

AMENDMENT NO. _____ Calendar No. _____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—112th Cong., 1st Sess.

S. 1855

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

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended
to be proposed by _____

Viz:

1 Strike all after the enacting clause and insert the fol-
2 lowing:

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

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

7 (b) TABLE OF CONTENTS.—The table of contents of
8 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. 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)—

1 (I) by striking “facilities), and
2 trauma care” and inserting “facilities
3 and which may include dental health
4 facilities), and trauma care, critical
5 care,”; and

6 (II) by inserting “(including re-
7 lated availability, accessibility, and co-
8 ordination)” after “public health
9 emergencies”;

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

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

15 (iv) by adding at the end the fol-
16 lowing:

17 “(F) Optimizing a coordinated and flexible
18 approach to the medical surge capacity of hos-
19 pitals, other healthcare facilities, and trauma
20 care (which may include trauma centers) and
21 emergency medical systems.”;

22 (B) in paragraph (4)—

23 (i) in subparagraph (A), by inserting
24 “, including the unique needs and consider-
25 ations of individuals with disabilities,”

1 after “medical needs of at-risk individ-
2 uals”; and

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

6 “(7) COUNTERMEASURES.—

7 “(A) Promoting strategic initiatives to ad-
8 vance countermeasures to diagnose, mitigate,
9 prevent, or treat harm from any biological
10 agent or toxin, chemical, radiological, or nuclear
11 agent or agents, whether naturally occurring,
12 unintentional, or deliberate.

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

19 “(8) MEDICAL AND PUBLIC HEALTH COMMU-
20 NITY RESILIENCY.—Strengthening the ability of
21 States, local communities, and tribal communities to
22 prepare for, respond to, and be resilient in the event
23 of public health emergencies, whether naturally oc-
24 ccurring, unintentional, or deliberate by—

1 “(A) optimizing alignment and integration
2 of medical and public health preparedness and
3 response planning and capabilities with and into
4 routine daily activities; and

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

7 (b) AT-RISK INDIVIDUALS.—Section 2814 of the
8 Public Health Service Act (42 U.S.C. 300hh–16) is
9 amended—

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

11 (2) by redesignating paragraphs (1) through
12 (4) as paragraphs (2) through (5), respectively;

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

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

20 (4) in paragraph (2) (as so redesignated), by
21 striking “National Preparedness goal” and inserting
22 “preparedness goals, as described in section
23 2802(b),”; and

24 (5) by inserting after paragraph (6), the fol-
25 lowing:

1 “(7) disseminate and, as appropriate, update
2 novel and best practices of outreach to and care of
3 at-risk individuals before, during, and following pub-
4 lic health emergencies in as timely a manner as is
5 practicable, including from the time a public health
6 threat is identified;

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

13 **SEC. 102. ASSISTANT SECRETARY FOR PREPAREDNESS AND**
14 **RESPONSE.**

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

17 (1) in subsection (b)(4), by adding at the end
18 the following:

19 “(D) **POLICY COORDINATION AND STRA-**
20 **TEGIC DIRECTION.**—Provide integrated policy
21 coordination and strategic direction with re-
22 spect to all matters related to Federal public
23 health and medical preparedness and execution
24 and deployment of the Federal response for
25 public health emergencies and incidents covered

1 by the National Response Plan developed pur-
2 suant to section 502(6) of the Homeland Secu-
3 rity Act of 2002, or any successor plan, before,
4 during, and following public health emer-
5 gencies.”;

6 (2) by striking subsection (c) and inserting the
7 following:

8 “(c) FUNCTIONS.—The Assistant Secretary for Pre-
9 paredness and Response shall—

10 “(1) have authority over and responsibility
11 for—

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

15 “(B) the Hospital Preparedness Coopera-
16 tive Agreement Program pursuant to section
17 319C–2;

18 “(C) the Medical Reserve Corps pursuant
19 to section 2813;

20 “(D) the Emergency System for Advance
21 Registration of Volunteer Health Professionals
22 pursuant to section 319I; and

23 “(E) administering grants and related au-
24 thorities related to trauma care under parts A
25 through C of title XII, such authority to be

1 transferred by the Secretary from the Adminis-
2 trator of the Health Resources and Services Ad-
3 ministration to such Assistant Secretary;

4 “(2) exercise the responsibilities and authorities
5 of the Secretary with respect to the coordination
6 of—

7 “(A) the Public Health Emergency Pre-
8 paredness Cooperative Agreement Program pur-
9 suant to section 319C-1;

10 “(B) the Strategic National Stockpile; and

11 “(C) the Cities Readiness Initiative;

12 “(3) align and coordinate medical and public
13 health grants and cooperative agreements as applica-
14 ble to preparedness and response activities author-
15 ized under this Act, to the extent possible, including
16 program requirements, timelines, and measurable
17 goals, and in coordination with the Secretary of
18 Homeland Security, to—

19 “(A) optimize and streamline medical and
20 public health preparedness capabilities and the
21 ability of local communities to respond to public
22 health emergencies;

23 “(B) minimize duplication of efforts with
24 regard to medical and public health prepared-
25 ness and response programs; and

1 “(C) gather and disseminate best practices
2 among grant and cooperative agreement recipi-
3 ents, as appropriate;

4 “(4) carry out drills and operational exercises,
5 in coordination with the Department of Homeland
6 Security, the Department of Defense, the Depart-
7 ment of Veterans Affairs, and other applicable Fed-
8 eral departments and agencies, as necessary and ap-
9 propriate, to identify, inform, and address gaps in
10 and policies related to all-hazards medical and public
11 health preparedness, including exercises based on—

12 “(A) identified threats for which counter-
13 measures are available and for which no coun-
14 termeasures are available; and

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

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

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

20 “(d) NATIONAL SECURITY PRIORITY.—The Sec-
21 retary, acting through the Assistant Secretary for Pre-
22 paredness and Response, shall on a periodic basis conduct
23 meetings, as applicable and appropriate, with the Assist-
24 ant to the President for National Security Affairs to pro-
25 vide an update on, and discuss, medical and public health

1 preparedness and response activities pursuant to this Act
2 and the Federal Food, Drug, and Cosmetic Act, including
3 progress on the development, approval, clearance, and li-
4 censure of medical countermeasures.

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

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

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

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

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

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

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

24 “(E) report on advanced research and de-
25 velopment awards and the date of the issuance

1 of contract awards, including awards made
2 through the special reserve fund (as defined in
3 section 319F–2(c)(10));

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

8 “(G) identify the progress made in meeting
9 the medical countermeasure priorities for at-
10 risk individuals, (as defined in 2802(b)(4)(B)),
11 as applicable under subparagraph (B), includ-
12 ing with regard to the projected needs for re-
13 lated stockpiling and replenishment of the Stra-
14 tegic National Stockpile; and

15 “(H) be made publicly available.

16 “(3) GAO REPORT.—

17 “(A) IN GENERAL.—Not later than 1 year
18 after the date on which a Public Health Emer-
19 gency Medical Countermeasures Enterprise
20 Strategy and Implementation Plan under this
21 subsection is issued by the Secretary, the Gov-
22 ernment Accountability Office shall conduct an
23 independent evaluation and submit to the ap-
24 propriate committees of Congress a report con-
25 cerning such strategy and implementation plan.

1 “(B) CONTENT.—The report described in
2 subparagraph (A) shall review and assess—

3 “(i) the near-term, mid-term, and
4 long-term medical countermeasure needs
5 and identified priorities of the Federal
6 Government pursuant to subparagraphs
7 (A) and (B) of paragraph (2);

8 “(ii) the activities of the Department
9 of Health and Human Services with re-
10 spect to advanced research and develop-
11 ment pursuant to section 319L; and

12 “(iii) the progress made toward meet-
13 ing the goals, benchmarks, and milestones
14 identified in the Public Health Emergency
15 Medical Countermeasures Enterprise
16 Strategy and Implementation Plan under
17 this subsection.

18 “(f) INTERNAL MULTIYEAR PLANNING PROCESS.—
19 The Secretary shall develop, and update on an annual
20 basis, a coordinated 5-year budget plan based on the med-
21 ical countermeasure priorities and goals described in sub-
22 section (e). Each such plan shall—

23 “(1) include consideration of the entire medical
24 countermeasures enterprise, including—

1 “(A) basic research, advanced research and
2 development;

3 “(B) approval, clearance, licensure, and
4 authorized uses of products; and

5 “(C) procurement, stockpiling, mainte-
6 nance, and replenishment of all products in the
7 Strategic National Stockpile;

8 “(2) include measurable outputs and outcomes
9 to allow for the tracking of the progress made to-
10 ward identified goals;

11 “(3) identify medical countermeasure life-cycle
12 costs to inform planning, budgeting, and anticipated
13 needs within the continuum of the medical counter-
14 measure enterprise consistent with section 319F-2;
15 and

16 “(4) be made available to the appropriate com-
17 mittees of Congress upon request.

18 “(g) INTERAGENCY COORDINATION PLAN.—Not
19 later than one year after the date of enactment of this
20 subsection, the Secretary, in coordination with the Sec-
21 retary of Defense, shall submit to the appropriate commit-
22 tees of Congress a report concerning the manner in which
23 the Department of Health and Human Services is coordi-
24 nating with the Department of Defense regarding counter-
25 measure activities to address chemical, biological, radio-

1 logical, and nuclear threats. Such report shall include in-
2 formation with respect to—

3 “(1) the research, advanced research, develop-
4 ment, procurement, stockpiling, and distribution of
5 countermeasures to meet identified needs; and

6 “(2) the coordination of efforts between the De-
7 partment of Health and Human Services and the
8 Department of Defense to address countermeasure
9 needs for various segments of the population.

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

14 **SEC. 103. MODERNIZATION OF THE NATIONAL DISASTER**
15 **MEDICAL SYSTEM.**

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

18 (1) in subsection (a)(3)—

19 (A) in subparagraph (A), in clause (i) by
20 inserting “, including at-risk individuals as ap-
21 plicable” after “victims of a public health emer-
22 gency”;

23 (B) by redesignating subparagraph (C) as
24 subparagraph (E); and

1 (C) by inserting after subparagraph (B),
2 the following:

3 “(C) CONSIDERATIONS FOR AT-RISK POPU-
4 LATIONS.—The Secretary shall take steps to
5 ensure that an appropriate specialized and fo-
6 cused range of public health and medical capa-
7 bilities are represented in the National Disaster
8 Medical System, which take into account the
9 needs of at-risk individuals, in the event of a
10 public health emergency.”.

11 “(D) ADMINISTRATION.—The Secretary
12 may determine and pay claims for reimburse-
13 ment for services under subparagraph (A) di-
14 rectly or through contracts that provide for
15 payment in advance or by way of reimburse-
16 ment.”; and

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

21 **SEC. 104. CONTINUING THE ROLE OF THE DEPARTMENT OF**
22 **VETERANS AFFAIRS.**

23 Section 8117(g) of title 38, United States Code, is
24 amended by striking “such sums as may be necessary to
25 carry out this section for each of fiscal years 2007 through

1 2011” and inserting “\$156,500,000 for each of fiscal
2 years 2012 through 2016 to carry out this section”.

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

7 **SEC. 201. IMPROVING STATE AND LOCAL PUBLIC HEALTH**
8 **SECURITY.**

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

12 (1) in subsection (b)(2)—

13 (A) in subparagraph (A)—

14 (i) by striking clauses (i) and (ii) and
15 inserting the following:

16 “(i) a description of the activities such
17 entity will carry out under the agreement
18 to meet the goals identified under section
19 2802, including with respect to chemical,
20 biological, radiological, or nuclear threats,
21 whether naturally occurring, unintentional,
22 or deliberate;

23 “(ii) a description of the activities
24 such entity will carry out with respect to
25 pandemic influenza, as a component of the

1 activities carried out under clause (i), and
2 consistent with the requirements of para-
3 graphs (2) and (5) of subsection (g);”;

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

6 (iii) by adding at the end the fol-
7 lowing:

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

13 “(vii) a description of how the entity,
14 as applicable and appropriate, will coordi-
15 nate with State emergency preparedness
16 and response plans in public health emer-
17 gency preparedness, including State edu-
18 cational agencies (as defined in section
19 9101(41) of the Elementary and Sec-
20 ondary Education Act of 1965) and State
21 child care lead agencies (as defined in sec-
22 tion 658D of the Child Care and Develop-
23 ment Block Grant Act); and

24 “(viii) in the case of entities that op-
25 erate on the United States-Mexico border

1 or the United States-Canada border, a de-
2 scription of the activities such entity will
3 carry out under the agreement that are
4 specific to the border area including dis-
5 ease detection, identification, and inves-
6 tigation, and preparedness and response
7 activities related to emerging diseases and
8 infectious disease outbreaks whether natu-
9 rally-occurring or due to bioterrorism, con-
10 sistent with the requirements of this sec-
11 tion;” 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” and

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

1 cally 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).”;

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 “(B) FUNDS CONTINGENT ON ACHIEVING
2 BENCHMARKS.—The continued availability of
3 funds under subparagraph (A) with respect to
4 an entity shall be contingent upon such entity
5 achieving the benchmarks and submitting the
6 pandemic influenza plan as described in sub-
7 section (g).”; and

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

9 (b) VACCINE TRACKING AND DISTRIBUTION.—Sec-
10 tion 319A(e) of the Public Health Service Act (42 U.S.C.
11 247d–1(e)) is amended by striking “such sums for each
12 of fiscal years 2007 through 2011” and inserting
13 “\$30,800,000 for each of fiscal years 2012 through
14 2016”.

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

18 “(l) GAO REPORT.—

19 “(1) IN GENERAL.—Not later than 1 year after
20 the date of enactment of the Pandemic and All-Haz-
21 ards Preparedness Act Reauthorization of 2011, the
22 Government Accountability Office shall conduct an
23 independent evaluation, and submit to the appro-
24 priate committees of Congress a report, concerning
25 Federal programs at the Department of Health and

1 Human Services that support medical and public
2 health preparedness and response programs at the
3 State and local levels.

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

6 “(A) the extent to which grant and cooper-
7 ative agreement requirements and goals have
8 been met by recipients;

9 “(B) the extent to which such grants and
10 cooperative agreements have supported medical
11 and public health preparedness and response
12 goals pursuant to section 2802(b), as appro-
13 priate and applicable;

14 “(C) whether recipients or the Department
15 of Health and Human Services have identified
16 any factors that may impede a recipient’s abil-
17 ity to achieve programmatic goals and require-
18 ments; and

19 “(D) instances in which funds may not
20 have been used appropriately, in accordance
21 with grant and cooperative agreement require-
22 ments, and actions taken to address inappro-
23 priate expenditures.”.

1 **SEC. 202. HOSPITAL PREPAREDNESS AND MEDICAL SURGE**
2 **CAPACITY.**

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

9 (b) ENCOURAGING HEALTH PROFESSIONAL VOLUN-
10 TEERS.—

11 (1) EMERGENCY SYSTEM FOR ADVANCE REG-
12 ISTRATION OF VOLUNTEER HEALTH PROFES-
13 SIONALS.—Section 319I(k) of the Public Health
14 Service Act (42 U.S.C. 247d–7b(k)) is amended by
15 striking “\$2,000,000 for fiscal year 2002, and such
16 sums as may be necessary for each of the fiscal
17 years 2003 through 2011” and inserting
18 “\$5,900,000 for each of fiscal years 2012 through
19 2016”.

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

23 (A) in subsection (d)(2), by adding at the
24 end the following: “Such training exercises
25 shall, as appropriate and applicable, incorporate

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

3 (B) in subsection (i), by striking
4 “\$22,000,000 for fiscal year 2007, and such
5 sums as may be necessary for each of fiscal
6 years 2008 through 2011” and inserting
7 “\$11,900,000 for each of fiscal years 2012
8 through 2016”.

9 (c) PARTNERSHIPS FOR STATE AND REGIONAL PRE-
10 PAREDNESS TO IMPROVE SURGE CAPACITY.—Section
11 319C–2 of the Public Health Service Act (42 U.S.C.
12 247d–3b) is amended—

13 (1) in subsection (b)(1)(A)(ii), by striking “cen-
14 ters, primary” and inserting “centers, community
15 health centers, primary”;

16 (2) by striking subsection (c) and inserting the
17 following:

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

24 (3) by striking subsection (g) and inserting the
25 following:

1 “(g) COORDINATION.—

2 “(1) LOCAL RESPONSE CAPABILITIES.—An eli-
3 gible entity shall, to the extent practicable, ensure
4 that activities carried out under an award under
5 subsection (a) are coordinated with activities of rel-
6 evant local Metropolitan Medical Response Systems,
7 local Medical Reserve Corps, the local Cities Readiness
8 Initiative, and local emergency plans.

9 “(2) NATIONAL COLLABORATION.—Partner-
10 ships consisting of one or more eligible entities
11 under this section may, to the extent practicable,
12 collaborate with other partnerships consisting of one
13 or more eligible entities under this section for pur-
14 poses of national coordination and collaboration with
15 respect to activities to achieve the preparedness
16 goals described under paragraphs (1), (3), (4), (5),
17 and (6) of section 2802(b).”; and

18 (4) in subsection (j)—

19 (A) in paragraph (1), by striking
20 “\$474,000,000 for fiscal year 2007, and such
21 sums as may be necessary for each of fiscal
22 years 2008 through 2011” and inserting
23 “\$378,000,000 for each of fiscal years 2012
24 through 2016”; and

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

1 “(4) AVAILABILITY OF COOPERATIVE AGREE-
2 MENT FUNDS.—

3 “(A) IN GENERAL.—Amounts provided to
4 an eligible entity under a cooperative agreement
5 under subsection (a) for a fiscal year and re-
6 maining unobligated at the end of such year
7 shall remain available to such entity for the
8 next fiscal year for the purposes for which such
9 funds were provided.

10 “(B) FUNDS CONTINGENT ON ACHIEVING
11 BENCHMARKS.—The continued availability of
12 funds under subparagraph (A) with respect to
13 an entity shall be contingent upon such entity
14 achieving the benchmarks and submitting the
15 pandemic influenza plan as required under sub-
16 section (i).”.

17 **SEC. 203. ENHANCING SITUATIONAL AWARENESS AND BIO-**
18 **SURVEILLANCE.**

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

21 (1) in subsection (b)—

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

24 (B) in paragraph (2), by inserting before
25 the period the following: “, allowing for coordi-

1 nation to maximize all-hazards medical and
2 public health preparedness and response and to
3 minimize duplication of effort”; and

4 (C) in paragraph (3), by inserting before
5 the period the following: “and update such
6 standards as necessary”;

7 (2) in subsection (d)—

8 (A) in the subsection heading, by striking
9 “PUBLIC HEALTH SITUATIONAL AWARENESS”
10 and inserting “MODERNIZING PUBLIC HEALTH
11 SITUATIONAL AWARENESS AND BIOSURVEIL-
12 LANCE”;

13 (B) in paragraph (1)—

14 (i) by striking “Pandemic and All-
15 Hazards Preparedness Act” and inserting
16 “Pandemic and All-Hazards Preparedness
17 Act Reauthorization of 2011”; and

18 (ii) by inserting “, novel emerging
19 threats,” after “disease outbreaks”;

20 (C) by striking paragraph (2) and insert-
21 ing the following:

22 “(2) STRATEGY AND IMPLEMENTATION
23 PLAN.—Not later than 180 days after the date of
24 enactment of the Pandemic and All-Hazards Pre-
25 paredness Act Reauthorization of 2011, the Sec-

1 retary shall submit to the appropriate committees of
2 Congress, a coordinated strategy and an accom-
3 panying implementation plan that identifies and
4 demonstrates the measurable steps the Secretary will
5 carry out to—

6 “(A) develop, implement, and evaluate the
7 network described in paragraph (1), utilizing
8 the elements described in paragraph (3); and

9 “(B) modernize and enhance biosurveil-
10 lance activities.”;

11 (D) in paragraph (3)(D), by inserting
12 “community health centers, health centers”
13 after “poison control,”;

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

16 “(A) utilize applicable interoperability
17 standards as determined by the Secretary, and
18 in consultation with the Office of the National
19 Coordinator for Health Information Tech-
20 nology, through a joint public and private sec-
21 tor process;”;

22 (F) by adding at the end the following:

23 “(6) CONSULTATION WITH THE NATIONAL BIO-
24 DEFENSE SCIENCE BOARD.—In carrying out this
25 section consistent with section 319M, the National

1 Biodefense Science Board shall provide expert advice
2 and guidance, including recommendations, regarding
3 the measurable steps the Secretary should take to
4 modernize and enhance biosurveillance activities pur-
5 suant to the efforts of the Department of Health
6 and Humans Services to ensure comprehensive, real-
7 time all-hazards biosurveillance capabilities. In com-
8 plying with the preceding sentence, the National
9 Biodefense Science Board shall—

10 “(A) identify the steps necessary to achieve
11 a national biosurveillance system for human
12 health, with international connectivity, where
13 appropriate, that is predicated on State, re-
14 gional, and community level capabilities and
15 creates a networked system to allow for two-
16 way information flow between and among Fed-
17 eral, State, and local government public health
18 authorities and clinical health care providers;

19 “(B) identify any duplicative surveillance
20 programs under the authority of the Secretary,
21 or changes that are necessary to existing pro-
22 grams, in order to enhance and modernize such
23 activities, minimize duplication, strengthen and
24 streamline such activities under the authority of
25 the Secretary, and achieve real-time and appro-

1 primate data that relate to disease activity, both
2 human and zoonotic; and

3 “(C) coordinate with applicable existing
4 advisory committees of the Director of the Cen-
5 ters for Disease Control and Prevention, includ-
6 ing such advisory committees consisting of rep-
7 resentatives from State, local, and tribal public
8 health authorities and appropriate public and
9 private sector health care entities and academic
10 institutions, in order to provide guidance on
11 public health surveillance activities.”;

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

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

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

23 “(h) DEFINITION.—For purposes of this section the
24 term ‘biosurveillance’ means the process of gathering near
25 real-time, biological data that relates to disease activity

1 and threats to human or zoonotic health, in order to
2 achieve early warning and identification of such health
3 threats, early detection and prompt ongoing tracking of
4 health events, and overall situational awareness of disease
5 activity.”.

6 **TITLE III—ENHANCING MEDICAL**
7 **COUNTERMEASURE REVIEW**

8 **SEC. 301. SPECIAL PROTOCOL ASSESSMENT.**

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

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

16 “(II) in the case where human efficacy studies
17 are not ethical or feasible, of animal and any associ-
18 ated clinical trials which, in combination, are in-
19 tended to form the primary basis of an effectiveness
20 claim; or

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

25 The sponsor or applicant”.

1 **SEC. 302. AUTHORIZATION FOR MEDICAL PRODUCTS FOR**
2 **USE IN EMERGENCIES.**

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

6 (1) in subsection (a)—

7 (A) in paragraph (1), by striking “sections
8 505, 510(k), and 515 of this Act” and inserting
9 “any provision of this Act”;

10 (B) in paragraph (2)(A), by striking
11 “under a provision of law referred to in such
12 paragraph” and inserting “under a provision of
13 law in section 505, 510(k), or 515 of this Act
14 or section 351 of the Public Health Service
15 Act”; and

16 (C) in paragraph (3), by striking “a provi-
17 sion of law referred to in such paragraph” and
18 inserting “a provision of law referred to in
19 paragraph (2)(A)”;

20 (2) in subsection (b)—

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

25 (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 (A), by striking
6 “specified”;

7 (iii) in subparagraph (B)—

8 (I) by striking “specified”; and

9 (II) by striking “; or” and insert-
10 ing a semicolon;

11 (iv) by amending subparagraph (C) to
12 read as follows:

13 “(C) a determination by the Secretary that
14 there is a public health emergency, or a signifi-
15 cant potential for a public health emergency,
16 that affects, or has a significant potential to af-
17 fect, national security or the health and security
18 of United States citizens abroad, and that in-
19 volves a biological, chemical, radiological, or nu-
20 clear agent or agents, or a disease or condition
21 that may be attributable to such agent or
22 agents; or”; and

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

24 “(D) the identification of a material threat
25 pursuant to section 319F–2 of the Public

1 Health Service Act sufficient to affect national
2 security or the health and security of United
3 States citizens living abroad.”;

4 (C) in paragraph (2)(A)—

5 (i) by amending clause (ii) to read as
6 follows:

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

11 (ii) by striking subparagraph (B); and

12 (iii) by redesignating subparagraph
13 (C) as subparagraph (B);

14 (D) in paragraph (4), by striking “advance
15 notice of termination, and renewal under this
16 subsection.” and inserting “, and advance no-
17 tice of termination under this subsection. The
18 Secretary shall make any renewal under this
19 subsection available on the Internet Web site of
20 the Food and Drug Administration.”; and

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

22 “(5) EXPLANATION BY SECRETARY.—If an au-
23 thorization under this section with respect to an un-
24 approved product has been in effect for more than
25 1 year, the Secretary shall provide in writing to

1 sponsor of such product, an explanation of the sci-
2 entific, regulatory, or other obstacles to approval, li-
3 censure, or clearance of such product, including spe-
4 cific actions to be taken by the Secretary and the
5 sponsor to overcome such obstacles.”;

6 (3) in subsection (c)—

7 (A) in the matter preceding paragraph

8 (1)—

9 (i) by inserting “the Assistant Sec-
10 retary for Preparedness and Response,”
11 after “consultation with”;

12 (ii) by striking “Health and” and in-
13 serting “Health, and”; and

14 (iii) by striking “circumstances of the
15 emergency involved” and inserting “appli-
16 cable circumstances described in subsection
17 (b)(1)”;

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

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

1 (4) in subsection (d)(3), by inserting “, to the
2 extent practicable given the circumstances of the
3 emergency,” after “including”;

4 (5) in subsection (e)—

5 (A) in paragraph (1)(A), by striking “cir-
6 cumstances of the emergency” and inserting
7 “applicable circumstances described in sub-
8 section (b)(1)”;

9 (B) in paragraph (2)—

10 (i) in subparagraph (A)—

11 (I) by striking “manufacturer of
12 the product” and inserting “person”;

13 (II) by striking “circumstances of
14 the emergency” and inserting “appli-
15 cable circumstances described in sub-
16 section (b)(1)”;

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

20 (ii) in subparagraph (B)(i), by insert-
21 ing before the period at the end “, except
22 as provided in section 564A with respect to
23 authorized changes to the product expira-
24 tion date”; and

1 (iii) by amending subparagraph (C) to
2 read as follows:

3 “(C) In establishing conditions under this
4 paragraph with respect to the distribution and
5 administration of the product for the unap-
6 proved use, the Secretary shall not impose con-
7 ditions that would restrict distribution or ad-
8 ministration of the product when done solely for
9 the approved use.”; and

10 (C) by amending paragraph (3) to read as
11 follows:

12 “(3) GOOD MANUFACTURING PRACTICE; PRE-
13 SCRIPTON.—With respect to the emergency use of a
14 product for which an authorization under this sec-
15 tion is issued (whether an unapproved product or an
16 unapproved use of an approved product), the Sec-
17 retary may waive or limit, to the extent appropriate
18 given the applicable circumstances described in sub-
19 section (b)(1)—

20 “(A) requirements regarding current good
21 manufacturing practice otherwise applicable to
22 the manufacture, processing, packing, or hold-
23 ing of products subject to regulation under this
24 Act, including such requirements established
25 under section 510 or 520(f)(1), and including

1 relevant conditions prescribed with respect to
2 the product by an order under section
3 520(f)(2);

4 “(B) requirements established under sec-
5 tion 503(b); and

6 “(C) requirements established under sec-
7 tion 520(e).”;

8 (6) in subsection (g)—

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

11 (B) in paragraph (1), by inserting after
12 the period at the end the following: “As part of
13 such review, the Secretary shall regularly review
14 the progress made with respect to the approval,
15 licensure, or clearance of—

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

18 “(B) an unapproved use of an approved
19 product for which an authorization was issued
20 under this section.”; and

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

23 “(2) REVISION AND REVOCATION.—The Sec-
24 retary may revise or revoke an authorization under
25 this section if—

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

3 “(B) the criteria under subsection (c) for
4 issuance of such authorization are no longer
5 met; or

6 “(C) other circumstances make such revi-
7 sion or revocation appropriate to protect the
8 public health or safety.”;

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

14 (8) by adding at the end of subsection (j) the
15 following:

16 “(4) Nothing in this section shall be construed
17 as authorizing a delay in the review or other consid-
18 eration by the Food and Drug Administration of any
19 application pending before the Administration for a
20 countermeasure or product referred to in subsection
21 (a).”.

22 (b) EMERGENCY USE OF MEDICAL PRODUCTS.—
23 Subchapter E of chapter V of the Federal Food, Drug,
24 and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended
25 by inserting after section 564 the following:

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

2 “(a) DEFINITIONS.—In this section:

3 “(1) ELIGIBLE PRODUCT.—The term ‘eligible
4 product’ means a product that—

5 “(A) is approved or cleared under this
6 chapter or licensed under section 351 of the
7 Public Health Service Act;

8 “(B)(i) is intended for use to prevent, di-
9 agnose, or treat a disease or condition involving
10 a biological, chemical, radiological, or nuclear
11 agent or agents, including a product intended
12 to be used to prevent or treat pandemic influ-
13 enza; or

14 “(ii) is intended for use to prevent, diag-
15 nose, or treat a serious or life-threatening dis-
16 ease or condition caused by a product described
17 in clause (i); and

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

20 “(i) a determination described in sub-
21 paragraph (A), (B), or (C) of section
22 564(b)(1) has been made by the Secretary
23 of Homeland Security, the Secretary of
24 Defense, or the Secretary, respectively; or

25 “(ii) the identification of a material
26 threat described in subparagraph (D) of

1 section 564(b)(1) has been made pursuant
2 to section 319F-2 of the Public Health
3 Service Act.

4 “(2) PRODUCT.—The term ‘product’ means a
5 drug, device, or biological product.

6 “(b) EXTENSION OF EXPIRATION DATE.—

7 “(1) AUTHORITY TO EXTEND EXPIRATION
8 DATE.—The Secretary may extend the expiration
9 date of a eligible product in accordance with this
10 subsection.

11 “(2) EXPIRATION DATE.—For purposes of this
12 subsection, the term ‘expiration date’ means the
13 date established through appropriate stability testing
14 required by the regulations issued by the Secretary
15 to ensure that the product meets applicable stand-
16 ards of identity, strength, quality, and purity at the
17 time of use.

18 “(3) EFFECT OF EXTENSION.—Notwith-
19 standing any other provision of this Act or the Pub-
20 lic Health Service Act, if the expiration date of an
21 eligible product is extended in accordance with this
22 section, the introduction or delivery for introduction
23 into interstate commerce of such product after the
24 expiration date provided by the manufacturer and

1 within the duration of such extension shall not be
2 deemed to render the product—

3 “(A) an unapproved product; or

4 “(B) adulterated or misbranded under this
5 Act.

6 “(4) DETERMINATIONS BY SECRETARY.—Be-
7 fore extending the expiration date of an eligible
8 product under this subsection, the Secretary shall
9 determine—

10 “(A) that extension of the expiration date
11 will help protect public health;

12 “(B) that any extension of expiration is
13 supported by scientific evaluation that is con-
14 ducted or accepted by the Secretary;

15 “(C) what changes to the product labeling,
16 if any, are required or permitted, including
17 whether and how any additional labeling com-
18 municating the extension of the expiration date
19 may alter or obscure the labeling provided by
20 the manufacturer; and

21 “(D) that any other conditions that the
22 Secretary deems appropriate have been met.

23 “(5) SCOPE OF EXTENSION.—With respect to
24 each extension of an expiration date granted under
25 this subsection, the Secretary shall determine—

1 “(A) the batch, lot, or unit to which such
2 extension shall apply;

3 “(B) the duration of such extension; and

4 “(C) any conditions to effectuate such ex-
5 tension that are necessary and appropriate to
6 protect public health or safety.

7 “(c) CURRENT GOOD MANUFACTURING PRACTICE.—

8 “(1) IN GENERAL.—The Secretary may, when
9 the circumstances of a domestic, military, or public
10 health emergency or material threat described in
11 subsection (a)(1)(C) so warrant, authorize, with re-
12 spect to an eligible product, deviations from current
13 good manufacturing practice requirements otherwise
14 applicable to the manufacture, processing, packing,
15 or holding of products subject to regulation under
16 this Act, including requirements under section 501
17 or 520(f)(1) or applicable conditions prescribed with
18 respect to the eligible product by an order under sec-
19 tion 520(f)(2).

20 “(2) EFFECT.—Notwithstanding any other pro-
21 vision of this Act or the Public Health Service Act,
22 an eligible product shall not be considered an unap-
23 proved product and shall not be deemed adulterated
24 or misbranded under this Act because, with respect
25 to such product, the Secretary has authorized devi-

1 ations from current good manufacturing practices
2 under paragraph (1).

3 “(d) EMERGENCY USE INSTRUCTIONS.—

4 “(1) IN GENERAL.—The Secretary, acting
5 through an appropriate official within the Depart-
6 ment of Health and Human Services, may create
7 and issue emergency use instructions to inform
8 health care providers or individuals to whom an eli-
9 gible product is to be administered concerning such
10 product’s approved, licensed, or cleared conditions of
11 use.

12 “(2) EFFECT.—Notwithstanding any other pro-
13 visions of this Act or the Public Health Service Act,
14 a product shall not be considered an unapproved
15 product and shall not be deemed adulterated or mis-
16 branded under this Act because of the issuance of
17 emergency use instructions under paragraph (1)
18 with respect to such product or the introduction or
19 delivery for introduction of such product into inter-
20 state commerce accompanied by such instructions—

21 “(A) during an emergency response to an
22 actual emergency that is the basis for a deter-
23 mination described in subsection (a)(1)(C)(i); or

24 “(B) by a government entity (including a
25 Federal, State, local, and tribal government en-

1 tity), or a person acting on behalf of such a
2 government entity, in preparation for an emer-
3 gency response.”.

4 (c) RISK EVALUATION AND MITIGATION STRATE-
5 GIES.—Section 505–1 of the Federal Food, Drug, and
6 Cosmetic Act (21 U.S.C. 355–1), is amended—

7 (1) in subsection (f), by striking paragraph (7);

8 and

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

10 “(k) WAIVER IN PUBLIC HEALTH EMERGENCIES.—

11 The Secretary may waive any requirement of this section
12 with respect to a qualified countermeasure (as defined in
13 section 319F–1(a)(2) of the Public Health Service Act)
14 to which a requirement under this section has been ap-
15 plied, if the Secretary determines that such waiver is re-
16 quired to mitigate the effects of, or reduce the severity
17 of, the circumstances under which—

18 “(1) a determination described in subparagraph
19 (A), (B), or (C) of section 564(b)(1) has been made
20 by the Secretary of Homeland Security, the Sec-
21 retary of Defense, or the Secretary, respectively; or

22 “(2) the identification of a material threat de-
23 scribed in subparagraph (D) of section 564(b)(1)
24 has been made pursuant to section 319F–2 of the
25 Public Health Service Act.”.

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

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

6 “It is not a violation of any section of this Act or
7 of the Public Health Service Act for a government entity
8 (including a Federal, State, local, and tribal government
9 entity), or a person acting on behalf of such a government
10 entity, to introduce into interstate commerce a product (as
11 defined in section 564(a)(4)) intended for emergency use,
12 if that product—

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

14 “(2) is held and not used, unless and until that
15 product—

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

19 “(B) is authorized for investigational use
20 under section 505 or 520 of this Act or section
21 351 of the Public Health Service Act; or

22 “(C) is authorized for use under section
23 564.”.

1 **SEC. 303. DEFINITIONS.**

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

5 “(a) DEFINITIONS.—In this section—

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

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

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

15 “(4) the term ‘qualified pandemic or epidemic
16 product’ means a product that meets the definition
17 given such term in section 319F-3 of the Public
18 Health Service Act and—

19 “(A) that has been identified by the De-
20 partment of Health and Human Services or the
21 Department of Defense as receiving funding di-
22 rectly related to addressing chemical, biological,
23 radiological or nuclear threats, including pan-
24 demic influenza; or

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

1 “(b) GENERAL DUTIES.—The Secretary, in consulta-
2 tion”.

3 **SEC. 304. ENHANCING MEDICAL COUNTERMEASURE AC-**
4 **TIVITIES.**

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

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

12 (2) in subsection (b), by striking the subsection
13 heading and all that follows through “shall estab-
14 lish” and inserting the following:

15 “(b) GENERAL DUTIES.—In order to accelerate the
16 development, stockpiling, approval, licensure, and clear-
17 ance of qualified countermeasures, security counter-
18 measures, and qualified pandemic or epidemic products,
19 the Secretary, in consultation with the Assistant Secretary
20 for Preparedness and Response, shall—

21 “(1) ensure the appropriate involvement of
22 Food and Drug Administration personnel in inter-
23 agency activities related to countermeasure advanced
24 research and development, consistent with sections

1 319F, 319F-1, 319F-2, 319F-3, and 319L of the
2 Public Health Service Act;

3 “(2) ensure the appropriate involvement and
4 consultation of Food and Drug Administration per-
5 sonnel in any flexible manufacturing activities car-
6 ried out under section 319L of the Public Health
7 Service Act, including with respect to meeting regu-
8 latory requirements set forth in this Act;

9 “(3) promote countermeasure expertise within
10 the Food and Drug Administration by—

11 “(A) ensuring that Food and Drug Admin-
12 istration personnel involved in reviewing coun-
13 termeasures for approval, licensure, or clear-
14 ance are informed by the Assistant Secretary
15 for Preparedness and Response on the material
16 threat assessment conducted under section
17 319F-2 of the Public Health Service Act for
18 the agent or agents for which the counter-
19 measure under review is intended;

20 “(B) training Food and Drug Administra-
21 tion personnel regarding review of counter-
22 measures for approval, licensure, or clearance;

23 “(C) holding public meetings at least twice
24 annually to encourage the exchange of scientific
25 ideas; and

1 “(D) establishing protocols to ensure that
2 countermeasure reviewers have sufficient train-
3 ing or experience with countermeasures;

4 “(4) maintain teams, composed of Food and
5 Drug Administration personnel with expertise on
6 countermeasures, including specific counter-
7 measures, populations with special clinical needs (in-
8 cluding children and pregnant women that may use
9 countermeasures, as applicable and appropriate),
10 classes or groups of countermeasures, or other coun-
11 termeasure-related technologies and capabilities, that
12 shall—

13 “(A) consult with countermeasure experts,
14 including countermeasure sponsors and appli-
15 cants, to identify and help resolve scientific
16 issues related to the approval, licensure, or
17 clearance of countermeasures, through work-
18 shops or public meetings;

19 “(B) improve and advance the science re-
20 lating to the development of new tools, stand-
21 ards, and approaches to assessing and evalu-
22 ating countermeasures—

23 “(i) in order to inform the process for
24 countermeasure approval, clearance, and li-
25 censure; and

1 “(ii) with respect to the development
2 of countermeasures for populations with
3 special clinical needs, including children
4 and pregnant women, in order to meet the
5 needs of such populations, as necessary
6 and appropriate; and

7 “(5) establish”; and

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

9 “(c) DEVELOPMENT AND ANIMAL MODELING PRO-
10 CEDURES.—

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

23 “(A) a meeting to discuss proposed animal
24 model development activities; and

1 “(B) a meeting prior to initiating pivotal
2 animal studies.

3 “(2) PEDIATRIC MODELS.—To facilitate the de-
4 velopment and selection of animal models that could
5 translate to pediatric studies, any meeting conducted
6 under paragraph (1) shall include discussion of ani-
7 mal models for pediatric populations, as appropriate.

8 “(d) REVIEW AND APPROVAL OF COUNTER-
9 MEASURES.—

10 “(1) MATERIAL THREAT.—When evaluating an
11 application or submission for approval, licensure, or
12 clearance of a countermeasure, the Secretary shall
13 take into account the material threat posed by the
14 chemical, biological, radiological, or nuclear agent or
15 agents identified under section 319F–2 of the Public
16 Health Service Act for which the countermeasure
17 under review is intended.

18 “(2) REVIEW EXPERTISE.—When practicable
19 and appropriate, teams of Food and Drug Adminis-
20 tration personnel reviewing applications or submis-
21 sions described under paragraph (1) shall include a
22 reviewer with sufficient training or experience with
23 countermeasures pursuant to the protocols estab-
24 lished under subsection (b)(3)(D).”.

1 **SEC. 305. REGULATORY MANAGEMENT PLANS.**

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

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

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

8 “(A) a security countermeasure; or

9 “(B) a countermeasure with respect to
10 which the Biomedical Advanced Research and
11 Development Authority has provided funding
12 under section 319L of the Public Health Serv-
13 ice Act for advanced research and development.

14 “(2) **REGULATORY MANAGEMENT PLAN PROC-**
15 **ESS.**—The Secretary, in consultation with the As-
16 sistant Secretary for Preparedness and Response
17 and the Director of the Biomedical Advanced Re-
18 search and Development Authority, shall establish a
19 formal process for obtaining scientific feedback and
20 interactions regarding the development and regu-
21 latory review of eligible countermeasures by facili-
22 tating the development of written regulatory man-
23 agement plans in accordance with this subsection.

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

1 “(A) IN GENERAL.—A sponsor or appli-
2 cant of an eligible countermeasure may initiate
3 the process described under paragraph (2) upon
4 submission of written request to the Secretary.
5 Such request shall include a proposed regu-
6 latory management plan.

7 “(B) TIMING OF SUBMISSION.—A sponsor
8 or applicant may submit a written request
9 under subparagraph (A) after the eligible coun-
10 termeasure has an investigational new drug or
11 investigational device exemption in effect.

12 “(C) RESPONSE BY SECRETARY.—The
13 Secretary shall direct the Food and Drug Ad-
14 ministration, upon submission of a written re-
15 quest by a sponsor or applicant under subpara-
16 graph (A), to work with the sponsor or appli-
17 cant to agree on a regulatory management plan
18 within a reasonable time not to exceed 90 days.
19 If the Secretary determines that no plan can be
20 agreed upon, the Secretary shall provide to the
21 sponsor or applicant, in writing, the scientific
22 or regulatory rationale why such agreement
23 cannot be reached.

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

4 “(A) an agreement between the Secretary
5 and the sponsor or applicant regarding develop-
6 mental milestones that will trigger responses by
7 the Secretary as described in subparagraph (B);

8 “(B) performance targets and goals for
9 timely and appropriate responses by the Sec-
10 retary to the triggers described under subpara-
11 graph (A), including meetings between the Sec-
12 retary and the sponsor or applicant, written
13 feedback, decisions by the Secretary, and other
14 activities carried out as part of the development
15 and review process; and

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

18 “(5) MILESTONES AND PERFORMANCE TAR-
19 GETS.—The developmental milestones described in
20 paragraph (4)(A) and the performance targets and
21 goals described in paragraph (4)(B) shall include—

22 “(A) feedback from the Secretary regard-
23 ing the data required to support the approval,
24 clearance, or licensure of the eligible counter-
25 measure involved;

1 “(B) feedback from the Secretary regard-
2 ing the data necessary to inform any authoriza-
3 tion under section 564;

4 “(C) feedback from the Secretary regard-
5 ing the data necessary to support the posi-
6 tioning and delivery of the eligible counter-
7 measure, including to the Strategic National
8 Stockpile;

9 “(D) feedback from the Secretary regard-
10 ing the data necessary to support the submis-
11 sion of protocols for review under section
12 505(b)(5)(B);

13 “(E) feedback from the Secretary regard-
14 ing any gaps in scientific knowledge that will
15 need resolution prior to approval, licensure, or
16 clearance of the eligible countermeasure, and
17 plans for conducting the necessary scientific re-
18 search;

19 “(F) identification of the population for
20 which the countermeasure sponsor or applicant
21 seeks approval, licensure, or clearance, and the
22 population for which desired labeling would not
23 be appropriate, if known; and

24 “(G) as necessary and appropriate, and to
25 the extent practicable, a plan for demonstrating

1 safety and effectiveness in pediatric popu-
2 lations, and for developing pediatric dosing, for-
3 mulation, and administration with respect to
4 the eligible countermeasure, provided that such
5 plan would not delay authorization under sec-
6 tion 564, approval, licensure, or clearance for
7 adults.

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

20 **SEC. 306. REPORT.**

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

24 “(f) **ANNUAL REPORT.**—Not later than 180 days
25 after the date of enactment of this subsection, and annu-

1 ally thereafter, the Secretary shall submit to the Com-
2 mittee on Health, Education, Labor, and Pensions of the
3 Senate and the Committee on Energy and Commerce of
4 the House of Representatives a report that details the
5 countermeasure development and review activities of the
6 Food and Drug Administration, including—

7 “(1) with respect to the development of new
8 tools, standards, and approaches to assess and
9 evaluate countermeasures—

10 “(A) the identification of the priorities of
11 the Food and Drug Administration and the
12 progress made on such priorities; and

13 “(B) the identification of scientific gaps
14 that impede the development or approval, licen-
15 sure, or clearance of countermeasures for popu-
16 lations with special clinical needs, including
17 children and pregnant women, and the progress
18 made on resolving these challenges;

19 “(2) with respect to countermeasures for which
20 a regulatory management plan has been agreed upon
21 under subsection (e), the extent to which the per-
22 formance targets and goals set forth in subsection
23 (e)(4)(B) and the regulatory management plan has
24 been met, including, for each such countermeasure—

1 “(A) whether the regulatory management
2 plan was completed within the required time-
3 frame, and the length of time taken to complete
4 such plan;

5 “(B) whether the Secretary adhered to the
6 timely and appropriate response times set forth
7 in such plan; and

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

10 “(3) the number of regulatory teams estab-
11 lished pursuant to subsection (b)(4), the number of
12 products, classes of products, or technologies as-
13 signed to each such team, and the number of, type
14 of, and any progress made as a result of consulta-
15 tions carried out under subsection (b)(4)(A);

16 “(4) an estimate of resources obligated to coun-
17 termeasure development and regulatory assessment,
18 including Center specific objectives and accomplish-
19 ments;

20 “(5) the number of countermeasure applications
21 submitted, the number of countermeasures approved,
22 licensed, or cleared, the status of remaining sub-
23 mitted applications, and the number of each type of
24 authorization issued pursuant to section 564; and

1 “(6) the number of written requests for a regu-
2 latory management plan submitted under subsection
3 (e)(3)(A), the number of regulatory management
4 plans developed, and the number of such plans de-
5 veloped for security countermeasures.”.

6 **SEC. 307. PEDIATRIC MEDICAL COUNTERMEASURES.**

7 (a) PEDIATRIC STUDIES OF DRUGS.—Section 505A
8 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 355a) is amended—

10 (1) in subsection (d), by adding at the end the
11 following:

12 “(5) CONSULTATION.—With respect to a drug
13 that is a qualified countermeasure (as defined in sec-
14 tion 319F–1 of the Public Health Service Act), a se-
15 curity countermeasure (as defined in section 319F–
16 2 of the Public Health Service Act), or a qualified
17 pandemic or epidemic product (as defined in section
18 319F–3 of the Public Health Service Act), the Sec-
19 retary shall solicit input from the Assistant Sec-
20 retary for Preparedness and Response regarding the
21 need for and, from the Director of the Biomedical
22 Advanced Research and Development Authority re-
23 garding the conduct of, pediatric studies under this
24 section.”; and

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

3 “(C) For a drug that is a qualified coun-
4 termeasure (as defined in section 319F–1 of the
5 Public Health Service Act), a security counter-
6 measure (as defined in section 319F–2 of the
7 Public Health Service Act), or a qualified pan-
8 demic or epidemic product (as defined in sec-
9 tion 319F–3 of such Act), in addition to any
10 action with respect to such drug under subpara-
11 graph (A) or (B), the Secretary shall notify the
12 Assistant Secretary for Preparedness and Re-
13 sponse and the Director of the Biomedical Ad-
14 vanced Research and Development Authority of
15 all pediatric studies in the written request
16 issued by the Commissioner of Food and
17 Drugs.”.

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

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

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

1 “(A) shall consider—

2 “(i) therapeutic gaps in pediatrics
3 that may include developmental pharma-
4 cology, pharmacogenetic determinants of
5 drug response, metabolism of drugs and
6 biologics in children, and pediatric clinical
7 trials;

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

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

18 “(B) may consider the availability of quali-
19 fied countermeasures (as defined in section
20 319F-1), security countermeasures (as defined
21 in section 319F-2), and qualified pandemic or
22 epidemic products (as defined in section 319F-
23 3) to address the needs of pediatric populations,
24 in consultation with the Assistant Secretary for

1 Preparedness and Response, consistent with the
2 purposes of this section.”; and

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

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

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

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

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

18 **TITLE IV—ACCELERATING MED-**
19 **ICAL COUNTERMEASURE AD-**
20 **VANCED RESEARCH AND DE-**
21 **VELOPMENT**

22 **SEC. 401. BIOSHIELD.**

23 (a) REAUTHORIZATION OF THE SPECIAL RESERVE
24 FUND.—Section 319F–2(c) of the Public Health Service

1 Act (42 U.S.C. 247d-6b(e)) is amended by adding at the
2 end 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
7 fiscal 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
12 Secretary shall submit to the appropriate committees
13 of Congress a report detailing the amount of such
14 funds available for procurement and the impact such
15 reduction in funding will have—

16 “(A) in meeting the security counter-
17 measure 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.—Sec-
23 tion 319F-2(c) of the Public Health Service Act (42
24 U.S.C. 247d-6b(e)) 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”;
12 and

13 (ii) by striking subclause (IX) and in-
14 serting the following:

15 “(IX) CONTRACT TERMS.—The
16 Secretary, in any contract for procure-
17 ment under this section—

18 “(aa) may specify—

19 “(AA) the dosing and
20 administration requirements
21 for the countermeasure to be
22 developed and procured;

23 “(BB) the amount of
24 funding that will be dedi-
25 cated by the Secretary for

1 advanced research, develop-
2 ment, and procurement of
3 the countermeasure; and

4 “(CC) the specifications
5 the countermeasure must
6 meet to qualify for procure-
7 ment under a contract under
8 this section; and

9 “(bb) shall provide a clear
10 statement of defined Government
11 purpose limited to uses related to
12 a security countermeasure, as de-
13 fined in paragraph (1)(B).”; and

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

15 “(viii) FLEXIBILITY.—In carrying out
16 this section, the Secretary may, consistent
17 with the applicable provisions of this sec-
18 tion, enter into contracts and other agree-
19 ments that are in the best interest of the
20 Government in meeting identified security
21 countermeasure needs, including with re-
22 spect to reimbursement of the cost of ad-
23 vanced research and development as a rea-
24 sonable, allowable, and allocable direct cost
25 of the contract involved.”;

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

6 (5) in paragraph (10), by adding at the end the
7 following:

8 “(C) ADVANCED RESEARCH AND DEVELOP-
9 MENT.—For purposes of this paragraph, the
10 term ‘advanced research and development’ shall
11 have the meaning given such term in section
12 319L(a).”.

13 **SEC. 402. BIOMEDICAL ADVANCED RESEARCH AND DEVEL-**
14 **OPMENT AUTHORITY.**

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

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

23 (2) in subparagraph (D)(iii), by striking “and
24 vaccine manufacturing technologies” and inserting
25 “vaccine manufacturing technologies, dose sparing

1 technologies, efficacy increasing technologies, and
2 platform technologies”.

3 (b) STRATEGIC PUBLIC-PRIVATE PARTNERSHIP.—
4 Section 319L(c)(4) of the Public Health Service Act (42
5 U.S.C. 247d-7e(c)(4)) is amended by adding at the end
6 the following:

7 “(E) STRATEGIC INVESTOR.—

8 “(i) IN GENERAL.—To support the
9 purposes described in paragraph (2), the
10 Secretary, acting through the Director of
11 BARDA, may enter into an agreement (in-
12 cluding through the use of grants, con-
13 tracts, cooperative agreements, or other
14 transactions consistent with paragraph
15 (5)) with an independent, non-profit entity
16 to—

17 “(I) foster and accelerate the de-
18 velopment and innovation of medical
19 countermeasures and technologies
20 that may assist advanced research
21 and development of qualified counter-
22 measures and qualified pandemic or
23 epidemic products, including strategic
24 investment through the use of venture
25 capital practices and methods;

1 “(II) promote the development of
2 new and promising technologies that
3 address urgent medical counter-
4 measure needs, as identified by the
5 Secretary;

6 “(III) address unmet public
7 health needs that are directly related
8 to medical countermeasure require-
9 ments, such as novel antimicrobials
10 for multidrug resistant organisms and
11 multiuse platform technologies for
12 diagnostics, prophylaxis, vaccines, and
13 therapeutics; and

14 “(IV) provide expert consultation
15 and advice to foster viable medical
16 countermeasure innovators, including
17 helping qualified countermeasure
18 innovators navigate unique industry
19 challenges with respect to developing
20 chemical, biological, radiological, and
21 nuclear countermeasure products.

22 “(ii) ELIGIBILITY.—

23 “(I) IN GENERAL.—To be eligible
24 to enter into an agreement under
25 clause (i) an entity shall—

1 “(aa) be an independent,
2 non-profit entity not otherwise
3 affiliated with the Department of
4 Health and Human Services;

5 “(bb) have a demonstrated
6 record of being able to create
7 linkages between innovators and
8 investors and leverage such part-
9 nerships and resources for the
10 purpose of addressing identified
11 strategic needs of the Federal
12 Government;

13 “(cc) have experience in pro-
14 moting novel technology innova-
15 tion;

16 “(dd) be problem driven and
17 solution focused based on the
18 needs, requirements, and prob-
19 lems identified by the Secretary
20 under clause (iv);

21 “(ee) demonstrate the abil-
22 ity, or the potential ability, to
23 promote the development of med-
24 ical countermeasure products;
25 and

1 “(ff) demonstrate expertise,
2 or the capacity to develop or ac-
3 quire expertise, related to tech-
4 nical and regulatory consider-
5 ations with respect to medical
6 countermeasures.

7 “(II) PARTNERING EXPERI-
8 ENCE.—In selecting an entity with
9 which to enter into an agreement
10 under clause (i), the Secretary shall
11 place a high value on the dem-
12 onstrated experience of the entity in
13 partnering with the Federal Govern-
14 ment to meet identified strategic
15 needs.

16 “(iii) NOT AGENCY.—An entity that
17 enters into an agreement under clause (i)
18 shall not be deemed to be a Federal agency
19 for any purpose, including for any purpose
20 under title 5, United States Code.

21 “(iv) DIRECTION.—Pursuant to an
22 agreement entered into under this subpara-
23 graph, the Secretary, acting through the
24 Director of BARDA, shall provide direc-
25 tion to the entity that enters into an agree-

1 ment under clause (i). As part of this
2 agreement the Director of BARDA shall—

3 “(I) communicate the medical
4 countermeasure needs, requirements,
5 and problems to be addressed by the
6 entity under the agreement;

7 “(II) develop a description of
8 work to be performed by the entity
9 under the agreement;

10 “(III) provide technical feedback
11 and appropriate oversight over work
12 carried out by the entity under the
13 agreement, including subsequent de-
14 velopment and partnerships consistent
15 with the needs and requirements set
16 forth in this subparagraph;

17 “(IV) ensure fair consideration of
18 products developed under the agree-
19 ment in order to maintain competition
20 to the maximum practical extent, as
21 applicable and appropriate under ap-
22 plicable provisions of this section; and

23 “(V) ensure, as a condition of the
24 agreement—

1 “(aa) a comprehensive set of
2 policies that demonstrate a com-
3 mitment to transparency and ac-
4 countability;

5 “(bb) protection against con-
6 flicts of interest through a com-
7 prehensive set of policies that ad-
8 dress potential conflicts of inter-
9 est, ethics, disclosure, and report-
10 ing requirements;

11 “(cc) that the entity pro-
12 vides monthly accounting on the
13 use of funds provided under such
14 agreement; and

15 “(dd) that the entity pro-
16 vides on a quarterly basis, re-
17 ports regarding the progress
18 made toward meeting the identi-
19 fied needs set forth in the agree-
20 ment.

21 “(v) SUPPLEMENT NOT SUPPLANT.—
22 Activities carried out under this subpara-
23 graph shall supplement, and not supplant,
24 other activities carried out under this sec-
25 tion.

1 “(vi) NO ESTABLISHMENT OF ENTI-
2 TY.—To prevent unnecessary duplication
3 and target resources effectively, nothing in
4 this subparagraph shall be construed to
5 authorize the Secretary to establish within
6 the Department of Health and Human
7 Services a strategic investor entity.

8 “(vii) TRANSPARENCY AND OVER-
9 SIGHT.—Upon request, the Secretary shall
10 provide to Congress the information pro-
11 vided to the Secretary under clause
12 (iv)(V)(dd).

13 “(viii) INDEPENDENT EVALUATION.—
14 Not later than 4 years after the date of en-
15 actment of this subparagraph, the Govern-
16 ment Accountability Office shall conduct
17 an independent evaluation, and submit to
18 the Secretary and the appropriate commit-
19 tees of Congress a report, concerning the
20 activities conducted under this subpara-
21 graph. Such report shall include rec-
22 ommendations with respect to any agree-
23 ment or activities carried out pursuant to
24 this subparagraph.

1 “(ix) SUNSET.—This subparagraph
2 shall have no force or effect after Sep-
3 tember 30, 2016.”.

4 (c) TRANSACTION AUTHORITIES.—Section
5 319L(c)(5) of the Public Health Service Act (42 U.S.C.
6 247d–7e(c)(5)) is amended by adding at the end the fol-
7 lowing:

8 “(G) GOVERNMENT PURPOSE.—In award-
9 ing contracts, grants, and cooperative agree-
10 ments under this section, the Secretary shall
11 provide a clear statement of defined Govern-
12 ment purpose related to activities included in
13 subsection (a)(6)(B) for a qualified counter-
14 measure or qualified pandemic or epidemic
15 product.”.

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

19 “(2) FUNDING.—To carry out the purposes of
20 this section, there is authorized to be appropriated
21 to the Fund \$415,000,000 for each of fiscal years
22 2012 through 2016, such amounts to remain avail-
23 able until expended.”.

24 (e) CONTINUED INAPPLICABILITY OF CERTAIN PRO-
25 VISIONS.—Section 319L(e)(1)(C) of the Public Health

1 Service Act (42 U.S.C. 247d–7e(e)(1)(C)) is amended by
2 striking “7 years” and inserting “10 years”.

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

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

10 “(f) INDEPENDENT EVALUATION.—

11 “(1) IN GENERAL.—Not later than 180 days
12 after the date of enactment of this subsection, the
13 Government Accountability Office shall conduct an
14 independent evaluation of the activities carried out
15 to facilitate flexible manufacturing capacity pursu-
16 ant to this section.

17 “(2) REPORT.—Not later than 1 year after the
18 date of enactment of this subsection, the Govern-
19 ment Accountability Office shall submit to the ap-
20 propriate committees of Congress a report con-
21 cerning the results of the evaluation conducted
22 under paragraph (1). Such report shall review and
23 assess—

24 “(A) the extent to which flexible manufac-
25 turing capacity under this section is dedicated

1 to chemical, biological, radiological, and nuclear
2 threats;

3 “(B) the activities supported by flexible
4 manufacturing initiatives; and

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

7 “(i) secure and leverage leading tech-
8 nical expertise with respect to counter-
9 measure advanced research, development,
10 and manufacturing processes; and

11 “(ii) meet the surge manufacturing
12 capacity needs presented by novel and
13 emerging threats, including chemical, bio-
14 logical, radiological and nuclear agents.”.

15 (h) DEFINITIONS.—

16 (1) QUALIFIED COUNTERMEASURE.—Section
17 319F–1(a)(2)(A) of the Public Health Service Act
18 (42 U.S.C. 247d–6a(a)(2)(A)) is amended—

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

21 (B) in clause (i)—

22 (i) by striking “diagnose” and insert-
23 ing “to diagnose”; and

24 (ii) by striking “; or” and inserting a
25 semicolon;

1 (C) in clause (ii)—

2 (i) by striking “diagnose” and insert-
3 ing “to diagnose”; and

4 (ii) by striking the period at the end
5 and inserting “; or”; and

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

7 “(iii) is a product or technology in-
8 tended to enhance the use or effect of a
9 drug, biological product, or device de-
10 scribed in clause (i) or (ii).”.

11 (2) QUALIFIED PANDEMIC OR EPIDEMIC PROD-
12 UCT.—Section 319F-3(i)(7)(A) of the Public Health
13 Service Act (42 U.S.C. 247d-6d(i)(7)(A)) is amend-
14 ed—

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

17 (B) in clause (ii), by striking “; and” and
18 inserting “; or”; and

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

20 “(iii) a product or technology intended
21 to enhance the use or effect of a drug, bio-
22 logical product, or device described in
23 clause (i) or (ii); and”.

1 (3) TECHNICAL AMENDMENTS.—Section 319F–
2 3(i) of the Public Health Service Act (42 U.S.C.
3 247d–6d(i)) is amended—

4 (A) in paragraph (1)(C), by inserting “,
5 564A, or 564B” after “564”; and

6 (B) in paragraph (7)(B)(iii), by inserting
7 “, 564A, or 564B” after “564”.

8 **SEC. 403. STRATEGIC NATIONAL STOCKPILE.**

9 (a) IN GENERAL.—Section 319F–2 of the Public
10 Health Service Act (42 U.S.C. 247d–6b) is amended—

11 (1) in subsection (a)—

12 (A) in paragraph (1)—

13 (i) by inserting “consistent with sec-
14 tion 2811” before “by the Secretary to be
15 appropriate”; and

16 (ii) by inserting before the period at
17 the end the following: “and shall submit
18 such review annually to the appropriate
19 Congressional committees of jurisdiction to
20 the extent that disclosure of such informa-
21 tion does not compromise national secu-
22 rity”; and

23 (B) in paragraph (2)—

1 (i) by redesignating subparagraphs
2 (E) through (H) as subparagraphs (F)
3 through (I), respectively; and

4 (ii) by inserting after subparagraph
5 (D), the following:

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

10 (2) in subsection (f)(1), by striking
11 “\$640,000,000 for fiscal year 2002, and such sums
12 as may be necessary for each of fiscal years 2003
13 through 2006” and inserting “\$522,486,000 for
14 each of fiscal years 2012 through 2016”.

15 (b) REPORT ON POTASSIUM IODIDE.—Not later than
16 270 days after the date of enactment of this Act, the Sec-
17 retary of Health and Human Services shall submit to the
18 appropriate Committees of Congress a report regarding
19 the stockpiling of potassium iodide. Such report shall in-
20 clude—

21 (1) an assessment of the availability of potas-
22 sium iodide at Federal, State, and local levels; and

23 (2) a description of the extent to which such ac-
24 tivities and policies provide public health protection

1 in the event of a nuclear incident, whether uninten-
2 tional or deliberate, including an act of terrorism.

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

4 Section 319M(a) of the Public Health Service Act (42
5 U.S.C. 247d–f(a)) is amended—

6 (1) in paragraph (2)—

7 (A) in subparagraph (D)—

8 (i) in the matter preceding clause (i),
9 by striking “five” and inserting “six”;

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

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

14 (iv) by adding at the end the fol-
15 lowing:

16 “(iii) one such member shall be an in-
17 dividual with pediatric subject matter ex-
18 pertise; and

19 “(iv) one such member shall be a
20 State, tribal, territorial, or local public
21 health official.”; and

22 (B) by adding at the end the following
23 flush sentence:

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

4 (2) in paragraph (5)—

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

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

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

10 “(D) provide any recommendation, finding,
11 or report provided to the Secretary under this
12 paragraph to the appropriate committees of
13 Congress.”; and

14 (3) in paragraph (8), by adding at the end the
15 following: “Such chairperson shall serve as the de-
16 ciding vote in the event that a deciding vote is nec-
17 essary with respect to voting by members of the
18 Board.”.