

113TH CONGRESS
1ST SESSION

S. 242

To reauthorize certain programs under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to public health security and all-hazards preparedness and response, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 7, 2013

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

A BILL

To reauthorize certain programs under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to public health security and all-hazards preparedness and response, and for other purposes.

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

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Pandemic and All-Hazards Preparedness Reauthoriza-
6 tion Act of 2013”.

1 (b) TABLE OF CONTENTS.—The table of contents of
2 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. National Advisory Committee on Children and Disasters.
- Sec. 104. Modernization of the National Disaster Medical System.
- Sec. 105. Continuing the role of the Department of Veterans Affairs.

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

- Sec. 201. Temporary reassignment of State and local personnel during a public health emergency.
- Sec. 202. Improving State and local public health security.
- Sec. 203. Hospital preparedness and medical surge capacity.
- Sec. 204. Enhancing situational awareness and biosurveillance.
- Sec. 205. Eliminating duplicative Project Bioshield reports.

TITLE III—ENHANCING MEDICAL COUNTERMEASURE REVIEW

- Sec. 301. Special protocol assessment.
- Sec. 302. Authorization for 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 (1)(A), by inserting “,
 12 including drills and exercises to ensure medical
 13 surge capacity for events without notice” after
 14 “exercises”; and

15 (B) in paragraph (3)—

16 (i) in the matter preceding subpara-
 17 graph (A)—

18 (I) by striking “facilities), and
 19 trauma care” and inserting “and am-
 20 bulatory care facilities and which may
 21 include dental health facilities), and
 22 trauma care, critical care,”; and

23 (II) by inserting “(including re-
 24 lated availability, accessibility, and co-

1 ordination)” after “public health
2 emergencies”;

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

5 (iii) in subparagraph (B), by striking
6 “Medical evacuation and fatality manage-
7 ment” and inserting “Fatality manage-
8 ment”;

9 (iv) by redesignating subparagraphs
10 (C), (D), and (E) as subparagraphs (D),
11 (E), and (F), respectively;

12 (v) by inserting after subparagraph
13 (B), the following the new subparagraph:

14 “(C) Coordinated medical triage and evac-
15 uation to appropriate medical institutions based
16 on patient medical need, taking into account re-
17 gionalized systems of care.”;

18 (vi) in subparagraph (E), as redesign-
19 ated by clause (iv), by inserting “(which
20 may include such dental health assets)”
21 after “medical assets”; and

22 (vii) by adding at the end the fol-
23 lowing:

24 “(G) Optimizing a coordinated and flexible
25 approach to the medical surge capacity of hos-

1 pitals, other health care facilities, critical care,
2 trauma care (which may include trauma cen-
3 ters), and emergency medical systems.”;

4 (C) in paragraph (4)—

5 (i) in subparagraph (A), by inserting
6 “, including the unique needs and consider-
7 ations of individuals with disabilities,”
8 after “medical needs of at-risk individ-
9 uals”; and

10 (ii) in subparagraph (B), by inserting
11 “the” before “purpose of this section”; and
12 (D) by adding at the end the following:

13 “(7) COUNTERMEASURES.—

14 “(A) Promoting strategic initiatives to ad-
15 vance countermeasures to diagnose, mitigate,
16 prevent, or treat harm from any biological
17 agent or toxin, chemical, radiological, or nuclear
18 agent or agents, whether naturally occurring,
19 unintentional, or deliberate.

20 “(B) For purposes of this paragraph, the
21 term ‘countermeasures’ has the same meaning
22 as the terms ‘qualified countermeasures’ under
23 section 319F-1, ‘qualified pandemic and epi-
24 demic products’ under section 319F-3, and ‘se-
25 curity countermeasures’ under section 319F-2.

1 “(8) MEDICAL AND PUBLIC HEALTH COMMU-
 2 NITY RESILIENCY.—Strengthening the ability of
 3 States, local communities, and tribal communities to
 4 prepare for, respond to, and be resilient in the event
 5 of public health emergencies, whether naturally oc-
 6 curring, unintentional, or deliberate by—

7 “(A) optimizing alignment and integration
 8 of medical and public health preparedness and
 9 response planning and capabilities with and into
 10 routine daily activities; and

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

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

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

17 (2) in paragraph (4), by striking
 18 “2811(b)(3)(B)” and inserting “2802(b)(4)(B)”;

19 (3) by redesignating paragraphs (1) through
 20 (4) as paragraphs (2) through (5), respectively;

21 (4) by inserting before paragraph (2) (as so re-
 22 designated), the following:

23 “(1) monitor emerging issues and concerns as
 24 they relate to medical and public health prepared-
 25 ness and response for at-risk individuals in the event

1 of a public health emergency declared by the Sec-
2 retary under section 319;”;

3 (5) by amending paragraph (2) (as so redesign-
4 nated) to read as follows:

5 “(2) oversee the implementation of the pre-
6 paredness goals described in section 2802(b) with re-
7 spect to the public health and medical needs of at-
8 risk individuals in the event of a public health emer-
9 gency, as described in section 2802(b)(4);”;

10 (6) by inserting after paragraph (6), the fol-
11 lowing:

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

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

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

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

5 (1) in subsection (b)—

6 (A) in paragraph (3), by inserting “, secu-
7 rity countermeasures (as defined in section
8 319F–2),” after “qualified countermeasures (as
9 defined in section 319F–1”;

10 (B) in paragraph (4), by adding at the end
11 the following:

12 “(D) POLICY COORDINATION AND STRA-
13 TEGIC DIRECTION.—Provide integrated policy
14 coordination and strategic direction with re-
15 spect to all matters related to Federal public
16 health and medical preparedness and execution
17 and deployment of the Federal response for
18 public health emergencies and incidents covered
19 by the National Response Plan developed pur-
20 suant to section 504(6) of the Homeland Secu-
21 rity Act of 2002, or any successor plan, before,
22 during, and following public health emergencies.

23 “(E) IDENTIFICATION OF INEFFICIEN-
24 CIES.—Identify and minimize gaps, duplication,
25 and other inefficiencies in medical and public
26 health preparedness and response activities and

1 the actions necessary to overcome these obsta-
2 cles.

3 “(F) COORDINATION OF GRANTS AND
4 AGREEMENTS.—Align and coordinate medical
5 and public health grants and cooperative agree-
6 ments as applicable to preparedness and re-
7 sponse activities authorized under this Act, to
8 the extent possible, including program require-
9 ments, timelines, and measurable goals, and in
10 consultation with the Secretary of Homeland
11 Security, to—

12 “(i) optimize and streamline medical
13 and public health preparedness and re-
14 sponse capabilities and the ability of local
15 communities to respond to public health
16 emergencies; and

17 “(ii) gather and disseminate best
18 practices among grant and cooperative
19 agreement recipients, as appropriate.

20 “(G) DRILL AND OPERATIONAL EXER-
21 CISES.—Carry out drills and operational exer-
22 cises, in consultation with the Department of
23 Homeland Security, the Department of De-
24 fense, the Department of Veterans Affairs, and
25 other applicable Federal departments and agen-

1 cies, as necessary and appropriate, to identify,
2 inform, and address gaps in and policies related
3 to all-hazards medical and public health pre-
4 paredness and response, including exercises
5 based on—

6 “(i) identified threats for which coun-
7 termeasures are available and for which no
8 countermeasures are available; and

9 “(ii) unknown threats for which no
10 countermeasures are available.

11 “(H) NATIONAL SECURITY PRIORITY.—On
12 a periodic basis consult with, as applicable and
13 appropriate, the Assistant to the President for
14 National Security Affairs, to provide an update
15 on, and discuss, medical and public health pre-
16 paredness and response activities pursuant to
17 this Act and the Federal Food, Drug, and Cos-
18 metic Act, including progress on the develop-
19 ment, approval, clearance, and licensure of
20 medical countermeasures.”; and

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

22 “(7) COUNTERMEASURES BUDGET PLAN.—De-
23 velop, and update on an annual basis, a coordinated
24 5-year budget plan based on the medical counter-

1 measure priorities described in subsection (d). Each
2 such plan shall—

3 “(A) include consideration of the entire
4 medical countermeasures enterprise, includ-
5 ing—

6 “(i) basic research and advanced re-
7 search and development;

8 “(ii) approval, clearance, licensure,
9 and authorized uses of products; and

10 “(iii) procurement, stockpiling, main-
11 tenance, and replenishment of all products
12 in the Strategic National Stockpile;

13 “(B) inform prioritization of resources and
14 include measurable outputs and outcomes to
15 allow for the tracking of the progress made to-
16 ward identified priorities;

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

22 “(D) be made available to the appropriate
23 committees of Congress upon request.”;

24 (2) by striking subsection (c) and inserting the
25 following:

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

3 “(1) have lead responsibility within the Depart-
4 ment of Health and Human Services for emergency
5 preparedness and response policy coordination and
6 strategic direction;

7 “(2) have authority over and responsibility
8 for—

9 “(A) the National Disaster Medical System
10 pursuant to section 2812;

11 “(B) the Hospital Preparedness Coopera-
12 tive Agreement Program pursuant to section
13 319C-2;

14 “(C) the Biomedical Advanced Research
15 and Development Authority pursuant to section
16 319L;

17 “(D) the Medical Reserve Corps pursuant
18 to section 2813;

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

22 “(F) administering grants and related au-
23 thorities related to trauma care under parts A
24 through C of title XII, such authority to be
25 transferred by the Secretary from the Adminis-

1 trator of the Health Resources and Services Ad-
2 ministration to such Assistant Secretary;

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

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

9 “(B) the Strategic National Stockpile pur-
10 suant to section 319F-2; and

11 “(C) the Cities Readiness Initiative; and

12 “(4) assume other duties as determined appro-
13 priate by the Secretary.”; and

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

15 “(d) PUBLIC HEALTH EMERGENCY MEDICAL COUN-
16 TERMEASURES ENTERPRISE STRATEGY AND IMPLEMEN-
17 TATION PLAN.—

18 “(1) IN GENERAL.—Not later than 180 days
19 after the date of enactment of this subsection, and
20 every year thereafter, the Assistant Secretary for
21 Preparedness and Response shall develop and submit
22 to the appropriate committees of Congress a coordi-
23 nated strategy and accompanying implementation
24 plan for medical countermeasures to address chem-
25 ical, biological, radiological, and nuclear threats. In

1 developing such a plan, the Assistant Secretary for
2 Preparedness and Response shall consult with the
3 Director of the Biomedical Advanced Research and
4 Development Authority, the Director of the National
5 Institutes of Health, the Director of the Centers for
6 Disease Control and Prevention, and the Commis-
7 sioner of Food and Drugs. Such strategy and plan
8 shall be known as the ‘Public Health Emergency
9 Medical Countermeasures Enterprise Strategy and
10 Implementation Plan’.

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

13 “(A) describe the chemical, biological, radi-
14 ological, and nuclear agent or agents that may
15 present a threat to the Nation and the cor-
16 responding efforts to develop qualified counter-
17 measures (as defined in section 319F–1), secu-
18 rity countermeasures (as defined in section
19 319F–2), or qualified pandemic or epidemic
20 products (as defined in section 319F–3) for
21 each threat;

22 “(B) evaluate the progress of all activities
23 with respect to such countermeasures or prod-
24 ucts, including research, advanced research, de-

1 velopment, procurement, stockpiling, deploy-
2 ment, distribution, and utilization;

3 “(C) identify and prioritize near-, mid-,
4 and long-term needs with respect to such coun-
5 termeasures or products to address a chemical,
6 biological, radiological, and nuclear threat or
7 threats;

8 “(D) identify, with respect to each cat-
9 egory of threat, a summary of all awards and
10 contracts, including advanced research and de-
11 velopment and procurement, that includes—

12 “(i) the time elapsed from the
13 issuance of the initial solicitation or re-
14 quest for a proposal to the adjudication
15 (such as the award, denial of award, or so-
16 licitation termination); and

17 “(ii) an identification of projected
18 timelines, anticipated funding allocations,
19 benchmarks, and milestones for each med-
20 ical countermeasure priority under sub-
21 paragraph (C), including projected needs
22 with regard to replenishment of the Stra-
23 tegic National Stockpile;

1 “(E) be informed by the recommendations
2 of the National Biodefense Science Board pur-
3 suant to section 319M;

4 “(F) evaluate progress made in meeting
5 timelines, allocations, benchmarks, and mile-
6 stones identified under subparagraph (D)(ii);

7 “(G) report on the amount of funds avail-
8 able for procurement in the special reserve fund
9 as defined in section 319F–2(h) and the impact
10 this funding will have on meeting the require-
11 ments under section 319F–2;

12 “(H) incorporate input from Federal,
13 State, local, and tribal stakeholders;

14 “(I) identify the progress made in meeting
15 the medical countermeasure priorities for at-
16 risk individuals (as defined in 2802(b)(4)(B)),
17 as applicable under subparagraph (C), including
18 with regard to the projected needs for related
19 stockpiling and replenishment of the Strategic
20 National Stockpile, including by addressing the
21 needs of pediatric populations with respect to
22 such countermeasures and products in the Stra-
23 tegic National Stockpile, including—

1 “(i) a list of such countermeasures
2 and products necessary to address the
3 needs of pediatric populations;

4 “(ii) a description of measures taken
5 to coordinate with the Office of Pediatric
6 Therapeutics of the Food and Drug Ad-
7 ministration to maximize the labeling, dos-
8 ages, and formulations of such counter-
9 measures and products for pediatric popu-
10 lations;

11 “(iii) a description of existing gaps in
12 the Strategic National Stockpile and the
13 development of such countermeasures and
14 products to address the needs of pediatric
15 populations; and

16 “(iv) an evaluation of the progress
17 made in addressing priorities identified
18 pursuant to subparagraph (C);

19 “(J) identify the use of authority and ac-
20 tivities undertaken pursuant to sections 319F-
21 1(b)(1), 319F-1(b)(2), 319F-1(b)(3), 319F-
22 1(e), 319F-1(d), 319F-1(e), 319F-
23 2(e)(7)(C)(iii), 319F-2(e)(7)(C)(iv), and 319F-
24 2(e)(7)(C)(v) of this Act, and subsections
25 (a)(1), (b)(1), and (e) of section 564 of the

1 Federal Food, Drug, and Cosmetic Act, by
2 summarizing—

3 “(i) the particular actions that were
4 taken under the authorities specified, in-
5 cluding, as applicable, the identification of
6 the threat agent, emergency, or the bio-
7 medical countermeasure with respect to
8 which the authority was used;

9 “(ii) the reasons underlying the deci-
10 sion to use such authorities, including, as
11 applicable, the options that were consid-
12 ered and rejected with respect to the use of
13 such authorities;

14 “(iii) the number of, nature of, and
15 other information concerning the persons
16 and entities that received a grant, coopera-
17 tive agreement, or contract pursuant to the
18 use of such authorities, and the persons
19 and entities that were considered and re-
20 jected for such a grant, cooperative agree-
21 ment, or contract, except that the report
22 need not disclose the identity of any such
23 person or entity;

24 “(iv) whether, with respect to each
25 procurement that is approved by the Presi-

1 dent under section 319F–2(c)(6), a con-
2 tract was entered into within one year
3 after such approval by the President; and

4 “(v) with respect to section 319F–
5 1(d), for the one-year period for which the
6 report is submitted, the number of persons
7 who were paid amounts totaling \$100,000
8 or greater and the number of persons who
9 were paid amounts totaling at least
10 \$50,000 but less than \$100,000; and

11 “(K) be made publicly available.

12 “(3) GAO REPORT.—

13 “(A) IN GENERAL.—Not later than 1 year
14 after the date of the submission to the Congress
15 of the first Public Health Emergency Medical
16 Countermeasures Enterprise Strategy and Im-
17 plementation Plan, the Comptroller General of
18 the United States shall conduct an independent
19 evaluation, and submit to the appropriate com-
20 mittees of Congress a report, concerning such
21 Strategy and Implementation Plan.

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

24 “(i) the near-term, mid-term, and
25 long-term medical countermeasure needs

1 and identified priorities of the Federal
2 Government pursuant to paragraph (2)(C);

3 “(ii) the activities of the Department
4 of Health and Human Services with re-
5 spect to advanced research and develop-
6 ment pursuant to section 319L; and

7 “(iii) the progress made toward meet-
8 ing the timelines, allocations, benchmarks,
9 and milestones identified in the Public
10 Health Emergency Medical Counter-
11 measures Enterprise Strategy and Imple-
12 mentation Plan under this subsection.

13 “(e) PROTECTION OF NATIONAL SECURITY.—In car-
14 rying out subsections (b)(7) and (d), the Secretary shall
15 ensure that information and items that could compromise
16 national security, contain confidential commercial infor-
17 mation, or contain proprietary information are not dis-
18 closed.”.

19 (b) INTERAGENCY COORDINATION PLAN.—In the
20 first Public Health Emergency Countermeasures Enter-
21 prise Strategy and Implementation Plan submitted under
22 subsection (d) of section 2811 of the Public Health Service
23 Act (42 U.S.C. 300hh–10) (as added by subsection
24 (a)(3)), the Secretary of Health and Human Services, in
25 consultation with the Secretary of Defense, shall include

1 a description of the manner in which the Department of
2 Health and Human Services is coordinating with the De-
3 partment of Defense regarding countermeasure activities
4 to address chemical, biological, radiological, and nuclear
5 threats. Such report shall include information with respect
6 to—

7 (1) the research, advanced research, develop-
8 ment, procurement, stockpiling, and distribution of
9 countermeasures to meet identified needs; and

10 (2) the coordination of efforts between the De-
11 partment of Health and Human Services and the
12 Department of Defense to address countermeasure
13 needs for various segments of the population.

14 **SEC. 103. NATIONAL ADVISORY COMMITTEE ON CHILDREN**
15 **AND DISASTERS.**

16 Subtitle B of title XXVIII of the Public Health Serv-
17 ice Act (42 U.S.C. 300hh et seq.) is amended by inserting
18 after section 2811 the following:

19 **“SEC. 2811A. NATIONAL ADVISORY COMMITTEE ON CHIL-**
20 **DREN AND DISASTERS.**

21 “(a) ESTABLISHMENT.—The Secretary, in consulta-
22 tion with the Secretary of Homeland Security, shall estab-
23 lish an advisory committee to be known as the ‘National
24 Advisory Committee on Children and Disasters’ (referred
25 to in this section as the ‘Advisory Committee’).

1 “(b) DUTIES.—The Advisory Committee shall—

2 “(1) provide advice and consultation with re-
3 spect to the activities carried out pursuant to section
4 2814, as applicable and appropriate;

5 “(2) evaluate and provide input with respect to
6 the medical and public health needs of children as
7 they relate to preparation for, response to, and re-
8 covery from all-hazards emergencies; and

9 “(3) provide advice and consultation with re-
10 spect to State emergency preparedness and response
11 activities and children, including related drills and
12 exercises pursuant to the preparedness goals under
13 section 2802(b).

14 “(c) ADDITIONAL DUTIES.—The Advisory Committee
15 may provide advice and recommendations to the Secretary
16 with respect to children and the medical and public health
17 grants and cooperative agreements as applicable to pre-
18 paredness and response activities authorized under this
19 title and title III.

20 “(d) MEMBERSHIP.—

21 “(1) IN GENERAL.—The Secretary, in consulta-
22 tion with such other Secretaries as may be appro-
23 priate, shall appoint not to exceed 15 members to
24 the Advisory Committee. In appointing such mem-
25 bers, the Secretary shall ensure that the total mem-

1 bership of the Advisory Committee is an odd num-
2 ber.

3 “(2) REQUIRED MEMBERS.—The Secretary, in
4 consultation with such other Secretaries as may be
5 appropriate, may appoint to the Advisory Committee
6 under paragraph (1) such individuals as may be ap-
7 propriate to perform the duties described in sub-
8 sections (b) and (c), which may include—

9 “(A) the Assistant Secretary for Prepared-
10 ness and Response;

11 “(B) the Director of the Biomedical Ad-
12 vanced Research and Development Authority;

13 “(C) the Director of the Centers for Dis-
14 ease Control and Prevention;

15 “(D) the Commissioner of Food and
16 Drugs;

17 “(E) the Director of the National Insti-
18 tutes of Health;

19 “(F) the Assistant Secretary of the Admin-
20 istration for Children and Families;

21 “(G) the Administrator of the Federal
22 Emergency Management Agency;

23 “(H) at least two non-Federal health care
24 professionals with expertise in pediatric medical

1 disaster planning, preparedness, response, or
2 recovery;

3 “(I) at least two representatives from
4 State, local, territorial, or tribal agencies with
5 expertise in pediatric disaster planning, pre-
6 paredness, response, or recovery; and

7 “(J) representatives from such Federal
8 agencies (such as the Department of Education
9 and the Department of Homeland Security) as
10 determined necessary to fulfill the duties of the
11 Advisory Committee, as established under sub-
12 sections (b) and (c).

13 “(e) MEETINGS.—The Advisory Committee shall
14 meet not less than biannually.

15 “(f) SUNSET.—The Advisory Committee shall termi-
16 nate on September 30, 2018.”.

17 **SEC. 104. MODERNIZATION OF THE NATIONAL DISASTER**
18 **MEDICAL SYSTEM.**

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

21 (1) in subsection (a)(3)—

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

1 (B) by redesignating subparagraph (C) as
2 subparagraph (E); and

3 (C) by inserting after subparagraph (B),
4 the following:

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

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

19 (2) in subsection (g), by striking “such sums as
20 may be necessary for each of the fiscal years 2007
21 through 2011” and inserting “\$52,700,000 for each
22 of fiscal years 2014 through 2018”.

1 **SEC. 105. CONTINUING THE ROLE OF THE DEPARTMENT OF**
2 **VETERANS AFFAIRS.**

3 Section 8117(g) of title 38, United States Code, is
4 amended by striking “such sums as may be necessary to
5 carry out this section for each of fiscal years 2007 through
6 2011” and inserting “\$155,300,000 for each of fiscal
7 years 2014 through 2018 to carry out this section”.

8 **TITLE II—OPTIMIZING STATE**
9 **AND LOCAL ALL-HAZARDS**
10 **PREPAREDNESS AND RE-**
11 **SPONSE**

12 **SEC. 201. TEMPORARY REASSIGNMENT OF STATE AND**
13 **LOCAL PERSONNEL DURING A PUBLIC**
14 **HEALTH EMERGENCY.**

15 Section 319 of the Public Health Service Act (42
16 U.S.C. 247d) is amended by adding at the end the fol-
17 lowing:

18 “(e) TEMPORARY REASSIGNMENT OF STATE AND
19 LOCAL PERSONNEL DURING A PUBLIC HEALTH EMER-
20 GENCY.—

21 “(1) EMERGENCY REASSIGNMENT OF FEDER-
22 ALLY FUNDED PERSONNEL.—Notwithstanding any
23 other provision of law, and subject to paragraph (2),
24 upon request by the Governor of a State or a tribal
25 organization or such Governor or tribal organiza-
26 tion’s designee, the Secretary may authorize the re-

1 requesting State or Indian tribe to temporarily reas-
2 sign, for purposes of immediately addressing a pub-
3 lic health emergency in the State or Indian tribe,
4 State and local public health department or agency
5 personnel funded in whole or in part through pro-
6 grams authorized under this Act, as appropriate.

7 “(2) ACTIVATION OF EMERGENCY REASSIGN-
8 MENT.—

9 “(A) PUBLIC HEALTH EMERGENCY.—The
10 Secretary may authorize a temporary reassign-
11 ment of personnel under paragraph (1) only
12 during the period of a public health emergency
13 determined pursuant to subsection (a).

14 “(B) CONTENTS OF REQUEST.—To seek
15 authority for a temporary reassignment of per-
16 sonnel under paragraph (1), the Governor of a
17 State or a tribal organization shall submit to
18 the Secretary a request for such reassignment
19 flexibility and shall include in the request each
20 of the following:

21 “(i) An assurance that the public
22 health emergency in the geographic area of
23 the requesting State or Indian tribe cannot
24 be adequately and appropriately addressed

1 by the public health workforce otherwise
2 available.

3 “(ii) An assurance that the public
4 health emergency would be addressed more
5 efficiently and effectively through the re-
6 quested temporary reassignment of State
7 and local personnel described in paragraph
8 (1).

9 “(iii) An assurance that the requested
10 temporary reassignment of personnel is
11 consistent with any applicable All-Hazards
12 Public Health Emergency Preparedness
13 and Response Plan under section 319C–1.

14 “(iv) An identification of—

15 “(I) each Federal program from
16 which personnel would be temporarily
17 reassigned pursuant to the requested
18 authority; and

19 “(II) the number of personnel
20 who would be so reassigned from each
21 such program.

22 “(v) Such other information and as-
23 surances upon which the Secretary and
24 Governor of a State or tribal organization
25 agree.

1 “(C) CONSIDERATION.—In reviewing a re-
2 quest for temporary reassignment under para-
3 graph (1), the Secretary shall consider the de-
4 gree to which the program or programs funded
5 in whole or in part by programs authorized
6 under this Act would be adversely affected by
7 the reassignment.

8 “(D) TERMINATION AND EXTENSION.—

9 “(i) TERMINATION.—A State or In-
10 dian tribe’s temporary reassignment of
11 personnel under paragraph (1) shall termi-
12 nate upon the earlier of the following:

13 “(I) The Secretary’s determina-
14 tion that the public health emergency
15 no longer exists.

16 “(II) Subject to clause (ii), the
17 expiration of the 30-day period fol-
18 lowing the date on which the Sec-
19 retary approved the State or Indian
20 tribe’s request for such reassignment
21 flexibility.

22 “(ii) EXTENSION OF REASSIGNMENT
23 FLEXIBILITY.—The Secretary may extend
24 a temporary reassignment of personnel
25 under paragraph (1) beyond the date oth-

1 otherwise applicable under clause (i)(II) if the
2 public health emergency still exists as of
3 such date, but only if—

4 “(I) the State or Indian tribe
5 that submitted the initial request for
6 a temporary reassignment of per-
7 sonnel submits a request for an exten-
8 sion of such temporary reassignment;
9 and

10 “(II) the request for an extension
11 contains the same information and as-
12 surances necessary for the approval of
13 an initial request for such temporary
14 reassignment pursuant to subpara-
15 graph (B).

16 “(3) VOLUNTARY NATURE OF TEMPORARY RE-
17 ASSIGNMENT OF STATE AND LOCAL PERSONNEL.—

18 “(A) IN GENERAL.—Unless otherwise pro-
19 vided under the law of the State or Indian tribe
20 that receives authorization for temporary reas-
21 signment of personnel under paragraph (1),
22 personnel eligible for reassignment pursuant to
23 such authorization—

24 “(i) shall have the opportunity to vol-
25 unteer for temporary reassignment; and

1 “(ii) shall not be required to agree to
2 a temporary reassignment.

3 “(B) PROHIBITION ON CONDITIONING
4 FEDERAL AWARDS.—The Secretary may not
5 condition the award of a grant, contract, or co-
6 operative agreement under this Act on the re-
7 quirement that a State or Indian tribe require
8 that personnel eligible for reassignment pursu-
9 ant to an authorization under paragraph (1)
10 agree to such reassignment.

11 “(4) NOTICE TO CONGRESS.—The Secretary
12 shall give notice to the Congress in conjunction with
13 the approval under this subsection of—

14 “(A) any initial request for temporary re-
15 assignment of personnel; and

16 “(B) any request for an extension of such
17 temporary reassignment.

18 “(5) GUIDANCE.—The Secretary shall—

19 “(A) not later than 6 months after the en-
20 actment of this subsection, issue proposed guid-
21 ance on the temporary reassignment of per-
22 sonnel under this subsection; and

23 “(B) after providing notice and a 60-day
24 period for public comment, finalize such guid-
25 ance.

1 “(6) REPORT TO CONGRESS.—Not later than 4
2 years after the date of enactment of the Pandemic
3 and All-Hazards Preparedness Reauthorization Act
4 of 2013, the Comptroller General of the United
5 States shall conduct an independent evaluation, and
6 submit to the appropriate committees of the Con-
7 gress a report, on temporary reassignment under
8 this subsection, including—

9 “(A) a description of how, and under what
10 circumstances, such temporary reassignment
11 has been used by States and Indian tribes;

12 “(B) an analysis of how such temporary
13 reassignment has assisted States and Indian
14 tribes in responding to public health emer-
15 gencies;

16 “(C) an evaluation of how such temporary
17 reassignment has improved operational effi-
18 ciencies in responding to public health emer-
19 gencies;

20 “(D) an analysis of the extent to which, if
21 any, Federal programs from which personnel
22 have been temporarily reassigned have been ad-
23 versely affected by the reassignment; and

24 “(E) recommendations on how medical
25 surge capacity could be improved in responding

1 to public health emergencies and the impact of
 2 the reassignment flexibility under this section
 3 on such surge capacity.

4 “(7) DEFINITIONS.—In this subsection—

5 “(A) the terms ‘Indian tribe’ and ‘tribal
 6 organization’ have the meanings given such
 7 terms in section 4 of the Indian Self-Deter-
 8 mination and Education Assistance Act; and

9 “(B) the term ‘State’ includes, in addition
 10 to the entities listed in the definition of such
 11 term in section 2, the Freely Associated States.

12 “(8) SUNSET.—This subsection shall terminate
 13 on September 30, 2018.”.

14 **SEC. 202. IMPROVING STATE AND LOCAL PUBLIC HEALTH**
 15 **SECURITY.**

16 (a) COOPERATIVE AGREEMENTS.—Section 319C–1
 17 of the Public Health Service Act (42 U.S.C. 247d–3a) is
 18 amended—

19 (1) in subsection (b)(1)(C), by striking “consor-
 20 tium of entities described in subparagraph (A)” and
 21 inserting “consortium of States”;

22 (2) in subsection (b)(2)—

23 (A) in subparagraph (A)—

24 (i) by striking clauses (i) and (ii) and
 25 inserting the following:

1 “(i) a description of the activities such
2 entity will carry out under the agreement
3 to meet the goals identified under section
4 2802, including with respect to chemical,
5 biological, radiological, or nuclear threats,
6 whether naturally occurring, unintentional,
7 or deliberate;

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

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

16 (iii) by adding at the end the fol-
17 lowing:

18 “(vi) a description of how, as appro-
19 priate, the entity may partner with rel-
20 evant public and private stakeholders in
21 public health emergency preparedness and
22 response;

23 “(vii) a description of how the entity,
24 as applicable and appropriate, will coordi-
25 nate with State emergency preparedness

1 and response plans in public health emer-
2 gency preparedness, including State edu-
3 cational agencies (as defined in section
4 9101(41) of the Elementary and Sec-
5 ondary Education Act of 1965) and State
6 child care lead agencies (designated under
7 section 658D of the Child Care and Devel-
8 opment Block Grant Act of 1990);

9 “(viii) in the case of entities that op-
10 erate on the United States-Mexico border
11 or the United States-Canada border, a de-
12 scription of the activities such entity will
13 carry out under the agreement that are
14 specific to the border area including dis-
15 ease detection, identification, investigation,
16 and preparedness and response activities
17 related to emerging diseases and infectious
18 disease outbreaks whether naturally occur-
19 ring or due to bioterrorism, consistent with
20 the requirements of this section; and

21 “(ix) a description of any activities
22 that such entity will use to analyze real-
23 time clinical specimens for pathogens of
24 public health or bioterrorism significance,

1 including any utilization of poison control
2 centers;” and

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

6 (3) in subsection (f)—

7 (A) in paragraph (2), by adding “and” at
8 the end;

9 (B) in paragraph (3), by striking “; and”
10 and inserting a period; and

11 (C) by striking paragraph (4);

12 (4) in subsection (g)—

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

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

21 (B) in paragraph (2)(A), by adding at the
22 end the following: “The Secretary shall periodi-
23 cally update, as necessary and appropriate,
24 such pandemic influenza plan criteria and shall
25 require the integration of such criteria into the

1 benchmarks and standards described in para-
2 graph (1).”;

3 (5) by striking subsection (h);

4 (6) by redesignating subsections (i), (j), and (k)
5 as subsections (h), (i), and (j), respectively;

6 (7) in subsection (h), as so redesignated—

7 (A) in paragraph (1)—

8 (i) in subparagraph (A)—

9 (I) by striking “\$824,000,000 for
10 fiscal year 2007, of which
11 \$35,000,000 shall be used to carry
12 out subsection (h),” and inserting
13 “\$641,900,000 for fiscal year 2014”;

14 and

15 (II) by striking “such sums as
16 may be necessary for each of fiscal
17 years 2008 through 2011” and insert-
18 ing “\$641,900,000 for each of fiscal
19 years 2015 through 2018”;

20 (ii) by striking subparagraph (B);

21 (iii) by redesignating subparagraphs
22 (C) and (D) as subparagraphs (B) and
23 (C), respectively; and

1 (iv) in subparagraph (C), as so redese-
2 ignated, by striking “subparagraph (C)”
3 and inserting “subparagraph (B)”;

4 (B) in subparagraphs (C) and (D) of para-
5 graph (3), by striking “(1)(A)(i)(I)” each place
6 it appears and inserting “(1)(A)”;

7 (C) in paragraph (4)(B), by striking “sub-
8 section (c)” and inserting “subsection (b)”;

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

10 “(7) AVAILABILITY OF COOPERATIVE AGREE-
11 MENT FUNDS.—

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

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

1 (8) in subsection (i), as so redesignated—

2 (A) in paragraph (1)(E), by striking “sub-
3 section (k)” and inserting “subsection (j)”; and

4 (B) by striking paragraph (3).

5 (b) VACCINE TRACKING AND DISTRIBUTION.—Sec-
6 tion 319A(e) of the Public Health Service Act (42 U.S.C.
7 247d–1(e)) is amended by striking “such sums for each
8 of fiscal years 2007 through 2011” and inserting
9 “\$30,800,000 for each of fiscal years 2014 through
10 2018”.

11 (c) TECHNICAL AND CONFORMING AMENDMENTS.—

12 (1) Section 319C–1(b)(1)(B) of the Public
13 Health Service Act (42 U.S.C. 247d–3a(b)(1)(B)) is
14 amended by striking “subsection (i)(4)” and insert-
15 ing “subsection (h)(4)”.

16 (2) Section 319C–2 of the Public Health Serv-
17 ice Act (42 U.S.C. 247d–3b) is amended—

18 (A) in subsection (i), by striking “(j), and
19 (k)” and inserting “(i), and (j)”; and

20 (B) in subsection (j)(3), by striking
21 “319C–1(i)” and inserting “319C–1(h)”.

22 **SEC. 203. HOSPITAL PREPAREDNESS AND MEDICAL SURGE**
23 **CAPACITY.**

24 (a) ALL-HAZARDS PUBLIC HEALTH AND MEDICAL
25 RESPONSE CURRICULA AND TRAINING.—Section

1 319F(a)(5)(B) of the Public Health Service Act (42
2 U.S.C. 247d–6(a)(5)(B)) is amended by striking “public
3 health or medical” and inserting “public health, medical,
4 or dental”.

5 (b) ENCOURAGING HEALTH PROFESSIONAL VOLUN-
6 TEERS.—

7 (1) EMERGENCY SYSTEM FOR ADVANCE REG-
8 ISTRATION OF VOLUNTEER HEALTH PROFES-
9 SIONALS.—Section 319I(k) of the Public Health
10 Service Act (42 U.S.C. 247d–7b(k)) is amended by
11 striking “\$2,000,000 for fiscal year 2002, and such
12 sums as may be necessary for each of the fiscal
13 years 2003 through 2011” and inserting
14 “\$5,000,000 for each of fiscal years 2014 through
15 2018”.

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

19 (A) in subsection (d)(2), by adding at the
20 end the following: “Such training exercises
21 shall, as appropriate and applicable, incorporate
22 the needs of at-risk individuals in the event of
23 a public health emergency.”; and

24 (B) in subsection (i), by striking
25 “\$22,000,000 for fiscal year 2007, and such

1 sums as may be necessary for each of fiscal
2 years 2008 through 2011” and inserting
3 “\$11,200,000 for each of fiscal years 2014
4 through 2018”.

5 (c) PARTNERSHIPS FOR STATE AND REGIONAL PRE-
6 PAREDNESS TO IMPROVE SURGE CAPACITY.—Section
7 319C–2 of the Public Health Service Act (42 U.S.C.
8 247d–3b) is amended—

9 (1) in subsection (a), by inserting “, including,
10 as appropriate, capacity and preparedness to address
11 the needs of children and other at-risk individuals”
12 before the period at the end;

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

16 (3) 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 (4) 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).”;

18 (5) in subsection (i)—

19 (A) by striking “The requirements of” and
20 inserting the following:

21 “(1) IN GENERAL.—The requirements of”; and

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

23 “(2) MEETING GOALS OF NATIONAL HEALTH
24 SECURITY STRATEGY.—The Secretary shall imple-
25 ment objective, evidence-based metrics to ensure that

1 entities receiving awards under this section are
2 meeting, to the extent practicable, the applicable
3 goals of the National Health Security Strategy
4 under section 2802.”; and

5 (6) in subsection (j)—

6 (A) by amending paragraph (1) to read as
7 follows:

8 “(1) IN GENERAL.—For purposes of carrying
9 out this section, there is authorized to be appro-
10 priated \$374,700,000 for each of fiscal years 2014
11 through 2018.”; and

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

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

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

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

1 achieving the benchmarks and submitting the
2 pandemic influenza plan as required under sub-
3 section (i).”.

4 **SEC. 204. ENHANCING SITUATIONAL AWARENESS AND BIO-**
5 **SURVEILLANCE.**

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

8 (1) in subsection (b)—

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

11 (B) in paragraph (2), by inserting before
12 the period at the end the following: “, allowing
13 for coordination to maximize all-hazards med-
14 ical and public health preparedness and re-
15 sponse and to minimize duplication of effort”;
16 and

17 (C) in paragraph (3), by inserting before
18 the period at the end the following: “and up-
19 date such standards as necessary”;

20 (2) by striking subsection (c); and

21 (3) in subsection (d)—

22 (A) in the subsection heading, by striking
23 “PUBLIC HEALTH SITUATIONAL AWARENESS”
24 and inserting “MODERNIZING PUBLIC HEALTH

1 SITUATIONAL AWARENESS AND BIOSURVEIL-
2 LANCE”;

3 (B) in paragraph (1)—

4 (i) by striking “Pandemic and All-
5 Hazards Preparedness Act” and inserting
6 “Pandemic and All-Hazards Preparedness
7 Reauthorization Act of 2013”; and

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

10 (C) by striking paragraph (2) and insert-
11 ing the following:

12 “(2) STRATEGY AND IMPLEMENTATION
13 PLAN.—Not later than 180 days after the date of
14 enactment of the Pandemic and All-Hazards Pre-
15 paredness Reauthorization Act of 2013, the Sec-
16 retary shall submit to the appropriate committees of
17 Congress a coordinated strategy and an accom-
18 panying implementation plan that identifies and
19 demonstrates the measurable steps the Secretary will
20 carry out to—

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

24 “(B) modernize and enhance biosurveil-
25 lance activities; and

1 “(C) improve information sharing, coordi-
2 nation, and communication among disparate
3 biosurveillance systems supported by the De-
4 partment of Health and Human Services.”;

5 (D) in paragraph (3)(D), by inserting
6 “community health centers, health centers”
7 after “poison control,”;

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

10 “(A) utilize applicable interoperability
11 standards as determined by the Secretary, and
12 in consultation with the Office of the National
13 Coordinator for Health Information Tech-
14 nology, through a joint public and private sec-
15 tor process;” and

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

17 “(6) CONSULTATION WITH THE NATIONAL BIO-
18 DEFENSE SCIENCE BOARD.—In carrying out this
19 section and consistent with section 319M, the Na-
20 tional Biodefense Science Board shall provide expert
21 advice and guidance, including recommendations, re-
22 garding the measurable steps the Secretary should
23 take to modernize and enhance biosurveillance activi-
24 ties pursuant to the efforts of the Department of
25 Health and Human Services to ensure comprehen-

1 sive, real-time, all-hazards biosurveillance capabilities.
2 ties. In complying with the preceding sentence, the
3 National Biodefense Science Board shall—

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

13 “(B) identify any duplicative surveillance
14 programs under the authority of the Secretary,
15 or changes that are necessary to existing pro-
16 grams, in order to enhance and modernize such
17 activities, minimize duplication, strengthen and
18 streamline such activities under the authority of
19 the Secretary, and achieve real-time and appro-
20 priate data that relate to disease activity, both
21 human and zoonotic; and

22 “(C) coordinate with applicable existing
23 advisory committees of the Director of the Cen-
24 ters for Disease Control and Prevention, includ-
25 ing such advisory committees consisting of rep-

1 representatives from State, local, and tribal public
2 health authorities and appropriate public and
3 private sector health care entities and academic
4 institutions, in order to provide guidance on
5 public health surveillance activities.”;

6 (4) in subsection (e)(5), by striking “4 years
7 after the date of enactment of the Pandemic and
8 All-Hazards Preparedness Act” and inserting “3
9 years after the date of enactment of the Pandemic
10 and All-Hazards Preparedness Reauthorization Act
11 of 2013”;

12 (5) in subsection (g), by striking “such sums as
13 may be necessary in each of fiscal years 2007
14 through 2011” and inserting “\$138,300,000 for
15 each of fiscal years 2014 through 2018”; and

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

17 “(h) DEFINITION.—For purposes of this section the
18 term ‘biosurveillance’ means the process of gathering near
19 real-time biological data that relates to human and
20 zoonotic disease activity and threats to human or animal
21 health, in order to achieve early warning and identification
22 of such health threats, early detection and prompt ongoing
23 tracking of health events, and overall situational aware-
24 ness of disease activity.”.

1 **SEC. 205. ELIMINATING DUPLICATIVE PROJECT BIOSHIELD**
2 **REPORTS.**

3 Section 5 of the Project Bioshield Act of 2004 (42
4 U.S.C. 247d–6e) is repealed.

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

7 **SEC. 301. SPECIAL PROTOCOL ASSESSMENT.**

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

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

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

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

24 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 section 505,
13 510(k), or 515 of this Act or section 351 of the
14 Public Health Service Act”; and

15 (C) in paragraph (3), by striking “a provi-
16 sion of law referred to in such paragraph” and
17 inserting “a section of this Act or the Public
18 Health Service Act referred to in paragraph
19 (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 living abroad, and that
19 involves a biological, chemical, radiological, or
20 nuclear agent or agents, or a disease or condi-
21 tion 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)—

5 (i) in subparagraph (A), by amending
6 clause (ii) to read as 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.”; and

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

19 “(5) EXPLANATION BY SECRETARY.—If an au-
20 thorization under this section with respect to an un-
21 approved product or an unapproved use of an ap-
22 proved product has been in effect for more than 1
23 year, the Secretary shall provide in writing to the
24 sponsor of such product an explanation of the sci-
25 entific, regulatory, or other obstacles to approval, li-

1 censure, or clearance of such product or use, includ-
2 ing specific actions to be taken by the Secretary and
3 the sponsor to overcome such obstacles.”;

4 (3) in subsection (c)—

5 (A) in the matter preceding paragraph

6 (1)—

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

10 (ii) by striking “Health and” and in-
11 serting “Health, and”; and

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

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

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

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

1 (5) in subsection (e)—

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

6 (B) in paragraph (1)(B), by amending
7 clause (iii) to read as follows:

8 “(iii) Appropriate conditions with re-
9 spect to collection and analysis of informa-
10 tion concerning the safety and effectiveness
11 of the product with respect to the use of
12 such product during the period when the
13 authorization is in effect and a reasonable
14 time following such period.”;

15 (C) in paragraph (2)—

16 (i) in subparagraph (A)—

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

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

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

1 (ii) in subparagraph (B)(i), by insert-
2 ing before the period at the end “, except
3 as provided in section 564A with respect to
4 authorized changes to the product expira-
5 tion date”; and

6 (iii) by amending subparagraph (C) to
7 read as follows:

8 “(C) In establishing conditions under this
9 paragraph with respect to the distribution and
10 administration of the product for the unap-
11 proved use, the Secretary shall not impose con-
12 ditions that would restrict distribution or ad-
13 ministration of the product when distributed or
14 administered for the approved use.”; and

15 (D) by amending paragraph (3) to read as
16 follows:

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

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

10 “(B) requirements established under sec-
11 tion 503(b); and

12 “(C) requirements established under sec-
13 tion 520(e).”;

14 (6) in subsection (g)—

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

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

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

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

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

6 “(2) REVISION AND REVOCATION.—The Sec-
7 retary may revise or revoke an authorization under
8 this section if—

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

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

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

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

22 (8) by adding at the end of subsection (j) the
23 following:

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

1 eration by the Secretary of any application or sub-
2 mission pending before the Food and Drug Adminis-
3 tration for a product for which an authorization
4 under this section is issued.”; and

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

6 “(m) CATEGORIZATION OF LABORATORY TESTS AS-
7 SOCIATED WITH DEVICES SUBJECT TO AUTHORIZA-
8 TION.—

9 “(1) IN GENERAL.—In issuing an authorization
10 under this section with respect to a device, the Sec-
11 retary may, subject to the provisions of this section,
12 determine that a laboratory examination or proce-
13 dure associated with such device shall be deemed, for
14 purposes of section 353 of the Public Health Service
15 Act, to be in a particular category of examinations
16 and procedures (including the category described by
17 subsection (d)(3) of such section) if, based on the to-
18 tality of scientific evidence available to the Sec-
19 retary—

20 “(A) such categorization would be bene-
21 ficial to protecting the public health; and

22 “(B) the known and potential benefits of
23 such categorization under the circumstances of
24 the authorization outweigh the known and po-
25 tential risks of the categorization.

1 “(2) CONDITIONS OF DETERMINATION.—The
2 Secretary may establish appropriate conditions on
3 the performance of the examination or procedure
4 pursuant to such determination.

5 “(3) EFFECTIVE PERIOD.—A determination
6 under this subsection shall be effective for purposes
7 of section 353 of the Public Health Service Act not-
8 withstanding any other provision of that section dur-
9 ing the effective period of the relevant declaration
10 under subsection (b).”.

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

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

16 “(a) DEFINITIONS.—In this section:

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

19 “(A) is approved or cleared under this
20 chapter or licensed under section 351 of the
21 Public Health Service Act;

22 “(B)(i) is intended for use to prevent, di-
23 agnose, or treat a disease or condition involving
24 a biological, chemical, radiological, or nuclear
25 agent or agents; or

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

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

7 “(i) a determination described in sub-
8 paragraph (A), (B), or (C) of section
9 564(b)(1) has been made by the Secretary
10 of Homeland Security, the Secretary of
11 Defense, or the Secretary, respectively; or

12 “(ii) the identification of a material
13 threat described in subparagraph (D) of
14 section 564(b)(1) has been made pursuant
15 to section 319F-2 of the Public Health
16 Service Act.

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

19 “(b) EXPIRATION DATING.—

20 “(1) IN GENERAL.—The Secretary may extend
21 the expiration date and authorize the introduction or
22 delivery for introduction into interstate commerce of
23 an eligible product after the expiration date provided
24 by the manufacturer if—

1 “(A) the expiration date extension is in-
2 tended to support the United States ability to
3 protect—

4 “(i) the public health; or

5 “(ii) military preparedness and effec-
6 tiveness; and

7 “(B) the expiration date extension is sup-
8 ported by an appropriate scientific evaluation
9 that is conducted or accepted by the Secretary.

10 “(2) REQUIREMENTS AND CONDITIONS.—Any
11 extension of an expiration date under paragraph (1)
12 shall, as part of the extension, identify—

13 “(A) each specific lot, batch, or other unit
14 of the product for which extended expiration is
15 authorized;

16 “(B) the duration of the extension; and

17 “(C) any other requirements or conditions
18 as the Secretary may deem appropriate for the
19 protection of the public health, which may in-
20 clude requirements for, or conditions on, prod-
21 uct sampling, storage, packaging or repack-
22 aging, transport, labeling, notice to product re-
23 cipients, recordkeeping, periodic testing or re-
24 testing, or product disposition.

1 “(3) EFFECT.—Notwithstanding any other pro-
2 vision of this Act or the Public Health Service Act,
3 an eligible product shall not be considered an unap-
4 proved product (as defined in section 564(a)(2)(A))
5 and shall not be deemed adulterated or misbranded
6 under this Act because, with respect to such prod-
7 uct, the Secretary has, under paragraph (1), ex-
8 tended the expiration date and authorized the intro-
9 duction or delivery for introduction into interstate
10 commerce of such product after the expiration date
11 provided by the manufacturer.

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

19 “(c) CURRENT GOOD MANUFACTURING PRACTICE.—

20 “(1) IN GENERAL.—The Secretary may, when
21 the circumstances of a domestic, military, or public
22 health emergency or material threat described in
23 subsection (a)(1)(C) so warrant, authorize, with re-
24 spect to an eligible product, deviations from current
25 good manufacturing practice requirements otherwise

1 applicable to the manufacture, processing, packing,
2 or holding of products subject to regulation under
3 this Act, including requirements under section 501
4 or 520(f)(1) or applicable conditions prescribed with
5 respect to the eligible product by an order under sec-
6 tion 520(f)(2).

7 “(2) EFFECT.—Notwithstanding any other pro-
8 vision of this Act or the Public Health Service Act,
9 an eligible product shall not be considered an unap-
10 proved product (as defined in section 564(a)(2)(A))
11 and shall not be deemed adulterated or misbranded
12 under this Act because, with respect to such prod-
13 uct, the Secretary has authorized deviations from
14 current good manufacturing practices under para-
15 graph (1).

16 “(d) EMERGENCY DISPENSING.—The requirements
17 of sections 503(b) and 520(e) shall not apply to an eligible
18 product, and the product shall not be considered an unap-
19 proved product (as defined in section 564(a)(2)(A)) and
20 shall not be deemed adulterated or misbranded under this
21 Act because it is dispensed without an individual prescrip-
22 tion, if—

23 “(1) the product is dispensed during the cir-
24 cumstances described in subsection (a)(1)(C); and

1 “(2) such dispensing without an individual pre-
2 scription occurs—

3 “(A) as permitted under the law of the
4 State in which the product is dispensed; or

5 “(B) in accordance with an order issued by
6 the Secretary, for the purposes and duration of
7 the circumstances described in subsection
8 (a)(1)(C).

9 “(e) EMERGENCY USE INSTRUCTIONS.—

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

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

1 delivery for introduction of such product into inter-
2 state commerce accompanied by such instructions—

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

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

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

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

15 and

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

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

18 The Secretary may waive any requirement of this section
19 with respect to a qualified countermeasure (as defined in
20 section 319F–1(a)(2) of the Public Health Service Act)
21 to which a requirement under this section has been ap-
22 plied, if the Secretary determines that such waiver is re-
23 quired to mitigate the effects of, or reduce the severity
24 of, the circumstances under which—

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

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

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

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

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

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

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

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

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

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

9 **SEC. 303. DEFINITIONS.**

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

13 “(a) DEFINITIONS.—In this section—

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

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

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

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

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

3 “(A) that has been identified by the De-
4 partment of Health and Human Services or the
5 Department of Defense as receiving funding di-
6 rectly related to addressing chemical, biological,
7 radiological, or nuclear threats, including pan-
8 demic influenza; or

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

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

13 **SEC. 304. ENHANCING MEDICAL COUNTERMEASURE AC-**
14 **TIVITIES.**

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

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

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

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

7 “(1) ensure the appropriate involvement of
8 Food and Drug Administration personnel in inter-
9 agency activities related to countermeasure advanced
10 research and development, consistent with sections
11 319F, 319F–1, 319F–2, 319F–3, 319L, and 2811
12 of the Public Health Service Act;

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

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

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

1 threat assessment conducted under section
2 319F-2 of the Public Health Service Act for
3 the agent or agents for which the counter-
4 measure under review is intended;

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

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

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

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

23 “(A) consult with countermeasure experts,
24 including countermeasure sponsors and appli-
25 cants, to identify and help resolve scientific

1 issues related to the approval, licensure, or
2 clearance of countermeasures, through work-
3 shops or public meetings; and

4 “(B) improve and advance the science re-
5 lating to the development of new tools, stand-
6 ards, and approaches to assessing and evalu-
7 ating countermeasures—

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

11 “(ii) with respect to the development
12 of countermeasures for populations with
13 special clinical needs, including children
14 and pregnant women, in order to meet the
15 needs of such populations, as necessary
16 and appropriate; and

17 “(5) establish”; and

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

19 “(c) FINAL GUIDANCE ON DEVELOPMENT OF ANI-
20 MAL MODELS.—

21 “(1) IN GENERAL.—Not later than 1 year after
22 the date of the enactment of the Pandemic and All-
23 Hazards Preparedness Reauthorization Act of 2013,
24 the Secretary shall provide final guidance to indus-
25 try regarding the development of animal models to

1 support approval, clearance, or licensure of counter-
2 measures referred to in subsection (a) when human
3 efficacy studies are not ethical or feasible.

4 “(2) AUTHORITY TO EXTEND DEADLINE.—The
5 Secretary may extend the deadline for providing
6 final guidance under paragraph (1) by not more
7 than 6 months upon submission by the Secretary of
8 a report on the status of such guidance to the Com-
9 mittee on Energy and Commerce of the House of
10 Representatives and the Committee on Health, Edu-
11 cation, Labor, and Pensions of the Senate.

12 “(d) DEVELOPMENT AND ANIMAL MODELING PRO-
13 CEDURES.—

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

1 “(A) a meeting to discuss proposed animal
2 model development activities; and

3 “(B) a meeting prior to initiating pivotal
4 animal studies.

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

10 “(e) REVIEW AND APPROVAL OF COUNTER-
11 MEASURES.—

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

20 “(2) REVIEW EXPERTISE.—When practicable
21 and appropriate, teams of Food and Drug Adminis-
22 tration personnel reviewing applications or submis-
23 sions described under paragraph (1) shall include a
24 reviewer with sufficient training or experience with

1 countermeasures pursuant to the protocols estab-
2 lished under subsection (b)(3)(D).”.

3 **SEC. 305. REGULATORY MANAGEMENT PLANS.**

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

7 “(f) REGULATORY MANAGEMENT PLAN.—

8 “(1) DEFINITION.—In this subsection, the term
9 ‘eligible countermeasure’ means—

10 “(A) a security countermeasure with re-
11 spect to which the Secretary has entered into a
12 procurement contract under section 319F-2(c)
13 of the Public Health Service Act; or

14 “(B) a countermeasure with respect to
15 which the Biomedical Advanced Research and
16 Development Authority has provided funding
17 under section 319L of the Public Health Serv-
18 ice Act for advanced research and development.

19 “(2) REGULATORY MANAGEMENT PLAN PROC-
20 ESS.—The Secretary, in consultation with the As-
21 sistant Secretary for Preparedness and Response
22 and the Director of the Biomedical Advanced Re-
23 search and Development Authority, shall establish a
24 formal process for obtaining scientific feedback and
25 interactions regarding the development and regu-

1 latory review of eligible countermeasures by facili-
2 tating the development of written regulatory man-
3 agement plans in accordance with this subsection.

4 “(3) SUBMISSION OF REQUEST AND PROPOSED
5 PLAN BY SPONSOR OR APPLICANT.—

6 “(A) IN GENERAL.—A sponsor or appli-
7 cant of an eligible countermeasure may initiate
8 the process described under paragraph (2) upon
9 submission of a written request to the Sec-
10 retary. Such request shall include a proposed
11 regulatory management plan.

12 “(B) TIMING OF SUBMISSION.—A sponsor
13 or applicant may submit a written request
14 under subparagraph (A) after the eligible coun-
15 termeasure has an investigational new drug or
16 investigational device exemption in effect.

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

1 sponsor or applicant, in writing, the scientific
2 or regulatory rationale why such agreement
3 cannot be reached.

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

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

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

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

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

1 “(A) feedback from the Secretary regard-
2 ing the data required to support the approval,
3 clearance, or licensure of the eligible counter-
4 measure involved;

5 “(B) feedback from the Secretary regard-
6 ing the data necessary to inform any authoriza-
7 tion under section 564;

8 “(C) feedback from the Secretary regard-
9 ing the data necessary to support the posi-
10 tioning and delivery of the eligible counter-
11 measure, including to the Strategic National
12 Stockpile;

13 “(D) feedback from the Secretary regard-
14 ing the data necessary to support the submis-
15 sion of protocols for review under section
16 505(b)(5)(B);

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

23 “(F) identification of the population for
24 which the countermeasure sponsor or applicant
25 seeks approval, licensure, or clearance and the

1 population for which desired labeling would not
2 be appropriate, if known; and

3 “(G) as necessary and appropriate, and to
4 the extent practicable, a plan for demonstrating
5 safety and effectiveness in pediatric popu-
6 lations, and for developing pediatric dosing, for-
7 mulation, and administration with respect to
8 the eligible countermeasure, provided that such
9 plan would not delay authorization under sec-
10 tion 564, approval, licensure, or clearance for
11 adults.

12 “(6) PRIORITIZATION.—

13 “(A) PLANS FOR SECURITY COUNTER-
14 MEASURES.—The Secretary shall establish reg-
15 ulatory management plans for all security coun-
16 termeasures for which a request is submitted
17 under paragraph (3)(A).

18 “(B) PLANS FOR OTHER ELIGIBLE COUN-
19 TERMEASURES.—The Secretary shall determine
20 whether resources are available to establish reg-
21 ulatory management plans for eligible counter-
22 measures that are not security counter-
23 measures. If resources are available to establish
24 regulatory management plans for eligible coun-
25 termeasures that are not security counter-

1 measures, and if resources are not available to
2 establish regulatory management plans for all
3 eligible countermeasures for which requests
4 have been submitted, the Director of the Bio-
5 medical Advanced Research and Development
6 Authority, in consultation with the Commis-
7 sioner, shall prioritize which eligible counter-
8 measures may receive regulatory management
9 plans.”.

10 **SEC. 306. REPORT.**

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

14 “(g) ANNUAL REPORT.—Not later than 180 days
15 after the date of enactment of this subsection, and annu-
16 ally thereafter, the Secretary shall make publicly available
17 on the Web site of the Food and Drug Administration a
18 report that details the countermeasure development and
19 review activities of the Food and Drug Administration, in-
20 cluding—

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, 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) with respect to countermeasures for which
11 a regulatory management plan has been agreed upon
12 under subsection (f), the extent to which the per-
13 formance targets and goals set forth in subsection
14 (f)(4)(B) and the regulatory management plan have
15 been met, including, for each such countermeasure—

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

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

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

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

7 “(4) an estimate of resources obligated to coun-
8 termeasure development and regulatory assessment,
9 including—

10 “(A) Center-specific objectives and accom-
11 plishments; and

12 “(B) the number of full-time equivalent
13 employees of the Food and Drug Administra-
14 tion who directly support the review of counter-
15 measures;

16 “(5) the number of countermeasure applications
17 and submissions submitted, the number of counter-
18 measures approved, licensed, or cleared, the status
19 of remaining submitted applications and submis-
20 sions, and the number of each type of authorization
21 issued pursuant to section 564;

22 “(6) the number of written requests for a regu-
23 latory management plan submitted under subsection
24 (f)(3)(A), the number of regulatory management

1 plans developed, and the number of such plans de-
2 veloped for security countermeasures; and

3 “(7) the number, type, and frequency of meet-
4 ings between the Food and Drug Administration
5 and—

6 “(A) sponsors of a countermeasure as de-
7 fined in subsection (a); or

8 “(B) another agency engaged in develop-
9 ment or management of portfolios for such
10 countermeasures, including the Centers for Dis-
11 ease Control and Prevention, the Biomedical
12 Advanced Research and Development Authority,
13 the National Institutes of Health, and the ap-
14 propriate agencies of the Department of De-
15 fense.”.

16 **SEC. 307. PEDIATRIC MEDICAL COUNTERMEASURES.**

17 (a) PEDIATRIC STUDIES OF DRUGS.—Section 505A
18 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
19 355a) is amended—

20 (1) in subsection (d), by adding at the end the
21 following:

22 “(5) CONSULTATION.—With respect to a drug
23 that is a qualified countermeasure (as defined in sec-
24 tion 319F–1 of the Public Health Service Act), a se-
25 curity countermeasure (as defined in section 319F–

1 2 of the Public Health Service Act), or a qualified
2 pandemic or epidemic product (as defined in section
3 319F–3 of the Public Health Service Act), the Sec-
4 retary shall solicit input from the Assistant Sec-
5 retary for Preparedness and Response regarding the
6 need for and, from the Director of the Biomedical
7 Advanced Research and Development Authority re-
8 garding the conduct of, pediatric studies under this
9 section.”; and

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

12 “(C) For a drug that is a qualified coun-
13 termeasure (as defined in section 319F–1 of the
14 Public Health Service Act), a security counter-
15 measure (as defined in section 319F–2 of the
16 Public Health Service Act), or a qualified pan-
17 demic or epidemic product (as defined in sec-
18 tion 319F–3 of such Act), in addition to any
19 action with respect to such drug under subpara-
20 graph (A) or (B), the Secretary shall notify the
21 Assistant Secretary for Preparedness and Re-
22 sponse and the Director of the Biomedical Ad-
23 vanced Research and Development Authority of
24 all pediatric studies in the written request

1 issued by the Commissioner of Food and
2 Drugs.”.

3 (b) ADDITION TO PRIORITY LIST CONSIDER-
4 ATIONS.—Section 409I of the Public Health Service Act
5 (42 U.S.C. 284m) is amended—

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

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

11 “(A) shall consider—

12 “(i) therapeutic gaps in pediatrics
13 that may include developmental pharma-
14 cology, pharmacogenetic determinants of
15 drug response, metabolism of drugs and
16 biologics in children, and pediatric clinical
17 trials;

18 “(ii) particular pediatric diseases, dis-
19 orders or conditions where more complete
20 knowledge and testing of therapeutics, in-
21 cluding drugs and biologics, may be bene-
22 ficial in pediatric populations; and

23 “(iii) the adequacy of necessary infra-
24 structure to conduct pediatric pharma-
25 cological research, including research net-

1 works and trained pediatric investigators;
2 and

3 “(B) may consider the availability of quali-
4 fied countermeasures (as defined in section
5 319F–1), security countermeasures (as defined
6 in section 319F–2), and qualified pandemic or
7 epidemic products (as defined in section 319F–
8 3) to address the needs of pediatric populations,
9 in consultation with the Assistant Secretary for
10 Preparedness and Response, consistent with the
11 purposes of this section.”; and

12 (2) in subsection (b), by striking “subsection
13 (a)” and inserting “paragraphs (1) and (2)(A) of
14 subsection (a)”.

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

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

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

23 “(D) the development of countermeasures
24 (as defined in section 565(a) of the Federal

1 Food, Drug, and Cosmetic Act) for pediatric
2 populations.”.

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

7 **SEC. 401. BIOSHIELD.**

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

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

13 (2) in paragraph (2)(C), by striking “the des-
14 ignated congressional committees (as defined in
15 paragraph (10))” and inserting “the appropriate
16 committees of Congress”;

17 (3) in paragraph (5)(B)(ii), by striking “eight
18 years” and inserting “10 years”;

19 (4) in subparagraph (C) of paragraph (6)—

20 (A) in the subparagraph heading, by strik-
21 ing “DESIGNATED CONGRESSIONAL COMMIT-
22 TEES” and inserting “APPROPRIATE CONGRES-
23 SIONAL COMMITTEES”; and

1 (B) by striking “the designated congress-
2 sional committees” and inserting “the appro-
3 priate congressional committees”; and

4 (5) in paragraph (7)(C)—

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

8 (B) in clause (ii)—

9 (i) in subclause (III), by striking
10 “eight years” and inserting “10 years”;
11 and

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

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

17 “(aa) may specify—

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

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

1 ment, and procurement of
2 the countermeasure; and

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

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

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

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

1 (b) REAUTHORIZATION OF THE SPECIAL RESERVE
2 FUND.—Section 319F–2 of the Public Health Service Act
3 (42 U.S.C. 247d–6b) is amended—

4 (1) in subsection (c)—

5 (A) by striking “special reserve fund under
6 paragraph (10)” each place it appears and in-
7 serting “special reserve fund as defined in sub-
8 section (h)”; and

9 (B) by striking paragraphs (9) and (10);
10 and

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

12 “(g) SPECIAL RESERVE FUND.—

13 “(1) AUTHORIZATION OF APPROPRIATIONS.—In
14 addition to amounts appropriated to the special re-
15 serve fund prior to the date of the enactment of this
16 subsection, there is authorized to be appropriated,
17 for the procurement of security countermeasures
18 under subsection (c) and for carrying out section
19 319L (relating to the Biomedical Advanced Research
20 and Development Authority), \$2,800,000,000 for the
21 period of fiscal years 2014 through 2018. Amounts
22 appropriated pursuant to the preceding sentence are
23 authorized to remain available until September 30,
24 2019.

1 “(2) USE OF SPECIAL RESERVE FUND FOR AD-
2 VANCED RESEARCH AND DEVELOPMENT.—The Sec-
3 retary may utilize not more than 50 percent of the
4 amounts authorized to be appropriated under para-
5 graph (1) to carry out section 319L (related to the
6 Biomedical Advanced Research and Development
7 Authority). Amounts authorized to be appropriated
8 under this subsection to carry out section 319L are
9 in addition to amounts otherwise authorized to be
10 appropriated to carry out such section.

11 “(3) RESTRICTIONS ON USE OF FUNDS.—
12 Amounts in the special reserve fund shall not be
13 used to pay costs other than payments made by the
14 Secretary to a vendor for advanced development
15 (under section 319L) or for procurement of a secu-
16 rity countermeasure under subsection (c)(7).

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

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

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

7 “(h) DEFINITIONS.—In this section:

8 “(1) The term ‘advanced research and develop-
9 ment’ has the meaning given such term in section
10 319L(a).

11 “(2) The term ‘special reserve fund’ means the
12 ‘Biodefense Countermeasures’ appropriations ac-
13 count, any appropriation made available pursuant to
14 section 521(a) of the Homeland Security Act of
15 2002, and any appropriation made available pursu-
16 ant to subsection (g)(1).”.

17 **SEC. 402. BIOMEDICAL ADVANCED RESEARCH AND DEVEL-**
18 **OPMENT AUTHORITY.**

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

22 (1) in subparagraph (B)(iii), by inserting
23 “(which may include advanced research and develop-
24 ment for purposes of fulfilling requirements under

1 the Federal Food, Drug, and Cosmetic Act or sec-
2 tion 351 of this Act)” after “development”; and

3 (2) in subparagraph (D)(iii), by striking “and
4 vaccine manufacturing technologies” and inserting
5 “vaccine-manufacturing technologies, dose-sparing
6 technologies, efficacy-increasing technologies, and
7 platform technologies”.

8 (b) TRANSACTION AUTHORITIES.—Section
9 319L(c)(5) of the Public Health Service Act (42 U.S.C.
10 247d–7e(c)(5)) is amended by adding at the end the fol-
11 lowing:

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

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

23 “(2) FUNDING.—To carry out the purposes of
24 this section, there is authorized to be appropriated
25 to the Fund \$415,000,000 for each of fiscal years

1 2014 through 2018, such amounts to remain avail-
2 able until expended.”.

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

7 (e) EXTENSION OF LIMITED ANTITRUST EXEMP-
8 TION.—

9 (1) IN GENERAL.—Section 405(b) of the Pan-
10 demic and All-Hazards Preparedness Act (42 U.S.C.
11 247d–6a note) is amended by striking “6-year” and
12 inserting “12-year”.

13 (2) EFFECTIVE DATE.—This subsection shall
14 take effect as if enacted on December 17, 2012.

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

18 “(f) INDEPENDENT EVALUATION.—

19 “(1) IN GENERAL.—Not later than 180 days
20 after the date of enactment of this subsection, the
21 Comptroller General of the United States shall con-
22 duct an independent evaluation of the activities car-
23 ried out to facilitate flexible manufacturing capacity
24 pursuant to this section.

1 “(2) REPORT.—Not later than 1 year after the
2 date of enactment of this subsection, the Comp-
3 troller General of the United States shall submit to
4 the appropriate committees of Congress a report
5 concerning the results of the evaluation conducted
6 under paragraph (1). Such report shall review and
7 assess—

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

12 “(B) the activities supported by flexible
13 manufacturing initiatives; and

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

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

20 “(ii) meet the surge manufacturing
21 capacity needs presented by novel and
22 emerging threats, including chemical, bio-
23 logical, radiological, and nuclear agents.”.

24 (g) DEFINITIONS.—

1 (1) QUALIFIED COUNTERMEASURE.—Section
2 319F–1(a)(2)(A) of the Public Health Service Act
3 (42 U.S.C. 247d–6a(a)(2)(A)) is amended—

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

6 (B) in clause (i)—

7 (i) by striking “diagnose” and insert-
8 ing “to diagnose”; and

9 (ii) by striking “; or” and inserting a
10 semicolon;

11 (C) in clause (ii)—

12 (i) by striking “diagnose” and insert-
13 ing “to diagnose”; and

14 (ii) by striking the period at the end
15 and inserting “; or”; and

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

17 “(iii) is a product or technology in-
18 tended to enhance the use or effect of a
19 drug, biological product, or device de-
20 scribed in clause (i) or (ii).”.

21 (2) QUALIFIED PANDEMIC OR EPIDEMIC PROD-
22 UCT.—Section 319F–3(i)(7)(A) of the Public Health
23 Service Act (42 U.S.C. 247d–6d(i)(7)(A)) is amend-
24 ed—

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

3 (B) in clause (ii), by striking “; and” and
 4 inserting “; or”; and

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

6 “(iii) a product or technology intended
 7 to enhance the use or effect of a drug, bio-
 8 logical product, or device described in
 9 clause (i) or (ii); and”.

10 (3) TECHNICAL AMENDMENTS.—Section 319F-
 11 3(i) of the Public Health Service Act (42 U.S.C.
 12 247d-6d(i)) is amended—

13 (A) in paragraph (1)(C), by inserting “,
 14 564A, or 564B” after “564”; and

15 (B) in paragraph (7)(B)(iii), by inserting
 16 “, 564A, or 564B” after “564”.

17 **SEC. 403. STRATEGIC NATIONAL STOCKPILE.**

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

20 (1) in subsection (a)—

21 (A) in paragraph (1)—

22 (i) by inserting “consistent with sec-
 23 tion 2811” before “by the Secretary to be
 24 appropriate”; and

1 (ii) by inserting before the period at
2 the end of the second sentence the fol-
3 lowing: “and shall submit such review an-
4 nually to the appropriate congressional
5 committees of jurisdiction to the extent
6 that disclosure of such information does
7 not compromise national security”; and

8 (B) in paragraph (2)(D), by inserting be-
9 fore the semicolon at the end the following:
10 “and that the potential depletion of counter-
11 measures currently in the stockpile is identified
12 and appropriately addressed, including through
13 necessary replenishment”; and

14 (2) in subsection (f)(1), by striking
15 “\$640,000,000 for fiscal year 2002, and such sums
16 as may be necessary for each of fiscal years 2003
17 through 2006. Such authorization is in addition to
18 amounts in the special reserve fund referred to in
19 subsection (c)(10)(A).” and inserting “\$533,800,000
20 for each of fiscal years 2014 through 2018. Such
21 authorization is in addition to amounts in the special
22 reserve fund referred to in subsection (h).”.

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

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

1 (1) in paragraph (2)—

2 (A) in subparagraph (D)—

3 (i) in clause (i), by striking “and” at
4 the end;

5 (ii) in clause (ii), by striking the pe-
6 riod and inserting a semicolon; and

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

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

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

15 (B) by adding at the end the following
16 flush sentence:

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

20 (2) in paragraph (5)—

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

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

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

1 “(D) provide any recommendation, finding,
2 or report provided to the Secretary under this
3 paragraph to the appropriate committees of
4 Congress.”.

○