapons Con-*
15 *vention”) by the States party to the Convention by*
16 *promoting transparency with respect to legitimate ac-*
17 *tivities and pursuing compliance diplomatically to*
18 *address concerns;*

19 *(2) promote universal membership in the Con-*
20 *vention;*

21 *(3) develop an action plan for increasing inter-*
22 *national adherence to the Convention; and*

23 *(4) ensure that United States participation in*
24 *Convention meetings is broadly inclusive of represent-*
25 *atives of relevant Federal departments and agencies.*

Union Calendar No. 411

11TH CONGRESS
2^D SESSION

H. R. 5498

[Report No. 111-659, Part I]

A BILL

To enhance homeland security by improving efforts to prevent, deter, prepare for, detect, attribute, respond to, and recover from an attack with a weapon of mass destruction, and for other purposes.

DECEMBER 22, 2010

The Committee on Energy and Commerce discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed