

Calendar No. 263112TH CONGRESS
1ST SESSION**S. 1855**

To amend the Public Health Service Act to reauthorize various programs under the Pandemic and All-Hazards Preparedness Act.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 10, 2011

Mr. BURR (for himself, Mr. HARKIN, Mr. ENZI, Mr. CASEY, Ms. MIKULSKI, Mr. ALEXANDER, Mr. LIEBERMAN, Ms. COLLINS, Mrs. HAGAN, Mr. ROBERTS, and Mr. BENNET) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

DECEMBER 16, 2011

Reported by Mr. HARKIN, with an amendment

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

A BILL

To amend the Public Health Service Act to reauthorize various programs under the Pandemic and All-Hazards Preparedness Act.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) **SHORT TITLE.**—This Act may be cited as the
 3 “Pandemic and All-Hazards Preparedness Act Reauthor-
 4 ization of 2011”.

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

Sec. 1. Short title; table of contents.

**TITLE I—STRENGTHENING NATIONAL PREPAREDNESS AND
 RESPONSE FOR PUBLIC HEALTH EMERGENCIES**

Sec. 101. National Health Security Strategy.

Sec. 102. Assistant Secretary for Preparedness and Response.

Sec. 103. Modernization of the National Disaster Medical System.

Sec. 104. Continuing the role of the Department of Veterans Affairs.

**TITLE II—OPTIMIZING STATE AND LOCAL ALL-HAZARDS
 PREPAREDNESS AND RESPONSE**

Sec. 201. Improving State and local public health security.

Sec. 202. Hospital preparedness and medical surge capacity.

Sec. 203. Enhancing situational awareness and biosurveillance.

TITLE III—ENHANCING MEDICAL COUNTERMEASURE REVIEW

Sec. 301. Special protocol assessment.

Sec. 302. Authorized use for medical products.

Sec. 303. Definitions.

Sec. 304. Enhancing medical countermeasure activities.

Sec. 305. Regulatory management plans.

Sec. 306. Report.

Sec. 307. Pediatric medical countermeasures.

Sec. 308. Technical and conforming amendments.

**TITLE IV—ACCELERATING MEDICAL COUNTERMEASURE
 ADVANCED RESEARCH AND DEVELOPMENT**

Sec. 401. BioShield.

Sec. 402. Biomedical Advanced Research and Development Authority.

Sec. 403. Strategic National Stockpile.

Sec. 404. National Biodefense Science Board.

1 **TITLE I—STRENGTHENING NA-**
 2 **TIONAL PREPAREDNESS AND**
 3 **RESPONSE FOR PUBLIC**
 4 **HEALTH EMERGENCIES**

5 **SEC. 101. NATIONAL HEALTH SECURITY STRATEGY.**

6 (a) IN GENERAL.—Section 2802 of the Public Health
 7 Service Act (42 U.S.C. 300hh-1) is amended—

8 (1) in subsection (a)(1), by striking “2009” and
 9 inserting “2014”; and

10 (2) in subsection (b)—

11 (A) in paragraph (3)—

12 (i) in the matter preceding subpara-
 13 graph (A), by inserting “and which may
 14 include dental health facilities” after
 15 “mental health facilities”; and

16 (ii) in subparagraph (D), by inserting
 17 “(which may include such dental health as-
 18 sets)” after “medical assets”;

19 (B) in paragraph (4)—

20 (i) in subparagraph (A), by inserting
 21 “, including the unique needs and consider-
 22 ations of individuals with disabilities,”
 23 after “medical needs of at-risk individ-
 24 uals”; and

1 (ii) in subparagraph (B), by inserting
 2 “the” before “purpose of this section”; and
 3 (C) by adding at the end the following:

4 “(7) COUNTERMEASURES.—

5 “(A) Promoting strategic initiatives to ad-
 6 vance countermeasures to diagnose, mitigate,
 7 prevent, or treat harm from any biological
 8 agent or toxin, chemical, radiological, or nuclear
 9 agent or agents.

10 “(B) For purposes of this paragraph the
 11 term ‘countermeasures’ has the same meaning
 12 as the terms ‘qualified countermeasures’ under
 13 section 319F-1, ‘qualified pandemic and epi-
 14 demic products’ under section 319F-3, and ‘se-
 15 curity countermeasures’ under section 319F-2.

16 “(8) MEDICAL AND PUBLIC HEALTH COMMU-
 17 NITY RESILIENCY.—Strengthening the ability of
 18 State and local communities to prepare for, respond
 19 to, and ensure resiliency in the event of public health
 20 emergencies, whether naturally occurring, uninten-
 21 tional, or deliberate by—

22 “(A) optimizing alignment and integration
 23 of medical and public health preparedness and
 24 response planning and capabilities with and into
 25 routine daily activities; and

1 “(B) promoting familiarity with local med-
2 ical and public health systems.”.

3 (b) ~~AT-RISK INDIVIDUALS.~~—Section 2814 of the
4 Public Health Service Act (42 U.S.C. 300hh-16) is
5 amended—

6 (1) by striking paragraph (7);

7 (2) by redesignating paragraphs (1) through
8 (6) and (8) as paragraphs (2) through (7) and (10),
9 respectively;

10 (3) by inserting before paragraph (2) (as so re-
11 designated), the following:

12 “(1) monitor emerging issues and concerns as
13 they relate to medical and public health prepared-
14 ness and response for at-risk individuals in the event
15 of a public health emergency declared by the Sec-
16 retary under section 319;” and

17 (4) by inserting after paragraph (7) (as so re-
18 designated), the following:

19 “(8) disseminate and, as appropriate, update
20 novel and best practices of outreach to and care of
21 at-risk individuals before, during, and following pub-
22 lic health emergencies in as timely a manner as is
23 practicable, including from the time a public health
24 threat is identified;

1 “(9) ensure that public health and medical in-
 2 formation distributed by the Department of Health
 3 and Human Services during a public health emer-
 4 gency is delivered in a manner that takes into ac-
 5 count the range of communication needs of the in-
 6 tended recipients, including at-risk individuals; and”.

7 **SEC. 102. ASSISTANT SECRETARY FOR PREPAREDNESS AND**
 8 **RESPONSE.**

9 Section 2811 of the Public Health Service Act (42
 10 U.S.C. 300hh-10) is amended—

11 (1) in subsection (b)(4), by adding at the end
 12 the following:

13 “(D) POLICY COORDINATION AND STRA-
 14 TEGIC DIRECTION.—Provide integrated policy
 15 coordination and strategic direction with re-
 16 spect to all matters related to Federal public
 17 health and medical preparedness and execution
 18 and deployment of the Federal response for
 19 public health emergencies and incidents covered
 20 by the National Response Plan developed pur-
 21 suant to section 502(6) of the Homeland Secu-
 22 rity Act of 2002, or any successor plan, before,
 23 during, and following public health emer-
 24 gencies.”;

1 (2) by striking subsection (e) and inserting the
2 following:

3 “(e) FUNCTIONS.—The Assistant Secretary for Pre-
4 paredness and Response shall—

5 “(1) have authority over and responsibility
6 for—

7 “(A) the National Disaster Medical System
8 (in accordance with section 301 of the Pan-
9 demic and All-Hazards Preparedness Act);

10 “(B) the Hospital Preparedness Coopera-
11 tive Agreement Program pursuant to section
12 319C-2;

13 “(C) the Medical Reserve Corps pursuant
14 to section 2813;

15 “(D) the Emergency System for Advance
16 Registration of Volunteer Health Professionals
17 pursuant to section 319I; and

18 “(E) administering grants and related au-
19 thorities related to trauma care under parts A
20 through C of title XII, such authority to be
21 transferred by the Secretary from the Adminis-
22 trator of the Health Resources and Services Ad-
23 ministration to such Assistant Secretary;

1 “(2) exercise the responsibilities and authorities
2 of the Secretary with respect to the coordination
3 of—

4 “(A) the Public Health Emergency Pre-
5 paredness Cooperative Agreement Program pur-
6 suant to section 319C-1;

7 “(B) the Strategic National Stockpile; and

8 “(C) the Cities Readiness Initiative;

9 “(3) align and coordinate medical and public
10 health preparedness and response grants and cooper-
11 ative agreements authorized under this Act, to the
12 extent possible, including program requirements,
13 timelines, and measurable goals, and in coordination
14 with the Secretary of Homeland Security, to—

15 “(A) optimize and streamline medical and
16 public health preparedness capabilities and the
17 ability of local communities to respond to public
18 health emergencies;

19 “(B) minimize duplication of efforts with
20 regard to medical and public health prepared-
21 ness and response programs; and

22 “(C) gather and disseminate best practices
23 among grant and cooperative agreement recipi-
24 ents, as appropriate;

1 “(4) carry out drills and operational exercises,
2 in coordination with the Department of Homeland
3 Security, the Department of Defense, and other ap-
4 plicable Federal departments and agencies, as nec-
5 essary and appropriate, to identify, inform, and ad-
6 dress gaps in and policies related to all-hazards med-
7 ical and public health preparedness, including exer-
8 cises based on—

9 “(A) identified threats for which counter-
10 measures are available and for which no coun-
11 termeasures are available; and

12 “(B) unknown threats for which no coun-
13 termeasures are available; and

14 “(5) assume other duties as determined appro-
15 priate by the Secretary.”; and

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

17 “(d) NATIONAL SECURITY PRIORITY.—The Sec-
18 retary, acting through the Assistant Secretary for Pre-
19 paredness and Response, shall on a periodic basis conduct
20 meetings, as applicable and appropriate, with the Assist-
21 ant to the President for National Security Affairs to pro-
22 vide an update on, and discuss, medical and public health
23 preparedness and response activities pursuant to this Act
24 and the Federal Food, Drug, and Cosmetic Act, including

1 progress on the development, approval, clearance, and li-
2 censure of medical countermeasures.

3 “(e) PUBLIC HEALTH EMERGENCY MEDICAL COUN-
4 TERMEASURES ENTERPRISE STRATEGY AND IMPLEMEN-
5 TATION PLAN.—

6 “(1) IN GENERAL.—Not later than 180 days
7 after the date of enactment of this subsection, and
8 every other year thereafter, the Secretary, acting
9 through the Assistant Secretary for Preparedness
10 and Response and in coordination with the Director
11 of the Biomedical Advanced Research and Develop-
12 ment Authority, the Director of the National Insti-
13 tutes of Health, the Director of the Centers for Dis-
14 ease Control and Prevention, and the Commissioner
15 of the Food and Drug Administration, shall develop
16 and submit to the appropriate committees of Con-
17 gress a coordinated strategy and accompanying im-
18 plementation plan for medical countermeasures to
19 address chemical, biological, radiological, and nu-
20 clear threats. Such strategy and plan shall be known
21 as the ‘Public Health Emergency Medical Counter-
22 measures Enterprise Strategy and Implementation
23 Plan’.

24 “(2) REQUIREMENTS.—The plan under para-
25 graph (1) shall—

1 “(A) consider and reflect the full spectrum
2 of medical countermeasure-related activities, in-
3 cluding research, advanced research, develop-
4 ment, procurement, stockpiling, deployment,
5 and distribution;

6 “(B) identify and prioritize near-term,
7 mid-term, and long-term priority qualified and
8 security countermeasure (as defined in sections
9 ~~319F-1~~ and ~~319F-2~~) needs and goals of the
10 Federal Government according to chemical, bio-
11 logical, radiological, and nuclear threat or
12 threats;

13 “(C) identify projected timelines, antici-
14 pated funding allocations, benchmarks, and
15 milestones for each medical countermeasure pri-
16 ority under subparagraph (B), including pro-
17 jected needs with regard to replenishment of
18 the Strategic National Stockpile;

19 “(D) be informed by the recommendations
20 of the National Biodefense Science Board pur-
21 suant to section ~~319M~~;

22 “(E) report on advanced research and de-
23 velopment awards and the date of the issuance
24 of contract awards, including awards made

1 through the special reserve fund (as defined in
2 section ~~319F-2(e)(10)~~);

3 ~~“(F) identify progress made in meeting the~~
4 ~~goals, benchmarks, and milestones identified~~
5 ~~under subparagraph (C) in plans submitted~~
6 ~~subsequent to the initial plan; and~~

7 ~~“(G) be made publically available.~~

8 ~~“(3) GAO REPORT.—~~

9 ~~“(A) IN GENERAL.—Not later than 1 year~~
10 ~~after the date on which a Public Health Emer-~~
11 ~~gency Medical Countermeasures Enterprise~~
12 ~~Strategy and Implementation Plan under this~~
13 ~~subsection is issued by the Secretary, the Gov-~~
14 ~~ernment Accountability Office shall conduct an~~
15 ~~independent evaluation and submit to the ap-~~
16 ~~propriate committees of Congress a report con-~~
17 ~~cerning such strategy and implementation plan.~~

18 ~~“(B) CONTENT.—The report described in~~
19 ~~subparagraph (A) shall review and assess—~~

20 ~~“(i) the near-term, mid-term, and~~
21 ~~long-term medical countermeasure needs~~
22 ~~and identified priorities of the Federal~~
23 ~~Government pursuant to paragraph (2)(B);~~

24 ~~“(ii) the activities of the Department~~
25 ~~of Health and Human Services with re-~~

1 spect to advanced research and develop-
2 ment pursuant to section 319L; and

3 “(iii) the progress made toward meet-
4 ing the goals, benchmarks, and milestones
5 identified in the Public Health Emergency
6 Medical Countermeasures Enterprise
7 Strategy and Implementation Plan under
8 this subsection.

9 “(f) INTERNAL MULTIYEAR PLANNING PROCESS.—

10 The Secretary shall develop, and update on an annual
11 basis, a coordinated 5-year budget plan based on the med-
12 ical countermeasure priorities and goals described in sub-
13 section (e). Each such plan shall—

14 “(1) include consideration of the entire medical
15 countermeasures enterprise, including—

16 “(A) basic research, advanced research and
17 development;

18 “(B) approval, clearance, licensure, and
19 authorized uses of products; and

20 “(C) procurement, stockpiling, mainte-
21 nance, and replenishment of all products in the
22 Strategic National Stockpile;

23 “(2) include measurable outputs and outcomes
24 to allow for the tracking of the progress made to-
25 ward identified goals;

1 ~~“(3) identify medical countermeasure life-cycle~~
2 ~~costs to inform planning, budgeting, and anticipated~~
3 ~~needs within the continuum of the medical counter-~~
4 ~~measure enterprise consistent with section 319F-2;~~
5 ~~and~~

6 ~~“(4) be made available to the appropriate com-~~
7 ~~mittees of Congress upon request.~~

8 ~~“(g) INTERAGENCY COORDINATION PLAN.—Not~~
9 ~~later than one year after the date of enactment of this~~
10 ~~subsection, the Secretary, in coordination with the Sec-~~
11 ~~retary of Defense, shall submit to the appropriate commit-~~
12 ~~tees of Congress a report concerning the manner in which~~
13 ~~the Department of Health and Human Services is coordi-~~
14 ~~nating with the Department of Defense regarding counter-~~
15 ~~measure activities to address chemical, biological, radio-~~
16 ~~logical, and nuclear threats. Such report shall include in-~~
17 ~~formation with respect to—~~

18 ~~“(1) the research, advanced research, develop-~~
19 ~~ment, procurement, stockpiling, and distribution of~~
20 ~~countermeasures to meet identified needs; and~~

21 ~~“(2) the coordination of efforts between the De-~~
22 ~~partment of Health and Human Services and the~~
23 ~~Department of Defense to address countermeasure~~
24 ~~needs for various segments of the population.~~

1 “(h) PROTECTION OF NATIONAL SECURITY.—In car-
 2 rying out subsections (e), (f), and (g), the Secretary shall
 3 ensure that information and items that could compromise
 4 national security are not disclosed.”.

5 **SEC. 103. MODERNIZATION OF THE NATIONAL DISASTER**
 6 **MEDICAL SYSTEM.**

7 Section 2812 of the Public Health Service Act (42
 8 U.S.C. 300hh–11) is amended—

9 (1) in subsection (a)(3), by adding at the end
 10 the following:

11 (A) in subparagraph (A), in clause (i) by
 12 inserting “, including at-risk individuals as ap-
 13 plicable” after “victims of a public health emer-
 14 gency”;

15 (B) by redesignating subparagraph (C) as
 16 subparagraph (E); and

17 (C) by inserting after subparagraph (B),
 18 the following:

19 “(C) CONSIDERATIONS FOR AT-RISK POPU-
 20 LATIONS.—The Secretary shall take steps to
 21 ensure that an appropriate specialized and fo-
 22 cused range of public health and medical capa-
 23 bilities are represented in the National Disaster
 24 Medical System, which take into account the

1 needs of at-risk individuals, in the event of a
2 public health emergency.”.

3 “(D) ADMINISTRATION.—The Secretary
4 may determine and pay claims for reimburse-
5 ment for services under subparagraph (A) di-
6 rectly or through contracts that provide for
7 payment in advance or by way of reimburse-
8 ment.”; and

9 (2) in subsection (g), by striking “such sums as
10 may be necessary for each of the fiscal years 2007
11 through 2011” and inserting “\$56,000,000 for each
12 of fiscal years 2012 through 2016”.

13 **SEC. 104. CONTINUING THE ROLE OF THE DEPARTMENT OF**
14 **VETERANS AFFAIRS.**

15 Section 8117(g) of title 38, United States Code, is
16 amended by striking “such sums as may be necessary to
17 carry out this section for each of fiscal years 2007 through
18 2011” and inserting “\$156,500,000 for each of fiscal
19 years 2012 through 2016 to carry out this section”.

1 **TITLE II—OPTIMIZING STATE**
 2 **AND LOCAL ALL-HAZARDS**
 3 **PREPAREDNESS AND RE-**
 4 **SPONSE**

5 **SEC. 201. IMPROVING STATE AND LOCAL PUBLIC HEALTH**
 6 **SECURITY.**

7 (a) COOPERATIVE AGREEMENTS.—Section 319C-1
 8 of the Public Health Service Act (42 U.S.C. 247d-3a) is
 9 amended—

10 (1) in subsection (b)(2)—

11 (A) in subparagraph (A)—

12 (i) by striking clauses (i) and (ii) and
 13 inserting the following:

14 “(i) a description of the activities such
 15 entity will carry out under the agreement
 16 to meet the goals identified under section
 17 2802, including with respect to chemical,
 18 biological, radiological, or nuclear threats;

19 “(ii) a description of the activities
 20 such entity will carry out with respect to
 21 pandemic influenza, as a component of the
 22 activities carried out under clause (i), and
 23 consistent with the requirements of para-
 24 graphs (2) and (5) of subsection (g);”;

1 (ii) in clause (iv), by striking “and” at
2 the end;

3 (iii) in clause (v), by adding “and”
4 after the semicolon; and

5 (iv) by adding at the end the fol-
6 lowing:

7 “(vi) a description of how, as appro-
8 priate, the entity may partner with rel-
9 evant public and private stakeholders in
10 public health emergency preparedness and
11 response”; and

12 (B) in subparagraph (C), by inserting “,
13 including addressing the needs of at-risk indi-
14 viduals,” after “capabilities of such entity”;

15 (2) in subsection (g)—

16 (A) in paragraph (1), by striking subpara-
17 graph (A) and inserting the following:

18 “(A) include outcome goals representing
19 operational achievements of the National Pre-
20 paredness Goals developed under section
21 2802(b) with respect to all-hazards, including
22 chemical, biological, radiological, or nuclear
23 threats”; and

24 (B) in paragraph (2)(A), by adding at the
25 end the following: “The Secretary shall periodi-

1 eally update, as necessary and appropriate,
 2 such pandemic influenza plan criteria and shall
 3 require the integration of such criteria into the
 4 benchmarks and standards described in para-
 5 graph (1).”; and

6 ~~(3)~~ in subsection (i)—

7 (A) in paragraph (1)(A)—

8 (i) by striking “\$824,000,000 for fis-
 9 cal year 2007” and inserting
 10 “\$632,900,000 for fiscal year 2012”; and

11 (ii) by striking “such sums as may be
 12 necessary for each of fiscal years 2008
 13 through 2011” and inserting
 14 “\$632,900,000 for each of fiscal years
 15 2013 through 2016”; and

16 (B) by adding at the end the following:

17 “(7) AVAILABILITY OF COOPERATIVE AGREE-
 18 MENT FUNDS.—

19 “(A) IN GENERAL.—Amounts provided to
 20 an eligible entity under a cooperative agreement
 21 under subsection (a) for a fiscal year and re-
 22 maining unobligated at the end of such year
 23 shall remain available to such entity for the
 24 next fiscal year for the purposes for which such
 25 funds were provided.

1 SIONALS.—Section 319I(k) of the Public Health
 2 Service Act (42 U.S.C. 247d–7b(k)) is amended by
 3 striking “\$2,000,000 for fiscal year 2002, and such
 4 sums as may be necessary for each of the fiscal
 5 years 2003 through 2011” and inserting
 6 “\$5,900,000 for each of fiscal years 2012 through
 7 2016”.

8 (2) VOLUNTEERS.—Section 2813 of the Public
 9 Health Service Act (42 U.S.C. 300hh–15) is amend-
 10 ed—

11 (A) in subsection (d)(2), by adding at the
 12 end the following: “Such training exercises
 13 shall, as appropriate and applicable, incorporate
 14 the needs of at-risk individuals in the event of
 15 a public health emergency.”; and

16 (B) in subsection (i), by striking
 17 “\$22,000,000 for fiscal year 2007, and such
 18 sums as may be necessary for each of fiscal
 19 years 2008 through 2011” and inserting
 20 “\$11,900,000 for each of fiscal years 2012
 21 through 2016”.

22 (c) PARTNERSHIPS FOR STATE AND REGIONAL PRE-
 23 PAREDNESS TO IMPROVE SURGE CAPACITY.—Section
 24 319C–2 of the Public Health Service Act (42 U.S.C.
 25 247d–3b) is amended—

1 (1) by striking subsection (e) and inserting the
2 following:

3 “~~(e) USE OF FUNDS.—An award under subsection~~
4 ~~(a) shall be expended for activities to achieve the prepared-~~
5 ~~ness goals described under paragraphs (1), (3), (4), (5),~~
6 ~~and (6) of section 2802(b) with respect to all hazards, in-~~
7 ~~cluding chemical, biological, radiological, or nuclear~~
8 ~~threats.”;~~

9 (2) by striking subsection (g) and inserting the
10 following:

11 “~~(g) COORDINATION.—~~

12 “~~(1) LOCAL RESPONSE CAPABILITIES.—An eli-~~
13 ~~gible entity shall, to the extent practicable, ensure~~
14 ~~that activities carried out under an award under~~
15 ~~subsection (a) are coordinated with activities of rel-~~
16 ~~evant local Metropolitan Medical Response Systems,~~
17 ~~local Medical Reserve Corps, the local Cities Read-~~
18 ~~iness Initiative, and local emergency plans.~~

19 “~~(2) NATIONAL COLLABORATION.—Partner-~~
20 ~~ships consisting of one or more eligible entities~~
21 ~~under this section may, to the extent practicable,~~
22 ~~collaborate with other partnerships consisting of one~~
23 ~~or more eligible entities under this section for pur-~~
24 ~~poses of national coordination and collaboration with~~
25 ~~respect to activities to achieve the preparedness~~

1 goals described under paragraphs (1), (2), (4), (5),
2 and (6) of section 2802(b).”; and

3 (3) in subsection (j)—

4 (A) in paragraph (1), by striking
5 “\$474,000,000 for fiscal year 2007, and such
6 sums as may be necessary for each of fiscal
7 years 2008 through 2011” and inserting
8 “\$378,000,000 for each of fiscal years 2012
9 through 2016”; and

10 (B) by adding at the end the following:

11 “(4) AVAILABILITY OF COOPERATIVE AGREE-
12 MENT FUNDS.—

13 “(A) IN GENERAL.—Amounts provided to
14 an eligible entity under a cooperative agreement
15 under subsection (a) for a fiscal year and re-
16 maining unobligated at the end of such year
17 shall remain available to such entity for the
18 next fiscal year for the purposes for which such
19 funds were provided.

20 “(B) FUNDS CONTINGENT ON ACHIEVING
21 BENCHMARKS.—The continued availability of
22 funds under subparagraph (A) with respect to
23 an entity shall be contingent upon such entity
24 achieving the benchmarks and submitting the

1 pandemic influenza plan as required under sub-
 2 section (i).”.

3 **SEC. 203. ENHANCING SITUATIONAL AWARENESS AND BIO-**
 4 **SURVEILLANCE.**

5 Section 319D of the Public Health Service Act (42
 6 U.S.C. 247d-4) is amended—

7 (1) in subsection (b)—

8 (A) in paragraph (1)(B), by inserting “poi-
 9 son control centers,” after “hospitals,”;

10 (B) in paragraph (2), by inserting before
 11 the period the following: “, allowing for coordi-
 12 nation to maximize all-hazards medical and
 13 public health preparedness and response and to
 14 minimize duplication of effort”; and

15 (C) in paragraph (3), by inserting before
 16 the period the following: “and update such
 17 standards as necessary”;

18 (2) in subsection (d)—

19 (A) in the subsection heading, by striking
 20 “PUBLIC HEALTH SITUATIONAL AWARENESS”
 21 and inserting “MODERNIZING PUBLIC HEALTH
 22 SITUATIONAL AWARENESS AND BIOSURVEIL-
 23 LANCE”;

24 (B) in paragraph (1)—

1 (i) by striking “Pandemic and All-
2 Hazards Preparedness Act” and inserting
3 “Pandemic and All-Hazards Preparedness
4 Act Reauthorization of 2011”; and

5 (ii) by inserting “, novel emerging
6 threats,” after “disease outbreaks”;

7 (C) by striking paragraph (2) and insert-
8 ing the following:

9 “(2) STRATEGY AND IMPLEMENTATION
10 PLAN.—Not later than 180 days after the date of
11 enactment of the Pandemic and All-Hazards Pre-
12 paredness Act Reauthorization of 2011, the Sec-
13 retary shall submit to the appropriate committees of
14 Congress, a coordinated strategy and an accom-
15 panying implementation plan that identifies and
16 demonstrates the measurable steps the Secretary will
17 carry out to—

18 “(A) develop, implement, and evaluate the
19 network described in paragraph (1), utilizing
20 the elements described in paragraph (3); and

21 “(B) modernize and enhance biosurveil-
22 lance activities.”;

23 (D) in paragraph (5), by striking subpara-
24 graph (A) and inserting the following:

1 “(A) utilize applicable interoperability
2 standards as determined by the Secretary, and
3 in coordination with the Office of the National
4 Coordinator for Health Information Tech-
5 nology, through a joint public and private sec-
6 tor process;” and

7 (E) by adding at the end the following:

8 “(6) CONSULTATION WITH THE NATIONAL BIO-
9 DEFENSE SCIENCE BOARD.—In carrying out this
10 section consistent with section 319M, the National
11 Biodefense Science Board shall provide expert advice
12 and guidance, including recommendations, regarding
13 the measurable steps the Secretary should take to
14 modernize and enhance biosurveillance activities pur-
15 suant to the efforts of the Department of Health
16 and Humans Services to ensure comprehensive, real-
17 time all-hazards biosurveillance capabilities. In com-
18 plying with the preceding sentence, the National
19 Biodefense Science Board shall—

20 “(A) identify the steps necessary to achieve
21 a national biosurveillance system for human
22 health, with international connectivity, where
23 appropriate, that is predicated on State, re-
24 gional, and community level capabilities and
25 creates a networked system to allow for two-

1 way information flow between and among Fed-
2 eral, State, and local government public health
3 authorities and clinical health care providers;
4 and

5 “(B) identify any duplicative surveillance
6 programs under the authority of the Secretary,
7 or changes that are necessary to existing pro-
8 grams, in order to enhance and modernize such
9 activities, minimize duplication, strengthen and
10 streamline such activities under the authority of
11 the Secretary, and achieve real-time and appro-
12 priate data that relate to disease activity, both
13 human and zoonotic.”;

14 (3) in subsection (e)(5), by striking “4 years
15 after the date of enactment of the Pandemic and
16 All-Hazards Preparedness Act, the Government Ac-
17 countability Office” and inserting “3 years after the
18 date of enactment of the Pandemic and All-Hazards
19 Preparedness Act Reauthorization of 2011”;

20 (4) in subsection (g), by striking “such sums as
21 may be necessary in each of fiscal years 2007
22 through 2011” and inserting “\$160,121,000 for
23 each of fiscal years 2012 through 2016”; and

24 (5) by adding at the end the following:

1 “(h) DEFINITION.—For purposes of this section the
 2 term ‘biosurveillance’ means the process of gathering near
 3 real-time, biological data that relates to disease activity
 4 and threats to human or zoonotic health, in order to
 5 achieve early warning of such health threats; early detec-
 6 tion of health events; and overall situational awareness of
 7 disease activity.”.

8 **TITLE III—ENHANCING MEDICAL** 9 **COUNTERMEASURE REVIEW**

10 **SEC. 301. SPECIAL PROTOCOL ASSESSMENT.**

11 Section 505(b)(5)(B) of the Federal Food, Drug, and
 12 Cosmetic Act (21 U.S.C. 355(b)(5)(B)) is amended by
 13 striking “size of clinical trials intended” and all that fol-
 14 lows through “. The sponsor or applicant” and inserting
 15 the following: “size—

16 “(i)(I) of clinical trials intended to form the
 17 primary basis of an effectiveness claim; or

18 “(II) in the case where human efficacy studies
 19 are not ethical or practicable; of animal and clinical
 20 trials which, in combination, are intended to form
 21 the primary basis of an effectiveness claim; or

22 “(ii) with respect to an application for approval
 23 of a biological product under section 351(k) of the
 24 Public Health Service Act, of any necessary clinical
 25 study or studies.

1 The sponsor or applicant”.

2 **SEC. 302. AUTHORIZED USE FOR MEDICAL PRODUCTS.**

3 Section 564 of the Federal Food, Drug, and Cosmetic
4 Act (21 U.S.C. 360bbb-3) is amended—

5 (1) in the section heading, by striking “**FOR**
6 **USE IN EMERGENCIES**” and inserting “**FOR USE**
7 **IN RESPONSE TO DECLARED EMERGENCY OR**
8 **IDENTIFIED MATERIAL THREAT**”;

9 (2) in subsection (a)—

10 (A) in paragraph (1)—

11 (i) in the paragraph heading, by strik-
12 ing “**EMERGENCY**” and inserting “**AU-**
13 **THORIZED**”; and

14 (ii) by striking “(referred to in this
15 section as an ‘emergency use’)” and insert-
16 ing “or with respect to a material threat
17 (referred to in this section as an ‘author-
18 ized use’)”;

19 (B) in paragraph (2), by striking “an
20 emergency use” and inserting “the use”;

21 (C) in paragraph (3), by striking “An
22 emergency use authorized” and inserting “An
23 authorized use”;

24 (D) by redesignating paragraph (4) as
25 paragraph (5);

1 (E) by inserting after paragraph (3) the
2 following:

3 “(4) EXTENSION OF EXPIRATION DATE.—

4 “(A) AUTHORITY TO EXTEND EXPIRATION
5 DATE.—The Secretary may extend the expira-
6 tion date of an approved product in accordance
7 with this paragraph.

8 “(B) EXPIRATION DATE.—For purposes of
9 this paragraph, the term ‘expiration date’
10 means the date that appears on the label of an
11 approved product to reflect the results of sta-
12 bility testing and to ensure that the product
13 meets applicable standards of identity, strength,
14 quality, and purity at the time of use.

15 “(C) EFFECT OF EXTENSION.—If the expi-
16 ration date of an approved product is extended
17 by the Secretary under this paragraph, then,
18 notwithstanding any other provision of this Act,
19 the extended expiration date shall not affect the
20 approval status of the product or the authoriza-
21 tion of the product under this section.

22 “(D) ELIGIBILITY.—A product shall be eli-
23 gible for extension of the expiration date of
24 such product if—

1 “(i)(I) the product is intended for use
2 to prevent, diagnose, or treat a disease or
3 condition involving a biological, chemical,
4 radiological, or nuclear agent or agents, in-
5 cluding a product intended to be used to
6 prevent or treat pandemic influenza; or

7 “(II) the product is intended for use
8 to prevent, diagnose, or treat a serious or
9 life-threatening disease or condition caused
10 by a product described in subclause (I);
11 and

12 “(ii) the product is intended for use
13 during the circumstances of an emergency
14 or a material threat described in sub-
15 section (b)(1).

16 “(E) DETERMINATIONS BY SECRETARY.—
17 Before extending the expiration date of an ap-
18 proved product under this paragraph, the Sec-
19 retary shall determine—

20 “(i) that extension of the expiration
21 date will help protect public health;

22 “(ii) that any extension of expiration
23 is supported by scientific evaluation; and

24 “(iii) what changes to the product la-
25 beling, if any, are required or permitted;

1 including whether and how any additional
2 labeling communicating the extension of
3 the expiration date may alter or obscure
4 the labeling provided by the manufacturer.

5 “(F) SCOPE OF EXTENSION.—With respect
6 to each extension of an expiration date granted
7 under this paragraph, the Secretary shall deter-
8 mine—

9 “(i) the batch, lot, or unit to which
10 such extension shall apply;

11 “(ii) the duration of such extension;
12 and

13 “(iii) any conditions to effectuate such
14 extension that are necessary and appro-
15 priate to protect public health or safety.”;
16 and

17 (F) in paragraph (5)(B), as so redesign-
18 nated, by striking “emergency use” and insert-
19 ing “authorized use”;

20 (3) in subsection (b)—

21 (A) in the subsection heading, by striking
22 “EMERGENCY” and inserting “EMERGENCY OR
23 THREAT JUSTIFYING AUTHORIZED USE”;

24 (B) in paragraph (1)—

1 (i) in the matter preceding subpara-
2 graph (A), by striking “may declare an
3 emergency” and inserting “may make a
4 declaration that the circumstances exist”;

5 (ii) in subparagraph (B), by striking
6 “; or” and inserting a semicolon;

7 (iii) in subparagraph (C), by striking
8 “national security” and all that follows
9 through the period and inserting “national
10 security, or the health and security of
11 United States citizens living abroad, and
12 that involves a specified biological, chem-
13 ical, radiological, or nuclear agent or
14 agents, or a specified disease or condition
15 that may be attributable to such agent or
16 agents; or”; and

17 (iv) by adding at the end the fol-
18 lowing:

19 “(D) the identification of a material threat
20 pursuant to section 319F-2 of the Public
21 Health Service Act sufficient to affect national
22 security or the health and security of United
23 States citizens living abroad.”;

24 (C) in paragraph (2)(A)—

1 (i) in clause (i), by striking “; or” and
2 inserting a semicolon;

3 (ii) by redesignating clause (ii) as
4 clause (iii); and

5 (iii) by inserting after clause (i) the
6 following:

7 “(ii) a change in the regulatory status
8 of the product such that the circumstances
9 described in subsection (a)(2) have ceased
10 to exist; or”; and

11 (D) in paragraph (3)(B), by striking
12 “emergency use” and inserting “authorized
13 use”;

14 (4) in subsection (c)—

15 (A) in the matter preceding paragraph
16 (1)—

17 (i) by striking “emergency use” and
18 inserting “authorized use”;

19 (ii) by inserting “the Assistant Sec-
20 retary for Preparedness and Response,”
21 after “consultation with”;

22 (iii) by striking “Health and” and in-
23 sserting “Health, and”;

24 (iv) by striking “circumstances of the
25 emergency involved” and inserting “appli-

1 cable circumstances described in subsection
2 (b)(1)”; and

3 (B) in paragraph (2)—

4 (i) in the matter preceding subpara-
5 graph (A), by inserting “and the material
6 threat posed by the agent or agents identi-
7 fied in a declaration under subsection
8 (b)(1)(D), if applicable” after “if avail-
9 able,”; and

10 (ii) in subparagraph (B), by inserting
11 “taking into consideration the material
12 threat posed by the agent or agents identi-
13 fied in a declaration under subsection
14 (b)(1)(D), if applicable” after “risks of the
15 product,”;

16 (5) in subsection (c)(1)—

17 (A) in subparagraph (A), in the matter
18 preceding clause (i)—

19 (i) by striking “emergency use” and
20 inserting “authorized use”; and

21 (ii) by striking “circumstances of the
22 emergency” and inserting “applicable cir-
23 cumstances described in subsection
24 (b)(1)”;

25 (B) in subparagraph (A)(i)—

1 (i) in subclause (I), by striking “has
2 authorized the emergency use” and insert-
3 ing “has authorized under this section the
4 use”; and

5 (ii) in subclause (II), by striking
6 “emergency use” and inserting “authorized
7 use”;

8 (C) in subparagraph (A)(ii)(I), by striking
9 “authorized the emergency use” and inserting
10 “has authorized under this section the use”;

11 (D) in clauses (iii) and (iv) of subpara-
12 graph (A), by striking “emergency use” each
13 place such term appears and inserting “author-
14 ized use”;

15 (E) in subparagraph (A), by adding at the
16 end the following:

17 “(v) Appropriate conditions with re-
18 spect to the collection and analysis of safe-
19 ty and effectiveness information useful to
20 inform the approval, licensure, or clearance
21 of the product, especially for a product for
22 which human efficacy studies are not eth-
23 ical or practicable.”;

24 (F) in subparagraph (B)—

- 1 (i) by striking “emergency use” each
2 place such term appears and inserting “au-
3 thorized use”;
- 4 (ii) by striking clause (iii); and
- 5 (iii) by redesignating clause (iv) as
6 clause (iii);
- 7 (6) in subsection (e)—
- 8 (A) in paragraph (2)—
- 9 (i) by striking “emergency use” each
10 place such term appears and inserting “au-
11 thorized use”; and
- 12 (ii) in subparagraph (A), by striking
13 “circumstances of the emergency” and in-
14 serting “applicable circumstances described
15 in subsection (b)(1)”;
- 16 (B) in paragraph (3)—
- 17 (i) by striking “emergency use” and
18 inserting “use”; and
- 19 (ii) by striking “circumstances of the
20 emergency” and inserting “applicable cir-
21 cumstances described in subsection
22 (b)(1)”;
- 23 (C) in paragraph (4), by striking “emer-
24 gency use” and inserting “use”;
- 25 (7) in subsection (g)—

1 (A) in the subsection heading, by inserting
2 “REVIEW AND” before “REVOCATION”;

3 (B) in paragraph (1), by inserting after
4 the period at the end the following: “As part of
5 such review, the Secretary shall regularly review
6 the progress made with respect to the approval,
7 licensure, or clearance of—

8 “(A) an unapproved product for which an
9 authorization was issued under this section; or

10 “(B) an unapproved use of an approved
11 product for which an authorization was issued
12 under this section.”; and

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

15 “(2) REVISION AND REVOCATION.—The Sec-
16 retary may revise or revoke an authorization under
17 this section if—

18 “(A) the circumstances described under
19 subsection (b)(1) no longer exist;

20 “(B) the criteria under subsection (e) for
21 issuance of such authorization are no longer
22 met; or

23 “(C) other circumstances make such revi-
24 sion or revocation appropriate to protect the
25 public health or safety.”; and

1 (8) in subsection (h)(1), by inserting “, revi-
2 sion,” after “termination”.

3 **SEC. 303. DEFINITIONS.**

4 Section 565 of the Federal Food, Drug, and Cosmetic
5 Act (~~21 U.S.C. 360bbb-4~~) is amended by striking “The
6 Secretary, in consultation” and inserting the following:

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

8 “(1) the term ‘countermeasure’ means a quali-
9 fied countermeasure, a security countermeasure, and
10 a qualified pandemic or epidemic product;

11 “(2) the term ‘qualified countermeasure’ has
12 the meaning given such term in section ~~319F-1~~ of
13 the Public Health Service Act;

14 “(3) the term ‘qualified pandemic or epidemic
15 product’ has the meaning given such term in section
16 ~~319F-3~~ of such Act; and

17 “(4) the term ‘security countermeasure’ has the
18 meaning given such term in section ~~319F-2~~ of such
19 Act.

20 “(b) **GENERAL DUTIES.**—The Secretary, in consulta-
21 tion”.

1 **SEC. 304. ENHANCING MEDICAL COUNTERMEASURE AC-**
 2 **TIVITIES.**

3 Section 565 of the Federal Food, Drug, and Cosmetic
 4 Act (~~21 U.S.C. 360bbb-4~~), as amended by section 303,
 5 is further amended—

6 (1) in the section heading, by striking “**TECH-**
 7 **NICAL ASSISTANCE**” and inserting “**COUNTER-**
 8 **MEASURE DEVELOPMENT, REVIEW, AND TECH-**
 9 **NICAL ASSISTANCE**”;

10 (2) in subsection (b), by striking the subsection
 11 heading and all that follows through “shall estab-

12 lish” and inserting the following:
 13 “(b) **GENERAL DUTIES.**—The Secretary, in consulta-
 14 tion with the Assistant Secretary for Preparedness and
 15 Response, shall accelerate the development, stockpiling,
 16 approval, licensure, and clearance of qualified counter-
 17 measures, security countermeasures, and qualified pan-
 18 demic or epidemic products—

19 “(1) by ensuring the appropriate involvement of
 20 Food and Drug Administration personnel in inter-
 21 agency activities related to countermeasure advanced
 22 research and development, consistent with sections
 23 319F, ~~319F-1~~, ~~319F-2~~, ~~319F-3~~, and 319L of the
 24 Public Health Service Act,

25 “(2) by ensuring the appropriate involvement
 26 and consultation of Food and Drug Administration

1 personnel in any flexible manufacturing activities
2 carried out under section 319L of the Public Health
3 Service Act, including with respect to meeting regu-
4 latory requirements set forth in this Act;

5 “(3) by promoting countermeasure expertise
6 within the Food and Drug Administration by—

7 “(A) ensuring that Food and Drug Admin-
8 istration personnel involved in reviewing coun-
9 termeasures for approval, licensure, or clear-
10 ance are informed by the Assistant Secretary
11 for Preparedness and Response on the material
12 threat assessment conducted under section
13 319F-2 of the Public Health Service Act for
14 the agent or agents for which the counter-
15 measure under review is intended;

16 “(B) training Food and Drug Administra-
17 tion personnel regarding review of counter-
18 measures for approval, licensure, or clearance;
19 and

20 “(C) establishing protocols to ensure that
21 countermeasure reviewers have sufficient train-
22 ing or experience with countermeasures;

23 “(4) by maintaining teams, composed of Food
24 and Drug Administration personnel with expertise
25 on countermeasures (including specific counter-

1 measures, classes or groups of countermeasures, or
2 other countermeasure-related technologies and capa-
3 bilities); that shall—

4 “(A) work with countermeasure sponsors
5 and applicants to identify and help resolve sci-
6 entific issues related to the approval, licensure,
7 or clearance of countermeasures;

8 “(B) encourage the exchange of scientific
9 ideas by holding public meetings at least twice
10 annually; and

11 “(C) improve and advance the science re-
12 lating to the development of new tools, stand-
13 ards, and approaches to assessing and evalu-
14 ating countermeasures—

15 “(i) in order to inform the process for
16 countermeasure approval, clearance, and li-
17 censure; and

18 “(ii) with respect to the development
19 of countermeasures for populations with
20 special clinical needs, including children
21 and pregnant women, in order to meet the
22 needs of such populations, as necessary
23 and appropriate; and

24 “(5) by establishing”; and

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

1 “(c) DEVELOPMENT AND ANIMAL MODELING PRO-
2 CEDURES.—

3 “(1) AVAILABILITY OF ANIMAL MODEL MEET-
4 INGS.—To facilitate the timely development of ani-
5 mal models and support the development, stock-
6 piling, licensure, approval, and clearance of counter-
7 measures, the Secretary shall, not later than 180
8 days after the enactment of this subsection, establish
9 a procedure by which a sponsor or applicant that is
10 developing a countermeasure for which human effi-
11 cacy studies are not ethical or practicable, and that
12 has an approved investigational new drug application
13 or investigational device exemption, may request and
14 receive—

15 “(A) a meeting to discuss proposed animal
16 model development activities; and

17 “(B) a meeting prior to initiating pivotal
18 animal studies.

19 “(2) JUVENILE MODELS.—To facilitate the de-
20 velopment and selection of animal models that could
21 translate to juvenile studies, any meeting conducted
22 under paragraph (1) shall include discussion of juve-
23 nile animal models, as appropriate.

24 “(d) REVIEW AND APPROVAL OF COUNTER-
25 MEASURES.—

1 “(1) MATERIAL THREAT.—When evaluating an
 2 application or submission for approval, licensure, or
 3 clearance of a countermeasure, the Secretary shall
 4 take into account the material threat posed by the
 5 chemical, biological, radiological, or nuclear agent or
 6 agents identified under section ~~319F-2~~ of the Public
 7 Health Service Act for which the countermeasure
 8 under review is intended.

9 “(2) REVIEW EXPERTISE.—When practicable
 10 and appropriate, teams of Food and Drug Adminis-
 11 tration personnel reviewing applications or submis-
 12 sions described under paragraph (1) shall include a
 13 reviewer with sufficient training or experience with
 14 countermeasures pursuant to the protocols estab-
 15 lished under subsection (b)(3)(C).”.

16 **SEC. 305. REGULATORY MANAGEMENT PLANS.**

17 Section 565 of the Federal Food, Drug, and Cosmetic
 18 Act (~~21 U.S.C. 360bbb-4~~), as amended by section 304,
 19 is further amended by adding at the end the following:

20 “(e) REGULATORY MANAGEMENT PLAN.—

21 “(1) IN GENERAL.—

22 “(A) INITIATION OF PROCESS.—The Sec-
 23 retary, in consultation with the Assistant Sec-
 24 retary for Preparedness and Response and the
 25 product sponsor or applicant, shall initiate a

1 formal process for obtaining scientific feedback
2 and interactions regarding the development and
3 regulatory review of any countermeasure.

4 “(B) CONTENT.—

5 “(i) IN GENERAL.—The process initi-
6 ated under subparagraph (A) shall include
7 the development of a written regulatory
8 management plan that shall be made part
9 of the administrative record. Except as
10 provided in paragraph (2), such plan shall
11 be completed not later than 45 days after
12 the date on which an investigational new
13 drug application or investigational device
14 exemption is approved with respect to the
15 countermeasure involved.

16 “(ii) CONTENT OF PLAN.—The con-
17 tent of a regulatory management plan
18 under clause (i) shall be consistent with
19 sections 319L and 319F-2 of the Public
20 Health Service Act. Such plan shall in-
21 clude—

22 “(I) guidance from the Secretary
23 regarding the data required to sup-
24 port the approval, clearance, or licen-
25 sure of the countermeasure involved;

1 “(II) guidance from the Sec-
2 retary regarding the data necessary to
3 inform any authorization under sec-
4 tion 564;

5 “(III) guidance from the Sec-
6 retary regarding the data necessary to
7 support the positioning and delivery of
8 countermeasures, including to the
9 Strategic National Stockpile;

10 “(IV) guidance from the Sec-
11 retary regarding the data necessary to
12 support the submission of protocols
13 for review under section 505(b)(5)(B);

14 “(V) an agreement between the
15 Secretary and the countermeasure
16 sponsor or applicant regarding devel-
17 opmental milestones that will trigger
18 responses by the Secretary as de-
19 scribed in subclause (VI);

20 “(VI) performance targets and
21 goals for timely and appropriate re-
22 sponses by the Secretary to the trig-
23 gers described under subclause (V),
24 including meetings between the Sec-
25 retary and the sponsor or applicant;

1 written feedback, decisions by the Sec-
2 retary, and other activities carried out
3 as part of the development and review
4 process;

5 “(VII) guidance from the Sec-
6 retary regarding any gaps in scientific
7 knowledge that will need resolution
8 prior to countermeasure approval, li-
9 censure, or clearance, and plans for
10 conducting the necessary scientific re-
11 search;

12 “(VIII) identification of the pop-
13 ulation for which the countermeasure
14 sponsor or applicant seeks approval,
15 licensure, or clearance, and the popu-
16 lation for which desired labeling would
17 not be appropriate, if known; and

18 “(IX) as necessary and appro-
19 priate, and to the extent practicable, a
20 plan for developing pediatric dosing
21 and administration with respect to the
22 countermeasure.

23 “(iii) MODIFICATION OF PLAN.—Not
24 later than 45 days after the Secretary be-
25 comes aware of a new substantial scientific

1 issue essential to the review of a counter-
2 measure, the Secretary shall—

3 “(I) determine, in consultation
4 with the countermeasure sponsor or
5 applicant, if such issue necessitates a
6 modification to the regulatory man-
7 agement plan; and

8 “(II) if the Secretary so deter-
9 mines, make such modification.

10 “(2) COUNTERMEASURES UNDER REVIEW.—

11 “(A) IN GENERAL.—Not later than 45
12 days after the date of enactment of this sub-
13 section, the Secretary shall establish a proce-
14 dure for developing regulatory management
15 plans for countermeasures that are under re-
16 view by the Food and Drug Administration as
17 of the date of enactment of this subsection.
18 Subject to subparagraph (B), the regulatory
19 management plans for all such countermeasures
20 shall be developed not later than 274 days after
21 the date of enactment of this subsection.

22 “(B) EXCEPTION.—The sponsor or appli-
23 cant with respect to a countermeasure described
24 subparagraph (A) may elect not to establish a
25 regulatory management plan under this sub-

1 section. Such sponsor or applicant shall notify
 2 the Secretary of such an election not later than
 3 30 days after the Secretary makes the proce-
 4 dures established under subparagraph (A) pub-
 5 licly available. If notification of such an election
 6 is not received by the Secretary by such date,
 7 the procedures established under subparagraph
 8 (A) shall apply to the countermeasure.”.

9 **SEC. 306. REPORT.**

10 Section 565 of the Federal Food, Drug, and Cosmetic
 11 Act (~~21 U.S.C. 360bbb-4~~), as amended by section 305,
 12 is further amended by adding at the end the following:

13 “(f) ANNUAL REPORT.—Not later than 180 days
 14 after the date of enactment of this subsection, and annu-
 15 ally thereafter, the Secretary shall submit to the Com-
 16 mittee on Health, Education, Labor, and Pensions of the
 17 Senate and the Committee on Energy and Commerce of
 18 the House of Representatives a report that details the
 19 countermeasure development and review activities of the
 20 Food and Drug Administration, including—

21 “(1) with respect to the development of new
 22 tools, standards, and approaches to assess and
 23 evaluate countermeasures—

1 “(A) the identification of the priorities of
2 the Food and Drug Administration and the
3 progress made on such priorities; and

4 “(B) the identification of scientific gaps
5 that impede the development or approval, licen-
6 sure, or clearance of countermeasures for popu-
7 lations with special clinical needs, including
8 children and pregnant women; and the progress
9 made on resolving these challenges;

10 “(2) the extent to which the performance tar-
11 gets and goals set forth in subsection (c)(1)(B) and
12 the regulatory management plans established under
13 such subsection have been met, including, for each
14 countermeasure reviewed—

15 “(A) whether the regulatory management
16 plan was completed within the required time-
17 frame; and the length of time taken to complete
18 such plan;

19 “(B) whether the Secretary adhered to the
20 timely and appropriate response times set forth
21 in such plan; and

22 “(C) explanations for any failure to meet
23 such performance targets and goals;

24 “(3) the number of regulatory teams estab-
25 lished pursuant to subsection (b)(4) and the number

1 of products, classes of products, or technologies as-
2 signed to each such team;

3 “(4) an estimate of resources obligated to coun-
4 termeasure development and regulatory assessment,
5 including Center specific objectives and accomplish-
6 ments; and

7 “(5) the number of countermeasure applications
8 submitted, the number of countermeasures approved,
9 licensed, or cleared, the status of remaining sub-
10 mitted applications, and the number of each type of
11 authorization issued pursuant to section 564.”

12 **SEC. 307. PEDIATRIC MEDICAL COUNTERMEASURES.**

13 (a) PEDIATRIC STUDIES OF DRUGS.—Section 505A
14 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
15 355a) is amended—

16 (1) in subsection (d), by adding at the end the
17 following:

18 “(5) CONSULTATION.—With respect to a drug
19 that is a qualified countermeasure (as defined in sec-
20 tion 319F–1 of the Public Health Service Act), a se-
21 curity countermeasure (as defined in section 319F–
22 2 of the Public Health Service Act), or a qualified
23 pandemic or epidemic product (as defined in section
24 319F–3 of the Public Health Service Act), the Sec-
25 retary shall solicit input from the Assistant Sec-

1 retary for Preparedness and Response regarding the
 2 need for and conduct of pediatric studies under this
 3 section.”; and

4 (2) in subsection (n)(1), by adding at the end
 5 the following:

6 “(C) For a drug that is a qualified coun-
 7 termeasure (as defined in section 319F-1 of the
 8 Public Health Service Act), a security counter-
 9 measure (as defined in section 319F-2 of the
 10 Public Health Service Act), or a qualified pan-
 11 demic or epidemic product (as defined in sec-
 12 tion 319F-3 of such Act), prior to any action
 13 with respect to such drug under subparagraph
 14 (A) or (B), the Secretary shall refer all pedi-
 15 atric studies in the written request to the As-
 16 sistant Secretary for Preparedness and Re-
 17 sponse and the Director of the Biomedical Ad-
 18 vanced Research and Development Authority.”.

19 (b) ADDITION TO PRIORITY LIST CONSIDER-
 20 ATIONS.—Section 409I of the Public Health Service Act
 21 (42 U.S.C. 284m) is amended—

22 (1) by striking subsection (a)(2) and inserting
 23 the following:

1 “(2) CONSIDERATION OF AVAILABLE INFORMA-
2 TION.—In developing and prioritizing the list under
3 paragraph (1), the Secretary—

4 “(A) shall consider—

5 “(i) therapeutic gaps in pediatries
6 that may include developmental pharma-
7 cology, pharmacogenetic determinants of
8 drug response, metabolism of drugs and
9 biologies in children, and pediatric clinical
10 trials;

11 “(ii) particular pediatric diseases, dis-
12 orders or conditions where more complete
13 knowledge and testing of therapeutics, in-
14 cluding drugs and biologics, may be bene-
15 ficial in pediatric populations; and

16 “(iii) the adequacy of necessary infra-
17 structure to conduct pediatric pharma-
18 cological research, including research net-
19 works and trained pediatric investigators;
20 and

21 “(B) may consider the availability of quali-
22 fied countermeasures (as defined in section
23 319F-1), security countermeasures (as defined
24 in section 319F-2), and qualified pandemic or
25 epidemic products (as defined in section 319F-

1 3) to address the needs of pediatric populations;
 2 in consultation with the Assistant Secretary for
 3 Preparedness and Response, consistent with the
 4 purposes of this section.”; and

5 (2) in subsection (b), by striking “subsection
 6 (a)” and inserting “paragraphs (1) and (2)(A) of
 7 subsection (a)”.

8 (e) ~~ADVICE AND RECOMMENDATIONS OF THE PEDI-~~
 9 ~~ATRIC ADVISORY COMMITTEE REGARDING COUNTER-~~
 10 ~~MEASURES FOR PEDIATRIC POPULATIONS.~~—Subsection
 11 (b)(2) of section 14 of the Best Pharmaceuticals for Chil-
 12 dren Act (42 U.S.C. 284m note) is amended—

13 (1) in subparagraph (C), by striking the period
 14 and inserting “; and”; and

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

16 “(D) the development of countermeasures
 17 (as defined in section 565(a) of the Federal
 18 Food, Drug, and Cosmetic Act) for pediatric
 19 populations.”.

20 **SEC. 308. TECHNICAL AND CONFORMING AMENDMENTS.**

21 (a) Section ~~319F-2(c)(1)(B)(ii)~~ of the Public Health
 22 Service Act (42 U.S.C. ~~247d-6b(c)(1)(B)(ii)~~) is amended
 23 by striking “emergency”.

24 (b) Section ~~319F-3(i)~~ of such Act (42 U.S.C. ~~247d-~~
 25 ~~6d(i)~~) is amended—

1 (1) in paragraph (1)(C), by striking “emer-
2 gency”; and

3 (2) in paragraph (7)(B)(iii), by striking “emer-
4 gency”.

5 **TITLE IV—ACCELERATING MED-**
6 **ICAL COUNTERMEASURE AD-**
7 **VANCED RESEARCH AND DE-**
8 **VELOPMENT**

9 **SEC. 401. BIOSHIELD.**

10 (a) REAUTHORIZATION OF THE SPECIAL RESERVE
11 FUND.—Section 319F-2(e) of the Public Health Service
12 Act (42 U.S.C. 247d-6b(e)) is amended by adding at the
13 end the following:

14 “(11) REAUTHORIZATION OF THE SPECIAL RE-
15 SERVE FUND.—In addition to amounts otherwise ap-
16 propriated, there are authorized to be appropriated
17 for the special reserve fund, \$2,800,000,000 for the
18 fiscal years 2014 through 2018.

19 “(12) REPORT.—Not later than 30 days after
20 any date on which the Secretary determines that the
21 amount of funds in the special reserve fund available
22 for procurement is less than \$1,500,000,000, the
23 Secretary shall submit to the appropriate committees
24 of Congress a report detailing the amount of such

1 funds available for procurement and the impact such
2 reduction in funding will have—

3 “(A) in meeting the security counter-
4 measure needs identified under this section; and

5 “(B) on the annual Public Health Emer-
6 gency Medical Countermeasures Enterprise and
7 Strategy Implementation Plan (pursuant to sec-
8 tion 2811(d)).”.

9 (b) ~~PROCUREMENT OF COUNTERMEASURES.~~—Sec-
10 tion ~~319F-2(e)~~ of the Public Health Service Act (42
11 U.S.C. ~~247d-6b(e)~~) is amended—

12 (1) in paragraph (1)(B)(i)(III)(bb), by striking
13 “eight years” and inserting “10 years”;

14 (2) in paragraph (5)(B)(ii), by striking “eight
15 years” and inserting “10 years”;

16 (3) in paragraph (7)(C)—

17 (A) in clause (i)(I), by inserting “including
18 advanced research and development,” after “as
19 may reasonably be required,”;

20 (B) in clause (ii)—

21 (i) in subclause (III), by striking
22 “eight years” and inserting “10 years”;
23 and

24 (ii) by striking subclause (IX) and in-
25 serting the following:

1 “(IX) CONTRACT TERMS.—The
2 Secretary, in any contract for procure-
3 ment under this section—

4 “(aa) may specify—

5 “(AA) the dosing and
6 administration requirements
7 for the countermeasure to be
8 developed and procured;

9 “(BB) the amount of
10 funding that will be dedi-
11 cated by the Secretary for
12 advanced research, develop-
13 ment, and procurement of
14 the countermeasure; and

15 “(CC) the specifications
16 the countermeasure must
17 meet to qualify for procure-
18 ment under a contract under
19 this section; and

20 “(bb) shall provide a clear
21 statement of defined Government
22 purpose limited to uses related to
23 a security countermeasure, as de-
24 fined in paragraph (1)(B).”;

25 (C) by adding at the end the following:

1 “(viii) FLEXIBILITY.—In carrying out
2 this section, the Secretary may, consistent
3 with the applicable provisions of this sec-
4 tion, enter into contracts and other agree-
5 ments that are in the best interest of the
6 Government in meeting identified security
7 countermeasure needs, including with re-
8 spect to reimbursement of the cost of ad-
9 vanced research and development as an al-
10 lowable and allocable direct cost of the
11 contract involved.”;

12 (4) in paragraph (9)(B), by inserting before the
13 period the following: “, except that this subpara-
14 graph shall not be construed to prohibit the use of
15 such amounts as otherwise authorized in this title”;
16 and

17 (5) in paragraph (10), by adding at the end the
18 following:

19 “(C) ADVANCED RESEARCH AND DEVELOP-
20 MENT.—For purposes of this paragraph, the
21 term ‘advanced research and development’ shall
22 have the meaning given such term in section
23 319L(a).”.

1 **SEC. 402. BIOMEDICAL ADVANCED RESEARCH AND DEVEL-**
2 **OPMENT AUTHORITY.**

3 (a) **DUTIES.**—Section 319L(e)(4) of the Public
4 Health Service Act (42 U.S.C. 247d–7e(e)(4)) is amend-
5 ed—

6 (1) in subparagraph (B)(iii), by inserting
7 “(which may include advanced research and develop-
8 ment for purposes of fulfilling requirements under
9 the Federal Food, Drug, and Cosmetic Act or sec-
10 tion 351 of this Act)” after “development”; and

11 (2) in subparagraph (D)(iii), by striking “and
12 vaccine manufacturing technologies” and inserting
13 “vaccine manufacturing technologies, dose sparing
14 technologies, efficacy increasing technologies, and
15 platform technologies”.

16 (b) **TRANSACTION AUTHORITIES.**—Section
17 319L(e)(5) of the Public Health Service Act (42 U.S.C.
18 247d–7e(e)(5)) is amended by adding at the end the fol-
19 lowing:

20 “(G) **GOVERNMENT PURPOSE.**—In award-
21 ing contracts, grants, and cooperative agree-
22 ments under this section, the Secretary shall
23 provide a clear statement of defined Govern-
24 ment purpose related to activities included in
25 subsection (a)(6)(B) for a qualified counter-

1 measure or qualified pandemic or epidemic
2 product.”.

3 (c) FUND.—Paragraph (2) of section 319L(d) of the
4 Public Health Service Act (42 U.S.C. 247d–7e(d)(2)) is
5 amended to read as follows:

6 “(2) FUNDING.—To carry out the purposes of
7 this section, there is authorized to be appropriated
8 to the Fund \$415,000,000 for each of fiscal years
9 2012 through 2016, such amounts to remain avail-
10 able until expended.”.

11 (d) CONTINUED INAPPLICABILITY OF CERTAIN PRO-
12 VISIONS.—Section 319L(e)(1)(C) of the Public Health
13 Service Act (42 U.S.C. 247d–7e(e)(1)(C)) is amended by
14 striking “7 years” and inserting “10 years”.

15 (e) EXTENSION OF LIMITED ANTITRUST EXEMP-
16 TION.—Section 405(b) of the Pandemic and All-Hazards
17 Preparedness Act (42 U.S.C. 247d–6a note) is amended
18 by striking “6-year” and inserting “10-year”.

19 (f) INDEPENDENT EVALUATION.—Section 319L of
20 the Public Health Service Act (42 U.S.C. 247d–7e) is
21 amended by adding at the end the following:

22 “(f) INDEPENDENT EVALUATION.—

23 “(1) IN GENERAL.—Not later than 180 days
24 after the date of enactment of this subsection, the
25 Government Accountability Office shall conduct an

1 independent evaluation of the activities carried out
2 to facilitate flexible manufacturing capacity pursu-
3 ant to this section.

4 “(2) REPORT.—Not later than 1 year after the
5 date of enactment of this subsection, the Govern-
6 ment Accountability Office shall submit to the ap-
7 propriate committees of Congress a report con-
8 cerning the results of the evaluation conducted
9 under paragraph (1). Such report shall review and
10 assess—

11 “(A) the extent to which flexible manufac-
12 turing capacity under this section is dedicated
13 to chemical, biological, radiological, and nuclear
14 threats;

15 “(B) the activities supported by flexible
16 manufacturing initiatives; and

17 “(C) the ability of flexible manufacturing
18 activities carried out under this section to—

19 “(i) secure and leverage leading tech-
20 nical expertise with respect to counter-
21 measure advanced research, development,
22 and manufacturing processes; and

23 “(ii) meet the surge manufacturing
24 capacity needs presented by novel and

1 emerging threats, including chemical, bio-
 2 logical, radiological and nuclear agents.”.

3 ~~(g)~~ DEFINITIONS.—

4 (1) QUALIFIED COUNTERMEASURE.—Section
 5 ~~319F-1(a)(2)(A)~~ of the Public Health Service Act
 6 (~~42 U.S.C. 247d-6a(a)(2)(A)~~) is amended—

7 (A) in the matter preceding clause (i), by
 8 striking “to—” and inserting “—”;

9 (B) in clause (i)—

10 (i) by striking “diagnose” and insert-
 11 ing “to diagnose”; and

12 (ii) by striking “; or” and inserting a
 13 semicolon;

14 (C) in clause (ii)—

15 (i) by striking “diagnose” and insert-
 16 ing “to diagnose”; and

17 (ii) by striking the period at the end
 18 and inserting “; or”; and

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

20 “(iii) is a product or technology in-
 21 tended to enhance the purpose of a drug,
 22 biological product, or device described in
 23 clause (i) or (ii).”.

24 (2) QUALIFIED PANDEMIC OR EPIDEMIC PROD-
 25 UCT.—Section ~~319F-3(i)(7)(A)~~ of the Public Health

1 Service Act (42 U.S.C. 247d-6d(i)(7)(A)) is amend-
2 ed—

3 (A) in clause (i)(II), by striking “; or” and
4 inserting “;”,

5 (B) in clause (ii), by striking “; and” and
6 inserting “; or”; and

7 (C) by adding at the end the following:

8 “(B) a product or technology intended to
9 enhance the purpose of a drug, biological prod-
10 uct, or device described in clause (i) or (ii);
11 and”.

12 **SEC. 403. STRATEGIC NATIONAL STOCKPILE.**

13 Section 319F-2 of the Public Health Service Act (42
14 U.S.C. 247d-6b) is amended—

15 (1) in subsection (a)—

16 (A) in paragraph (1)—

17 (i) by inserting “consistent with sec-
18 tion 2811” before “by the Secretary to be
19 appropriate”; and

20 (ii) by inserting before the period at
21 the end the following: “and shall submit
22 such review annually to the appropriate
23 Congressional committees of jurisdiction to
24 the extent that disclosure of such informa-

1 tion does not compromise national secu-
2 rity"; and

3 ~~(B)~~ in paragraph ~~(2)~~—

4 (i) by redesignating subparagraphs
5 ~~(E)~~ through ~~(H)~~ as subparagraphs ~~(F)~~
6 through ~~(I)~~, respectively; and

7 (ii) by inserting after subparagraph
8 ~~(D)~~, the following:

9 ~~“(E) identify and address the potential de-~~
10 ~~pletion and ensure appropriate replenishment of~~
11 ~~medical countermeasures, including those cur-~~
12 ~~rently in the stockpile;”~~; and

13 ~~(2)~~ in subsection ~~(f)~~(1), by striking
14 ~~“\$640,000,000 for fiscal year 2002, and such sums~~
15 ~~as may be necessary for each of fiscal years 2003~~
16 ~~through 2006”~~ and inserting ~~“\$522,486,000 for~~
17 ~~each of fiscal years 2012 through 2016”~~.

18 **SEC. 404. NATIONAL BIODEFENSE SCIENCE BOARD.**

19 Section 319M(a) of the Public Health Service Act (42
20 U.S.C. 247d-f(a)) is amended—

21 ~~(1)~~ in paragraph ~~(2)~~—

22 ~~(A)~~ in subparagraph ~~(D)~~—

23 (i) in the matter preceding clause (i),
24 by striking ~~“five”~~ and inserting ~~“six”~~;

1 (ii) in clause (i), by striking “and” at
2 the end;

3 (iii) in clause (ii), by striking the pe-
4 riod and inserting a semicolon; and

5 (iv) by adding at the end the fol-
6 lowing:

7 “~~(iii)~~ one such member shall be an in-
8 dividual with pediatric subject matter ex-
9 pertise; and

10 “~~(iv)~~ one such member shall be a
11 State, tribal, territorial, or local public
12 health official.”; and

13 (B) by adding at the end the following
14 flush sentence:

15 “Nothing in this paragraph shall preclude a member
16 of the Board from satisfying two or more of the re-
17 quirements described in subparagraph (D).”;

18 (2) in paragraph (5)—

19 (A) in subparagraph (B), by striking
20 “and” at the end;

21 (B) in subparagraph (C), by striking the
22 period and inserting “; and”; and

23 (C) by adding at the end the following:

24 “~~(D)~~ provide any recommendation, finding,
25 or report provided to the Secretary under this

1 paragraph to the appropriate committees of
 2 Congress.”; and
 3 ~~(3) in paragraph (8), by adding at the end the~~
 4 following: “Such chairperson shall serve as the de-
 5 ciding vote in the event that a deciding vote is nec-
 6 essary with respect to voting by members of the
 7 Board.”.

8 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

9 (a) *SHORT TITLE.*—*This Act may be cited as the*
 10 *“Pandemic and All-Hazards Preparedness Act Reauthor-*
 11 *ization of 2011”.*

12 (b) *TABLE OF CONTENTS.*—*The table of contents of this*
 13 *Act is as follows:*

Sec. 1. Short title; table of contents.

*TITLE I—STRENGTHENING NATIONAL PREPAREDNESS AND
 RESPONSE FOR PUBLIC HEALTH EMERGENCIES*

Sec. 101. National Health Security Strategy.

Sec. 102. Assistant Secretary for Preparedness and Response.

Sec. 103. National Advisory Committee on Children and Disasters.

Sec. 104. Modernization of the National Disaster Medical System.

Sec. 105. Continuing the role of the Department of Veterans Affairs.

*TITLE II—OPTIMIZING STATE AND LOCAL ALL-HAZARDS
 PREPAREDNESS AND RESPONSE*

Sec. 201. Improving State and local public health security.

Sec. 202. Hospital preparedness and medical surge capacity.

Sec. 203. Enhancing situational awareness and biosurveillance.

TITLE III—ENHANCING MEDICAL COUNTERMEASURE REVIEW

Sec. 301. Special protocol assessment.

Sec. 302. Authorization of medical products for use in emergencies.

Sec. 303. Definitions.

Sec. 304. Enhancing medical countermeasure activities.

Sec. 305. Regulatory management plans.

Sec. 306. Report.

Sec. 307. Pediatric medical countermeasures.

*TITLE IV—ACCELERATING MEDICAL COUNTERMEASURE ADVANCED
RESEARCH AND DEVELOPMENT*

Sec. 401. BioShield.

Sec. 402. Biomedical Advanced Research and Development Authority.

Sec. 403. Strategic National Stockpile.

Sec. 404. National Biodefense Science Board.

1 ***TITLE I—STRENGTHENING NA-***
 2 ***TIONAL PREPAREDNESS AND***
 3 ***RESPONSE FOR PUBLIC***
 4 ***HEALTH EMERGENCIES***

5 ***SEC. 101. NATIONAL HEALTH SECURITY STRATEGY.***

6 *(a) IN GENERAL.—Section 2802 of the Public Health*
 7 *Service Act (42 U.S.C. 300hh–1) is amended—*

8 *(1) in subsection (a)(1), by striking “2009” and*
 9 *inserting “2014”; and*

10 *(2) in subsection (b)—*

11 *(A) in paragraph (3)—*

12 *(i) in the matter preceding subpara-*
 13 *graph (A)—*

14 *(I) by striking “facilities), and*
 15 *trauma care” and inserting “facilities*
 16 *and which may include dental health*
 17 *facilities), and trauma care, critical*
 18 *care,”; and*

19 *(II) by inserting “(including re-*
 20 *lated availability, accessibility, and co-*
 21 *ordination)” after “public health emer-*
 22 *gencies”;*

1 (ii) in subparagraph (A), by inserting
2 “and trauma” after “medical”;

3 (iii) in subparagraph (D), by inserting
4 “(which may include such dental health as-
5 sets)” after “medical assets”;

6 (iv) by adding at the end the following:

7 “(F) Optimizing a coordinated and flexible
8 approach to the medical surge capacity of hos-
9 pitals, other healthcare facilities, and trauma
10 care (which may include trauma centers) and
11 emergency medical systems.”;

12 (B) in paragraph (4)—

13 (i) in subparagraph (A), by inserting
14 “, including the unique needs and consider-
15 ations of individuals with disabilities,”
16 after “medical needs of at-risk individuals”;
17 and

18 (ii) in subparagraph (B), by inserting
19 “the” before “purpose of this section”; and

20 (C) by adding at the end the following:

21 “(7) COUNTERMEASURES.—

22 “(A) Promoting strategic initiatives to ad-
23 vance countermeasures to diagnose, mitigate,
24 prevent, or treat harm from any biological agent
25 or toxin, chemical, radiological, or nuclear agent

1 or agents, whether naturally occurring, uninten-
2 tional, or deliberate.

3 “(B) For purposes of this paragraph the
4 term ‘countermeasures’ has the same meaning as
5 the terms ‘qualified countermeasures’ under sec-
6 tion 319F-1, ‘qualified pandemic and epidemic
7 products’ under section 319F-3, and ‘security
8 countermeasures’ under section 319F-2.

9 “(8) *MEDICAL AND PUBLIC HEALTH COMMUNITY*
10 *RESILIENCY.—Strengthening the ability of States,*
11 *local communities, and tribal communities to prepare*
12 *for, respond to, and be resilient in the event of public*
13 *health emergencies, whether naturally occurring, un-*
14 *intentional, or deliberate by—*

15 “(A) *optimizing alignment and integration*
16 *of medical and public health preparedness and*
17 *response planning and capabilities with and*
18 *into routine daily activities; and*

19 “(B) *promoting familiarity with local med-*
20 *ical and public health systems.”.*

21 (b) *AT-RISK INDIVIDUALS.—Section 2814 of the Public*
22 *Health Service Act (42 U.S.C. 300hh-16) is amended—*

23 (1) *by striking paragraphs (5), (7), and (8);*

24 (2) *by redesignating paragraphs (1) through (4)*
25 *as paragraphs (2) through (5), respectively;*

1 (3) by inserting before paragraph (2) (as so re-
2 designated), the following:

3 “(1) monitor emerging issues and concerns as
4 they relate to medical and public health preparedness
5 and response for at-risk individuals in the event of a
6 public health emergency declared by the Secretary
7 under section 319;”;

8 (4) in paragraph (2) (as so redesignated), by
9 striking “National Preparedness goal” and inserting
10 “preparedness goals, as described in section 2802(b),”;
11 and

12 (5) by inserting after paragraph (6), the fol-
13 lowing:

14 “(7) disseminate and, as appropriate, update
15 novel and best practices of outreach to and care of at-
16 risk individuals before, during, and following public
17 health emergencies in as timely a manner as is prac-
18 ticable, including from the time a public health threat
19 is identified; and

20 “(8) ensure that public health and medical infor-
21 mation distributed by the Department of Health and
22 Human Services during a public health emergency is
23 delivered in a manner that takes into account the
24 range of communication needs of the intended recipi-
25 ents, including at-risk individuals.”.

1 **SEC. 102. ASSISTANT SECRETARY FOR PREPAREDNESS AND**
2 **RESPONSE.**

3 *Section 2811 of the Public Health Service Act (42*
4 *U.S.C. 300hh–10) is amended—*

5 *(1) in subsection (b)(4), by adding at the end the*
6 *following:*

7 *“(D) POLICY COORDINATION AND STRA-*
8 *TEGIC DIRECTION.—Provide integrated policy co-*
9 *ordination and strategic direction with respect to*
10 *all matters related to Federal public health and*
11 *medical preparedness and execution and deploy-*
12 *ment of the Federal response for public health*
13 *emergencies and incidents covered by the Na-*
14 *tional Response Plan developed pursuant to sec-*
15 *tion 502(6) of the Homeland Security Act of*
16 *2002, or any successor plan, before, during, and*
17 *following public health emergencies.”;*

18 *(2) by striking subsection (c) and inserting the*
19 *following:*

20 *“(c) FUNCTIONS.—The Assistant Secretary for Pre-*
21 *paredness and Response shall—*

22 *“(1) have authority over and responsibility for—*

23 *“(A) the National Disaster Medical System*
24 *(in accordance with section 301 of the Pandemic*
25 *and All-Hazards Preparedness Act);*

1 “(B) the Hospital Preparedness Cooperative
2 Agreement Program pursuant to section 319C-2;

3 “(C) the Medical Reserve Corps pursuant to
4 section 2813;

5 “(D) the Emergency System for Advance
6 Registration of Volunteer Health Professionals
7 pursuant to section 319I; and

8 “(E) administering grants and related au-
9 thorities related to trauma care under parts A
10 through C of title XII, such authority to be
11 transferred by the Secretary from the Adminis-
12 trator of the Health Resources and Services Ad-
13 ministration to such Assistant Secretary;

14 “(2) exercise the responsibilities and authorities
15 of the Secretary with respect to the coordination of—

16 “(A) the Public Health Emergency Pre-
17 paredness Cooperative Agreement Program pur-
18 suant to section 319C-1;

19 “(B) the Strategic National Stockpile; and

20 “(C) the Cities Readiness Initiative;

21 “(3) align and coordinate medical and public
22 health grants and cooperative agreements as applica-
23 ble to preparedness and response activities authorized
24 under this Act, to the extent possible, including pro-
25 gram requirements, timelines, and measurable goals,

1 *and in coordination with the Secretary of Homeland*
2 *Security, to—*

3 “(A) *optimize and streamline medical and*
4 *public health preparedness capabilities and the*
5 *ability of local communities to respond to public*
6 *health emergencies;*

7 “(B) *minimize duplication of efforts with*
8 *regard to medical and public health preparedness*
9 *and response programs; and*

10 “(C) *gather and disseminate best practices*
11 *among grant and cooperative agreement recipi-*
12 *ents, as appropriate;*

13 “(4) *carry out drills and operational exercises,*
14 *in coordination with the Department of Homeland*
15 *Security, the Department of Defense, the Department*
16 *of Veterans Affairs, and other applicable Federal de-*
17 *partments and agencies, as necessary and appro-*
18 *priate, to identify, inform, and address gaps in and*
19 *policies related to all-hazards medical and public*
20 *health preparedness, including exercises based on—*

21 “(A) *identified threats for which counter-*
22 *measures are available and for which no counter-*
23 *measures are available; and*

24 “(B) *unknown threats for which no counter-*
25 *measures are available; and*

1 “(5) assume other duties as determined appro-
2 priate by the Secretary.”; and

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

4 “(d) NATIONAL SECURITY PRIORITY.—The Secretary,
5 acting through the Assistant Secretary for Preparedness
6 and Response, shall on a periodic basis conduct meetings,
7 as applicable and appropriate, with the Assistant to the
8 President for National Security Affairs to provide an up-
9 date on, and discuss, medical and public health prepared-
10 ness and response activities pursuant to this Act and the
11 Federal Food, Drug, and Cosmetic Act, including progress
12 on the development, approval, clearance, and licensure of
13 medical countermeasures.

14 “(e) PUBLIC HEALTH EMERGENCY MEDICAL COUN-
15 TERMEASURES ENTERPRISE STRATEGY AND IMPLEMENTA-
16 TION PLAN.—

17 “(1) IN GENERAL.—Not later than 180 days
18 after the date of enactment of this subsection, and
19 every other year thereafter, the Secretary, acting
20 through the Assistant Secretary for Preparedness and
21 Response and in consultation with the Director of the
22 Biomedical Advanced Research and Development Au-
23 thority, the Director of the National Institutes of
24 Health, the Director of the Centers for Disease Control
25 and Prevention, and the Commissioner of the Food

1 *and Drug Administration, shall develop and submit*
2 *to the appropriate committees of Congress a coordi-*
3 *nated strategy and accompanying implementation*
4 *plan for medical countermeasures to address chemical,*
5 *biological, radiological, and nuclear threats. Such*
6 *strategy and plan shall be known as the ‘Public*
7 *Health Emergency Medical Countermeasures Enter-*
8 *prise Strategy and Implementation Plan’.*

9 *“(2) REQUIREMENTS.—The plan under para-*
10 *graph (1) shall—*

11 *“(A) consider and reflect the full spectrum*
12 *of medical countermeasure-related activities, in-*
13 *cluding research, advanced research, develop-*
14 *ment, procurement, stockpiling, deployment, and*
15 *distribution;*

16 *“(B) identify and prioritize near-term,*
17 *mid-term, and long-term priority qualified and*
18 *security countermeasure (as defined in sections*
19 *319F–1 and 319F–2) needs and goals of the Fed-*
20 *eral Government according to chemical, biologi-*
21 *cal, radiological, and nuclear threat or threats;*

22 *“(C) identify projected timelines, antici-*
23 *ipated funding allocations, benchmarks, and mile-*
24 *stones for each medical countermeasure priority*
25 *under subparagraph (B), including projected*

1 *needs with regard to replenishment of the Stra-*
2 *tegic National Stockpile;*

3 “(D) *be informed by the recommendations*
4 *of the National Biodefense Science Board pursu-*
5 *ant to section 319M;*

6 “(E) *report on advanced research and devel-*
7 *opment awards and the date of the issuance of*
8 *contract awards, including awards made through*
9 *the special reserve fund (as defined in section*
10 *319F–2(c)(10));*

11 “(F) *identify progress made in meeting the*
12 *goals, benchmarks, and milestones identified*
13 *under subparagraph (C) in plans submitted sub-*
14 *sequent to the initial plan;*

15 “(G) *identify the progress made in meeting*
16 *the medical countermeasure priorities for at-risk*
17 *individuals, (as defined in 2802(b)(4)(B)), as*
18 *applicable under subparagraph (B), including*
19 *with regard to the projected needs for related*
20 *stockpiling and replenishment of the Strategic*
21 *National Stockpile; and*

22 “(H) *be made publicly available.*

23 “(3) *GAO REPORT.—*

24 “(A) *IN GENERAL.—Not later than 1 year*
25 *after the date on which a Public Health Emer-*

1 *gency Medical Countermeasures Enterprise*
2 *Strategy and Implementation Plan under this*
3 *subsection is issued by the Secretary, the Govern-*
4 *ment Accountability Office shall conduct an*
5 *independent evaluation and submit to the appro-*
6 *priate committees of Congress a report con-*
7 *cerning such strategy and implementation plan.*

8 “(B) *CONTENT.*—*The report described in*
9 *subparagraph (A) shall review and assess—*

10 “(i) *the near-term, mid-term, and*
11 *long-term medical countermeasure needs*
12 *and identified priorities of the Federal Gov-*
13 *ernment pursuant to subparagraphs (A)*
14 *and (B) of paragraph (2);*

15 “(ii) *the activities of the Department of*
16 *Health and Human Services with respect to*
17 *advanced research and development pursu-*
18 *ant to section 319L; and*

19 “(iii) *the progress made toward meet-*
20 *ing the goals, benchmarks, and milestones*
21 *identified in the Public Health Emergency*
22 *Medical Countermeasures Enterprise Strat-*
23 *egy and Implementation Plan under this*
24 *subsection.*

1 “(f) *INTERNAL MULTIYEAR PLANNING PROCESS.*—*The*
2 *Secretary shall develop, and update on an annual basis,*
3 *a coordinated 5-year budget plan based on the medical*
4 *countermeasure priorities and goals described in subsection*
5 *(e). Each such plan shall—*

6 “(1) *include consideration of the entire medical*
7 *countermeasures enterprise, including—*

8 “(A) *basic research, advanced research and*
9 *development;*

10 “(B) *approval, clearance, licensure, and au-*
11 *thorized uses of products; and*

12 “(C) *procurement, stockpiling, maintenance,*
13 *and replenishment of all products in the Stra-*
14 *tegic National Stockpile;*

15 “(2) *include measurable outputs and outcomes to*
16 *allow for the tracking of the progress made toward*
17 *identified goals;*

18 “(3) *identify medical countermeasure life-cycle*
19 *costs to inform planning, budgeting, and anticipated*
20 *needs within the continuum of the medical counter-*
21 *measure enterprise consistent with section 319F-2;*
22 *and*

23 “(4) *be made available to the appropriate com-*
24 *mittees of Congress upon request.*

1 “(g) *INTERAGENCY COORDINATION PLAN.*—Not later
2 than 1 year after the date of enactment of this subsection,
3 the Secretary, in coordination with the Secretary of De-
4 fense, shall submit to the appropriate committees of Con-
5 gress a report concerning the manner in which the Depart-
6 ment of Health and Human Services is coordinating with
7 the Department of Defense regarding countermeasure ac-
8 tivities to address chemical, biological, radiological, and
9 nuclear threats. Such report shall include information with
10 respect to—

11 “(1) the research, advanced research, develop-
12 ment, procurement, stockpiling, and distribution of
13 countermeasures to meet identified needs; and

14 “(2) the coordination of efforts between the De-
15 partment of Health and Human Services and the De-
16 partment of Defense to address countermeasure needs
17 for various segments of the population.

18 “(h) *PROTECTION OF NATIONAL SECURITY.*—In car-
19 rying out subsections (e), (f), and (g), the Secretary shall
20 ensure that information and items that could compromise
21 national security are not disclosed.”.

1 **SEC. 103. NATIONAL ADVISORY COMMITTEE ON CHILDREN**
2 **AND DISASTERS.**

3 *Subtitle B of title XXVIII of the Public Health Service*
4 *Act (42 U.S.C. 300hh et seq.) is amended by inserting after*
5 *section 2811 the end the following:*

6 **“SEC. 2811A. NATIONAL ADVISORY COMMITTEE ON CHIL-**
7 **DREN AND DISASTERS.**

8 *“(a) ESTABLISHMENT.—The Secretary, in consulta-*
9 *tion with the Secretary of Homeland Security, shall estab-*
10 *lish an advisory committee to be known as the ‘National*
11 *Advisory Committee on Children and Disasters’ (referred*
12 *to in this section as the ‘Advisory Committee’).*

13 *“(b) DUTIES.—The Advisory Committee shall—*

14 *“(1) provide advice and consultation with re-*
15 *spect to the activities carried out pursuant to section*
16 *2814, as applicable and appropriate;*

17 *“(2) evaluate and provide input with respect to*
18 *the needs of children as they relate to preparation for,*
19 *response to, and recovery from all-hazards, including*
20 *public health emergencies; and*

21 *“(3) provide advice and consultation to States*
22 *and territories with respect to State emergency pre-*
23 *paredness and response activities and children, in-*
24 *cluding related drills and exercises pursuant to the*
25 *preparedness goals under section 2802(b).*

1 “(c) *ADDITIONAL DUTIES.*—*The Advisory Committee*
2 *may provide advice and recommendations to the Secretary*
3 *with respect to children and the medical and public health*
4 *grants and cooperative agreements as applicable to pre-*
5 *paredness and response activities authorized under this title*
6 *and title III.*

7 “(d) *MEMBERSHIP.*—

8 “(1) *IN GENERAL.*—*The Secretary, in consulta-*
9 *tion with such other Secretaries as may be appro-*
10 *priate, shall appoint not to exceed 15 members to the*
11 *Advisory Committee. In appointing such members,*
12 *the Secretary shall ensure that the total membership*
13 *of the Advisory Committee is an odd number.*

14 “(2) *REQUIRED MEMBERS.*—*The Secretary, in*
15 *consultation with such other Secretaries as may be*
16 *appropriate, may appoint to the Advisory Committee*
17 *under paragraph (1) such individuals as may be ap-*
18 *propriate to perform the duties described in sub-*
19 *sections (b) and (c), which may include—*

20 “(A) *the Assistant Secretary for Prepared-*
21 *ness and Response;*

22 “(B) *the Director of the Biomedical Ad-*
23 *vanced Research and Development Authority;*

24 “(C) *the Director of the Centers for Disease*
25 *Control and Prevention;*

1 “(D) *the Commissioner of Food and Drugs;*

2 “(E) *the Director of the National Institutes*
3 *of Health;*

4 “(F) *the Assistant Secretary of the Admin-*
5 *istration for Children and Families;*

6 “(G) *at least two health care professionals*
7 *with expertise in pediatric medical disaster*
8 *planning, preparedness, response, or recovery;*

9 “(H) *at least two representatives from*
10 *State, local, territories, or tribal agencies with*
11 *expertise in pediatric disaster planning, pre-*
12 *paredness, response, or recovery; and*

13 “(I) *representatives from such Federal agen-*
14 *cies (such as the Department of Education and*
15 *the Department of Homeland Security) as deter-*
16 *mined necessary to fulfill the duties of the Advi-*
17 *sory Committee, as established under subsections*
18 *(b) and (c).*

19 “(e) *MEETINGS.—The Advisory Committee shall meet*
20 *not less than biannually.*

21 “(f) *SUNSET.—The Advisory Committee shall termi-*
22 *nate on the date that is 5 years after the date of enactment*
23 *of the Pandemic and All-Hazards Preparedness Act Reau-*
24 *thorization of 2011.”.*

1 **SEC. 104. MODERNIZATION OF THE NATIONAL DISASTER**
2 **MEDICAL SYSTEM.**

3 *Section 2812 of the Public Health Service Act (42*
4 *U.S.C. 300hh-11) is amended—*

5 *(1) in subsection (a)(3)—*

6 *(A) in subparagraph (A), in clause (i) by*
7 *inserting “, including at-risk individuals as ap-*
8 *plicable” after “victims of a public health emer-*
9 *gency”;*

10 *(B) by redesignating subparagraph (C) as*
11 *subparagraph (E); and*

12 *(C) by inserting after subparagraph (B),*
13 *the following:*

14 *“(C) CONSIDERATIONS FOR AT-RISK POPU-*
15 *LATIONS.—The Secretary shall take steps to en-*
16 *sure that an appropriate specialized and focused*
17 *range of public health and medical capabilities*
18 *are represented in the National Disaster Medical*
19 *System, which take into account the needs of at-*
20 *risk individuals, in the event of a public health*
21 *emergency.”.*

22 *“(D) ADMINISTRATION.—The Secretary*
23 *may determine and pay claims for reimburse-*
24 *ment for services under subparagraph (A) di-*
25 *rectly or through contracts that provide for pay-*

1 *ment in advance or by way of reimbursement.”;*
 2 *and*

3 *(2) in subsection (g), by striking “such sums as*
 4 *may be necessary for each of the fiscal years 2007*
 5 *through 2011” and inserting “\$56,000,000 for each of*
 6 *fiscal years 2012 through 2016”.*

7 **SEC. 105. CONTINUING THE ROLE OF THE DEPARTMENT OF**
 8 **VETERANS AFFAIRS.**

9 *Section 8117(g) of title 38, United States Code, is*
 10 *amended by striking “such sums as may be necessary to*
 11 *carry out this section for each of fiscal years 2007 through*
 12 *2011” and inserting “\$156,500,000 for each of fiscal years*
 13 *2012 through 2016 to carry out this section”.*

14 **TITLE II—OPTIMIZING STATE**
 15 **AND LOCAL ALL-HAZARDS**
 16 **PREPAREDNESS AND RE-**
 17 **SPONSE**

18 **SEC. 201. IMPROVING STATE AND LOCAL PUBLIC HEALTH**
 19 **SECURITY.**

20 *(a) COOPERATIVE AGREEMENTS.—Section 319C–1 of*
 21 *the Public Health Service Act (42 U.S.C. 247d–3a) is*
 22 *amended—*

23 *(1) in subsection (b)(2)—*

24 *(A) in subparagraph (A)—*

1 (i) by striking clauses (i) and (ii) and
2 inserting the following:

3 “(i) a description of the activities such
4 entity will carry out under the agreement to
5 meet the goals identified under section 2802,
6 including with respect to chemical, biologi-
7 cal, radiological, or nuclear threats, whether
8 naturally occurring, unintentional, or delib-
9 erate;

10 “(ii) a description of the activities such
11 entity will carry out with respect to pan-
12 demic influenza, as a component of the ac-
13 tivities carried out under clause (i), and
14 consistent with the requirements of para-
15 graphs (2) and (5) of subsection (g);”;

16 (ii) in clause (iv), by striking “and” at
17 the end; and

18 (iii) by adding at the end the fol-
19 lowing:

20 “(vi) a description of how, as appro-
21 priate, the entity may partner with relevant
22 public and private stakeholders in public
23 health emergency preparedness and re-
24 sponse;

1 “(vii) a description of how the entity,
2 as applicable and appropriate, will coordi-
3 nate with State emergency preparedness
4 and response plans in public health emer-
5 gency preparedness, including State edu-
6 cational agencies (as defined in section
7 9101(41) of the *Elementary and Secondary*
8 *Education Act of 1965*) and State child care
9 lead agencies (as defined in section 658D of
10 the *Child Care and Development Block*
11 *Grant Act*); and

12 “(viii) in the case of entities that oper-
13 ate on the United States-Mexico border or
14 the United States-Canada border, a descrip-
15 tion of the activities such entity will carry
16 out under the agreement that are specific to
17 the border area including disease detection,
18 identification, and investigation, and pre-
19 paredness and response activities related to
20 emerging diseases and infectious disease
21 outbreaks whether naturally-occurring or
22 due to bioterrorism, consistent with the re-
23 quirements of this section;” and

1 (B) in subparagraph (C), by inserting “,
2 including addressing the needs of at-risk individ-
3 uals,” after “capabilities of such entity”;

4 (2) in subsection (g)—

5 (A) in paragraph (1), by striking subpara-
6 graph (A) and inserting the following:

7 “(A) include outcome goals representing
8 operational achievements of the National Pre-
9 paredness Goals developed under section 2802(b)
10 with respect to all-hazards, including chemical,
11 biological, radiological, or nuclear threats; and”;
12 and

13 (B) in paragraph (2)(A), by adding at the
14 end the following: “The Secretary shall periodi-
15 cally update, as necessary and appropriate, such
16 pandemic influenza plan criteria and shall re-
17 quire the integration of such criteria into the
18 benchmarks and standards described in para-
19 graph (1).”;

20 (3) in subsection (i)—

21 (A) in paragraph (1)(A)—

22 (i) by striking “\$824,000,000 for fiscal
23 year 2007” and inserting “\$632,900,000 for
24 fiscal year 2012”; and

1 (ii) by striking “such sums as may be
 2 necessary for each of fiscal years 2008
 3 through 2011” and inserting “\$632,900,000
 4 for each of fiscal years 2013 through 2016”;
 5 and

6 (B) by adding at the end the following:

7 “(7) AVAILABILITY OF COOPERATIVE AGREEMENT
 8 FUNDS.—

9 “(A) IN GENERAL.—Amounts provided to
 10 an eligible entity under a cooperative agreement
 11 under subsection (a) for a fiscal year and re-
 12 maining unobligated at the end of such year
 13 shall remain available to such entity for the next
 14 fiscal year for the purposes for which such funds
 15 were provided.

16 “(B) FUNDS CONTINGENT ON ACHIEVING
 17 BENCHMARKS.—The continued availability of
 18 funds under subparagraph (A) with respect to an
 19 entity shall be contingent upon such entity
 20 achieving the benchmarks and submitting the
 21 pandemic influenza plan as described in sub-
 22 section (g).”; and

23 (4) in subsection (j), by striking paragraph (3).

24 (b) VACCINE TRACKING AND DISTRIBUTION.—Section
 25 319A(e) of the Public Health Service Act (42 U.S.C. 247d–

1 1(e)) is amended by striking “such sums for each of fiscal
2 years 2007 through 2011” and inserting “\$30,800,000 for
3 each of fiscal years 2012 through 2016”.

4 (c) GAO REPORT.—Section 319C-1 of the Public
5 Health Service Act (42 U.S.C. 247d-3a) is amended by
6 adding at the end the following:

7 “(l) GAO REPORT.—

8 “(1) IN GENERAL.—Not later than 1 year after
9 the date of enactment of the Pandemic and All-Haz-
10 ards Preparedness Act Reauthorization of 2011, the
11 Government Accountability Office shall conduct an
12 independent evaluation, and submit to the appro-
13 priate committees of Congress a report, concerning
14 Federal programs at the Department of Health and
15 Human Services that support medical and public
16 health preparedness and response programs at the
17 State and local levels.

18 “(2) CONTENT.—The report described in para-
19 graph (1) shall review and assess—

20 “(A) the extent to which grant and coopera-
21 tive agreement requirements and goals have been
22 met by recipients;

23 “(B) the extent to which such grants and
24 cooperative agreements have supported medical
25 and public health preparedness and response

1 goals pursuant to section 2802(b), as appro-
2 priate and applicable;

3 “(C) whether recipients or the Department
4 of Health and Human Services have identified
5 any factors that may impede a recipient’s abil-
6 ity to achieve programmatic goals and require-
7 ments; and

8 “(D) instances in which funds may not
9 have been used appropriately, in accordance
10 with grant and cooperative agreement require-
11 ments, and actions taken to address inappro-
12 priate expenditures.”.

13 **SEC. 202. HOSPITAL PREPAREDNESS AND MEDICAL SURGE**
14 **CAPACITY.**

15 (a) *ALL-HAZARDS PUBLIC HEALTH AND MEDICAL*
16 *RESPONSE CURRICULA AND TRAINING.*—Section
17 *319F(a)(5)(B) of the Public Health Service Act (42 U.S.C.*
18 *247d–6(a)(5)(B)) is amended by striking “public health or*
19 *medical” and inserting “public health, medical, or dental”.*

20 (b) *ENCOURAGING HEALTH PROFESSIONAL VOLUN-*
21 *TEERS.*—

22 (1) *EMERGENCY SYSTEM FOR ADVANCE REG-*
23 *ISTRATION OF VOLUNTEER HEALTH PROFES-*
24 *SIONALS.*—Section *319I(k) of the Public Health Serv-*
25 *ice Act (42 U.S.C. 247d–7b(k)) is amended by strik-*

1 *ing “\$2,000,000 for fiscal year 2002, and such sums*
 2 *as may be necessary for each of the fiscal years 2003*
 3 *through 2011” and inserting “\$5,900,000 for each of*
 4 *fiscal years 2012 through 2016”.*

5 (2) *VOLUNTEERS.—Section 2813 of the Public*
 6 *Health Service Act (42 U.S.C. 300hh–15) is amend-*
 7 *ed—*

8 (A) *in subsection (d)(2), by adding at the*
 9 *end the following: “Such training exercises shall,*
 10 *as appropriate and applicable, incorporate the*
 11 *needs of at-risk individuals in the event of a*
 12 *public health emergency.”; and*

13 (B) *in subsection (i), by striking*
 14 *“\$22,000,000 for fiscal year 2007, and such sums*
 15 *as may be necessary for each of fiscal years 2008*
 16 *through 2011” and inserting “\$11,900,000 for*
 17 *each of fiscal years 2012 through 2016”.*

18 (c) *PARTNERSHIPS FOR STATE AND REGIONAL PRE-*
 19 *PAREDNESS TO IMPROVE SURGE CAPACITY.—Section*
 20 *319C–2 of the Public Health Service Act (42 U.S.C. 247d–*
 21 *3b) is amended—*

22 (1) *in subsection (b)(1)(A)(ii), by striking “cen-*
 23 *ters, primary” and inserting “centers, community*
 24 *health centers, primary”;*

1 (2) *by striking subsection (c) and inserting the*
2 *following:*

3 “(c) *USE OF FUNDS.—An award under subsection (a)*
4 *shall be expended for activities to achieve the preparedness*
5 *goals described under paragraphs (1), (3), (4), (5), and (6)*
6 *of section 2802(b) with respect to all-hazards, including*
7 *chemical, biological, radiological, or nuclear threats.”;*

8 (3) *by striking subsection (g) and inserting the*
9 *following:*

10 “(g) *COORDINATION.—*

11 “(1) *LOCAL RESPONSE CAPABILITIES.—An eligi-*
12 *ble entity shall, to the extent practicable, ensure that*
13 *activities carried out under an award under sub-*
14 *section (a) are coordinated with activities of relevant*
15 *local Metropolitan Medical Response Systems, local*
16 *Medical Reserve Corps, the local Cities Readiness Ini-*
17 *tiative, and local emergency plans.*

18 “(2) *NATIONAL COLLABORATION.—Partnerships*
19 *consisting of one or more eligible entities under this*
20 *section may, to the extent practicable, collaborate*
21 *with other partnerships consisting of one or more eli-*
22 *gible entities under this section for purposes of na-*
23 *tional coordination and collaboration with respect to*
24 *activities to achieve the preparedness goals described*

1 under paragraphs (1), (3), (4), (5), and (6) of section
2 2802(b).”; and

3 (4) in subsection (j)—

4 (A) in paragraph (1), by striking
5 “\$474,000,000 for fiscal year 2007, and such
6 sums as may be necessary for each of fiscal years
7 2008 through 2011” and inserting “\$378,000,000
8 for each of fiscal years 2012 through 2016”; and

9 (B) by adding at the end the following:

10 “(4) AVAILABILITY OF COOPERATIVE AGREEMENT
11 FUNDS.—

12 “(A) IN GENERAL.—Amounts provided to
13 an eligible entity under a cooperative agreement
14 under subsection (a) for a fiscal year and re-
15 maining unobligated at the end of such year
16 shall remain available to such entity for the next
17 fiscal year for the purposes for which such funds
18 were provided.

19 “(B) FUNDS CONTINGENT ON ACHIEVING
20 BENCHMARKS.—The continued availability of
21 funds under subparagraph (A) with respect to an
22 entity shall be contingent upon such entity
23 achieving the benchmarks and submitting the
24 pandemic influenza plan as required under sub-
25 section (i).”.

1 **SEC. 203. ENHANCING SITUATIONAL AWARENESS AND BIO-**
2 **SURVEILLANCE.**

3 *Section 319D of the Public Health Service Act (42*
4 *U.S.C. 247d-4) is amended—*

5 *(1) in subsection (b)—*

6 *(A) in paragraph (1)(B), by inserting “poi-*
7 *son control centers,” after “hospitals,”;*

8 *(B) in paragraph (2), by inserting before*
9 *the period the following: “, allowing for coordi-*
10 *nation to maximize all-hazards medical and*
11 *public health preparedness and response and to*
12 *minimize duplication of effort”; and*

13 *(C) in paragraph (3), by inserting before*
14 *the period the following: “and update such*
15 *standards as necessary”;*

16 *(2) in subsection (d)—*

17 *(A) in the subsection heading, by striking*
18 *“PUBLIC HEALTH SITUATIONAL AWARENESS”*
19 *and inserting “MODERNIZING PUBLIC HEALTH*
20 *SITUATIONAL AWARENESS AND BIOSURVEIL-*
21 *LANCE”;*

22 *(B) in paragraph (1)—*

23 *(i) by striking “Pandemic and All-*
24 *Hazards Preparedness Act” and inserting*
25 *“Pandemic and All-Hazards Preparedness*
26 *Act Reauthorization of 2011”; and*

1 (ii) by inserting “, novel emerging
2 threats,” after “disease outbreaks”;

3 (C) by striking paragraph (2) and inserting
4 the following:

5 “(2) *STRATEGY AND IMPLEMENTATION PLAN.*—
6 *Not later than 180 days after the date of enactment*
7 *of the Pandemic and All-Hazards Preparedness Act*
8 *Reauthorization of 2011, the Secretary shall submit to*
9 *the appropriate committees of Congress, a coordinated*
10 *strategy and an accompanying implementation plan*
11 *that identifies and demonstrates the measurable steps*
12 *the Secretary will carry out to—*

13 “(A) *develop, implement, and evaluate the*
14 *network described in paragraph (1), utilizing the*
15 *elements described in paragraph (3); and*

16 “(B) *modernize and enhance biosurveillance*
17 *activities.*”;

18 (D) in paragraph (3)(D), by inserting
19 “community health centers, health centers” after
20 “poison control,”;

21 (E) in paragraph (5), by striking subpara-
22 graph (A) and inserting the following:

23 “(A) *utilize applicable interoperability*
24 *standards as determined by the Secretary, and*
25 *in consultation with the Office of the National*

1 *Coordinator for Health Information Technology,*
2 *through a joint public and private sector proc-*
3 *ess;”;* and

4 *(F) by adding at the end the following:*

5 “(6) *CONSULTATION WITH THE NATIONAL BIO-*
6 *DEFENSE SCIENCE BOARD.—In carrying out this sec-*
7 *tion consistent with section 319M, the National Bio-*
8 *defense Science Board shall provide expert advice and*
9 *guidance, including recommendations, regarding the*
10 *measurable steps the Secretary should take to mod-*
11 *ernize and enhance biosurveillance activities pursuant*
12 *to the efforts of the Department of Health and Hu-*
13 *mans Services to ensure comprehensive, real-time all-*
14 *hazards biosurveillance capabilities. In complying*
15 *with the preceding sentence, the National Biodefense*
16 *Science Board shall—*

17 “(A) *identify the steps necessary to achieve*
18 *a national biosurveillance system for human*
19 *health, with international connectivity, where*
20 *appropriate, that is predicated on State, re-*
21 *gional, and community level capabilities and*
22 *creates a networked system to allow for two-way*
23 *information flow between and among Federal,*
24 *State, and local government public health au-*
25 *thorities and clinical health care providers;*

1 “(B) identify any duplicative surveillance
2 programs under the authority of the Secretary,
3 or changes that are necessary to existing pro-
4 grams, in order to enhance and modernize such
5 activities, minimize duplication, strengthen and
6 streamline such activities under the authority of
7 the Secretary, and achieve real-time and appro-
8 priate data that relate to disease activity, both
9 human and zoonotic; and

10 “(C) coordinate with applicable existing ad-
11 visory committees of the Director of the Centers
12 for Disease Control and Prevention, including
13 such advisory committees consisting of represent-
14 atives from State, local, and tribal public health
15 authorities and appropriate public and private
16 sector health care entities and academic institu-
17 tions, in order to provide guidance on public
18 health surveillance activities.”;

19 (3) in subsection (e)(5), by striking “4 years
20 after the date of enactment of the Pandemic and All-
21 Hazards Preparedness Act” and inserting “3 years
22 after the date of enactment of the Pandemic and All-
23 Hazards Preparedness Act Reauthorization of 2011”;

24 (4) in subsection (g), by striking “such sums as
25 may be necessary in each of fiscal years 2007 through

1 2011” and inserting “\$160,121,000 for each of fiscal
2 years 2012 through 2016”; and

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

4 “(h) *DEFINITION.*—For purposes of this section the
5 term ‘biosurveillance’ means the process of gathering near
6 real-time, biological data that relates to disease activity and
7 threats to human or zoonotic health, in order to achieve
8 early warning and identification of such health threats,
9 early detection and prompt ongoing tracking of health
10 events, and overall situational awareness of disease activ-
11 ity.”.

12 **TITLE III—ENHANCING MEDICAL**
13 **COUNTERMEASURE REVIEW**

14 **SEC. 301. SPECIAL PROTOCOL ASSESSMENT.**

15 Section 505(b)(5)(B) of the Federal Food, Drug, and
16 Cosmetic Act (21 U.S.C. 355(b)(5)(B)) is amended by strik-
17 ing “size of clinical trials intended” and all that follows
18 through “. The sponsor or applicant” and inserting the fol-
19 lowing: “size—

20 “(i)(I) of clinical trials intended to form the pri-
21 mary basis of an effectiveness claim; or

22 “(II) in the case where human efficacy studies
23 are not ethical or feasible, of animal and any associ-
24 ated clinical trials which, in combination, are in-

1 *tended to form the primary basis of an effectiveness*
 2 *claim; or*

3 *“(i) with respect to an application for approval*
 4 *of a biological product under section 351(k) of the*
 5 *Public Health Service Act, of any necessary clinical*
 6 *study or studies.*

7 *The sponsor or applicant”.*

8 **SEC. 302. AUTHORIZATION FOR MEDICAL PRODUCTS FOR**
 9 **USE IN EMERGENCIES.**

10 *(a) IN GENERAL.—Section 564 of the Federal Food,*
 11 *Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) is amend-*
 12 *ed—*

13 *(1) in subsection (a)—*

14 *(A) in paragraph (1), by striking “sections*
 15 *505, 510(k), and 515 of this Act” and inserting*
 16 *“any provision of this Act”;*

17 *(B) in paragraph (2)(A), by striking*
 18 *“under a provision of law referred to in such*
 19 *paragraph” and inserting “under a provision of*
 20 *law in section 505, 510(k), or 515 of this Act or*
 21 *section 351 of the Public Health Service Act”;*
 22 *and*

23 *(C) in paragraph (3), by striking “a provi-*
 24 *sion of law referred to in such paragraph” and*

1 inserting “a provision of law referred to in para-
2 graph (2)(A)”;

3 (2) in subsection (b)—

4 (A) in the subsection heading, by striking
5 “EMERGENCY” and inserting “EMERGENCY OR
6 THREAT JUSTIFYING EMERGENCY AUTHORIZED
7 USE”;

8 (B) in paragraph (1)—

9 (i) in the matter preceding subpara-
10 graph (A), by striking “may declare an
11 emergency” and inserting “may make a
12 declaration that the circumstances exist”;

13 (ii) in subparagraph (A), by striking
14 “specified”;

15 (iii) in subparagraph (B)—

16 (I) by striking “specified”; and

17 (II) by striking “; or” and insert-
18 ing a semicolon;

19 (iv) by amending subparagraph (C) to
20 read as follows:

21 “(C) a determination by the Secretary that
22 there is a public health emergency, or a signifi-
23 cant potential for a public health emergency,
24 that affects, or has a significant potential to af-
25 fect, national security or the health and security

1 *of United States citizens abroad, and that in-*
2 *volves a biological, chemical, radiological, or nu-*
3 *clear agent or agents, or a disease or condition*
4 *that may be attributable to such agent or agents;*
5 *or”;* and

6 *(v) by adding at the end the following:*

7 *“(D) the identification of a material threat*
8 *pursuant to section 319F-2 of the Public Health*
9 *Service Act sufficient to affect national security*
10 *or the health and security of United States citi-*
11 *zens living abroad.”;*

12 *(C) in paragraph (2)(A)—*

13 *(i) by amending clause (ii) to read as*
14 *follows:*

15 *“(ii) a change in the approval status of*
16 *the product such that the circumstances de-*
17 *scribed in subsection (a)(2) have ceased to*
18 *exist.”;*

19 *(ii) by striking subparagraph (B); and*

20 *(iii) by redesignating subparagraph*
21 *(C) as subparagraph (B);*

22 *(D) in paragraph (4), by striking “advance*
23 *notice of termination, and renewal under this*
24 *subsection.” and inserting “, and advance notice*
25 *of termination under this subsection. The Sec-*

1 retary shall make any renewal under this sub-
2 section available on the Internet Web site of the
3 Food and Drug Administration.”; and

4 (E) by adding at the end the following:

5 “(5) *EXPLANATION BY SECRETARY.*—If an au-
6 thorization under this section with respect to an un-
7 approved product has been in effect for more than 1
8 year, the Secretary shall provide in writing to the
9 sponsor of such product, an explanation of the sci-
10 entific, regulatory, or other obstacles to approval, li-
11 censure, or clearance of such product, including spe-
12 cific actions to be taken by the Secretary and the
13 sponsor to overcome such obstacles.”;

14 (3) in subsection (c)—

15 (A) in the matter preceding paragraph

16 (1)—

17 (i) by inserting “the Assistant Sec-
18 retary for Preparedness and Response,”
19 after “consultation with”;

20 (ii) by striking “Health and” and in-
21 serting “Health, and”; and

22 (iii) by striking “circumstances of the
23 emergency involved” and inserting “appli-
24 cable circumstances described in subsection
25 (b)(1)”;

1 (B) in paragraph (1), by striking “speci-
2 fied” and inserting “referred to”; and

3 (C) in paragraph (2)(B), by inserting “,
4 taking into consideration the material threat
5 posed by the agent or agents identified in a dec-
6 laration under subsection (b)(1)(D), if applica-
7 ble” after “risks of the product”;

8 (4) in subsection (d)(3), by inserting “, to the ex-
9 tent practicable given the circumstances of the emer-
10 gency,” after “including”;

11 (5) in subsection (e)—

12 (A) in paragraph (1)(A), by striking “cir-
13 cumstances of the emergency” and inserting “ap-
14 plicable circumstances described in subsection
15 (b)(1)”;

16 (B) in paragraph (2)—

17 (i) in subparagraph (A)—

18 (I) by striking “manufacturer of
19 the product” and inserting “person”;

20 (II) by striking “circumstances of
21 the emergency” and inserting “appli-
22 cable circumstances described in sub-
23 section (b)(1)”;

1 (III) by inserting at the end be-
2 fore the period “or in paragraph
3 (1)(B)”;

4 (ii) in subparagraph (B)(i), by insert-
5 ing before the period at the end “, except as
6 provided in section 564A with respect to au-
7 thorized changes to the product expiration
8 date”; and

9 (iii) by amending subparagraph (C) to
10 read as follows:

11 “(C) In establishing conditions under this
12 paragraph with respect to the distribution and
13 administration of the product for the unap-
14 proved use, the Secretary shall not impose condi-
15 tions that would restrict distribution or adminis-
16 tration of the product when done solely for the
17 approved use.”; and

18 (C) by amending paragraph (3) to read as
19 follows:

20 “(3) *GOOD MANUFACTURING PRACTICE; PRE-*
21 *SCRIPTION.—With respect to the emergency use of a*
22 *product for which an authorization under this section*
23 *is issued (whether an unapproved product or an un-*
24 *approved use of an approved product), the Secretary*
25 *may waive or limit, to the extent appropriate given*

1 *the applicable circumstances described in subsection*
2 *(b)(1)—*

3 *“(A) requirements regarding current good*
4 *manufacturing practice otherwise applicable to*
5 *the manufacture, processing, packing, or holding*
6 *of products subject to regulation under this Act,*
7 *including such requirements established under*
8 *section 501 or 520(f)(1), and including relevant*
9 *conditions prescribed with respect to the product*
10 *by an order under section 520(f)(2);*

11 *“(B) requirements established under section*
12 *503(b); and*

13 *“(C) requirements established under section*
14 *520(e).”;*

15 *(6) in subsection (g)—*

16 *(A) in the subsection heading, by inserting*
17 *“REVIEW AND” before “REVOCATION”;*

18 *(B) in paragraph (1), by inserting after the*
19 *period at the end the following: “As part of such*
20 *review, the Secretary shall regularly review the*
21 *progress made with respect to the approval, li-*
22 *cence, or clearance of—*

23 *“(A) an unapproved product for which an*
24 *authorization was issued under this section; or*

1 “(B) an unapproved use of an approved
2 product for which an authorization was issued
3 under this section.”; and

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

6 “(2) *REVISION AND REVOCATION.*—The Secretary
7 may revise or revoke an authorization under this sec-
8 tion if—

9 “(A) the circumstances described under sub-
10 section (b)(1) no longer exist;

11 “(B) the criteria under subsection (c) for
12 issuance of such authorization are no longer met;
13 or

14 “(C) other circumstances make such revision
15 or revocation appropriate to protect the public
16 health or safety.”;

17 (7) in subsection (h)(1), by adding after the pe-
18 riod at the end the following: “The Secretary shall
19 make any revisions to an authorization under this
20 section available on the Internet Web site of the Food
21 and Drug Administration.”; and

22 (8) by adding at the end of subsection (j) the fol-
23 lowing:

24 “(4) Nothing in this section shall be construed as
25 authorizing a delay in the review or other consider-

1 *ation by the Food and Drug Administration of any*
 2 *application pending before the Administration for a*
 3 *countermeasure or product referred to in subsection*
 4 *(a).”.*

5 *(b) EMERGENCY USE OF MEDICAL PRODUCTS.—Sub-*
 6 *chapter E of chapter V of the Federal Food, Drug, and Cos-*
 7 *metic Act (21 U.S.C. 360bbb et seq.) is amended by insert-*
 8 *ing after section 564 the following:*

9 **“SEC. 564A. EMERGENCY USE OF MEDICAL PRODUCTS.**

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

11 *“(1) ELIGIBLE PRODUCT.—The term ‘eligible*
 12 *product’ means a product that—*

13 *“(A) is approved or cleared under this*
 14 *chapter or licensed under section 351 of the Pub-*
 15 *lic Health Service Act;*

16 *“(B)(i) is intended for use to prevent, diag-*
 17 *nose, or treat a disease or condition involving a*
 18 *biological, chemical, radiological, or nuclear*
 19 *agent or agents, including a product intended to*
 20 *be used to prevent or treat pandemic influenza;*
 21 *or*

22 *“(ii) is intended for use to prevent, diag-*
 23 *nose, or treat a serious or life-threatening disease*
 24 *or condition caused by a product described in*
 25 *clause (i); and*

1 “(C) is intended for use during the cir-
2 cumstances under which—

3 “(i) a determination described in sub-
4 paragraph (A), (B), or (C) of section
5 564(b)(1) has been made by the Secretary of
6 Homeland Security, the Secretary of De-
7 fense, or the Secretary, respectively; or

8 “(ii) the identification of a material
9 threat described in subparagraph (D) of sec-
10 tion 564(b)(1) has been made pursuant to
11 section 319F-2 of the Public Health Service
12 Act.

13 “(2) *PRODUCT*.—The term ‘product’ means a
14 drug, device, or biological product.

15 “(b) *EXTENSION OF EXPIRATION DATE*.—

16 “(1) *AUTHORITY TO EXTEND EXPIRATION*
17 *DATE*.—The Secretary may extend the expiration date
18 of an eligible product in accordance with this sub-
19 section.

20 “(2) *EXPIRATION DATE*.—For purposes of this
21 subsection, the term ‘expiration date’ means the date
22 established through appropriate stability testing re-
23 quired by the regulations issued by the Secretary to
24 ensure that the product meets applicable standards of

1 *identity, strength, quality, and purity at the time of*
2 *use.*

3 “(3) *EFFECT OF EXTENSION.*—*Notwithstanding*
4 *any other provision of this Act or the Public Health*
5 *Service Act, if the expiration date of an eligible prod-*
6 *uct is extended in accordance with this section, the*
7 *introduction or delivery for introduction into inter-*
8 *state commerce of such product after the expiration*
9 *date provided by the manufacturer and within the*
10 *duration of such extension shall not be deemed to*
11 *render the product—*

12 “(A) *an unapproved product; or*

13 “(B) *adulterated or misbranded under this*
14 *Act.*

15 “(4) *DETERMINATIONS BY SECRETARY.*—*Before*
16 *extending the expiration date of an eligible product*
17 *under this subsection, the Secretary shall determine—*

18 “(A) *that extension of the expiration date*
19 *will help protect public health;*

20 “(B) *that any extension of expiration is*
21 *supported by scientific evaluation that is con-*
22 *ducted or accepted by the Secretary;*

23 “(C) *what changes to the product labeling,*
24 *if any, are required or permitted, including*
25 *whether and how any additional labeling com-*

1 *communicating the extension of the expiration date*
2 *may alter or obscure the labeling provided by the*
3 *manufacturer; and*

4 “(D) *that any other conditions that the Sec-*
5 *retary deems appropriate have been met.*

6 “(5) *SCOPE OF EXTENSION.—With respect to*
7 *each extension of an expiration date granted under*
8 *this subsection, the Secretary shall determine—*

9 “(A) *the batch, lot, or unit to which such*
10 *extension shall apply;*

11 “(B) *the duration of such extension; and*

12 “(C) *any conditions to effectuate such exten-*
13 *sion that are necessary and appropriate to pro-*
14 *tect public health or safety.*

15 “(c) *CURRENT GOOD MANUFACTURING PRACTICE.—*

16 “(1) *IN GENERAL.—The Secretary may, when*
17 *the circumstances of a domestic, military, or public*
18 *health emergency or material threat described in sub-*
19 *section (a)(1)(C) so warrant, authorize, with respect*
20 *to an eligible product, deviations from current good*
21 *manufacturing practice requirements otherwise appli-*
22 *cable to the manufacture, processing, packing, or*
23 *holding of products subject to regulation under this*
24 *Act, including requirements under section 501 or*
25 *520(f)(1) or applicable conditions prescribed with re-*

1 *spect to the eligible product by an order under section*
2 *520(f)(2).*

3 “(2) *EFFECT.*—*Notwithstanding any other pro-*
4 *vision of this Act or the Public Health Service Act,*
5 *an eligible product shall not be considered an unap-*
6 *proved product and shall not be deemed adulterated*
7 *or misbranded under this Act because, with respect to*
8 *such product, the Secretary has authorized deviations*
9 *from current good manufacturing practices under*
10 *paragraph (1).*

11 “(d) *EMERGENCY USE INSTRUCTIONS.*—

12 “(1) *IN GENERAL.*—*The Secretary, acting*
13 *through an appropriate official within the Depart-*
14 *ment of Health and Human Services, may create and*
15 *issue emergency use instructions to inform health care*
16 *providers or individuals to whom an eligible product*
17 *is to be administered concerning such product’s ap-*
18 *proved, licensed, or cleared conditions of use.*

19 “(2) *EFFECT.*—*Notwithstanding any other pro-*
20 *visions of this Act or the Public Health Service Act,*
21 *a product shall not be considered an unapproved*
22 *product and shall not be deemed adulterated or mis-*
23 *branded under this Act because of the issuance of*
24 *emergency use instructions under paragraph (1) with*
25 *respect to such product or the introduction or delivery*

1 *for introduction of such product into interstate com-*
 2 *merce accompanied by such instructions—*

3 “(A) *during an emergency response to an*
 4 *actual emergency that is the basis for a deter-*
 5 *mination described in subsection (a)(1)(C)(i); or*

6 “(B) *by a government entity (including a*
 7 *Federal, State, local, and tribal government enti-*
 8 *ty), or a person acting on behalf of such a gov-*
 9 *ernment entity, in preparation for an emergency*
 10 *response.”.*

11 (c) *RISK EVALUATION AND MITIGATION STRATE-*
 12 *GIES.—Section 505–1 of the Federal Food, Drug, and Cos-*
 13 *metic Act (21 U.S.C. 355–1), is amended—*

14 (1) *in subsection (f), by striking paragraph (7);*
 15 *and*

16 (2) *by adding at the end the following:*

17 “(k) *WAIVER IN PUBLIC HEALTH EMERGENCIES.—*
 18 *The Secretary may waive any requirement of this section*
 19 *with respect to a qualified countermeasure (as defined in*
 20 *section 319F–1(a)(2) of the Public Health Service Act) to*
 21 *which a requirement under this section has been applied,*
 22 *if the Secretary determines that such waiver is required to*
 23 *mitigate the effects of, or reduce the severity of, the cir-*
 24 *cumstances under which—*

1 “(1) a determination described in subparagraph
2 (A), (B), or (C) of section 564(b)(1) has been made
3 by the Secretary of Homeland Security, the Secretary
4 of Defense, or the Secretary, respectively; or

5 “(2) the identification of a material threat de-
6 scribed in subparagraph (D) of section 564(b)(1) has
7 been made pursuant to section 319F-2 of the Public
8 Health Service Act.”.

9 (d) *PRODUCTS HELD FOR EMERGENCY USE.*—The
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
11 seq.) is amended by inserting after section 564A, as added
12 by subsection (b), the following:

13 “**SEC. 564B. PRODUCTS HELD FOR EMERGENCY USE.**

14 “*It is not a violation of any section of this Act or of*
15 *the Public Health Service Act for a government entity (in-*
16 *cluding a Federal, State, local, and tribal government enti-*
17 *ty), or a person acting on behalf of such a government enti-*
18 *ty, to introduce into interstate commerce a product (as de-*
19 *finied in section 564(a)(4)) intended for emergency use, if*
20 *that product—*

21 “(1) is intended to be held and not used; and

22 “(2) is held and not used, unless and until that
23 product—

1 “(A) is approved, cleared, or licensed under
2 section 505, 510(k), or 515 of this Act or section
3 351 of the Public Health Service Act;

4 “(B) is authorized for investigational use
5 under section 505 or 520 of this Act or section
6 351 of the Public Health Service Act; or

7 “(C) is authorized for use under section
8 564.”.

9 **SEC. 303. DEFINITIONS.**

10 Section 565 of the Federal Food, Drug, and Cosmetic
11 Act (21 U.S.C. 360bbb-4) is amended by striking “The Sec-
12 retary, in consultation” and inserting the following:

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

14 “(1) the term ‘countermeasure’ means a qualified
15 countermeasure, a security countermeasure, and a
16 qualified pandemic or epidemic product;

17 “(2) the term ‘qualified countermeasure’ has the
18 meaning given such term in section 319F-1 of the
19 Public Health Service Act;

20 “(3) the term ‘security countermeasure’ has the
21 meaning given such term in section 319F-2 of such
22 Act; and

23 “(4) the term ‘qualified pandemic or epidemic
24 product’ means a product that meets the definition

1 given such term in section 319F-3 of the Public
2 Health Service Act and—

3 “(A) that has been identified by the Depart-
4 ment of Health and Human Services or the De-
5 partment of Defense as receiving funding directly
6 related to addressing chemical, biological, radio-
7 logical or nuclear threats, including pandemic
8 influenza; or

9 “(B) is included under this paragraph pur-
10 suant to a determination by the Secretary.

11 “(b) *GENERAL DUTIES.*—The Secretary, in consulta-
12 tion”.

13 **SEC. 304. ENHANCING MEDICAL COUNTERMEASURE ACTIVI-**
14 **TIES.**

15 Section 565 of the Federal Food, Drug, and Cosmetic
16 Act (21 U.S.C. 360bbb-4), as amended by section 303, is
17 further amended—

18 (1) in the section heading, by striking “**TECH-**
19 **NICAL ASSISTANCE**” and inserting “**COUNTER-**
20 **MEASURE DEVELOPMENT, REVIEW, AND TECH-**
21 **NICAL ASSISTANCE**”;

22 (2) in subsection (b), by striking the subsection
23 heading and all that follows through “shall establish”
24 and inserting the following:

1 “(b) *GENERAL DUTIES.*—*In order to accelerate the de-*
2 *velopment, stockpiling, approval, licensure, and clearance*
3 *of qualified countermeasures, security countermeasures, and*
4 *qualified pandemic or epidemic products, the Secretary, in*
5 *consultation with the Assistant Secretary for Preparedness*
6 *and Response, shall—*

7 “(1) *ensure the appropriate involvement of Food*
8 *and Drug Administration personnel in interagency*
9 *activities related to countermeasure advanced research*
10 *and development, consistent with sections 319F,*
11 *319F-1, 319F-2, 319F-3, and 319L of the Public*
12 *Health Service Act;*

13 “(2) *ensure the appropriate involvement and*
14 *consultation of Food and Drug Administration per-*
15 *sonnel in any flexible manufacturing activities car-*
16 *ried out under section 319L of the Public Health*
17 *Service Act, including with respect to meeting regu-*
18 *latory requirements set forth in this Act;*

19 “(3) *promote countermeasure expertise within*
20 *the Food and Drug Administration by—*

21 “(A) *ensuring that Food and Drug Admin-*
22 *istration personnel involved in reviewing coun-*
23 *termeasures for approval, licensure, or clearance*
24 *are informed by the Assistant Secretary for Pre-*
25 *paredness and Response on the material threat*

1 *assessment conducted under section 319F-2 of*
2 *the Public Health Service Act for the agent or*
3 *agents for which the countermeasure under re-*
4 *view is intended;*

5 *“(B) training Food and Drug Administra-*
6 *tion personnel regarding review of counter-*
7 *measures for approval, licensure, or clearance;*

8 *“(C) holding public meetings at least twice*
9 *annually to encourage the exchange of scientific*
10 *ideas; and*

11 *“(D) establishing protocols to ensure that*
12 *countermeasure reviewers have sufficient train-*
13 *ing or experience with countermeasures;*

14 *“(4) maintain teams, composed of Food and*
15 *Drug Administration personnel with expertise on*
16 *countermeasures, including specific countermeasures,*
17 *populations with special clinical needs (including*
18 *children and pregnant women that may use counter-*
19 *measures, as applicable and appropriate), classes or*
20 *groups of countermeasures, or other countermeasure-*
21 *related technologies and capabilities, that shall—*

22 *“(A) consult with countermeasure experts,*
23 *including countermeasure sponsors and appli-*
24 *cants, to identify and help resolve scientific*
25 *issues related to the approval, licensure, or clear-*

1 *ance of countermeasures, through workshops or*
2 *public meetings;*

3 “(B) *improve and advance the science relat-*
4 *ing to the development of new tools, standards,*
5 *and approaches to assessing and evaluating*
6 *countermeasures—*

7 “(i) *in order to inform the process for*
8 *countermeasure approval, clearance, and li-*
9 *cence; and*

10 “(ii) *with respect to the development of*
11 *countermeasures for populations with spe-*
12 *cial clinical needs, including children and*
13 *pregnant women, in order to meet the needs*
14 *of such populations, as necessary and ap-*
15 *propriate; and*

16 “(5) *establish*”; and

17 (3) *by adding at the end the following:*

18 “(c) *DEVELOPMENT AND ANIMAL MODELING PROCE-*
19 *DURES.—*

20 “(1) *AVAILABILITY OF ANIMAL MODEL MEET-*
21 *INGS.—To facilitate the timely development of animal*
22 *models and support the development, stockpiling, li-*
23 *cence, approval, and clearance of countermeasures,*
24 *the Secretary shall, not later than 180 days after the*
25 *enactment of this subsection, establish a procedure by*

1 *which a sponsor or applicant that is developing a*
2 *countermeasure for which human efficacy studies are*
3 *not ethical or practicable, and that has an approved*
4 *investigational new drug application or investiga-*
5 *tional device exemption, may request and receive—*

6 “(A) *a meeting to discuss proposed animal*
7 *model development activities; and*

8 “(B) *a meeting prior to initiating pivotal*
9 *animal studies.*

10 “(2) *PEDIATRIC MODELS.—To facilitate the de-*
11 *velopment and selection of animal models that could*
12 *translate to pediatric studies, any meeting conducted*
13 *under paragraph (1) shall include discussion of ani-*
14 *mal models for pediatric populations, as appropriate.*

15 “(d) *REVIEW AND APPROVAL OF COUNTER-*
16 *MEASURES.—*

17 “(1) *MATERIAL THREAT.—When evaluating an*
18 *application or submission for approval, licensure, or*
19 *clearance of a countermeasure, the Secretary shall*
20 *take into account the material threat posed by the*
21 *chemical, biological, radiological, or nuclear agent or*
22 *agents identified under section 319F–2 of the Public*
23 *Health Service Act for which the countermeasure*
24 *under review is intended.*

1 “(2) *REVIEW EXPERTISE.*—When practicable
2 and appropriate, teams of Food and Drug Adminis-
3 tration personnel reviewing applications or submis-
4 sions described under paragraph (1) shall include a
5 reviewer with sufficient training or experience with
6 countermeasures pursuant to the protocols established
7 under subsection (b)(3)(D).”.

8 **SEC. 305. REGULATORY MANAGEMENT PLANS.**

9 Section 565 of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 360bbb–4), as amended by section 304, is
11 further amended by adding at the end the following:

12 “(e) *REGULATORY MANAGEMENT PLAN.*—

13 “(1) *DEFINITION.*—In this subsection, the term
14 ‘eligible countermeasure’ means—

15 “(A) a security countermeasure with respect
16 to which the Secretary has entered into a pro-
17 curement contract under section 319F-2(c) of the
18 Public Health Service Act; or

19 “(B) a countermeasure with respect to
20 which the Biomedical Advanced Research and
21 Development Authority has provided funding
22 under section 319L of the Public Health Service
23 Act for advanced research and development.

24 “(2) *REGULATORY MANAGEMENT PLAN PROC-*
25 *ESS.*—The Secretary, in consultation with the Assist-

1 *ant Secretary for Preparedness and Response and the*
2 *Director of the Biomedical Advanced Research and*
3 *Development Authority, shall establish a formal proc-*
4 *ess for obtaining scientific feedback and interactions*
5 *regarding the development and regulatory review of*
6 *eligible countermeasures by facilitating the develop-*
7 *ment of written regulatory management plans in ac-*
8 *cordance with this subsection.*

9 *“(3) SUBMISSION OF REQUEST AND PROPOSED*
10 *PLAN BY SPONSOR OR APPLICANT.—*

11 *“(A) IN GENERAL.—A sponsor or applicant*
12 *of an eligible countermeasure may initiate the*
13 *process described under paragraph (2) upon sub-*
14 *mission of written request to the Secretary. Such*
15 *request shall include a proposed regulatory man-*
16 *agement plan.*

17 *“(B) TIMING OF SUBMISSION.—A sponsor*
18 *or applicant may submit a written request*
19 *under subparagraph (A) after the eligible coun-*
20 *termeasure has an investigational new drug or*
21 *investigational device exemption in effect.*

22 *“(C) RESPONSE BY SECRETARY.—The Sec-*
23 *retary shall direct the Food and Drug Adminis-*
24 *tration, upon submission of a written request by*
25 *a sponsor or applicant under subparagraph (A),*

1 to work with the sponsor or applicant to agree
2 on a regulatory management plan within a rea-
3 sonable time not to exceed 90 days. If the Sec-
4 retary determines that no plan can be agreed
5 upon, the Secretary shall provide to the sponsor
6 or applicant, in writing, the scientific or regu-
7 latory rationale why such agreement cannot be
8 reached.

9 “(4) *PLAN.*—The content of a regulatory man-
10 agement plan agreed to by the Secretary and a spon-
11 sor or applicant shall include—

12 “(A) an agreement between the Secretary
13 and the sponsor or applicant regarding develop-
14 mental milestones that will trigger responses by
15 the Secretary as described in subparagraph (B);

16 “(B) performance targets and goals for
17 timely and appropriate responses by the Sec-
18 retary to the triggers described under subpara-
19 graph (A), including meetings between the Sec-
20 retary and the sponsor or applicant, written
21 feedback, decisions by the Secretary, and other
22 activities carried out as part of the development
23 and review process; and

24 “(C) an agreement on how the plan shall be
25 modified, if needed.

1 “(5) *MILESTONES AND PERFORMANCE TAR-*
2 *GETS.—The developmental milestones described in*
3 *paragraph (4)(A) and the performance targets and*
4 *goals described in paragraph (4)(B) shall include—*

5 “(A) *feedback from the Secretary regarding*
6 *the data required to support the approval, clear-*
7 *ance, or licensure of the eligible countermeasure*
8 *involved;*

9 “(B) *feedback from the Secretary regarding*
10 *the data necessary to inform any authorization*
11 *under section 564;*

12 “(C) *feedback from the Secretary regarding*
13 *the data necessary to support the positioning*
14 *and delivery of the eligible countermeasure, in-*
15 *cluding to the Strategic National Stockpile;*

16 “(D) *feedback from the Secretary regarding*
17 *the data necessary to support the submission of*
18 *protocols for review under section 505(b)(5)(B);*

19 “(E) *feedback from the Secretary regarding*
20 *any gaps in scientific knowledge that will need*
21 *resolution prior to approval, licensure, or clear-*
22 *ance of the eligible countermeasure, and plans*
23 *for conducting the necessary scientific research;*

24 “(F) *identification of the population for*
25 *which the countermeasure sponsor or applicant*

1 *seeks approval, licensure, or clearance, and the*
2 *population for which desired labeling would not*
3 *be appropriate, if known; and*

4 “(G) *as necessary and appropriate, and to*
5 *the extent practicable, a plan for demonstrating*
6 *safety and effectiveness in pediatric populations,*
7 *and for developing pediatric dosing, formulation,*
8 *and administration with respect to the eligible*
9 *countermeasure, provided that such plan would*
10 *not delay authorization under section 564, ap-*
11 *proval, licensure, or clearance for adults.*

12 “(6) *PRIORITIZATION.—If the Commissioner of*
13 *Food and Drugs determines that resources are not*
14 *available to establish regulatory management plans*
15 *under this section for all eligible countermeasures for*
16 *which a request is submitted under paragraph (3)(A),*
17 *the Director of the Biomedical Advanced Research*
18 *and Development Authority, in consultation with the*
19 *Commissioner of Food and Drugs, shall prioritize*
20 *which eligible countermeasures may receive regulatory*
21 *managements plans, and in doing so shall give pri-*
22 *ority to eligible countermeasures that are security*
23 *countermeasures.”.*

1 **SEC. 306. REPORT.**

2 *Section 565 of the Federal Food, Drug, and Cosmetic*
3 *Act (21 U.S.C. 360bbb-4), as amended by section 305, is*
4 *further amended by adding at the end the following:*

5 “(f) *ANNUAL REPORT.*—*Not later than 180 days after*
6 *the date of enactment of this subsection, and annually there-*
7 *after, the Secretary shall submit to the Committee on*
8 *Health, Education, Labor, and Pensions of the Senate and*
9 *the Committee on Energy and Commerce of the House of*
10 *Representatives a report that details the countermeasure de-*
11 *velopment and review activities of the Food and Drug Ad-*
12 *ministration, including—*

13 “(1) *with respect to the development of new tools,*
14 *standards, and approaches to assess and evaluate*
15 *countermeasures—*

16 “(A) *the identification of the priorities of*
17 *the Food and Drug Administration and the*
18 *progress made on such priorities; and*

19 “(B) *the identification of scientific gaps*
20 *that impede the development or approval, licen-*
21 *sure, or clearance of countermeasures for popu-*
22 *lations with special clinical needs, including*
23 *children and pregnant women, and the progress*
24 *made on resolving these challenges;*

25 “(2) *with respect to countermeasures for which a*
26 *regulatory management plan has been agreed upon*

1 *under subsection (e), the extent to which the perform-*
2 *ance targets and goals set forth in subsection*
3 *(e)(4)(B) and the regulatory management plan has*
4 *been met, including, for each such countermeasure—*

5 *“(A) whether the regulatory management*
6 *plan was completed within the required time-*
7 *frame, and the length of time taken to complete*
8 *such plan;*

9 *“(B) whether the Secretary adhered to the*
10 *timely and appropriate response times set forth*
11 *in such plan; and*

12 *“(C) explanations for any failure to meet*
13 *such performance targets and goals;*

14 *“(3) the number of regulatory teams established*
15 *pursuant to subsection (b)(4), the number of products,*
16 *classes of products, or technologies assigned to each*
17 *such team, and the number of, type of, and any*
18 *progress made as a result of consultations carried out*
19 *under subsection (b)(4)(A);*

20 *“(4) an estimate of resources obligated to coun-*
21 *termeasure development and regulatory assessment,*
22 *including Center specific objectives and accomplish-*
23 *ments;*

24 *“(5) the number of countermeasure applications*
25 *submitted, the number of countermeasures approved,*

1 *licensed, or cleared, the status of remaining submitted*
2 *applications, and the number of each type of author-*
3 *ization issued pursuant to section 564; and*

4 “(6) *the number of written requests for a regu-*
5 *latory management plan submitted under subsection*
6 *(e)(3)(A), the number of regulatory management*
7 *plans developed, and the number of such plans devel-*
8 *oped for security countermeasures.”.*

9 **SEC. 307. PEDIATRIC MEDICAL COUNTERMEASURES.**

10 *(a) PEDIATRIC STUDIES OF DRUGS.—Section 505A of*
11 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a)*
12 *is amended—*

13 *(1) in subsection (d), by adding at the end the*
14 *following:*

15 “(5) *CONSULTATION.—With respect to a drug*
16 *that is a qualified countermeasure (as defined in sec-*
17 *tion 319F–1 of the Public Health Service Act), a secu-*
18 *rity countermeasure (as defined in section 319F–2 of*
19 *the Public Health Service Act), or a qualified pan-*
20 *demic or epidemic product (as defined in section*
21 *319F–3 of the Public Health Service Act), the Sec-*
22 *retary shall solicit input from the Assistant Secretary*
23 *for Preparedness and Response regarding the need for*
24 *and, from the Director of the Biomedical Advanced*

1 *Research and Development Authority regarding the*
2 *conduct of, pediatric studies under this section.”; and*

3 *(2) in subsection (n)(1), by adding at the end the*
4 *following:*

5 *“(C) For a drug that is a qualified counter-*
6 *measure (as defined in section 319F–1 of the*
7 *Public Health Service Act), a security counter-*
8 *measure (as defined in section 319F–2 of the*
9 *Public Health Service Act), or a qualified pan-*
10 *demic or epidemic product (as defined in section*
11 *319F–3 of such Act), in addition to any action*
12 *with respect to such drug under subparagraph*
13 *(A) or (B), the Secretary shall notify the Assist-*
14 *ant Secretary for Preparedness and Response*
15 *and the Director of the Biomedical Advanced Re-*
16 *search and Development Authority of all pedi-*
17 *atric studies in the written request issued by the*
18 *Commissioner of Food and Drugs.”.*

19 *(b) ADDITION TO PRIORITY LIST CONSIDERATIONS.—*
20 *Section 409I of the Public Health Service Act (42 U.S.C.*
21 *284m) is amended—*

22 *(1) by striking subsection (a)(2) and inserting*
23 *the following:*

1 “(2) *CONSIDERATION OF AVAILABLE INFORMA-*
2 *TION.—In developing and prioritizing the list under*
3 *paragraph (1), the Secretary—*

4 “(A) *shall consider—*

5 “(i) *therapeutic gaps in pediatrics that*
6 *may include developmental pharmacology,*
7 *pharmacogenetic determinants of drug re-*
8 *sponse, metabolism of drugs and biologics in*
9 *children, and pediatric clinical trials;*

10 “(ii) *particular pediatric diseases, dis-*
11 *orders or conditions where more complete*
12 *knowledge and testing of therapeutics, in-*
13 *cluding drugs and biologics, may be bene-*
14 *ficial in pediatric populations; and*

15 “(iii) *the adequacy of necessary infra-*
16 *structure to conduct pediatric pharma-*
17 *cological research, including research net-*
18 *works and trained pediatric investigators;*
19 *and*

20 “(B) *may consider the availability of quali-*
21 *fied countermeasures (as defined in section*
22 *319F–1), security countermeasures (as defined in*
23 *section 319F–2), and qualified pandemic or epi-*
24 *demic products (as defined in section 319F–3) to*
25 *address the needs of pediatric populations, in*

1 *consultation with the Assistant Secretary for*
 2 *Preparedness and Response, consistent with the*
 3 *purposes of this section.”; and*

4 *(2) in subsection (b), by striking “subsection (a)”*
 5 *and inserting “paragraphs (1) and (2)(A) of sub-*
 6 *section (a)”.*

7 *(c) ADVICE AND RECOMMENDATIONS OF THE PEDI-*
 8 *ATRIC ADVISORY COMMITTEE REGARDING COUNTER-*
 9 *MEASURES FOR PEDIATRIC POPULATIONS.—Subsection*
 10 *(b)(2) of section 14 of the Best Pharmaceuticals for Children*
 11 *Act (42 U.S.C. 284m note) is amended—*

12 *(1) in subparagraph (C), by striking the period*
 13 *and inserting “; and”; and*

14 *(2) by adding at the end the following:*

15 *“(D) the development of countermeasures*
 16 *(as defined in section 565(a) of the Federal Food,*
 17 *Drug, and Cosmetic Act) for pediatric popu-*
 18 *lations.”.*

19 **TITLE IV—ACCELERATING MED-**
 20 **ICAL COUNTERMEASURE AD-**
 21 **VANCED RESEARCH AND DE-**
 22 **VELOPMENT**

23 **SEC. 401. BIOSHIELD.**

24 *(a) REAUTHORIZATION OF THE SPECIAL RESERVE*
 25 *FUND.—Section 319F–2(c) of the Public Health Service Act*

1 *(42 U.S.C. 247d-6b(c)) is amended by adding at the end*
2 *the following:*

3 “(11) *REAUTHORIZATION OF THE SPECIAL RE-*
4 *SERVE FUND.—In addition to amounts otherwise ap-*
5 *propriated, there are authorized to be appropriated*
6 *for the special reserve fund, \$2,800,000,000 for the fis-*
7 *cal years 2014 through 2018.*

8 “(12) *REPORT.—Not later than 30 days after*
9 *any date on which the Secretary determines that the*
10 *amount of funds in the special reserve fund available*
11 *for procurement is less than \$1,500,000,000, the Sec-*
12 *retary shall submit to the appropriate committees of*
13 *Congress a report detailing the amount of such funds*
14 *available for procurement and the impact such reduc-*
15 *tion in funding will have—*

16 “(A) *in meeting the security countermeasure*
17 *needs identified under this section; and*

18 “(B) *on the biennial Public Health Emer-*
19 *gency Medical Countermeasures Enterprise and*
20 *Strategy Implementation Plan (pursuant to sec-*
21 *tion 2811(d)).”.*

22 “(b) *PROCUREMENT OF COUNTERMEASURES.—Section*
23 *319F-2(c) of the Public Health Service Act (42 U.S.C.*
24 *247d-6b(c)) is amended—*

1 (1) in paragraph (1)(B)(i)(III)(bb), by striking
2 “eight years” and inserting “10 years”;

3 (2) in paragraph (5)(B)(ii), by striking “eight
4 years” and inserting “10 years”;

5 (3) in paragraph (7)(C)—

6 (A) in clause (i)(I), by inserting “including
7 advanced research and development,” after “as
8 may reasonably be required,”;

9 (B) in clause (ii)—

10 (i) in subclause (III), by striking
11 “eight years” and inserting “10 years”; and

12 (ii) by striking subclause (IX) and in-
13 serting the following:

14 “(IX) CONTRACT TERMS.—The
15 Secretary, in any contract for procure-
16 ment under this section—

17 “(aa) may specify—

18 “(AA) the dosing and
19 administration requirements
20 for the countermeasure to be
21 developed and procured;

22 “(BB) the amount of
23 funding that will be dedi-
24 cated by the Secretary for
25 advanced research, develop-

1 (4) in paragraph (9)(B), by inserting before the
2 period the following: “, except that this subparagraph
3 shall not be construed to prohibit the use of such
4 amounts as otherwise authorized in this title”; and

5 (5) in paragraph (10), by adding at the end the
6 following:

7 “(C) *ADVANCED RESEARCH AND DEVELOP-*
8 *MENT.—For purposes of this paragraph, the*
9 *term ‘advanced research and development’ shall*
10 *have the meaning given such term in section*
11 *319L(a).”.*

12 **SEC. 402. BIOMEDICAL ADVANCED RESEARCH AND DEVEL-**
13 **OPMENT AUTHORITY.**

14 (a) *DUTIES.—Section 319L(c)(4) of the Public Health*
15 *Service Act (42 U.S.C. 247d–7e(c)(4)) is amended—*

16 (1) in subparagraph (B)(iii), by inserting
17 “(which may include advanced research and develop-
18 ment for purposes of fulfilling requirements under the
19 Federal Food, Drug, and Cosmetic Act or section 351
20 of this Act)” after “development”; and

21 (2) in subparagraph (D)(iii), by striking “and
22 vaccine manufacturing technologies” and inserting
23 “vaccine manufacturing technologies, dose sparing
24 technologies, efficacy increasing technologies, and
25 platform technologies”.

1 **(b) STRATEGIC PUBLIC-PRIVATE PARTNERSHIP.**—*Sec-*
2 *tion 319L(c)(4) of the Public Health Service Act (42 U.S.C.*
3 *247d-7e(c)(4)) is amended by adding at the end the fol-*
4 *lowing:*

5 **“(E) STRATEGIC INVESTOR.**—

6 **“(i) IN GENERAL.**—*To support the*
7 *purposes described in paragraph (2), the*
8 *Secretary, acting through the Director of*
9 *BARDA, may enter into an agreement (in-*
10 *cluding through the use of grants, contracts,*
11 *cooperative agreements, or other trans-*
12 *actions as described in paragraph (5)) with*
13 *an independent, non-profit entity to—*

14 **“(I) foster and accelerate the de-**
15 *velopment and innovation of medical*
16 *countermeasures and technologies that*
17 *may assist advanced research and de-*
18 *velopment of qualified countermeasures*
19 *and qualified pandemic or epidemic*
20 *products, including strategic invest-*
21 *ment through the use of venture capital*
22 *practices and methods;*

23 **“(II) promote the development of**
24 *new and promising technologies that*

1 *address urgent medical countermeasure*
2 *needs, as identified by the Secretary;*

3 “(III) *address unmet public*
4 *health needs that are directly related to*
5 *medical countermeasure requirements,*
6 *such as novel antimicrobials for*
7 *multidrug resistant organisms and*
8 *multiuse platform technologies for*
9 *diagnostics, prophylaxis, vaccines, and*
10 *therapeutics; and*

11 “(IV) *provide expert consultation*
12 *and advice to foster viable medical*
13 *countermeasure innovators, including*
14 *helping qualified countermeasure*
15 *innovators navigate unique industry*
16 *challenges with respect to developing*
17 *chemical, biological, radiological, and*
18 *nuclear countermeasure products.*

19 “(i) *ELIGIBILITY.—*

20 “(I) *IN GENERAL.—To be eligible*
21 *to enter into an agreement under*
22 *clause (i) an entity shall—*

23 “(aa) *be an independent,*
24 *non-profit entity not otherwise af-*

1 *filiated with the Department of*
2 *Health and Human Services;*

3 *“(bb) have a demonstrated*
4 *record of being able to create link-*
5 *ages between innovators and in-*
6 *vestors and leverage such partner-*
7 *ships and resources for the pur-*
8 *pose of addressing identified stra-*
9 *tegic needs of the Federal Govern-*
10 *ment;*

11 *“(cc) have experience in pro-*
12 *moting novel technology innova-*
13 *tion;*

14 *“(dd) be problem driven and*
15 *solution focused based on the*
16 *needs, requirements, and problems*
17 *identified by the Secretary under*
18 *clause (iv);*

19 *“(ee) demonstrate the ability,*
20 *or the potential ability, to pro-*
21 *mote the development of medical*
22 *countermeasure products; and*

23 *“(ff) demonstrate expertise,*
24 *or the capacity to develop or ac-*
25 *quire expertise, related to tech-*

1 *nical and regulatory consider-*
2 *ations with respect to medical*
3 *countermeasures.*

4 “(II) *PARTNERING EXPERI-*
5 *ENCE.—In selecting an entity with*
6 *which to enter into an agreement*
7 *under clause (i), the Secretary shall*
8 *place a high value on the demonstrated*
9 *experience of the entity in partnering*
10 *with the Federal Government to meet*
11 *identified strategic needs.*

12 “(iii) *NOT AGENCY.—An entity that*
13 *enters into an agreement under clause (i)*
14 *shall not be deemed to be a Federal agency*
15 *for any purpose, including for any purpose*
16 *under title 5, United States Code.*

17 “(iv) *DIRECTION.—Pursuant to an*
18 *agreement entered into under this subpara-*
19 *graph, the Secretary, acting through the Di-*
20 *rector of BARDA, shall provide direction to*
21 *the entity that enters into an agreement*
22 *under clause (i). As part of this agreement*
23 *the Director of BARDA shall—*

24 “(I) *communicate the medical*
25 *countermeasure needs, requirements,*

1 *and problems to be addressed by the*
2 *entity under the agreement;*

3 *“(II) develop a description of*
4 *work to be performed by the entity*
5 *under the agreement;*

6 *“(III) provide technical feedback*
7 *and appropriate oversight over work*
8 *carried out by the entity under the*
9 *agreement, including subsequent devel-*
10 *opment and partnerships consistent*
11 *with the needs and requirements set*
12 *forth in this subparagraph;*

13 *“(IV) ensure fair consideration of*
14 *products developed under the agree-*
15 *ment in order to maintain competition*
16 *to the maximum practical extent, as*
17 *applicable and appropriate under ap-*
18 *plicable provisions of this section; and*

19 *“(V) ensure, as a condition of the*
20 *agreement—*

21 *“(aa) a comprehensive set of*
22 *policies that demonstrate a com-*
23 *mitment to transparency and ac-*
24 *countability;*

1 “(bb) protection against con-
2 flicts of interest through a com-
3 prehensive set of policies that ad-
4 dress potential conflicts of inter-
5 est, ethics, disclosure, and report-
6 ing requirements;

7 “(cc) that the entity provides
8 monthly accounting on the use of
9 funds provided under such agree-
10 ment; and

11 “(dd) that the entity provides
12 on a quarterly basis, reports re-
13 garding the progress made toward
14 meeting the identified needs set
15 forth in the agreement.

16 “(v) SUPPLEMENT NOT SUPPLANT.—
17 Activities carried out under this subpara-
18 graph shall supplement, and not supplant,
19 other activities carried out under this sec-
20 tion.

21 “(vi) NO ESTABLISHMENT OF ENTI-
22 TY.—To prevent unnecessary duplication
23 and target resources effectively, nothing in
24 this subparagraph shall be construed to au-
25 thorize the Secretary to establish within the

1 *Department of Health and Human Services*
2 *a strategic investor entity.*

3 “(vii) *TRANSPARENCY AND OVER-*
4 *SIGHT.—Upon request, the Secretary shall*
5 *provide to Congress the information pro-*
6 *vided to the Secretary under clause*
7 *(iv)(V)(dd).*

8 “(viii) *INDEPENDENT EVALUATION.—*
9 *Not later than 4 years after the date of en-*
10 *actment of this subparagraph, the Govern-*
11 *ment Accountability Office shall conduct an*
12 *independent evaluation, and submit to the*
13 *Secretary and the appropriate committees*
14 *of Congress a report, concerning the activi-*
15 *ties conducted under this subparagraph.*
16 *Such report shall include recommendations*
17 *with respect to any agreement or activities*
18 *carried out pursuant to this subparagraph.*

19 “(ix) *SUNSET.—This subparagraph*
20 *shall have no force or effect after September*
21 *30, 2016.”.*

22 (c) *TRANSACTION AUTHORITIES.—Section 319L(c)(5)*
23 *of the Public Health Service Act (42 U.S.C. 247d–7e(c)(5))*
24 *is amended by adding at the end the following:*

1 “(G) *GOVERNMENT PURPOSE.*—*In award-*
2 *ing contracts, grants, and cooperative agreements*
3 *under this section, the Secretary shall provide a*
4 *clear statement of defined Government purpose*
5 *related to activities included in subsection*
6 *(a)(6)(B) for a qualified countermeasure or*
7 *qualified pandemic or epidemic product.”.*

8 (d) *FUND.*—*Paragraph (2) of section 319L(d) of the*
9 *Public Health Service Act (42 U.S.C. 247d–7e(d)(2)) is*
10 *amended to read as follows:*

11 “(2) *FUNDING.*—*To carry out the purposes of*
12 *this section, there is authorized to be appropriated to*
13 *the Fund \$415,000,000 for each of fiscal years 2012*
14 *through 2016, such amounts to remain available until*
15 *expended.”.*

16 (e) *CONTINUED INAPPLICABILITY OF CERTAIN PROVI-*
17 *SIONS.*—*Section 319L(e)(1)(C) of the Public Health Service*
18 *Act (42 U.S.C. 247d–7e(e)(1)(C)) is amended by striking*
19 *“7 years” and inserting “10 years”.*

20 (f) *EXTENSION OF LIMITED ANTITRUST EXEMP-*
21 *TION.*—*Section 405(b) of the Pandemic and All-Hazards*
22 *Preparedness Act (42 U.S.C. 247d–6a note) is amended by*
23 *striking “6-year” and inserting “10-year”.*

1 (g) *INDEPENDENT EVALUATION.*—Section 319L of the
2 *Public Health Service Act (42 U.S.C. 247d–7e)* is amended
3 *by adding at the end the following:*

4 “(f) *INDEPENDENT EVALUATION.*—

5 “(1) *IN GENERAL.*—Not later than 180 days
6 *after the date of enactment of this subsection, the Gov-*
7 *ernment Accountability Office shall conduct an inde-*
8 *pendent evaluation of the activities carried out to fa-*
9 *facilitate flexible manufacturing capacity pursuant to*
10 *this section.*

11 “(2) *REPORT.*—Not later than 1 year after the
12 *date of enactment of this subsection, the Government*
13 *Accountability Office shall submit to the appropriate*
14 *committees of Congress a report concerning the results*
15 *of the evaluation conducted under paragraph (1).*
16 *Such report shall review and assess—*

17 “(A) *the extent to which flexible manufac-*
18 *turing capacity under this section is dedicated to*
19 *chemical, biological, radiological, and nuclear*
20 *threats;*

21 “(B) *the activities supported by flexible*
22 *manufacturing initiatives; and*

23 “(C) *the ability of flexible manufacturing*
24 *activities carried out under this section to—*

1 “(i) secure and leverage leading tech-
 2 nical expertise with respect to counter-
 3 measure advanced research, development,
 4 and manufacturing processes; and

5 “(ii) meet the surge manufacturing ca-
 6 pacity needs presented by novel and emerg-
 7 ing threats, including chemical, biological,
 8 radiological and nuclear agents.”.

9 (h) *DEFINITIONS.*—

10 (1) *QUALIFIED COUNTERMEASURE.*—Section
 11 319F–1(a)(2)(A) of the Public Health Service Act (42
 12 U.S.C. 247d–6a(a)(2)(A)) is amended—

13 (A) in the matter preceding clause (i), by
 14 striking “to—” and inserting “—”;

15 (B) in clause (i)—

16 (i) by striking “diagnose” and insert-
 17 ing “to diagnose”; and

18 (ii) by striking “; or” and inserting a
 19 semicolon;

20 (C) in clause (ii)—

21 (i) by striking “diagnose” and insert-
 22 ing “to diagnose”; and

23 (ii) by striking the period at the end
 24 and inserting “; or”; and

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

1 “(iii) is a product or technology in-
 2 tended to enhance the use or effect of a drug,
 3 biological product, or device described in
 4 clause (i) or (ii).”.

5 (2) *QUALIFIED PANDEMIC OR EPIDEMIC PROD-*
 6 *UCT.—Section 319F-3(i)(7)(A) of the Public Health*
 7 *Service Act (42 U.S.C. 247d-6d(i)(7)(A)) is amend-*
 8 *ed—*

9 (A) in clause (i)(II), by striking “; or” and
 10 inserting “;”;

11 (B) in clause (ii), by striking “; and” and
 12 inserting “; or”; and

13 (C) by adding at the end the following:

14 “(iii) a product or technology intended
 15 to enhance the use or effect of a drug, bio-
 16 logical product, or device described in clause
 17 (i) or (ii); and”.

18 (3) *TECHNICAL AMENDMENTS.—Section 319F-*
 19 *3(i) of the Public Health Service Act (42 U.S.C.*
 20 *247d-6d(i)) is amended—*

21 (A) in paragraph (1)(C), by inserting “,
 22 564A, or 564B” after “564”; and

23 (B) in paragraph (7)(B)(iii), by inserting
 24 “, 564A, or 564B” after “564”.

1 **SEC. 403. STRATEGIC NATIONAL STOCKPILE.**

2 (a) *IN GENERAL.*—Section 319F–2 of the Public
3 Health Service Act (42 U.S.C. 247d–6b) is amended—

4 (1) *in subsection (a)*—

5 (A) *in paragraph (1)*—

6 (i) *by inserting “consistent with sec-*
7 *tion 2811” before “by the Secretary to be*
8 *appropriate”; and*

9 (ii) *by inserting before the period at*
10 *the end the following: “and shall submit*
11 *such review annually to the appropriate*
12 *Congressional committees of jurisdiction to*
13 *the extent that disclosure of such informa-*
14 *tion does not compromise national secu-*
15 *rity”; and*

16 (B) *in paragraph (2)*—

17 (i) *by redesignating subparagraphs (E)*
18 *through (H) as subparagraphs (F) through*
19 *(I), respectively; and*

20 (ii) *by inserting after subparagraph*
21 *(D), the following:*

22 “(E) *identify and address the potential de-*
23 *pletion and ensure appropriate replenishment of*
24 *medical countermeasures, including those cur-*
25 *rently in the stockpile;” and*

1 (2) in subsection (f)(1), by striking
2 “\$640,000,000 for fiscal year 2002, and such sums as
3 may be necessary for each of fiscal years 2003 through
4 2006” and inserting “\$522,486,000 for each of fiscal
5 years 2012 through 2016”.

6 (b) *REPORT ON POTASSIUM IODIDE.*—Not later than
7 270 days after the date of enactment of this Act, the Sec-
8 retary of Health and Human Services shall submit to the
9 appropriate Committees of Congress a report regarding the
10 stockpiling of potassium iodide. Such report shall include—

11 (1) an assessment of the availability of potas-
12 sium iodide at Federal, State, and local levels; and

13 (2) a description of the extent to which such ac-
14 tivities and policies provide public health protection
15 in the event of a nuclear incident, whether uninten-
16 tional or deliberate, including an act of terrorism.

17 **SEC. 404. NATIONAL BIODEFENSE SCIENCE BOARD.**

18 Section 319M(a) of the Public Health Service Act (42
19 U.S.C. 247d–f(a)) is amended—

20 (1) in paragraph (2)—

21 (A) in subparagraph (D)—

22 (i) in the matter preceding clause (i),
23 by striking “five” and inserting “six”;

24 (ii) in clause (i), by striking “and” at
25 the end;

1 (iii) in clause (ii), by striking the pe-
2 riod and inserting a semicolon; and

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

4 “(iii) one such member shall be an in-
5 dividual with pediatric subject matter ex-
6 pertise; and

7 “(iv) one such member shall be a State,
8 tribal, territorial, or local public health offi-
9 cial.”; and

10 (B) by adding at the end the following flush
11 sentence:

12 “Nothing in this paragraph shall preclude a member
13 of the Board from satisfying two or more of the re-
14 quirements described in subparagraph (D).”;

15 (2) in paragraph (5)—

16 (A) in subparagraph (B), by striking “and”
17 at the end;

18 (B) in subparagraph (C), by striking the
19 period and inserting “; and”; and

20 (C) by adding at the end the following:

21 “(D) provide any recommendation, finding,
22 or report provided to the Secretary under this
23 paragraph to the appropriate committees of Con-
24 gress.”; and

1 (3) in paragraph (8), by adding at the end the
2 following: “Such chairperson shall serve as the decid-
3 ing vote in the event that a deciding vote is necessary
4 with respect to voting by members of the Board.”.

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112TH CONGRESS
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S. 1855

A BILL

To amend the Public Health Service Act to reauthorize various programs under the Pandemic and All-Hazards Preparedness Act.

DECEMBER 16, 2011

Reported with an amendment