

112TH 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, and Mr. ROBERTS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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,*

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. 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)—

(i) in the matter preceding subparagraph (A), by inserting “and which may include dental health facilities” after “mental health facilities”; and

(ii) in subparagraph (D), by inserting “(which may include such dental health assets)” after “medical assets”;

(B) in paragraph (4)—

(i) in subparagraph (A), by inserting “, including the unique needs and considerations of individuals with disabilities,” after “medical needs of at-risk individuals”; and

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

(C) by adding at the end the following:

“(7) COUNTERMEASURES.—

“(A) Promoting strategic initiatives to advance countermeasures to diagnose, mitigate, prevent, or treat harm from any biological agent or toxin, chemical, radiological, or nuclear agent or agents.

“(B) For purposes of this paragraph the term ‘countermeasures’ has the same meaning as the terms ‘qualified countermeasures’ under

1 section 319F–1, ‘qualified pandemic and epi-
 2 demic products’ under section 319F–3, and ‘se-
 3 curity countermeasures’ under section 319F–2.

4 “(8) MEDICAL AND PUBLIC HEALTH COMMU-
 5 NITY RESILIENCY.—Strengthening the ability of
 6 State and local communities to prepare for, respond
 7 to, and ensure resiliency in the event of public health
 8 emergencies, whether naturally occurring, uninten-
 9 tional, or deliberate by—

10 “(A) optimizing alignment and integration
 11 of medical and public health preparedness and
 12 response planning and capabilities with and into
 13 routine daily activities; and

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

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

19 (1) by striking paragraph (7);

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

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

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

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

8 “(8) disseminate and, as appropriate, update
 9 novel and best practices of outreach to and care of
 10 at-risk individuals before, during, and following pub-
 11 lic health emergencies in as timely a manner as is
 12 practicable, including from the time a public health
 13 threat is identified;

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

20 **SEC. 102. ASSISTANT SECRETARY FOR PREPAREDNESS AND**
 21 **RESPONSE.**

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

24 (1) in subsection (b)(4), by adding at the end
 25 the following:

1 “(D) POLICY COORDINATION AND STRA-
 2 TEGIC DIRECTION.—Provide integrated policy
 3 coordination and strategic direction with re-
 4 spect to all matters related to Federal public
 5 health and medical preparedness and execution
 6 and deployment of the Federal response for
 7 public health emergencies and incidents covered
 8 by the National Response Plan developed pur-
 9 suant to section 502(6) of the Homeland Secu-
 10 rity Act of 2002, or any successor plan, before,
 11 during, and following public health emer-
 12 gencies.”;

13 (2) by striking subsection (c) and inserting the
 14 following:

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

17 “(1) have authority over and responsibility
 18 for—

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

22 “(B) the Hospital Preparedness Coopera-
 23 tive Agreement Program pursuant to section
 24 319C–2;

1 “(C) the Medical Reserve Corps pursuant
2 to section 2813;

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

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

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

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

18 “(B) the Strategic National Stockpile; and

19 “(C) the Cities Readiness Initiative;

20 “(3) align and coordinate medical and public
21 health preparedness and response grants and cooper-
22 ative agreements authorized under this Act, to the
23 extent possible, including program requirements,
24 timelines, and measurable goals, and in coordination
25 with the Secretary of Homeland Security, to—

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

5 “(B) minimize duplication of efforts with
6 regard to medical and public health prepared-
7 ness and response programs; and

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

11 “(4) carry out drills and operational exercises,
12 in coordination with the Department of Homeland
13 Security, the Department of Defense, and other ap-
14 plicable Federal departments and agencies, as nec-
15 essary and appropriate, to identify, inform, and ad-
16 dress gaps in and policies related to all-hazards med-
17 ical and public health preparedness, including exer-
18 cises based on—

19 “(A) identified threats for which counter-
20 measures are available and for which no coun-
21 termeasures are available; and

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

24 “(5) assume other duties as determined appro-
25 prium by the Secretary.”; and

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

2 “(d) NATIONAL SECURITY PRIORITY.—The Sec-
3 retary, acting through the Assistant Secretary for Pre-
4 paredness and Response, shall on a periodic basis conduct
5 meetings, as applicable and appropriate, with the Assist-
6 ant to the President for National Security Affairs to pro-
7 vide an update on, and discuss, medical and public health
8 preparedness and response activities pursuant to this Act
9 and the Federal Food, Drug, and Cosmetic Act, including
10 progress on the development, approval, clearance, and li-
11 censure of medical countermeasures.

12 “(e) PUBLIC HEALTH EMERGENCY MEDICAL COUN-
13 TERMEASURES ENTERPRISE STRATEGY AND IMPLEMEN-
14 TATION PLAN.—

15 “(1) IN GENERAL.—Not later than 180 days
16 after the date of enactment of this subsection, and
17 every other year thereafter, the Secretary, acting
18 through the Assistant Secretary for Preparedness
19 and Response and in coordination with the Director
20 of the Biomedical Advanced Research and Develop-
21 ment Authority, the Director of the National Insti-
22 tutes of Health, the Director of the Centers for Dis-
23 ease Control and Prevention, and the Commissioner
24 of the Food and Drug Administration, shall develop
25 and submit to the appropriate committees of Con-

1 gress a coordinated strategy and accompanying im-
2 plementation plan for medical countermeasures to
3 address chemical, biological, radiological, and nu-
4 clear threats. Such strategy and plan shall be known
5 as the ‘Public Health Emergency Medical Counter-
6 measures Enterprise Strategy and Implementation
7 Plan’.

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

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

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

22 “(C) identify projected timelines, antici-
23 pated funding allocations, benchmarks, and
24 milestones for each medical countermeasure pri-
25 ority under subparagraph (B), including pro-

1 jected needs with regard to replenishment of
2 the Strategic National Stockpile;

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

6 “(E) report on advanced research and de-
7 velopment awards and the date of the issuance
8 of contract awards, including awards made
9 through the special reserve fund (as defined in
10 section 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
14 subsequent to the initial plan; and

15 “(G) be made publically 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 paragraph (2)(B);

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

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

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

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

24 “(A) basic research, advanced research and
25 development;

1 “(B) approval, clearance, licensure, and
2 authorized uses of products; and

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

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

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

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

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

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

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

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

12 **SEC. 103. MODERNIZATION OF THE NATIONAL DISASTER**
 13 **MEDICAL SYSTEM.**

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

16 (1) in subsection (a)(3), by adding at the end
 17 the following:

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

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

24 (C) by inserting after subparagraph (B),
 25 the following:

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

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

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

19 **SEC. 104. CONTINUING THE ROLE OF THE DEPARTMENT OF**
 20 **VETERANS AFFAIRS.**

21 Section 8117(g) of title 38, United States Code, is
 22 amended by striking “such sums as may be necessary to
 23 carry out this section for each of fiscal years 2007 through
 24 2011” and inserting “\$156,500,000 for each of fiscal
 25 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 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).”; 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 “(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).”.

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

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

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

22 (b) ENCOURAGING HEALTH PROFESSIONAL VOLUN-
 23 TEERS.—

24 (1) EMERGENCY SYSTEM FOR ADVANCE REG-
 25 ISTRATION OF VOLUNTEER HEALTH PROFES-

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 (c) and inserting the
2 following:

3 “(c) 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 Readiness
18 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

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

(3) in subsection (j)—

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

(B) by adding at the end the following:

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

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

“(B) FUNDS CONTINGENT ON ACHIEVING
BENCHMARKS.—The continued availability of
funds under subparagraph (A) with respect to
an entity shall be contingent upon such entity
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)—

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

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

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

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

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

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

(D) in paragraph (5), by striking subparagraph (A) and inserting the following:

“(A) utilize applicable interoperability standards as determined by the Secretary, and in coordination with the Office of the National Coordinator for Health Information Technology, through a joint public and private sector process;” and

(E) by adding at the end the following:

“(6) CONSULTATION WITH THE NATIONAL BIODEFENSE SCIENCE BOARD.—In carrying out this section consistent with section 319M, the National Biodefense Science Board shall provide expert advice and guidance, including recommendations, regarding the measurable steps the Secretary should take to modernize and enhance biosurveillance activities pursuant to the efforts of the Department of Health and Humans Services to ensure comprehensive, real-time all-hazards biosurveillance capabilities. In complying with the preceding sentence, the National Biodefense Science Board shall—

“(A) identify the steps necessary to achieve a national biosurveillance system for human health, with international connectivity, where appropriate, that is predicated on State, regional, and community level capabilities and 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 serting “Health, and”; 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 (e)(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 (c) 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 “, revision,” 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 spons-
23 or applicant with respect to a countermeasure described
24 in 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 (e)(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-

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

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

“(C) For a drug that is a qualified countermeasure (as defined in section 319F–1 of the Public Health Service Act), a security countermeasure (as defined in section 319F–2 of the Public Health Service Act), or a qualified pandemic or epidemic product (as defined in section 319F–3 of such Act), prior to any action with respect to such drug under subparagraph (A) or (B), the Secretary shall refer all pediatric studies in the written request to the Assistant Secretary for Preparedness and Response and the Director of the Biomedical Advanced Research and Development Authority.”.

(b) ADDITION TO PRIORITY LIST CONSIDERATIONS.—Section 409I of the Public Health Service Act (42 U.S.C. 284m) is amended—

(1) by striking subsection (a)(2) and inserting 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
6 that may include developmental pharma-
7 cology, pharmacogenetic determinants of
8 drug response, metabolism of drugs and
9 biologics 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 (c) 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(c) of the Public Health Service
 12 Act (42 U.S.C. 247d–6b(c)) 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(c) of the Public Health Service Act (42
11 U.S.C. 247d–6b(c)) 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).”; and

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(c)(4) of the Public
4 Health Service Act (42 U.S.C. 247d–7e(c)(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(c)(5) of the Public Health Service Act (42 U.S.C.
18 247d–7e(c)(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.”.

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