

Calendar No. _____

113TH CONGRESS
1ST SESSION**H. R. 307****[Report No. 113-_____]**

IN THE SENATE OF THE UNITED STATES

JANUARY 23 (legislative day, JANUARY 3), 2013

Received; read twice and referred to the Committee on Health, Education,
Labor, and Pensions

_____ (legislative day, _____), _____

Reported by Mr. HARKIN, with an amendment

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

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 redeployment of federally funded 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 evae-
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 and trauma care (which may include trauma
3 centers) 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 eles.

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 (e) and inserting the
25 following:

1 “(e) 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 pate 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 (c) 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.—~~

“(A) IN GENERAL.—Not later than 1 year after the date of the submission to the Congress of the first Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the appropriate committees of Congress a report, concerning such 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 ear-
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 the date that is 5 years after the date of enact-
17 ment of the Pandemic and All-Hazards Preparedness Re-
18 authorization Act of 2013.”.

19 **SEC. 104. MODERNIZATION OF THE NATIONAL DISASTER**
20 **MEDICAL SYSTEM.**

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

23 (1) in subsection (a)(3)—

24 (A) in subparagraph (A), in clause (i) by
25 inserting “, including at-risk individuals as ap-

1 plicable” after “victims of a public health emer-
2 gency”;

3 (B) by redesignating subparagraph (C) as
4 subparagraph (E); and

5 (C) by inserting after subparagraph (B),
6 the following:

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

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

21 (2) in subsection (g), by striking “such sums as
22 may be necessary for each of the fiscal years 2007
23 through 2011” and inserting “\$52,700,000 for each
24 of fiscal years 2013 through 2017”.

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 2013 through 2017 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 REDEPLOYMENT OF FEDERALLY**
13 **FUNDED 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 “(c) TEMPORARY REDEPLOYMENT OF FEDERALLY
19 FUNDED PERSONNEL DURING A PUBLIC HEALTH EMER-
20 GENCY.—

21 “(1) EMERGENCY REDEPLOYMENT 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 the chief
25 of a tribe or such Governor or chief’s designee, the
26 Secretary may authorize the requesting State or

1 tribe to temporarily redeploy, for purposes of imme-
2 diately addressing a public health emergency in the
3 State or tribe, non-Federal personnel funded in
4 whole or in part through, as appropriate, programs
5 under this Act.

6 ~~“(2) ACTIVATION OF EMERGENCY REDEPLOY-~~
7 ~~MENT.—~~

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

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

19 ~~“(i) An assurance that the public~~
20 ~~health emergency in the geographic area of~~
21 ~~the requesting State or tribe cannot be~~
22 ~~adequately and appropriately addressed by~~
23 ~~the public health workforce otherwise avail-~~
24 ~~able.~~

1 “(ii) An assurance that the public
2 health emergency would be addressed more
3 efficiently and effectively through the re-
4 quested temporary redeployment of per-
5 sonnel.

6 “(iii) An assurance that the requested
7 temporary redeployment of personnel is
8 consistent with any applicable All-Hazards
9 Public Health Emergency Preparedness
10 and Response Plan under section 319C-1.

11 “(iv) An identification of—

12 “(I) each Federal program from
13 which personnel would be temporarily
14 redeployed pursuant to the requested
15 authority; and

16 “(II) the number of personnel
17 who would be so redeployed from each
18 such program.

19 “(v) Such other information and as-
20 surances as the Secretary may require.

21 “(C) CONSIDERATION.—In reviewing a re-
22 quest for temporary redeployment under para-
23 graph (1) of personnel funded through a Fed-
24 eral program, the Secretary shall consider the

1 degree to which the program would be adversely
2 affected by the redeployment.

3 ~~“(D) TERMINATION AND EXTENSION.—~~

4 ~~“(i) TERMINATION.—A State or~~
5 ~~tribe’s authority for a temporary redeploy-~~
6 ~~ment of personnel under paragraph (1)~~
7 ~~shall terminate upon the earlier of the fol-~~
8 ~~lowing:~~

9 ~~“(I) The Secretary’s determina-~~
10 ~~tion that the public health emergency~~
11 ~~no longer exists.~~

12 ~~“(II) Subject to clause (ii), the~~
13 ~~expiration of the 30-day period fol-~~
14 ~~lowing the date on which the Sec-~~
15 ~~retary approved the State or tribe’s~~
16 ~~request for such authority.~~

17 ~~“(ii) EXTENSION AUTHORITY.—The~~
18 ~~Secretary may extend the authority to au-~~
19 ~~thorize a temporary redeployment of per-~~
20 ~~sonnel under paragraph (1) beyond the~~
21 ~~date otherwise applicable under clause~~
22 ~~(i)(II) if the public health emergency still~~
23 ~~exists as of such date, but only if—~~

24 ~~“(I) the State or tribe that sub-~~
25 ~~mitted the initial request for authority~~

1 “(B) any request for an extension of such
2 authority.

3 ~~“(5) GUIDANCE.—~~The Secretary shall—

4 ~~“(A) not later than 6 months after the en-~~
5 ~~actment of this subsection, issue proposed guid-~~
6 ~~ance on the temporary redeployment of per-~~
7 ~~sonnel under this subsection; and~~

8 ~~“(B) after providing notice and a 60-day~~
9 ~~period for public comment, finalize such guid-~~
10 ~~ance.~~

11 ~~“(6) REPORT TO CONGRESS.—~~Not later than 4
12 ~~years after the date of enactment of the Pandemic~~
13 ~~and All-Hazards Preparedness Reauthorization Act~~
14 ~~of 2013, the Comptroller General of the United~~
15 ~~States shall conduct an independent evaluation, and~~
16 ~~submit to the appropriate committees of the Con-~~
17 ~~gress a report, on the Secretary’s authority under~~
18 ~~this subsection, including—~~

19 ~~“(A) a description of how, and under what~~
20 ~~circumstances, such authority has been used by~~
21 ~~States and tribes;~~

22 ~~“(B) an analysis of how such authority has~~
23 ~~assisted States and tribes in responding to pub-~~
24 ~~lic health emergencies;~~

1 “(C) an evaluation of how such authority
2 has improved operational efficiencies in re-
3 sponding to public health emergencies;

4 “(D) an analysis of the extent to which, if
5 any, Federal programs from which personnel
6 have been temporarily redeployed pursuant to
7 such authority have been adversely affected by
8 the redeployment; and

9 “(E) recommendations on how such au-
10 thority could be improved to further assist in
11 responding to public health emergencies.

12 “(7) DEFINITION.—In this subsection, the term
13 ‘State’ includes, in addition to the entities listed in
14 the definition of such term in section 2, the Freely
15 Associated States.

16 “(8) SUNSET.—The authority under this sub-
17 section shall terminate on the date that is 5 years
18 after the date of enactment of the Pandemic and
19 All-Hazards Preparedness Reauthorization Act of
20 2013.”.

21 **SEC. 202. IMPROVING STATE AND LOCAL PUBLIC HEALTH**
22 **SECURITY.**

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

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

4 (2) in subsection (b)(2)—

5 (A) in subparagraph (A)—

6 (i) by striking clauses (i) and (ii) and
7 inserting the following:

8 “(i) a description of the activities such
9 entity will carry out under the agreement
10 to meet the goals identified under section
11 2802, including with respect to chemical,
12 biological, radiological, or nuclear threats,
13 whether naturally occurring, unintentional,
14 or deliberate;

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

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

23 (iii) by adding at the end the fol-
24 lowing:

1 “(vi) a description of how, as appro-
2 priate, the entity may partner with rel-
3 evant public and private stakeholders in
4 public health emergency preparedness and
5 response;

6 “(vii) a description of how the entity,
7 as applicable and appropriate, will coordi-
8 nate with State emergency preparedness
9 and response plans in public health emer-
10 gency preparedness, including State edu-
11 cational agencies (as defined in section
12 9101(41) of the Elementary and Sec-
13 ondary Education Act of 1965) and State
14 child care lead agencies (designated under
15 section 658D of the Child Care and Devel-
16 opment Block Grant Act of 1990);

17 “(viii) in the case of entities that op-
18 erate on the United States-Mexico border
19 or the United States-Canada border, a de-
20 scription of the activities such entity will
21 carry out under the agreement that are
22 specific to the border area including dis-
23 ease detection, identification, investigation,
24 and preparedness and response activities
25 related to emerging diseases and infectious

1 disease outbreaks whether naturally occur-
2 ring or due to bioterrorism, consistent with
3 the requirements of this section; and

4 “(ix) a description of any activities
5 that such entity will use to analyze real-
6 time clinical specimens for pathogens of
7 public health or bioterrorism significance,
8 including any utilization of poison control
9 centers;” and

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

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

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

18 (C) by striking paragraph (4);

19 (4) in subsection (g)—

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

22 “(A) include outcome goals representing
23 operational achievements of the National Pre-
24 paredness Goals developed under section
25 2802(b) with respect to all-hazards, including

1 chemical, biological, radiological, or nuclear
2 threats; and”; and

3 (B) in paragraph (2)(A), by adding at the
4 end the following: “The Secretary shall periodically update, as necessary and appropriate,
5 such pandemic influenza plan criteria and shall
6 require the integration of such criteria into the
7 benchmarks and standards described in paragraph (1).”;

10 (5) by striking subsection (h);

11 (6) in subsection (i)—

12 (A) in paragraph (1)—

13 (i) in subparagraph (A)—

14 (I) by striking “\$824,000,000 for
15 fiscal year 2007, of which
16 \$35,000,000 shall be used to carry
17 out subsection (h),” and inserting
18 “\$641,900,000 for fiscal year 2013”;
19 and

20 (II) by striking “such sums as
21 may be necessary for each of fiscal
22 years 2008 through 2011” and inserting
23 “\$641,900,000 for each of fiscal
24 years 2014 through 2017”;

25 (ii) by striking subparagraph (B);

1 (iii) by redesignating subparagraphs
2 (C) and (D) as subparagraphs (B) and
3 (C), respectively; and

4 (iv) in subparagraph (C), as so rededesignated,
5 by striking “subparagraph (C)”
6 and inserting “subparagraph (B)”;

7 (B) in subparagraphs (C) and (D) of paragraph (3),
8 by striking “(1)(A)(i)(I)” each place
9 it appears and inserting “(1)(A)”;

10 (C) in paragraph (4)(B), by striking “subsection (c)”
11 and inserting “subsection (b)”;

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

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

14

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

21

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

25

1 achieving the benchmarks and submitting the
2 pandemic influenza plan as described in sub-
3 section (g).”; and

4 (7) in subsection (j), 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 2013 through
10 2017”.

11 **SEC. 203. HOSPITAL PREPAREDNESS AND MEDICAL SURGE**
12 **CAPACITY.**

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

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

21 (1) EMERGENCY SYSTEM FOR ADVANCE REG-
22 ISTRATION OF VOLUNTEER HEALTH PROFES-
23 SIONALS.—Section 319I(k) of the Public Health
24 Service Act (42 U.S.C. 247d–7b(k)) is amended by
25 striking “\$2,000,000 for fiscal year 2002, and such

1 sums as may be necessary for each of the fiscal
2 years 2003 through 2011” and inserting
3 “\$5,000,000 for each of fiscal years 2013 through
4 2017”.

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

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

13 (B) in subsection (i), by striking
14 “\$22,000,000 for fiscal year 2007, and such
15 sums as may be necessary for each of fiscal
16 years 2008 through 2011” and inserting
17 “\$11,200,000 for each of fiscal years 2013
18 through 2017”.

19 (c) PARTNERSHIPS FOR STATE AND REGIONAL PRE-
20 PAREDNESS TO IMPROVE SURGE CAPACITY.—Section
21 319C–2 of the Public Health Service Act (42 U.S.C.
22 247d–3b) is amended—

23 (1) in subsection (a), by inserting “, including
24 capacity and preparedness to address the needs of

1 pediatric and other at-risk populations” before the
2 period at the end;

3 ~~(2)~~ in subsection (b)(1)(A)(ii), by striking “cen-
4 ters, primary” and inserting “centers, community
5 health centers, primary”;

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

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

14 ~~(4)~~ by striking subsection (g) and inserting the
15 following:

16 “(g) COORDINATION.—

17 “(1) LOCAL RESPONSE CAPABILITIES.—An eli-
18 gible entity shall, to the extent practicable, ensure
19 that activities carried out under an award under
20 subsection (a) are coordinated with activities of rel-
21 evant local Metropolitan Medical Response Systems,
22 local Medical Reserve Corps, the local Cities Readiness
23 Initiative, and local emergency plans.

24 “(2) NATIONAL COLLABORATION.—Partner-
25 ships consisting of one or more eligible entities

1 under this section may, to the extent practicable,
2 collaborate with other partnerships consisting of one
3 or more eligible entities under this section for pur-
4 poses of national coordination and collaboration with
5 respect to activities to achieve the preparedness
6 goals described under paragraphs (1), (3), (4), (5),
7 and (6) of section 2802(b).”;

8 (5) in subsection (i)—

9 (A) by striking “The requirements of” and
10 inserting the following:

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

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

13 “(2) MEETING GOALS OF NATIONAL HEALTH
14 SECURITY STRATEGY.—The Secretary shall imple-
15 ment objective, evidence-based metrics to ensure that
16 entities receiving awards under this section are
17 meeting, to the extent practicable, the applicable
18 goals of the National Health Security Strategy
19 under section 2802.”; and

20 (6) in subsection (j)—

21 (A) by amending paragraph (1) to read as
22 follows:

23 “(1) IN GENERAL.—For purposes of carrying
24 out this section, there is authorized to be appro-

1 priated \$374,700,000 for each of fiscal years 2013
2 through 2017.”; and

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

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

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

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

20 **SEC. 204. ENHANCING SITUATIONAL AWARENESS AND BIO-**
21 **SURVEILLANCE.**

22 Section 319D of the Public Health Service Act (42
23 U.S.C. 247d–4) is amended—

24 (1) in subsection (b)—

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

3 (B) in paragraph (2), by inserting before
4 the period at the end the following: “, allowing
5 for coordination to maximize all-hazards med-
6 ical and public health preparedness and re-
7 sponse and to minimize duplication of effort”;
8 and

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

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

13 (3) in subsection (d)—

14 (A) in the subsection heading, by striking
15 “PUBLIC HEALTH SITUATIONAL AWARENESS”
16 and inserting “MODERNIZING PUBLIC HEALTH
17 SITUATIONAL AWARENESS AND BIOSURVEIL-
18 LANCE”;

19 (B) in paragraph (1)—

20 (i) by striking “Pandemic and All-
21 Hazards Preparedness Act” and inserting
22 “Pandemic and All-Hazards Preparedness
23 Reauthorization Act of 2013”; and

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

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

3 “(2) STRATEGY AND IMPLEMENTATION
4 PLAN.—Not later than 180 days after the date of
5 enactment of the Pandemic and All-Hazards Pre-
6 paredness Reauthorization Act of 2013, the Sec-
7 retary shall submit to the appropriate committees of
8 Congress a coordinated strategy and an accom-
9 panying implementation plan that identifies and
10 demonstrates the measurable steps the Secretary will
11 carry out to—

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

15 “(B) modernize and enhance biosurveil-
16 lance activities; and

17 “(C) improve information sharing, coordi-
18 nation, and communication among disparate
19 biosurveillance systems supported by the De-
20 partment of Health and Human Services.”;

21 (D) in paragraph (3)(D), by inserting
22 “community health centers, health centers”
23 after “poison control,”;

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

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

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

8 “(6) CONSULTATION WITH THE NATIONAL BIO-
9 DEFENSE SCIENCE BOARD.—In carrying out this
10 section and consistent with section 319M, the Na-
11 tional Biodefense Science Board shall provide expert
12 advice and guidance, including recommendations, re-
13 garding the measurable steps the Secretary should
14 take to modernize and enhance biosurveillance activi-
15 ties pursuant to the efforts of the Department of
16 Health and Human Services to ensure comprehen-
17 sive, real-time, all-hazards biosurveillance capabili-
18 ties. In complying with the preceding sentence, the
19 National Biodefense Science Board shall—

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

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

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

13 “(C) coordinate with applicable existing
14 advisory committees of the Director of the Cen-
15 ters for Disease Control and Prevention, includ-
16 ing such advisory committees consisting of rep-
17 resentatives from State, local, and tribal public
18 health authorities and appropriate public and
19 private sector health care entities and academic
20 institutions, in order to provide guidance on
21 public health surveillance activities.”;

22 (4) in subsection (c)(5), by striking “4 years
23 after the date of enactment of the Pandemic and
24 All-Hazards Preparedness Act” and inserting “3
25 years after the date of enactment of the Pandemic

1 and All-Hazards Preparedness Reauthorization Act
2 of 2013”;

3 (5) in subsection (g), by striking “such sums as
4 may be necessary in each of fiscal years 2007
5 through 2011” and inserting “\$138,300,000 for
6 each of fiscal years 2013 through 2017”; and

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

8 “(h) DEFINITION.—For purposes of this section the
9 term ‘biosurveillance’ means the process of gathering near
10 real-time biological data that relates to human and
11 zoonotic disease activity and threats to human or animal
12 health, in order to achieve early warning and identification
13 of such health threats, early detection and prompt ongoing
14 tracking of health events, and overall situational aware-
15 ness of disease activity.”.

16 **SEC. 205. ELIMINATING DUPLICATIVE PROJECT BIOSHIELD**
17 **REPORTS.**

18 Section 5 of the Project Bioshield Act of 2004 (42
19 U.S.C. 247d–6c) is repealed.

20 **TITLE III—ENHANCING MEDICAL**
21 **COUNTERMEASURE REVIEW**

22 **SEC. 301. SPECIAL PROTOCOL ASSESSMENT.**

23 Section 505(b)(5)(B) of the Federal Food, Drug, and
24 Cosmetic Act (21 U.S.C. 355(b)(5)(B)) is amended by
25 striking “size of clinical trials intended” and all that fol-

1 lows through “: The sponsor or applicant” and inserting
2 the following: “size—

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

5 “(II) in the case where human efficacy studies
6 are not ethical or feasible; of animal and any associ-
7 ated clinical trials which, in combination, are in-
8 tended to form the primary basis of an effectiveness
9 claim; or

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

14 The sponsor or applicant”.

15 **SEC. 302. AUTHORIZATION FOR MEDICAL PRODUCTS FOR**
16 **USE IN EMERGENCIES.**

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

20 (1) in subsection (a)—

21 (A) in paragraph (1), by striking “sections
22 505, 510(k), and 515 of this Act” and inserting
23 “any provision of this Act”;

24 (B) in paragraph (2)(A), by striking
25 “under a provision of law referred to in such

1 paragraph” and inserting “under section 505;
2 510(k), or 515 of this Act or section 351 of the
3 Public Health Service Act”; and

4 (C) in paragraph (3), by striking “a provi-
5 sion of law referred to in such paragraph” and
6 inserting “a section of this Act or the Public
7 Health Service Act referred to in paragraph
8 (2)(A)”;

9 (2) in subsection (b)—

10 (A) in the subsection heading, by striking
11 “EMERGENCY” and inserting “EMERGENCY OR
12 THREAT JUSTIFYING EMERGENCY AUTHOR-
13 IZED USE”;

14 (B) in paragraph (1)—

15 (i) in the matter preceding subpara-
16 graph (A), by striking “may declare an
17 emergency” and inserting “may make a
18 declaration that the circumstances exist”;

19 (ii) in subparagraph (A), by striking
20 “specified”;

21 (iii) in subparagraph (B)—

22 (I) by striking “specified”; and

23 (II) by striking “; or” and insert-
24 ing a semicolon;

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

3 “(C) a determination by the Secretary that
4 there is a public health emergency, or a signifi-
5 cant potential for a public health emergency,
6 that affects, or has a significant potential to af-
7 fect, national security or the health and security
8 of United States citizens living abroad, and that
9 involves a biological, chemical, radiological, or
10 nuclear agent or agents, or a disease or condi-
11 tion that may be attributable to such agent or
12 agents; or”; and

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

14 “(D) the identification of a material threat
15 pursuant to section 319F-2 of the Public
16 Health Service Act sufficient to affect national
17 security or the health and security of United
18 States citizens living abroad.”;

19 (C) in paragraph (2)—

20 (i) in subparagraph (A), by amending
21 clause (ii) to read as follows:

22 “(ii) a change in the approval status
23 of the product such that the circumstances
24 described in subsection (a)(2) have ceased
25 to exist.”;

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

2 (iii) by redesignating subparagraph

3 ~~(C)~~ as subparagraph (B);

4 ~~(D)~~ in paragraph (4), by striking “advance

5 notice of termination, and renewal under this

6 subsection.” and inserting “, and advance no-

7 tice of termination under this subsection.”; and

8 ~~(E)~~ by adding at the end the following:

9 “~~(5)~~ EXPLANATION BY SECRETARY.—If an au-

10 thorization under this section with respect to an un-

11 approved product or an unapproved use of an ap-

12 proved product has been in effect for more than 1

13 year, the Secretary shall provide in writing to the

14 sponsor of such product an explanation of the sci-

15 entific, regulatory, or other obstacles to approval, li-

16 censure, or clearance of such product or use, includ-

17 ing specific actions to be taken by the Secretary and

18 the sponsor to overcome such obstacles.”;

19 ~~(3)~~ in subsection (c)—

20 (A) in the matter preceding paragraph

21 ~~(1)~~—

22 (i) by inserting “the Assistant Sec-

23 retary for Preparedness and Response,”

24 after “consultation with”;

1 (ii) by striking “Health and” and in-
2 serting “Health, and”; and

3 (iii) by striking “circumstances of the
4 emergency involved” and inserting “appli-
5 cable circumstances described in subsection
6 (b)(1)”;

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

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

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

17 (5) in subsection (e)—

18 (A) in paragraph (1)(A), by striking “cir-
19 cumstances of the emergency” and inserting
20 “applicable circumstances described in sub-
21 section (b)(1)”;

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

24 “(iii) Appropriate conditions with re-
25 spect to collection and analysis of informa-

tion concerning the safety and effectiveness of the product with respect to the use of such product during the period when the authorization is in effect and a reasonable time following such period.”;

(C) in paragraph (2)—

(i) in subparagraph (A)—

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

(II) by striking “circumstances of the emergency” and inserting “applicable circumstances described in subsection (b)(1)”; and

(III) by inserting at the end before the period “or in paragraph (1)(B)”;

(ii) in subparagraph (B)(i), by inserting before the period at the end “, except as provided in section 564A with respect to authorized changes to the product expiration date”; and

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

“(C) In establishing conditions under this paragraph with respect to the distribution and

1 administration of the product for the unap-
2 proved use, the Secretary shall not impose con-
3 ditions that would restrict distribution or ad-
4 ministration of the product when distributed or
5 administered for the approved use.”; and

6 (D) by amending paragraph (3) to read as
7 follows:

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

16 “(A) requirements regarding current good
17 manufacturing practice otherwise applicable to
18 the manufacture, processing, packing, or hold-
19 ing of products subject to regulation under this
20 Act, including such requirements established
21 under section 501 or 520(f)(1), and including
22 relevant conditions prescribed with respect to
23 the product by an order under section
24 520(f)(2);

1 ~~“(B) requirements established under sec-~~
2 ~~tion 503(b); and~~

3 ~~“(C) requirements established under sec-~~
4 ~~tion 520(e).”;~~
5 ~~(6) in subsection (g)—~~

6 ~~(A) in the subsection heading, by inserting~~
7 ~~“REVIEW AND” before “REVOCATION”;~~

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

13 ~~“(A) an unapproved product for which an~~
14 ~~authorization was issued under this section; or~~

15 ~~“(B) an unapproved use of an approved~~
16 ~~product for which an authorization was issued~~
17 ~~under this section.”; and~~

18 ~~(C) by amending paragraph (2) to read as~~
19 ~~follows:~~

20 ~~“(2) REVISION AND REVOCATION.—The Sec-~~
21 ~~retary may revise or revoke an authorization under~~
22 ~~this section if—~~

23 ~~“(A) the circumstances described under~~
24 ~~subsection (b)(1) no longer exist;~~

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

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

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

12 ~~(8) by adding at the end of subsection (j) the~~
13 ~~following:~~

14 ~~“(4) Nothing in this section shall be construed~~
15 ~~as authorizing a delay in the review or other consid-~~
16 ~~eration by the Secretary of any application or sub-~~
17 ~~mission pending before the Food and Drug Adminis-~~
18 ~~tration for a product for which an authorization~~
19 ~~under this section is issued.”; and~~

20 ~~(9) by adding at the end the following:~~

21 ~~“(m) CATEGORIZATION OF LABORATORY TESTS AS-~~
22 ~~SOCIATED WITH DEVICES SUBJECT TO AUTHORIZA-~~
23 ~~TION.—~~

24 ~~“(1) IN GENERAL.—In issuing an authorization~~
25 ~~under this section with respect to a device, the Sec-~~

1 retary may, subject to the provisions of this section;
2 determine that a laboratory examination or proce-
3 dure associated with such device shall be deemed, for
4 purposes of section 353 of the Public Health Service
5 Act, to be in a particular category of examinations
6 and procedures (including the category described by
7 subsection (d)(3) of such section) if, based on the to-
8 tality of scientific evidence available to the Sec-
9 retary—

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

12 “(B) the known and potential benefits of
13 such categorization under the circumstances of
14 the authorization outweigh the known and po-
15 tential risks of the categorization.

16 “(2) CONDITIONS OF DETERMINATION.—The
17 Secretary may establish appropriate conditions on
18 the performance of the examination or procedure
19 pursuant to such determination.

20 “(3) EFFECTIVE PERIOD.—A determination
21 under this subsection shall be effective for purposes
22 of section 353 of the Public Health Service Act not-
23 withstanding any other provision of that section dur-
24 ing the effective period of the relevant declaration
25 under subsection (b).”.

1 (b) **EMERGENCY USE OF MEDICAL PRODUCTS.—**

2 Subchapter E of chapter V of the Federal Food, Drug,
3 and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended
4 by inserting after section 564 the following:

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

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

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

9 **“(A) is approved or cleared under this**
10 chapter or licensed under section 351 of the
11 Public Health Service Act;

12 **“(B)(i) is intended for use to prevent, di-**
13 agnose, or treat a disease or condition involving
14 a biological, chemical, radiological, or nuclear
15 agent or agents; or

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

20 **“(C) is intended for use during the cir-**
21 cumstances under which—

22 **“(i) a determination described in sub-**
23 paragraph (A), (B), or (C) of section
24 564(b)(1) has been made by the Secretary

1 of Homeland Security, the Secretary of
2 Defense, or the Secretary, respectively; or
3 “(ii) the identification of a material
4 threat described in subparagraph (D) of
5 section 564(b)(1) has been made pursuant
6 to section 319F-2 of the Public Health
7 Service Act.

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

10 “(b) EXPIRATION DATING.—

11 “(1) IN GENERAL.—The Secretary may extend
12 the expiration date and authorize the introduction or
13 delivery for introduction into interstate commerce of
14 an eligible product after the expiration date provided
15 by the manufacturer if—

16 “(A) the expiration date extension is in-
17 tended to support the United States ability to
18 protect—

19 “(i) the public health; or

20 “(ii) military preparedness and effec-
21 tiveness; and

22 “(B) the expiration date extension is sup-
23 ported by an appropriate scientific evaluation
24 that is conducted or accepted by the Secretary.

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

4 ~~“(A) each specific lot, batch, or other unit~~
5 ~~of the product for which extended expiration is~~
6 ~~authorized;~~

7 ~~“(B) the duration of the extension; and~~

8 ~~“(C) any other requirements or conditions~~
9 ~~as the Secretary may deem appropriate for the~~
10 ~~protection of the public health, which may in-~~
11 ~~clude requirements for, or conditions on, prod-~~
12 ~~uct sampling, storage, packaging or repack-~~
13 ~~aging, transport, labeling, notice to product re-~~
14 ~~cipients, recordkeeping, periodic testing or re-~~
15 ~~testing, or product disposition.~~

16 ~~“(3) EFFECT.—Notwithstanding any other pro-~~
17 ~~vision of this Act or the Public Health Service Act,~~
18 ~~an eligible product shall not be considered an unap-~~
19 ~~proved product (as defined in section 564(a)(2)(A))~~
20 ~~and shall not be deemed adulterated or misbranded~~
21 ~~under this Act because, with respect to such prod-~~
22 ~~uct, the Secretary has, under paragraph (1), ex-~~
23 ~~tended the expiration date and authorized the intro-~~
24 ~~duction or delivery for introduction into interstate~~

1 commerce of such product after the expiration date
2 provided by the manufacturer.

3 “(4) EXPIRATION DATE.—For purposes of this
4 subsection, the term ‘expiration date’ means the
5 date established through appropriate stability testing
6 required by the regulations issued by the Secretary
7 to ensure that the product meets applicable stand-
8 ards of identity, strength, quality, and purity at the
9 time of use.

10 “(c) CURRENT GOOD MANUFACTURING PRACTICE.—

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

23 “(2) EFFECT.—Notwithstanding any other pro-
24 vision of this Act or the Public Health Service Act,
25 an eligible product shall not be considered an unap-

1 proved product (as defined in section 564(a)(2)(A))
2 and shall not be deemed adulterated or misbranded
3 under this Act because, with respect to such prod-
4 uct, the Secretary has authorized deviations from
5 current good manufacturing practices under para-
6 graph (1).

7 “(d) EMERGENCY DISPENSING.—The requirements
8 of sections 503(b) and 520(e) shall not apply to an eligible
9 product, and the product shall not be considered an unap-
10 proved product (as defined in section 564(a)(2)(A)) and
11 shall not be deemed adulterated or misbranded under this
12 Act because it is dispensed without an individual prescrip-
13 tion, if—

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

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

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

20 “(B) in accordance with an order issued by
21 the Secretary, for the purposes and duration of
22 the circumstances described in subsection
23 (a)(1)(C).

24 “(e) EMERGENCY USE INSTRUCTIONS.—

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

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

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

21 “(B) by a government entity (including a
22 Federal, State, local, or tribal government enti-
23 ty), or a person acting on behalf of such a gov-
24 ernment entity, in preparation for an emer-
25 gency response.”.

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

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

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

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

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

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

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

23 (d) PRODUCTS HELD FOR EMERGENCY USE.—The
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301

1 et seq.) is amended by inserting after section 564A, as
2 added by subsection (b), the following:

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

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

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

12 “(2) is held and not used, unless and until that
13 product—

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

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

20 “(C) is authorized for use under section
21 564.”.

22 **SEC. 303. DEFINITIONS.**

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

1 “(a) DEFINITIONS.—In this section—

2 “(1) the term ‘countermeasure’ means a quali-
3 fied countermeasure, a security countermeasure, and
4 a qualified pandemic or epidemic product;

5 “(2) the term ‘qualified countermeasure’ has
6 the meaning given such term in section 319F–1 of
7 the Public Health Service Act;

8 “(3) the term ‘security countermeasure’ has the
9 meaning given such term in section 319F–2 of such
10 Act; and

11 “(4) the term ‘qualified pandemic or epidemic
12 product’ means a product that meets the definition
13 given such term in section 319F–3 of the Public
14 Health Service Act and—

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

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

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

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

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

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

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

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

19 “(1) ensure the appropriate involvement of
20 Food and Drug Administration personnel in inter-
21 agency activities related to countermeasure advanced
22 research and development, consistent with sections
23 ~~319F, 319F-1, 319F-2, 319F-3, 319L, and 2811~~
24 of the Public Health Service Act;

25 “(2) ensure the appropriate involvement and
26 consultation of Food and Drug Administration per-

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

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

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

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

19 “(C) holding public meetings at least twice
20 annually to encourage the exchange of scientific
21 ideas; and

22 “(D) establishing protocols to ensure that
23 countermeasure reviewers have sufficient train-
24 ing or experience with countermeasures;

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

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

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

20 “(i) in order to inform the process for
21 countermeasure approval, clearance, and li-
22 censure; and

23 “(ii) with respect to the development
24 of countermeasures for populations with
25 special clinical needs, including children

1 and pregnant women, in order to meet the
2 needs of such populations, as necessary
3 and appropriate; and

4 “(5) establish”; and

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

6 “(e) FINAL GUIDANCE ON DEVELOPMENT OF ANI-
7 MAL MODELS.—

8 “(1) IN GENERAL.—Not later than 1 year after
9 the date of the enactment of the Pandemic and All-
10 Hazards Preparedness Reauthorization Act of 2013,
11 the Secretary shall provide final guidance to indus-
12 try regarding the development of animal models to
13 support approval, clearance, or licensure of counter-
14 measures referred to in subsection (a) when human
15 efficacy studies are not ethical or feasible.

16 “(2) AUTHORITY TO EXTEND DEADLINE.—The
17 Secretary may extend the deadline for providing
18 final guidance under paragraph (1) by not more
19 than 6 months upon submission by the Secretary of
20 a report on the status of such guidance to the Com-
21 mittee on Energy and Commerce of the House of
22 Representatives and the Committee on Health, Edu-
23 cation, Labor, and Pensions of the Senate.

24 “(d) DEVELOPMENT AND ANIMAL MODELING PRO-
25 CEDURES.—

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

13 “(A) a meeting to discuss proposed animal
14 model development activities; and

15 “(B) a meeting prior to initiating pivotal
16 animal studies.

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

22 “(c) REVIEW AND APPROVAL OF COUNTER-
23 MEASURES.—

24 “(1) MATERIAL THREAT.—When evaluating an
25 application or submission for approval, licensure, or

1 clearance of a countermeasure, the Secretary shall
2 take into account the material threat posed by the
3 chemical, biological, radiological, or nuclear agent or
4 agents identified under section 319F-2 of the Public
5 Health Service Act for which the countermeasure
6 under review is intended.

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

14 **SEC. 305. REGULATORY MANAGEMENT PLANS.**

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

18 “(f) REGULATORY MANAGEMENT PLAN.—

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

21 “(A) a security countermeasure with re-
22 spect to which the Secretary has entered into a
23 procurement contract under section 319F-2(e)
24 of the Public Health Service Act; or

1 ~~“(B) a countermeasure with respect to~~
2 ~~which the Biomedical Advanced Research and~~
3 ~~Development Authority has provided funding~~
4 ~~under section 319L of the Public Health Serv-~~
5 ~~ice Act for advanced research and development.~~

6 ~~“(2) REGULATORY MANAGEMENT PLAN PROC-~~
7 ~~ESS.—The Secretary, in consultation with the As-~~
8 ~~sistant Secretary for Preparedness and Response~~
9 ~~and the Director of the Biomedical Advanced Re-~~
10 ~~search and Development Authority, shall establish a~~
11 ~~formal process for obtaining scientific feedback and~~
12 ~~interactions regarding the development and regu-~~
13 ~~latory review of eligible countermeasures by facili-~~
14 ~~tating the development of written regulatory man-~~
15 ~~agement plans in accordance with this subsection.~~

16 ~~“(3) SUBMISSION OF REQUEST AND PROPOSED~~
17 ~~PLAN BY SPONSOR OR APPLICANT.—~~

18 ~~“(A) IN GENERAL.—A sponsor or appli-~~
19 ~~cant of an eligible countermeasure may initiate~~
20 ~~the process described under paragraph (2) upon~~
21 ~~submission of a written request to the Sec-~~
22 ~~retary. Such request shall include a proposed~~
23 ~~regulatory management plan.~~

24 ~~“(B) TIMING OF SUBMISSION.—A sponsor~~
25 ~~or applicant may submit a written request~~

1 under subparagraph (A) after the eligible coun-
2 termeasure has an investigational new drug or
3 investigational device exemption in effect.

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

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

19 “(A) an agreement between the Secretary
20 and the sponsor or applicant regarding develop-
21 mental milestones that will trigger responses by
22 the Secretary as described in subparagraph (B);

23 “(B) performance targets and goals for
24 timely and appropriate responses by the Sec-
25 retary to the triggers described under subpara-

1 graph (A), including meetings between the Sec-
2 retary and the sponsor or applicant, written
3 feedback, decisions by the Secretary, and other
4 activities carried out as part of the development
5 and review process; and

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

8 “(5) MILESTONES AND PERFORMANCE TAR-
9 GETS.—The developmental milestones described in
10 paragraph (4)(A) and the performance targets and
11 goals described in paragraph (4)(B) shall include—

12 “(A) feedback from the Secretary regard-
13 ing the data required to support the approval,
14 clearance, or licensure of the eligible counter-
15 measure involved;

16 “(B) feedback from the Secretary regard-
17 ing the data necessary to inform any authoriza-
18 tion under section 564;

19 “(C) feedback from the Secretary regard-
20 ing the data necessary to support the posi-
21 tioning and delivery of the eligible counter-
22 measure, including to the Strategic National
23 Stockpile;

24 “(D) feedback from the Secretary regard-
25 ing the data necessary to support the submis-

1 sion of protocols for review under section
2 505(b)(5)(B);

3 “(E) feedback from the Secretary regard-
4 ing any gaps in scientific knowledge that will
5 need resolution prior to approval, licensure, or
6 clearance of the eligible countermeasure and
7 plans for conducting the necessary scientific re-
8 search;

9 “(F) identification of the population for
10 which the countermeasure sponsor or applicant
11 seeks approval, licensure, or clearance and the
12 population for which desired labeling would not
13 be appropriate, if known; and

14 “(G) as necessary and appropriate, and to
15 the extent practicable, a plan for demonstrating
16 safety and effectiveness in pediatric popu-
17 lations; and for developing pediatric dosing, for-
18 mulation, and administration with respect to
19 the eligible countermeasure, provided that such
20 plan would not delay authorization under sec-
21 tion 564, approval, licensure, or clearance for
22 adults.

23 “(6) PRIORITIZATION.—

24 “(A) PLANS FOR SECURITY COUNTER-
25 MEASURES.—The Secretary shall establish reg-

1 ulatory management plans for all security coun-
2 termeasures for which a request is submitted
3 under paragraph (3)(A).

4 “~~(B)~~ PLANS FOR OTHER ELIGIBLE COUN-
5 TERMEASURES.—The Secretary shall determine
6 whether resources are available to establish reg-
7 ulatory management plans for eligible counter-
8 measures that are not security counter-
9 measures. If resources are available to establish
10 regulatory management plans for eligible coun-
11 termeasures that are not security counter-
12 measures, and if resources are not available to
13 establish regulatory management plans for all
14 eligible countermeasures for which requests
15 have been submitted, the Director of the Bio-
16 medical Advanced Research and Development
17 Authority, in consultation with the Commis-
18 sioner, shall prioritize which eligible counter-
19 measures may receive regulatory management
20 plans.”.

21 **SEC. 306. REPORT.**

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

1 “(g) ANNUAL REPORT.—Not later than 180 days
2 after the date of enactment of this subsection, and annu-
3 ally thereafter, the Secretary shall make publicly available
4 on the Web site of the Food and Drug Administration a
5 report that details the countermeasure development and
6 review activities of the Food and Drug Administration, in-
7 cluding—

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

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

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

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

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

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

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

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

16 “(4) an estimate of resources obligated to coun-
17 termeasure development and regulatory assessment,
18 including—

19 “(A) Center-specific objectives and accom-
20 plishments; and

21 “(B) the number of full-time equivalent
22 employees of the Food and Drug Administra-
23 tion who directly support the review of counter-
24 measures;

1 ~~“(5) the number of countermeasure applications~~
2 ~~and submissions submitted, the number of counter-~~
3 ~~measures approved, licensed, or cleared, the status~~
4 ~~of remaining submitted applications and submis-~~
5 ~~sions, and the number of each type of authorization~~
6 ~~issued pursuant to section 564;~~

7 ~~“(6) the number of written requests for a regu-~~
8 ~~latory management plan submitted under subsection~~
9 ~~(f)(3)(A), the number of regulatory management~~
10 ~~plans developed, and the number of such plans de-~~
11 ~~veloped for security countermeasures; and~~

12 ~~“(7) the number, type, and frequency of meet-~~
13 ~~ings between the Food and Drug Administration~~
14 ~~and—~~

15 ~~“(A) sponsors of a countermeasure as de-~~
16 ~~finied in subsection (a); or~~

17 ~~“(B) another agency engaged in develop-~~
18 ~~ment or management of portfolios for such~~
19 ~~countermeasures, including the Centers for Dis-~~
20 ~~ease Control and Prevention, the Biomedical~~
21 ~~Advanced Research and Development Authority,~~
22 ~~the National Institutes of Health, and the ap-~~
23 ~~propriate agencies of the Department of De-~~
24 ~~fense.”.~~

1 **SEC. 307. PEDIATRIC MEDICAL COUNTERMEASURES.**

2 (a) PEDIATRIC STUDIES OF DRUGS.—Section 505A
3 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 355a) is amended—

5 (1) in subsection (d), by adding at the end the
6 following:

7 “(5) CONSULTATION.—With respect to a drug
8 that is a qualified countermeasure (as defined in sec-
9 tion 319F–1 of the Public Health Service Act), a se-
10 curity countermeasure (as defined in section 319F–
11 2 of the Public Health Service Act), or a qualified
12 pandemic or epidemic product (as defined in section
13 319F–3 of the Public Health Service Act), the Sec-
14 retary shall solicit input from the Assistant Sec-
15 retary for Preparedness and Response regarding the
16 need for and, from the Director of the Biomedical
17 Advanced Research and Development Authority re-
18 garding the conduct of, pediatric studies under this
19 section.”; and

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

22 “(C) For a drug that is a qualified coun-
23 termeasure (as defined in section 319F–1 of the
24 Public Health Service Act), a security counter-
25 measure (as defined in section 319F–2 of the
26 Public Health Service Act), or a qualified pan-

1 demic or epidemic product (as defined in sec-
2 tion 319F-3 of such Act), in addition to any
3 action with respect to such drug under subpara-
4 graph (A) or (B), the Secretary shall notify the
5 Assistant Secretary for Preparedness and Re-
6 sponse and the Director of the Biomedical Ad-
7 vanced Research and Development Authority of
8 all pediatric studies in the written request
9 issued by the Commissioner of Food and
10 Drugs.”.

11 (b) ADDITION TO PRIORITY LIST CONSIDER-
12 ATIONS.—Section 409I of the Public Health Service Act
13 (42 U.S.C. 284m) is amended—

14 (1) by striking subsection (a)(2) and inserting
15 the following:

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

19 “(A) shall consider—

20 “(i) therapeutic gaps in pediatrics
21 that may include developmental pharma-
22 cology, pharmacogenetic determinants of
23 drug response, metabolism of drugs and
24 biologies in children, and pediatric clinical
25 trials;

1 “(ii) particular pediatric diseases, dis-
2 orders or conditions where more complete
3 knowledge and testing of therapeutics, in-
4 cluding drugs and biologics, may be bene-
5 ficial in pediatric populations; and

6 “(iii) the adequacy of necessary infra-
7 structure to conduct pediatric pharma-
8 ceutical research, including research net-
9 works and trained pediatric investigators;
10 and

11 “(B) may consider the availability of quali-
12 fied countermeasures (as defined in section
13 319F-1), security countermeasures (as defined
14 in section 319F-2), and qualified pandemic or
15 epidemic products (as defined in section 319F-
16 3) to address the needs of pediatric populations,
17 in consultation with the Assistant Secretary for
18 Preparedness and Response, consistent with the
19 purposes of this section.”; and

20 (2) in subsection (b), by striking “subsection
21 (a)” and inserting “paragraphs (1) and (2)(A) of
22 subsection (a)”.

23 (c) ADVICE AND RECOMMENDATIONS OF THE PEDI-
24 ATRIC ADVISORY COMMITTEE REGARDING COUNTER-
25 MEASURES FOR PEDIATRIC POPULATIONS.—Subsection

1 ~~(b)(2)~~ of section 14 of the Best Pharmaceuticals for Chil-
2 dren Act (42 U.S.C. 284m note) is amended—

3 ~~(1)~~ in subparagraph ~~(C)~~, by striking the period
4 and inserting “; and”; and

5 ~~(2)~~ by adding at the end the following:

6 “(D) the development of countermeasures
7 (as defined in section 565(a) of the Federal
8 Food, Drug, and Cosmetic Act) for pediatric
9 populations.”.

10 **TITLE IV—ACCELERATING MED-**
11 **ICAL COUNTERMEASURE AD-**
12 **VANCED RESEARCH AND DE-**
13 **VELOPMENT**

14 **SEC. 401. BIOSHIELD.**

15 (a) ~~PROCUREMENT OF COUNTERMEASURES.~~—Sec-
16 tion ~~319F-2(c)~~ of the Public Health Service Act (42
17 U.S.C. 247d-6b(c)) is amended—

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

20 ~~(2)~~ in paragraph ~~(2)(C)~~, by striking “the des-
21 ignated congressional committees (as defined in
22 paragraph (10))” and inserting “the appropriate
23 committees of Congress”;

24 ~~(3)~~ in paragraph ~~(5)(B)(ii)~~, by striking “eight
25 years” and inserting “10 years”;

1 for the countermeasure to be
2 developed and procured;

3 “(BB) the amount of
4 funding that will be dedi-
5 cated by the Secretary for
6 advanced research, develop-
7 ment, and procurement of
8 the countermeasure; and

9 “(CC) the specifications
10 the countermeasure must
11 meet to qualify for procure-
12 ment under a contract under
13 this section; and

14 “(bb) shall provide a clear
15 statement of defined Government
16 purpose limited to uses related to
17 a security countermeasure, as de-
18 fined in paragraph (1)(B).”; and

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

20 “(viii) FLEXIBILITY.—In carrying out
21 this section, the Secretary may, consistent
22 with the applicable provisions of this sec-
23 tion, enter into contracts and other agree-
24 ments that are in the best interest of the
25 Government in meeting identified security

1 countermeasure needs, including with re-
2 spect to reimbursement of the cost of ad-
3 vanced research and development as a rea-
4 sonable, allowable, and allocable direct cost
5 of the contract involved.”.

6 (b) REAUTHORIZATION OF THE SPECIAL RESERVE
7 FUND.—Section 319F-2 of the Public Health Service Act
8 (42 U.S.C. 247d-6b) is amended—

9 (1) in subsection (c)—

10 (A) by striking “special reserve fund under
11 paragraph (10)” each place it appears and in-
12 serting “special reserve fund as defined in sub-
13 section (h)”;

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

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

17 “(g) SPECIAL RESERVE FUND.—

18 “(1) AUTHORIZATION OF APPROPRIATIONS.—In
19 addition to amounts appropriated to the special re-
20 serve fund prior to the date of the enactment of this
21 subsection, there is authorized to be appropriated,
22 for the procurement of security countermeasures
23 under subsection (c) and for carrying out section
24 319L (relating to the Biomedical Advanced Research
25 and Development Authority), \$2,800,000,000 for the

1 period of fiscal years 2014 through 2018. Amounts
2 appropriated pursuant to the preceding sentence are
3 authorized to remain available until September 30,
4 2019.

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

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

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

1 of Congress a report detailing the amount of such
2 funds available for procurement and the impact such
3 reduction in funding will have—

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

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

10 “(h) DEFINITIONS.—In this section:

11 “(1) The term ‘advanced research and develop-
12 ment’ has the meaning given such term in section
13 319L(a).

14 “(2) The term ‘special reserve fund’ means the
15 ‘Biodefense Countermeasures’ appropriations ac-
16 count, any appropriation made available pursuant to
17 section 521(a) of the Homeland Security Act of
18 2002, and any appropriation made available pursu-
19 ant to subsection (g)(1).”.

20 **SEC. 402. BIOMEDICAL ADVANCED RESEARCH AND DEVEL-**
21 **OPMENT AUTHORITY.**

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

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

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

11 (b) TRANSACTION AUTHORITIES.—Section
12 319L(c)(5) of the Public Health Service Act (42 U.S.C.
13 247d–7e(c)(5)) is amended by adding at the end the fol-
14 lowing:

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

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

1 ~~“(2) FUNDING.—To carry out the purposes of~~
2 ~~this section, there is authorized to be appropriated~~
3 ~~to the Fund \$415,000,000 for each of fiscal years~~
4 ~~2013 through 2017, such amounts to remain avail-~~
5 ~~able until expended.”.~~

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

10 ~~(e) EXTENSION OF LIMITED ANTITRUST EXEMP-~~
11 ~~TION.—~~

12 ~~(1) IN GENERAL.—Section 405(b) of the Pan-~~
13 ~~demic and All-Hazards Preparedness Act (42 U.S.C.~~
14 ~~247d–6a note) is amended by striking “6-year” and~~
15 ~~inserting “11-year”.~~

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

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

21 ~~“(f) INDEPENDENT EVALUATION.—~~

22 ~~“(1) IN GENERAL.—Not later than 180 days~~
23 ~~after the date of enactment of this subsection, the~~
24 ~~Comptroller General of the United States shall con-~~
25 ~~duct an independent evaluation of the activities ear-~~

1 ried out to facilitate flexible manufacturing capacity
2 pursuant to this section.

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

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

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

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

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

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

1 ~~(g)~~ DEFINITIONS.—

2 (1) QUALIFIED COUNTERMEASURE.—Section
3 ~~319F-1(a)(2)(A)~~ of the Public Health Service Act
4 ~~(42 U.S.C. 247d-6a(a)(2)(A))~~ is amended—

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

7 (B) in clause (i)—

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

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

12 (C) in clause (ii)—

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

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

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

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

22 (2) QUALIFIED PANDEMIC OR EPIDEMIC PROD-
23 UCT.—Section ~~319F-3(i)(7)(A)~~ of the Public Health
24 Service Act ~~(42 U.S.C. 247d-6d(i)(7)(A))~~ is amend-
25 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 2013 through 2017. 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.”.~~

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

6 (a) *SHORT TITLE.*—*This Act may be cited as the*
 7 *“Pandemic and All-Hazards Preparedness Reauthorization*
 8 *Act of 2013”.*

9 (b) *TABLE OF CONTENTS.*—*The table of contents of this*
 10 *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 “, in-*
12 *cluding 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 emer-*
2 *gencies”;*

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 evacu-*
15 *ation 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 individuals”;*
9 *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 agent*
17 *or toxin, chemical, radiological, or nuclear agent*
18 *or agents, whether naturally occurring, uninten-*
19 *tional, or deliberate.*

20 *“(B) For purposes of this paragraph, the*
21 *term ‘countermeasures’ has the same meaning as*
22 *the terms ‘qualified countermeasures’ under sec-*
23 *tion 319F–1, ‘qualified pandemic and epidemic*
24 *products’ under section 319F–3, and ‘security*
25 *countermeasures’ under section 319F–2.*

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

7 “(A) *optimizing alignment and integration*
8 *of medical and public health preparedness and*
9 *response planning and capabilities with and*
10 *into 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 Public*
14 *Health Service Act (42 U.S.C. 300hh–16) is amended—*

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

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

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

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

22 “(1) *monitor emerging issues and concerns as*
23 *they relate to medical and public health preparedness*
24 *and response for at-risk individuals in the event of a*

1 *public health emergency declared by the Secretary*
2 *under section 319;”;*

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

5 *“(2) oversee the implementation of the prepared-*
6 *ness goals described in section 2802(b) with respect to*
7 *the public health and medical needs of at-risk indi-*
8 *viduals in the event of a public health emergency, as*
9 *described in section 2802(b)(4);”;* and

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 at-*
14 *risk individuals before, during, and following public*
15 *health emergencies in as timely a manner as is prac-*
16 *ticable, including from the time a public health threat*
17 *is identified; and*

18 *“(8) ensure that public health and medical infor-*
19 *mation distributed by the Department of Health and*
20 *Human Services during a public health emergency is*
21 *delivered in a manner that takes into account the*
22 *range of communication needs of the intended recipi-*
23 *ents, 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 co-
14 ordination and strategic direction with respect to
15 all matters related to Federal public health and
16 medical preparedness and execution and deploy-
17 ment of the Federal response for public health
18 emergencies and incidents covered by the Na-
19 tional Response Plan developed pursuant to sec-
20 tion 504(6) of the Homeland Security Act of
21 2002, or any successor plan, before, during, and
22 following public health emergencies.

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

1 *health preparedness and response activities and*
2 *the actions necessary to overcome these obstacles.*

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 the
8 extent possible, including program requirements,
9 timelines, and measurable goals, and in con-
10 sultation with the Secretary of Homeland Secu-
11 rity, 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 prac-
18 tices among grant and cooperative agree-
19 ment 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 Defense,
24 the Department of Veterans Affairs, and other
25 applicable Federal departments and agencies, as

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

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

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

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

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

21 “(7) *COUNTERMEASURES BUDGET PLAN.—De-*
22 *velop, and update on an annual basis, a coordinated*
23 *5-year budget plan based on the medical counter-*
24 *measure priorities described in subsection (d). Each*
25 *such plan shall—*

1 “(A) include consideration of the entire
2 medical countermeasures enterprise, including—

3 “(i) basic research and advanced re-
4 search and development;

5 “(ii) approval, clearance, licensure,
6 and authorized uses of products; and

7 “(iii) procurement, stockpiling, main-
8 tenance, and replenishment of all products
9 in the Strategic National Stockpile;

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

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

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

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

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

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

5 “(2) have authority over and responsibility for—

6 “(A) the National Disaster Medical System
7 pursuant to section 2812;

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

10 “(C) the Biomedical Advanced Research
11 and Development Authority pursuant to section
12 319L;

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

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

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

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

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

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

6 “(C) the Cities Readiness Initiative; and

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

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

10 “(d) PUBLIC HEALTH EMERGENCY MEDICAL COUN-
11 TERMEASURES ENTERPRISE STRATEGY AND IMPLEMENTA-
12 TION PLAN.—

13 “(1) IN GENERAL.—Not later than 180 days
14 after the date of enactment of this subsection, and
15 every year thereafter, the Assistant Secretary for Pre-
16 paredness and Response shall develop and submit to
17 the appropriate committees of Congress a coordinated
18 strategy and accompanying implementation plan for
19 medical countermeasures to address chemical, biologi-
20 cal, radiological, and nuclear threats. In developing
21 such a plan, the Assistant Secretary for Preparedness
22 and Response shall consult with the Director of the
23 Biomedical Advanced Research and Development Au-
24 thority, the Director of the National Institutes of
25 Health, the Director of the Centers for Disease Control

1 *and Prevention, and the Commissioner of Food and*
2 *Drugs. Such strategy and plan shall be known as the*
3 *‘Public Health Emergency Medical Countermeasures*
4 *Enterprise Strategy and Implementation Plan’.*

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

7 “(A) *describe the chemical, biological, radio-*
8 *logical, and nuclear agent or agents that may*
9 *present a threat to the Nation and the cor-*
10 *responding efforts to develop qualified counter-*
11 *measures (as defined in section 319F–1), secu-*
12 *rity countermeasures (as defined in section*
13 *319F–2), or qualified pandemic or epidemic*
14 *products (as defined in section 319F–3) for each*
15 *threat;*

16 “(B) *evaluate the progress of all activities*
17 *with respect to such countermeasures or prod-*
18 *ucts, including research, advanced research, de-*
19 *velopment, procurement, stockpiling, deployment,*
20 *distribution, and utilization;*

21 “(C) *identify and prioritize near-, mid-,*
22 *and long-term needs with respect to such coun-*
23 *termeasures or products to address a chemical,*
24 *biological, radiological, and nuclear threat or*
25 *threats;*

1 “(D) identify, with respect to each category
2 of threat, a summary of all awards and con-
3 tracts, including advanced research and develop-
4 ment and procurement, that includes—

5 “(i) the time elapsed from the issuance
6 of the initial solicitation or request for a
7 proposal to the adjudication (such as the
8 award, denial of award, or solicitation ter-
9 mination); and

10 “(ii) an identification of projected
11 timelines, anticipated funding allocations,
12 benchmarks, and milestones for each med-
13 ical countermeasure priority under sub-
14 paragraph (C), including projected needs
15 with regard to replenishment of the Stra-
16 tegic National Stockpile;

17 “(E) be informed by the recommendations of
18 the National Biodefense Science Board pursuant
19 to section 319M;

20 “(F) evaluate progress made in meeting
21 timelines, allocations, benchmarks, and mile-
22 stones identified under subparagraph (D)(ii);

23 “(G) report on the amount of funds avail-
24 able for procurement in the special reserve fund
25 as defined in section 319F–2(h) and the impact

1 *this funding will have on meeting the require-*
2 *ments under section 319F-2;*

3 *“(H) incorporate input from Federal, State,*
4 *local, and tribal stakeholders;*

5 *“(I) identify the progress made in meeting*
6 *the medical countermeasure priorities for at-risk*
7 *individuals (as defined in 2802(b)(4)(B)), as ap-*
8 *plicable under subparagraph (C), including with*
9 *regard to the projected needs for related stock-*
10 *piling and replenishment of the Strategic Na-*
11 *tional Stockpile, including by addressing the*
12 *needs of pediatric populations with respect to*
13 *such countermeasures and products in the Stra-*
14 *tegic National Stockpile, including—*

15 *“(i) a list of such countermeasures and*
16 *products necessary to address the needs of*
17 *pediatric populations;*

18 *“(ii) a description of measures taken to*
19 *coordinate with the Office of Pediatric*
20 *Therapeutics of the Food and Drug Admin-*
21 *istration to maximize the labeling, dosages,*
22 *and formulations of such countermeasures*
23 *and products for pediatric populations;*

24 *“(iii) a description of existing gaps in*
25 *the Strategic National Stockpile and the de-*

1 *velopment of such countermeasures and*
2 *products to address the needs of pediatric*
3 *populations; and*

4 *“(iv) an evaluation of the progress*
5 *made in addressing priorities identified*
6 *pursuant to subparagraph (C);*

7 *“(J) identify the use of authority and ac-*
8 *tivities undertaken pursuant to sections 319F-*
9 *1(b)(1), 319F-1(b)(2), 319F-1(b)(3), 319F-1(c),*
10 *319F-1(d), 319F-1(e), 319F-2(c)(7)(C)(iii),*
11 *319F-2(c)(7)(C)(iv), and 319F-2(c)(7)(C)(v) of*
12 *this Act, and subsections (a)(1), (b)(1), and (e)*
13 *of section 564 of the Federal Food, Drug, and*
14 *Cosmetic Act, by summarizing—*

15 *“(i) the particular actions that were*
16 *taken under the authorities specified, in-*
17 *cluding, as applicable, the identification of*
18 *the threat agent, emergency, or the bio-*
19 *medical countermeasure with respect to*
20 *which the authority was used;*

21 *“(ii) the reasons underlying the deci-*
22 *sion to use such authorities, including, as*
23 *applicable, the options that were considered*
24 *and rejected with respect to the use of such*
25 *authorities;*

1 “(iii) the number of, nature of, and
2 other information concerning the persons
3 and entities that received a grant, coopera-
4 tive agreement, or contract pursuant to the
5 use of such authorities, and the persons and
6 entities that were considered and rejected
7 for such a grant, cooperative agreement, or
8 contract, except that the report need not dis-
9 close the identity of any such person or en-
10 tity;

11 “(iv) whether, with respect to each pro-
12 curement that is approved by the President
13 under section 319F-2(c)(6), a contract was
14 entered into within one year after such ap-
15 proval by the President; and

16 “(v) with respect to section 319F-1(d),
17 for the one-year period for which the report
18 is submitted, the number of persons who
19 were paid amounts totaling \$100,000 or
20 greater and the number of persons who were
21 paid amounts totaling at least \$50,000 but
22 less than \$100,000; and

23 “(K) be made publicly available.

24 “(3) GAO REPORT.—

1 “(A) *IN GENERAL.*—Not later than 1 year
2 after the date of the submission to the Congress
3 of the first Public Health Emergency Medical
4 Countermeasures Enterprise Strategy and Imple-
5 mentation Plan, the Comptroller General of the
6 United States shall conduct an independent eval-
7 uation, and submit to the appropriate commit-
8 tees of Congress a report, concerning such Strat-
9 egy and Implementation Plan.

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

12 “(i) the near-term, mid-term, and
13 long-term medical countermeasure needs
14 and identified priorities of the Federal Gov-
15 ernment pursuant to paragraph (2)(C);

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

20 “(iii) the progress made toward meet-
21 ing the timelines, allocations, benchmarks,
22 and milestones identified in the Public
23 Health Emergency Medical Counter-
24 measures Enterprise Strategy and Imple-
25 mentation Plan under this subsection.

1 “(e) *PROTECTION OF NATIONAL SECURITY.*—In car-
2 rying out subsections (b)(7) and (d), the Secretary shall en-
3 sure that information and items that could compromise na-
4 tional security, contain confidential commercial informa-
5 tion, or contain proprietary information are not dis-
6 closed.”.

7 (b) *INTERAGENCY COORDINATION PLAN.*—In the first
8 Public Health Emergency Countermeasures Enterprise
9 Strategy and Implementation Plan submitted under sub-
10 section (d) of section 2811 of the Public Health Service Act
11 (42 U.S.C. 300hh–10) (as added by subsection (a)(3)), the
12 Secretary of Health and Human Services, in consultation
13 with the Secretary of Defense, shall include a description
14 of the manner in which the Department of Health and
15 Human Services is coordinating with the Department of
16 Defense regarding countermeasure activities to address
17 chemical, biological, radiological, and nuclear threats. Such
18 report shall include information with respect to—

19 (1) the research, advanced research, development,
20 procurement, stockpiling, and distribution of counter-
21 measures to meet identified needs; and

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

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

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

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

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

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

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

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

21 *“(3) provide advice and consultation with re-*
22 *spect to State emergency preparedness and response*
23 *activities and children, including related drills and*
24 *exercises pursuant to the preparedness goals under*
25 *section 2802(b).*

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

7 “(d) *MEMBERSHIP.—*

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

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

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

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

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

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

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

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

6 “(G) *the Administrator of the Federal*
7 *Emergency Management Agency;*

8 “(H) *at least two non-Federal health care*
9 *professionals with expertise in pediatric medical*
10 *disaster planning, preparedness, response, or re-*
11 *covery;*

12 “(I) *at least two representatives from State,*
13 *local, territorial, or tribal agencies with expertise*
14 *in pediatric disaster planning, preparedness, re-*
15 *sponse, or recovery; and*

16 “(J) *representatives from such Federal*
17 *agencies (such as the Department of Education*
18 *and the Department of Homeland Security) as*
19 *determined necessary to fulfill the duties of the*
20 *Advisory Committee, as established under sub-*
21 *sections (b) and (c).*

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

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

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

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

5 *(1) in subsection (a)(3)—*

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

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

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

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

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

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

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

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

9 *Section 8117(g) of title 38, United States Code, is*
10 *amended by striking “such sums as may be necessary to*
11 *carry out this section for each of fiscal years 2007 through*
12 *2011” and inserting “\$155,300,000 for each of fiscal years*
13 *2014 through 2018 to carry out this section”.*

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

18 **SEC. 201. TEMPORARY REASSIGNMENT OF STATE AND**
19 **LOCAL PERSONNEL DURING A PUBLIC**
20 **HEALTH EMERGENCY.**

21 *Section 319 of the Public Health Service Act (42*
22 *U.S.C. 247d) is amended by adding at the end the fol-*
23 *lowing:*

1 “(e) *TEMPORARY REASSIGNMENT OF STATE AND*
2 *LOCAL PERSONNEL DURING A PUBLIC HEALTH EMER-*
3 *GENCY.*—

4 “(1) *EMERGENCY REASSIGNMENT OF FEDERALLY*
5 *FUNDED PERSONNEL.*—*Notwithstanding any other*
6 *provision of law, and subject to paragraph (2), upon*
7 *request by the Governor of a State or a tribal organi-*
8 *zation or such Governor or tribal organization’s des-*
9 *ignee, the Secretary may authorize the requesting*
10 *State or Indian tribe to temporarily reassign, for*
11 *purposes of immediately addressing a public health*
12 *emergency in the State or Indian tribe, State and*
13 *local public health department or agency personnel*
14 *funded in whole or in part through programs author-*
15 *ized under this Act, as appropriate.*

16 “(2) *ACTIVATION OF EMERGENCY REASSIGN-*
17 *MENT.*—

18 “(A) *PUBLIC HEALTH EMERGENCY.*—*The*
19 *Secretary may authorize a temporary reassign-*
20 *ment of personnel under paragraph (1) only dur-*
21 *ing the period of a public health emergency de-*
22 *termined pursuant to subsection (a).*

23 “(B) *CONTENTS OF REQUEST.*—*To seek au-*
24 *thority for a temporary reassignment of per-*
25 *sonnel under paragraph (1), the Governor of a*

1 *State or a tribal organization shall submit to the*
2 *Secretary a request for such reassignment flexi-*
3 *bility and shall include in the request each of the*
4 *following:*

5 “(i) *An assurance that the public*
6 *health emergency in the geographic area of*
7 *the requesting State or Indian tribe cannot*
8 *be adequately and appropriately addressed*
9 *by the public health workforce otherwise*
10 *available.*

11 “(ii) *An assurance that the public*
12 *health emergency would be addressed more*
13 *efficiently and effectively through the re-*
14 *quested temporary reassignment of State*
15 *and local personnel described in paragraph*
16 *(1).*

17 “(iii) *An assurance that the requested*
18 *temporary reassignment of personnel is con-*
19 *sistent with any applicable All-Hazards*
20 *Public Health Emergency Preparedness and*
21 *Response Plan under section 319C–1.*

22 “(iv) *An identification of—*

23 “(I) *each Federal program from*
24 *which personnel would be temporarily*

1 *reassigned pursuant to the requested*
2 *authority; and*

3 “(II) *the number of personnel who*
4 *would be so reassigned from each such*
5 *program.*

6 “(v) *Such other information and as-*
7 *surances upon which the Secretary and*
8 *Governor of a State or tribal organization*
9 *agree.*

10 “(C) *CONSIDERATION.—In reviewing a re-*
11 *quest for temporary reassignment under para-*
12 *graph (1), the Secretary shall consider the degree*
13 *to which the program or programs funded in*
14 *whole or in part by programs authorized under*
15 *this Act would be adversely affected by the reas-*
16 *signment.*

17 “(D) *TERMINATION AND EXTENSION.—*

18 “(i) *TERMINATION.—A State or Indian*
19 *tribe’s temporary reassignment of personnel*
20 *under paragraph (1) shall terminate upon*
21 *the earlier of the following:*

22 “(I) *The Secretary’s determina-*
23 *tion that the public health emergency*
24 *no longer exists.*

1 “(II) *Subject to clause (ii), the ex-*
2 *piration of the 30-day period following*
3 *the date on which the Secretary ap-*
4 *proved the State or Indian tribe’s re-*
5 *quest for such reassignment flexibility.*

6 “(ii) *EXTENSION OF REASSIGNMENT*
7 *FLEXIBILITY.—The Secretary may extend*
8 *reassignment flexibility of personnel under*
9 *paragraph (1) beyond the date otherwise*
10 *applicable under clause (i)(II) if the public*
11 *health emergency still exists as of such date,*
12 *but only if—*

13 “(I) *the State or Indian tribe that*
14 *submitted the initial request for a tem-*
15 *porary reassignment of personnel sub-*
16 *mits a request for an extension of such*
17 *temporary reassignment; and*

18 “(II) *the request for an extension*
19 *contains the same information and as-*
20 *surances necessary for the approval of*
21 *an initial request for such temporary*
22 *reassignment pursuant to subpara-*
23 *graph (B).*

24 “(3) *VOLUNTARY NATURE OF TEMPORARY REAS-*
25 *SIGNMENT OF STATE AND LOCAL PERSONNEL.—*

1 “(A) *IN GENERAL.*—Unless otherwise pro-
2 vided under the law or regulation of the State or
3 Indian tribe that receives authorization for tem-
4 porary reassignment of personnel under para-
5 graph (1), personnel eligible for reassignment
6 pursuant to such authorization—

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

9 “(ii) shall not be required to agree to
10 a temporary reassignment.

11 “(B) *PROHIBITION ON CONDITIONING FED-*
12 *ERAL AWARDS.*—The Secretary may not condi-
13 tion the award of a grant, contract, or coopera-
14 tive agreement under this Act on the requirement
15 that a State or Indian tribe require that per-
16 sonnel eligible for reassignment pursuant to an
17 authorization under paragraph (1) agree to such
18 reassignment.

19 “(4) *NOTICE TO CONGRESS.*—The Secretary shall
20 give notice to the Congress in conjunction with the
21 approval under this subsection of—

22 “(A) any initial request for temporary reas-
23 signment of personnel; and

24 “(B) any request for an extension of such
25 temporary reassignment.

1 “(5) *GUIDANCE.—The Secretary shall—*

2 “(A) *not later than 6 months after the en-*
3 *actment of this subsection, issue proposed guid-*
4 *ance on the temporary reassignment of personnel*
5 *under this subsection; and*

6 “(B) *after providing notice and a 60-day*
7 *period for public comment, finalize such guid-*
8 *ance.*

9 “(6) *REPORT TO CONGRESS.—Not later than 4*
10 *years after the date of enactment of the Pandemic and*
11 *All-Hazards Preparedness Reauthorization Act of*
12 *2013, the Comptroller General of the United States*
13 *shall conduct an independent evaluation, and submit*
14 *to the appropriate committees of the Congress a re-*
15 *port, on temporary reassignment under this sub-*
16 *section, including—*

17 “(A) *a description of how, and under what*
18 *circumstances, such temporary reassignment has*
19 *been used by States and Indian tribes;*

20 “(B) *an analysis of how such temporary re-*
21 *assignment has assisted States and Indian tribes*
22 *in responding to public health emergencies;*

23 “(C) *an evaluation of how such temporary*
24 *reassignment has improved operational effi-*

1 *ciencies in responding to public health emer-*
2 *gencies;*

3 “(D) *an analysis of the extent to which, if*
4 *any, Federal programs from which personnel*
5 *have been temporarily reassigned have been ad-*
6 *versely affected by the reassignment; and*

7 “(E) *recommendations on how medical*
8 *surge capacity could be improved in responding*
9 *to public health emergencies and the impact of*
10 *the reassignment flexibility under this section on*
11 *such surge capacity.*

12 “(7) *DEFINITIONS.—In this subsection—*

13 “(A) *the terms ‘Indian tribe’ and ‘tribal or-*
14 *ganization’ have the meanings given such terms*
15 *in section 4 of the Indian Self-Determination*
16 *and Education Assistance Act; and*

17 “(B) *the term ‘State’ includes, in addition*
18 *to the entities listed in the definition of such*
19 *term in section 2, the Freely Associated States.*

20 “(8) *SUNSET.—This subsection shall terminate*
21 *on September 30, 2018.”.*

1 **SEC. 202. IMPROVING STATE AND LOCAL PUBLIC HEALTH**
2 **SECURITY.**

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

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

9 (2) in subsection (b)(2)—

10 (A) in subparagraph (A)—

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

13 “(i) a description of the activities such
14 entity will carry out under the agreement to
15 meet the goals identified under section 2802,
16 including with respect to chemical, biologi-
17 cal, radiological, or nuclear threats, whether
18 naturally occurring, unintentional, or delib-
19 erate;

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

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

3 (iii) by adding at the end the fol-
4 lowing:

5 “(vi) a description of how, as appro-
6 priate, the entity may partner with relevant
7 public and private stakeholders in public
8 health emergency preparedness and re-
9 sponse;

10 “(vii) a description of how the entity,
11 as applicable and appropriate, will coordi-
12 nate with State emergency preparedness
13 and response plans in public health emer-
14 gency preparedness, including State edu-
15 cational agencies (as defined in section
16 9101(41) of the Elementary and Secondary
17 Education Act of 1965) and State child care
18 lead agencies (designated under section
19 658D of the Child Care and Development
20 Block Grant Act of 1990);

21 “(viii) in the case of entities that oper-
22 ate on the United States-Mexico border or
23 the United States-Canada border, a descrip-
24 tion of the activities such entity will carry
25 out under the agreement that are specific to

1 *the border area including disease detection,*
2 *identification, investigation, and prepared-*
3 *ness and response activities related to*
4 *emerging diseases and infectious disease*
5 *outbreaks whether naturally occurring or*
6 *due to bioterrorism, consistent with the re-*
7 *quirements of this section; and*

8 *“(ix) a description of any activities*
9 *that such entity will use to analyze real-*
10 *time clinical specimens for pathogens of*
11 *public health or bioterrorism significance,*
12 *including any utilization of poison control*
13 *centers;”;* and

14 *(B) in subparagraph (C), by inserting “,*
15 *including addressing the needs of at-risk individ-*
16 *uals,” after “capabilities of such entity”;*

17 *(3) in subsection (f)—*

18 *(A) in paragraph (2), by adding “and” at*
19 *the end;*

20 *(B) in paragraph (3), by striking “; and”*
21 *and inserting a period; and*

22 *(C) by striking paragraph (4);*

23 *(4) in subsection (g)—*

24 *(A) in paragraph (1), by striking subpara-*
25 *graph (A) and inserting the following:*

1 “(A) include outcome goals representing
2 operational achievements of the National Pre-
3 paredness Goals developed under section 2802(b)
4 with respect to all-hazards, including chemical,
5 biological, radiological, or nuclear threats; and”;
6 and

7 (B) in paragraph (2)(A), by adding at the
8 end the following: “The Secretary shall periodi-
9 cally update, as necessary and appropriate, such
10 pandemic influenza plan criteria and shall re-
11 quire the integration of such criteria into the
12 benchmarks and standards described in para-
13 graph (1).”;

14 (5) by striking subsection (h);

15 (6) by redesignating subsections (i), (j), and (k)
16 as subsections (h), (i), and (j), respectively;

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

18 (A) in paragraph (1)—

19 (i) in subparagraph (A)—

20 (I) by striking “\$824,000,000 for
21 fiscal year 2007, of which \$35,000,000
22 shall be used to carry out subsection
23 (h),” and inserting “\$641,900,000 for
24 fiscal year 2014”; and

1 (II) by striking “such sums as
2 may be necessary for each of fiscal
3 years 2008 through 2011” and insert-
4 ing “\$641,900,000 for each of fiscal
5 years 2015 through 2018”;

6 (ii) by striking subparagraph (B);

7 (iii) by redesignating subparagraphs
8 (C) and (D) as subparagraphs (B) and (C),
9 respectively; and

10 (iv) in subparagraph (C), as so redes-
11 ignated, by striking “subparagraph (C)”
12 and inserting “subparagraph (B)”;

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

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

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

19 “(7) AVAILABILITY OF COOPERATIVE AGREEMENT
20 FUNDS.—

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

1 *fiscal year for the purposes for which such funds*
2 *were provided.*

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

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

13 *(B) by striking paragraph (3).*

14 (b) VACCINE TRACKING AND DISTRIBUTION.—*Section*
15 *319A(e) of the Public Health Service Act (42 U.S.C. 247d–*
16 *1(e)) is amended by striking “such sums for each of fiscal*
17 *years 2007 through 2011” and inserting “\$30,800,000 for*
18 *each of fiscal years 2014 through 2018”.*

19 (c) TECHNICAL AND CONFORMING AMENDMENTS.—

20 (1) *Section 319C–1(b)(1)(B) of the Public Health*
21 *Service Act (42 U.S.C. 247d–3a(b)(1)(B)) is amended*
22 *by striking “subsection (i)(4)” and inserting “sub-*
23 *section (h)(4)”.*

24 (2) *Section 319C–2 of the Public Health Service*
25 *Act (42 U.S.C. 247d–3b) is amended—*

1 (A) in subsection (i), by striking “(j), and
2 (k)” and inserting “(i), and (j)”; and
3 (B) in subsection (j)(3), by striking “319C–
4 1(i)” and inserting “319C–1(h)”.

5 **SEC. 203. HOSPITAL PREPAREDNESS AND MEDICAL SURGE**
6 **CAPACITY.**

7 (a) *ALL-HAZARDS PUBLIC HEALTH AND MEDICAL*
8 *RESPONSE CURRICULA AND TRAINING.*—Section
9 319F(a)(5)(B) of the Public Health Service Act (42 U.S.C.
10 247d–6(a)(5)(B)) is amended by striking “public health or
11 medical” and inserting “public health, medical, or dental”.

12 (b) *ENCOURAGING HEALTH PROFESSIONAL VOLUN-*
13 *TEERS.*—

14 (1) *EMERGENCY SYSTEM FOR ADVANCE REG-*
15 *ISTRATION OF VOLUNTEER HEALTH PROFES-*
16 *SIONALS.*—Section 319I(k) of the Public Health Serv-
17 ice Act (42 U.S.C. 247d–7b(k)) is amended by strik-
18 ing “\$2,000,000 for fiscal year 2002, and such sums
19 as may be necessary for each of the fiscal years 2003
20 through 2011” and inserting “\$5,000,000 for each of
21 fiscal years 2014 through 2018”.

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

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

6 (B) in subsection (i), by striking
7 “\$22,000,000 for fiscal year 2007, and such sums
8 as may be necessary for each of fiscal years 2008
9 through 2011” and inserting “\$11,200,000 for
10 each of fiscal years 2014 through 2018”.

11 (c) *PARTNERSHIPS FOR STATE AND REGIONAL PRE-*
12 *PAREDNESS TO IMPROVE SURGE CAPACITY.*—Section
13 *319C–2 of the Public Health Service Act (42 U.S.C. 247d–*
14 *3b) is amended—*

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

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

22 (3) by striking subsection (c) and inserting the
23 following:

24 “(c) *USE OF FUNDS.*—An award under subsection (a)
25 shall be expended for activities to achieve the preparedness

1 *goals described under paragraphs (1), (3), (4), (5), and (6)*
2 *of section 2802(b) with respect to all-hazards, including*
3 *chemical, biological, radiological, or nuclear threats.”;*

4 *(4) by striking subsection (g) and inserting the*
5 *following:*

6 *“(g) COORDINATION.—*

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

14 *“(2) NATIONAL COLLABORATION.—Partnerships*
15 *consisting of one or more eligible entities under this*
16 *section may, to the extent practicable, collaborate*
17 *with other partnerships consisting of one or more eli-*
18 *gible entities under this section for purposes of na-*
19 *tional coordination and collaboration with respect to*
20 *activities to achieve the preparedness goals described*
21 *under paragraphs (1), (3), (4), (5), and (6) of section*
22 *2802(b).”;*

23 *(5) in subsection (i)—*

24 *(A) by striking “The requirements of” and*
25 *inserting the following:*

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

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

3 “(2) *MEETING GOALS OF NATIONAL HEALTH SE-*
4 *CURITY STRATEGY.*—*The Secretary shall implement*
5 *objective, evidence-based metrics to ensure that enti-*
6 *ties receiving awards under this section are meeting,*
7 *to the extent practicable, the applicable goals of the*
8 *National Health Security Strategy under section*
9 *2802.*”; and

10 *(6) in subsection (j)—*

11 *(A) by amending paragraph (1) to read as*
12 *follows:*

13 “(1) *IN GENERAL.*—*For purposes of carrying out*
14 *this section, there is authorized to be appropriated*
15 *\$374,700,000 for each of fiscal years 2014 through*
16 *2018.*”; and

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

18 “(4) *AVAILABILITY OF COOPERATIVE AGREEMENT*
19 *FUNDS.*—

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

1 *fiscal year for the purposes for which such funds*
2 *were provided.*

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

10 **SEC. 204. ENHANCING SITUATIONAL AWARENESS AND BIO-**
11 **SURVEILLANCE.**

12 (a) *IN GENERAL.*—*Section 319D of the Public Health*
13 *Service Act (42 U.S.C. 247d–4) is amended—*

14 (1) *in subsection (b)—*

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

17 (B) *in paragraph (2), by inserting before*
18 *the period at the end the following: “, allowing*
19 *for coordination to maximize all-hazards medical*
20 *and public health preparedness and response and*
21 *to minimize duplication of effort”;* and

22 (C) *in paragraph (3), by inserting before*
23 *the period at the end the following: “and update*
24 *such standards as necessary”;*

25 (2) *by striking subsection (c);*

1 (3) *by redesignating subsections (d) through (g)*
2 *as subsections (c) through (f), respectively;*

3 (4) *in subsection (c), as so redesignated—*

4 (A) *in the subsection heading, by striking*
5 *“PUBLIC HEALTH SITUATIONAL AWARENESS”*
6 *and inserting “MODERNIZING PUBLIC HEALTH*
7 *SITUATIONAL AWARENESS AND BIOSURVEIL-*
8 *LANCE”;*

9 (B) *in paragraph (1)—*

10 (i) *by striking “Pandemic and All-*
11 *Hazards Preparedness Act” and inserting*
12 *“Pandemic and All-Hazards Preparedness*
13 *Reauthorization Act of 2013”;* *and*

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

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

18 “(2) *STRATEGY AND IMPLEMENTATION PLAN.—*

19 *Not later than 180 days after the date of enactment*
20 *of the Pandemic and All-Hazards Preparedness Reau-*
21 *thorization Act of 2013, the Secretary shall submit to*
22 *the appropriate committees of Congress a coordinated*
23 *strategy and an accompanying implementation plan*
24 *that identifies and demonstrates the measurable steps*
25 *the Secretary will carry out to—*

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

4 “(B) modernize and enhance biosurveillance
5 activities; and

6 “(C) improve information sharing, coordi-
7 nation, and communication among disparate
8 biosurveillance systems supported by the Depart-
9 ment of Health and Human Services.”;

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

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

15 “(A) utilize applicable interoperability
16 standards as determined by the Secretary, and
17 in consultation with the Office of the National
18 Coordinator for Health Information Technology,
19 through a joint public and private sector proc-
20 ess;”; and

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

22 “(6) CONSULTATION WITH THE NATIONAL BIO-
23 DEFENSE SCIENCE BOARD.—In carrying out this sec-
24 tion and consistent with section 319M, the National
25 Biodefense Science Board shall provide expert advice

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

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

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

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

3 *“(C) coordinate with applicable existing ad-*
4 *visory committees of the Director of the Centers*
5 *for Disease Control and Prevention, including*
6 *such advisory committees consisting of represent-*
7 *atives from State, local, and tribal public health*
8 *authorities and appropriate public and private*
9 *sector health care entities and academic institu-*
10 *tions, in order to provide guidance on public*
11 *health surveillance activities.”;*

12 *(5) in subsection (d), as so redesignated—*

13 *(A) in paragraph (1), by striking “sub-*
14 *section (d)” and inserting “subsection (c)”;*

15 *(B) in paragraph (4)(B), by striking “sub-*
16 *section (d)” and inserting “subsection (c)”;* and

17 *(C) in paragraph (5)—*

18 *(i) by striking “4 years after the date*
19 *of enactment of the Pandemic and All-Haz-*
20 *ards Preparedness Act” and inserting “3*
21 *years after the date of enactment of the*
22 *Pandemic and All-Hazards Preparedness*
23 *Reauthorization Act of 2013”;* and

24 *(ii) by striking “subsection (d)” and*
25 *inserting “subsection (c)”;*

1 (6) in subsection (f), as so redesignated, by strik-
2 ing “such sums as may be necessary in each of fiscal
3 years 2007 through 2011” and inserting
4 “\$138,300,000 for each of fiscal years 2014 through
5 2018”; and

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

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

(b) *TECHNICAL AND CONFORMING AMENDMENT.*—Section 319C–1(b)(2)(D) of the Public Health Service Act (42 U.S.C. 247d–3a(b)(2)(D)) is amended by striking “section 319D(d)(3)” and inserting “section 319D(c)(3)”.

19 *SEC. 205. ELIMINATING DUPLICATIVE PROJECT BIOSHIELD*
20 *REPORTS.*

21 *Section 5 of the Project Bioshield Act of 2004 (42*
22 *U.S.C. 247d-6c) is repealed.*

1 ***TITLE III—ENHANCING MEDICAL***
2 ***COUNTERMEASURE REVIEW***

3 ***SEC. 301. SPECIAL PROTOCOL ASSESSMENT.***

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

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

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

16 *“(ii) with respect to an application for approval*
17 *of a biological product under section 351(k) of the*
18 *Public Health Service Act, of any necessary clinical*
19 *study or studies.*

20 *The sponsor or applicant”.*

21 ***SEC. 302. AUTHORIZATION FOR MEDICAL PRODUCTS FOR***
22 ***USE IN EMERGENCIES.***

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

1 (1) *in subsection (a)—*

2 (A) *in paragraph (1), by striking “sections*
3 *505, 510(k), and 515 of this Act” and inserting*
4 *“any provision of this Act”;*

5 (B) *in paragraph (2)(A), by striking*
6 *“under a provision of law referred to in such*
7 *paragraph” and inserting “under section 505,*
8 *510(k), or 515 of this Act or section 351 of the*
9 *Public Health Service Act”; and*

10 (C) *in paragraph (3), by striking “a provi-*
11 *sion of law referred to in such paragraph” and*
12 *inserting “a section of this Act or the Public*
13 *Health Service Act referred to in paragraph*
14 *(2)(A)”;*

15 (2) *in subsection (b)—*

16 (A) *in the subsection heading, by striking*
17 *“EMERGENCY” and inserting “EMERGENCY OR*
18 *THREAT JUSTIFYING EMERGENCY AUTHORIZED*
19 *USE”;*

20 (B) *in paragraph (1)—*

21 (i) *in the matter preceding subpara-*
22 *graph (A), by striking “may declare an*
23 *emergency” and inserting “may make a*
24 *declaration that the circumstances exist”;*

1 (ii) in subparagraph (A), by striking
2 “specified”;

3 (iii) in subparagraph (B)—

4 (I) by striking “specified”; and

5 (II) by striking “; or” and insert-
6 ing a semicolon;

7 (iv) by amending subparagraph (C) to
8 read as follows:

9 “(C) a determination by the Secretary that
10 there is a public health emergency, or a signifi-
11 cant potential for a public health emergency,
12 that affects, or has a significant potential to af-
13 fect, national security or the health and security
14 of United States citizens living abroad, and that
15 involves a biological, chemical, radiological, or
16 nuclear agent or agents, or a disease or condition
17 that may be attributable to such agent or agents;
18 or”; and

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

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

25 (C) in paragraph (2)—

1 (i) in subparagraph (A), by amending
2 clause (ii) to read as follows:

3 “(ii) a change in the approval status of
4 the product such that the circumstances de-
5 scribed in subsection (a)(2) have ceased to
6 exist.”;

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

8 (iii) by redesignating subparagraph
9 (C) as subparagraph (B);

10 (D) in paragraph (4), by striking “advance
11 notice of termination, and renewal under this
12 subsection.” and inserting “, and advance notice
13 of termination under this subsection.”; and

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

15 “(5) *EXPLANATION BY SECRETARY.*—If an au-
16 thorization under this section with respect to an un-
17 approved product or an unapproved use of an ap-
18 proved product has been in effect for more than 1
19 year, the Secretary shall provide in writing to the
20 sponsor of such product an explanation of the sci-
21 entific, regulatory, or other obstacles to approval, li-
22 censure, or clearance of such product or use, including
23 specific actions to be taken by the Secretary and the
24 sponsor to overcome such obstacles.”;

25 (3) in subsection (c)—

1 (A) in the matter preceding paragraph

2 (1)—

3 (i) by inserting “the Assistant Sec-
4 retary for Preparedness and Response,”
5 after “consultation with”;

6 (ii) by striking “Health and” and in-
7 serting “Health, and”; and

8 (iii) by striking “circumstances of the
9 emergency involved” and inserting “appli-
10 cable circumstances described in subsection
11 (b)(1)”;

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

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

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

22 (5) in subsection (e)—

23 (A) in paragraph (1)(A), by striking “cir-
24 cumstances of the emergency” and inserting “ap-

1 *plicable circumstances described in subsection*
2 *(b)(1)”;*

3 *(B) in paragraph (1)(B), by amending*
4 *clause (iii) to read as follows:*

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

12 *(C) in paragraph (2)—*

13 *(i) in subparagraph (A)—*

14 *(I) by striking “manufacturer of*
15 *the product” and inserting “person”;*

16 *(II) by striking “circumstances of*
17 *the emergency” and inserting “appli-*
18 *cable circumstances described in sub-*
19 *section (b)(1)”; and*

20 *(III) by inserting at the end be-*
21 *fore the period “or in paragraph*
22 *(1)(B)”;*

23 *(ii) in subparagraph (B)(i), by insert-*
24 *ing before the period at the end “, except as*
25 *provided in section 564A with respect to au-*

1 *thorized changes to the product expiration*
2 *date”; and*

3 *(iii) by amending subparagraph (C) to*
4 *read as follows:*

5 *“(C) In establishing conditions under this*
6 *paragraph with respect to the distribution and*
7 *administration of the product for the unap-*
8 *proved use, the Secretary shall not impose condi-*
9 *tions that would restrict distribution or adminis-*
10 *tration of the product when distributed or ad-*
11 *ministered for the approved use.”; and*

12 *(D) by amending paragraph (3) to read as*
13 *follows:*

14 *“(3) GOOD MANUFACTURING PRACTICE; PRE-*
15 *SCRIPTION.—With respect to the emergency use of a*
16 *product for which an authorization under this section*
17 *is issued (whether an unapproved product or an un-*
18 *approved use of an approved product), the Secretary*
19 *may waive or limit, to the extent appropriate given*
20 *the applicable circumstances described in subsection*
21 *(b)(1)—*

22 *“(A) requirements regarding current good*
23 *manufacturing practice otherwise applicable to*
24 *the manufacture, processing, packing, or holding*
25 *of products subject to regulation under this Act,*

1 *including such requirements established under*
2 *section 501 or 520(f)(1), and including relevant*
3 *conditions prescribed with respect to the product*
4 *by an order under section 520(f)(2);*

5 *“(B) requirements established under section*
6 *503(b); and*

7 *“(C) requirements established under section*
8 *520(e).”;*
9 *(6) in subsection (g)—*

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

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

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

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

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

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

4 “(A) *the circumstances described under sub-*
5 *section (b)(1) no longer exist;*

6 “(B) *the criteria under subsection (c) for*
7 *issuance of such authorization are no longer met;*
8 *or*

9 “(C) *other circumstances make such revision*
10 *or revocation appropriate to protect the public*
11 *health or safety.”;*

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

17 (8) *by adding at the end of subsection (j) the fol-*
18 *lowing:*

19 “(4) *Nothing in this section shall be construed as*
20 *authorizing a delay in the review or other consider-*
21 *ation by the Secretary of any application or submis-*
22 *sion pending before the Food and Drug Administra-*
23 *tion for a product for which an authorization under*
24 *this section is issued.”; and*

25 (9) *by adding at the end the following:*

1 “(m) *CATEGORIZATION OF LABORATORY TESTS ASSO-*
2 *CIATED WITH DEVICES SUBJECT TO AUTHORIZATION.*—

3 “(1) *IN GENERAL.*—*In issuing an authorization*
4 *under this section with respect to a device, the Sec-*
5 *retary may, subject to the provisions of this section,*
6 *determine that a laboratory examination or procedure*
7 *associated with such device shall be deemed, for pur-*
8 *poses of section 353 of the Public Health Service Act,*
9 *to be in a particular category of examinations and*
10 *procedures (including the category described by sub-*
11 *section (d)(3) of such section) if, based on the totality*
12 *of scientific evidence available to the Secretary—*

13 “(A) *such categorization would be beneficial*
14 *to protecting the public health; and*

15 “(B) *the known and potential benefits of*
16 *such categorization under the circumstances of*
17 *the authorization outweigh the known and poten-*
18 *tial risks of the categorization.*

19 “(2) *CONDITIONS OF DETERMINATION.*—*The Sec-*
20 *retary may establish appropriate conditions on the*
21 *performance of the examination or procedure pursu-*
22 *ant to such determination.*

23 “(3) *EFFECTIVE PERIOD.*—*A determination*
24 *under this subsection shall be effective for purposes of*
25 *section 353 of the Public Health Service Act notwith-*

1 *standing any other provision of that section during*
2 *the effective period of the relevant declaration under*
3 *subsection (b).”.*

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

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

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

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

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

15 **“(B)(i)** *is intended for use to prevent, diag-*
16 *nose, or treat a disease or condition involving a*
17 *biological, chemical, radiological, or nuclear*
18 *agent or agents; or*

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

23 **“(C)** *is intended for use during the cir-*
24 *cumstances under which—*

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

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

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

13 “(b) *EXPIRATION DATING*.—

14 “(1) *IN GENERAL*.—The Secretary may extend
15 the expiration date and authorize the introduction or
16 delivery for introduction into interstate commerce of
17 an eligible product after the expiration date provided
18 by the manufacturer if—

19 “(A) the expiration date extension is in-
20 tended to support the United States ability to
21 protect—

22 “(i) the public health; or

23 “(ii) military preparedness and effec-
24 tiveness; and

1 “(B) the expiration date extension is sup-
2 ported by an appropriate scientific evaluation
3 that is conducted or accepted by the Secretary.

4 “(2) REQUIREMENTS AND CONDITIONS.—Any ex-
5 tension of an expiration date under paragraph (1)
6 shall, as part of the extension, identify—

7 “(A) each specific lot, batch, or other unit
8 of the product for which extended expiration is
9 authorized;

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

11 “(C) any other requirements or conditions
12 as the Secretary may deem appropriate for the
13 protection of the public health, which may in-
14 clude requirements for, or conditions on, product
15 sampling, storage, packaging or repackaging,
16 transport, labeling, notice to product recipients,
17 recordkeeping, periodic testing or retesting, or
18 product disposition.

19 “(3) EFFECT.—Notwithstanding any other pro-
20 vision of this Act or the Public Health Service Act,
21 an eligible product shall not be considered an unap-
22 proved product (as defined in section 564(a)(2)(A))
23 and shall not be deemed adulterated or misbranded
24 under this Act because, with respect to such product,
25 the Secretary has, under paragraph (1), extended the

1 *expiration date and authorized the introduction or*
2 *delivery for introduction into interstate commerce of*
3 *such product after the expiration date provided by the*
4 *manufacturer.*

5 “(4) *EXPIRATION DATE.*—*For purposes of this*
6 *subsection, the term ‘expiration date’ means the date*
7 *established through appropriate stability testing re-*
8 *quired by the regulations issued by the Secretary to*
9 *ensure that the product meets applicable standards of*
10 *identity, strength, quality, and purity at the time of*
11 *use.*

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

13 “(1) *IN GENERAL.*—*The Secretary may, when*
14 *the circumstances of a domestic, military, or public*
15 *health emergency or material threat described in sub-*
16 *section (a)(1)(C) so warrant, authorize, with respect*
17 *to an eligible product, deviations from current good*
18 *manufacturing practice requirements otherwise appli-*
19 *cable to the manufacture, processing, packing, or*
20 *holding of products subject to regulation under this*
21 *Act, including requirements under section 501 or*
22 *520(f)(1) or applicable conditions prescribed with re-*
23 *spect to the eligible product by an order under section*
24 *520(f)(2).*

1 “(2) *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 product,
7 the Secretary has authorized deviations from current
8 good manufacturing practices under paragraph (1).

9 “(d) *EMERGENCY DISPENSING.*—The requirements of
10 sections 503(b) and 520(e) shall not apply to an eligible
11 product, and the product shall not be considered an unap-
12 proved product (as defined in section 564(a)(2)(A)) and
13 shall not be deemed adulterated or misbranded under this
14 Act because it is dispensed without an individual prescrip-
15 tion, if—

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

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

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

22 “(B) in accordance with an order issued by
23 the Secretary, for the purposes and duration of
24 the circumstances described in subsection
25 (a)(1)(C).

1 “(e) *EMERGENCY USE INSTRUCTIONS.*—

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

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

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

21 “(B) *by a government entity (including a*
22 *Federal, State, local, or tribal government enti-*
23 *ty), or a person acting on behalf of such a gov-*
24 *ernment entity, in preparation for an emergency*
25 *response.”.*

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

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

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

7 “(k) *WAIVER IN PUBLIC HEALTH EMERGENCIES.*—
8 *The Secretary may waive any requirement of this section*
9 *with respect to a qualified countermeasure (as defined in*
10 *section 319F–1(a)(2) of the Public Health Service Act) to*
11 *which a requirement under this section has been applied,*
12 *if the Secretary determines that such waiver is required to*
13 *mitigate the effects of, or reduce the severity of, the cir-*
14 *cumstances under which—*

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

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

23 (d) *PRODUCTS HELD FOR EMERGENCY USE.*—*The*
24 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 301 et

1 *seq.) is amended by inserting after section 564A, as added*
2 *by subsection (b), the following:*

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

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

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

12 *“(2) is held and not used, unless and until that*
13 *product—*

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

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

20 *“(C) is authorized for use under section*
21 *564.”.*

22 **SEC. 303. DEFINITIONS.**

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

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

2 “(1) *the term ‘countermeasure’ means a qualified*
3 *countermeasure, a security countermeasure, and a*
4 *qualified pandemic or epidemic product;*

5 “(2) *the term ‘qualified countermeasure’ has the*
6 *meaning given such term in section 319F–1 of the*
7 *Public Health Service Act;*

8 “(3) *the term ‘security countermeasure’ has the*
9 *meaning given such term in section 319F–2 of such*
10 *Act; and*

11 “(4) *the term ‘qualified pandemic or epidemic*
12 *product’ means a product that meets the definition*
13 *given such term in section 319F–3 of the Public*
14 *Health Service Act and—*

15 “(A) *that has been identified by the Depart-*
16 *ment of Health and Human Services or the De-*
17 *partment of Defense as receiving funding directly*
18 *related to addressing chemical, biological, radio-*
19 *logical, or nuclear threats, including pandemic*
20 *influenza; or*

21 “(B) *is included under this paragraph pur-*
22 *suant to a determination by the Secretary.*

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

1 **SEC. 304. ENHANCING MEDICAL COUNTERMEASURE ACTIVI-**
2 **TIES.**

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

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

10 *(2) in subsection (b), by striking the subsection*
11 *enumerator and all that follows through “shall estab-*
12 *lish” and inserting the following:*

13 *“(b) GENERAL DUTIES.—In order to accelerate the de-*
14 *velopment, stockpiling, approval, licensure, and clearance*
15 *of qualified countermeasures, security countermeasures, and*
16 *qualified pandemic or epidemic products, the Secretary, in*
17 *consultation with the Assistant Secretary for Preparedness*
18 *and Response, shall—*

19 *“(1) ensure the appropriate involvement of Food*
20 *and Drug Administration personnel in interagency*
21 *activities related to countermeasure advanced research*
22 *and development, consistent with sections 319F,*
23 *319F–1, 319F–2, 319F–3, 319L, and 2811 of the*
24 *Public Health Service Act;*

25 *“(2) ensure the appropriate involvement and*
26 *consultation of Food and Drug Administration per-*

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

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

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

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

19 *“(C) holding public meetings at least twice*
20 *annually to encourage the exchange of scientific*
21 *ideas; and*

22 *“(D) establishing protocols to ensure that*
23 *countermeasure reviewers have sufficient train-*
24 *ing or experience with countermeasures;*

1 “(4) maintain teams, composed of Food and
2 *Drug Administration* personnel with expertise on
3 countermeasures, including specific countermeasures,
4 populations with special clinical needs (including
5 children and pregnant women that may use counter-
6 measures, as applicable and appropriate), classes or
7 groups of countermeasures, or other countermeasure-
8 related technologies and capabilities, that shall—

9 “(A) consult with countermeasure experts,
10 including countermeasure sponsors and appli-
11 cants, to identify and help resolve scientific
12 issues related to the approval, licensure, or clear-
13 ance of countermeasures, through workshops or
14 public meetings; and

15 “(B) improve and advance the science relat-
16 ing to the development of new tools, standards,
17 and approaches to assessing and evaluating
18 countermeasures—

19 “(i) in order to inform the process for
20 countermeasure approval, clearance, and li-
21 censure; and

22 “(ii) with respect to the development of
23 countermeasures for populations with spe-
24 cial clinical needs, including children and
25 pregnant women, in order to meet the needs

1 *of such populations, as necessary and ap-*
2 *propriate; and*

3 *“(5) establish”; and*

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

5 *“(c) FINAL GUIDANCE ON DEVELOPMENT OF ANIMAL*
6 *MODELS.—*

7 *“(1) IN GENERAL.—Not later than 1 year after*
8 *the date of the enactment of the Pandemic and All-*
9 *Hazards Preparedness Reauthorization Act of 2013,*
10 *the Secretary shall provide final guidance to industry*
11 *regarding the development of animal models to sup-*
12 *port approval, clearance, or licensure of counter-*
13 *measures referred to in subsection (a) when human ef-*
14 *ficacy studies are not ethical or feasible.*

15 *“(2) AUTHORITY TO EXTEND DEADLINE.—The*
16 *Secretary may extend the deadline for providing final*
17 *guidance under paragraph (1) by not more than 6*
18 *months upon submission by the Secretary of a report*
19 *on the status of such guidance to the Committee on*
20 *Energy and Commerce of the House of Representa-*
21 *tives and the Committee on Health, Education,*
22 *Labor, and Pensions of the Senate.*

23 *“(d) DEVELOPMENT AND ANIMAL MODELING PROCE-*
24 *DURES.—*

1 “(1) *AVAILABILITY OF ANIMAL MODEL MEET-*
2 *INGS.—To facilitate the timely development of animal*
3 *models and support the development, stockpiling, li-*
4 *censure, approval, and clearance of countermeasures,*
5 *the Secretary shall, not later than 180 days after the*
6 *enactment of this subsection, establish a procedure by*
7 *which a sponsor or applicant that is developing a*
8 *countermeasure for which human efficacy studies are*
9 *not ethical or practicable, and that has an approved*
10 *investigational new drug application or investiga-*
11 *tional device exemption, may request and receive—*

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

14 “(B) *a meeting prior to initiating pivotal*
15 *animal studies.*

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

21 “(e) *REVIEW AND APPROVAL OF COUNTER-*
22 *MEASURES.—*

23 “(1) *MATERIAL THREAT.—When evaluating an*
24 *application or submission for approval, licensure, or*
25 *clearance of a countermeasure, the Secretary shall*

1 *take into account the material threat posed by the*
2 *chemical, biological, radiological, or nuclear agent or*
3 *agents identified under section 319F–2 of the Public*
4 *Health Service Act for which the countermeasure*
5 *under review is intended.*

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

13 **SEC. 305. REGULATORY MANAGEMENT PLANS.**

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

17 “(f) *REGULATORY MANAGEMENT PLAN.*—

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

20 “(A) a security countermeasure with respect
21 to which the Secretary has entered into a pro-
22 curement contract under section 319F–2(c) of the
23 Public Health Service Act; or

24 “(B) a countermeasure with respect to
25 which the Biomedical Advanced Research and

1 *Development Authority has provided funding*
2 *under section 319L of the Public Health Service*
3 *Act for advanced research and development.*

4 “(2) *REGULATORY MANAGEMENT PLAN PROC-*
5 *ESS.—The Secretary, in consultation with the Assist-*
6 *ant Secretary for Preparedness and Response and the*
7 *Director of the Biomedical Advanced Research and*
8 *Development Authority, shall establish a formal proc-*
9 *ess for obtaining scientific feedback and interactions*
10 *regarding the development and regulatory review of*
11 *eligible countermeasures by facilitating the develop-*
12 *ment of written regulatory management plans in ac-*
13 *cordance with this subsection.*

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

16 “(A) *IN GENERAL.—A sponsor or applicant*
17 *of an eligible countermeasure may initiate the*
18 *process described under paragraph (2) upon sub-*
19 *mission of a written request to the Secretary.*
20 *Such request shall include a proposed regulatory*
21 *management plan.*

22 “(B) *TIMING OF SUBMISSION.—A sponsor*
23 *or applicant may submit a written request*
24 *under subparagraph (A) after the eligible coun-*

1 *termeasure has an investigational new drug or*
2 *investigational device exemption in effect.*

3 “(C) *RESPONSE BY SECRETARY.*—*The Sec-*
4 *retary shall direct the Food and Drug Adminis-*
5 *tration, upon submission of a written request by*
6 *a sponsor or applicant under subparagraph (A),*
7 *to work with the sponsor or applicant to agree*
8 *on a regulatory management plan within a rea-*
9 *sonable time not to exceed 90 days. If the Sec-*
10 *retary determines that no plan can be agreed*
11 *upon, the Secretary shall provide to the sponsor*
12 *or applicant, in writing, the scientific or regu-*
13 *latory rationale why such agreement cannot be*
14 *reached.*

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

18 “(A) *an agreement between the Secretary*
19 *and the sponsor or applicant regarding develop-*
20 *mental milestones that will trigger responses by*
21 *the Secretary as described in subparagraph (B);*

22 “(B) *performance targets and goals for*
23 *timely and appropriate responses by the Sec-*
24 *retary to the triggers described under subpara-*
25 *graph (A), including meetings between the Sec-*

1 *retary and the sponsor or applicant, written*
2 *feedback, decisions by the Secretary, and other*
3 *activities carried out as part of the development*
4 *and review process; and*

5 *“(C) an agreement on how the plan shall be*
6 *modified, if needed.*

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

11 *“(A) feedback from the Secretary regarding*
12 *the data required to support the approval, clear-*
13 *ance, or licensure of the eligible countermeasure*
14 *involved;*

15 *“(B) feedback from the Secretary regarding*
16 *the data necessary to inform any authorization*
17 *under section 564;*

18 *“(C) feedback from the Secretary regarding*
19 *the data necessary to support the positioning*
20 *and delivery of the eligible countermeasure, in-*
21 *cluding to the Strategic National Stockpile;*

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

1 “(E) feedback from the Secretary regarding
2 any gaps in scientific knowledge that will need
3 resolution prior to approval, licensure, or clear-
4 ance of the eligible countermeasure and plans for
5 conducting the necessary scientific research;

6 “(F) identification of the population for
7 which the countermeasure sponsor or applicant
8 seeks approval, licensure, or clearance and the
9 population for which desired labeling would not
10 be appropriate, if known; and

11 “(G) as necessary and appropriate, and to
12 the extent practicable, a plan for demonstrating
13 safety and effectiveness in pediatric populations,
14 and for developing pediatric dosing, formulation,
15 and administration with respect to the eligible
16 countermeasure, provided that such plan would
17 not delay authorization under section 564, ap-
18 proval, licensure, or clearance for adults.

19 “(6) *PRIORITIZATION.*—

20 “(A) *PLANS FOR SECURITY COUNTER-*
21 *MEASURES.*—The Secretary shall establish regu-
22 latory management plans for all security coun-
23 termeasures for which a request is submitted
24 under paragraph (3)(A).

1 “(B) *PLANS FOR OTHER ELIGIBLE COUN-*
2 *TERMEASURES.—The Secretary shall determine*
3 *whether resources are available to establish regu-*
4 *latory management plans for eligible counter-*
5 *measures that are not security countermeasures.*
6 *If resources are available to establish regulatory*
7 *management plans for eligible countermeasures*
8 *that are not security countermeasures, and if re-*
9 *sources are not available to establish regulatory*
10 *management plans for all eligible counter-*
11 *measures for which requests have been submitted,*
12 *the Director of the Biomedical Advanced Re-*
13 *search and Development Authority, in consulta-*
14 *tion with the Commissioner, shall prioritize*
15 *which eligible countermeasures may receive regu-*
16 *latory management plans.”.*

17 **SEC. 306. REPORT.**

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

21 “(g) *ANNUAL REPORT.—Not later than 180 days after*
22 *the date of enactment of this subsection, and annually there-*
23 *after, the Secretary shall make publicly available on the*
24 *Web site of the Food and Drug Administration a report*

1 *that details the countermeasure development and review ac-*
2 *tivities of the Food and Drug Administration, including—*

3 “(1) *with respect to the development of new tools,*
4 *standards, and approaches to assess and evaluate*
5 *countermeasures—*

6 “(A) *the identification of the priorities of*
7 *the Food and Drug Administration and the*
8 *progress made on such priorities; and*

9 “(B) *the identification of scientific gaps*
10 *that impede the development, approval, licensure,*
11 *or clearance of countermeasures for populations*
12 *with special clinical needs, including children*
13 *and pregnant women, and the progress made on*
14 *resolving these challenges;*

15 “(2) *with respect to countermeasures for which a*
16 *regulatory management plan has been agreed upon*
17 *under subsection (f), the extent to which the perform-*
18 *ance targets and goals set forth in subsection (f)(4)(B)*
19 *and the regulatory management plan have been met,*
20 *including, for each such countermeasure—*

21 “(A) *whether the regulatory management*
22 *plan was completed within the required time-*
23 *frame, and the length of time taken to complete*
24 *such plan;*

1 “(B) whether the Secretary adhered to the
2 timely and appropriate response times set forth
3 in such plan; and

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

6 “(3) the number of regulatory teams established
7 pursuant to subsection (b)(4), the number of products,
8 classes of products, or technologies assigned to each
9 such team, and the number of, type of, and any
10 progress made as a result of consultations carried out
11 under subsection (b)(4)(A);

12 “(4) an estimate of resources obligated to coun-
13 termeasure development and regulatory assessment,
14 including—

15 “(A) Center-specific objectives and accom-
16 plishments; and

17 “(B) the number of full-time equivalent em-
18 ployees of the Food and Drug Administration
19 who directly support the review of counter-
20 measures;

21 “(5) the number of countermeasure applications
22 and submissions submitted, the number of counter-
23 measures approved, licensed, or cleared, the status of
24 remaining submitted applications and submissions,

1 *and the number of each type of authorization issued*
2 *pursuant to section 564;*

3 “(6) *the number of written requests for a regu-*
4 *latory management plan submitted under subsection*
5 *(f)(3)(A), the number of regulatory management plans*
6 *developed, and the number of such plans developed for*
7 *security countermeasures; and*

8 “(7) *the number, type, and frequency of meetings*
9 *between the Food and Drug Administration and—*

10 “(A) *sponsors of a countermeasure as de-*
11 *finied in subsection (a); or*

12 “(B) *another agency engaged in develop-*
13 *ment or management of portfolios for such coun-*
14 *termeasures, including the Centers for Disease*
15 *Control and Prevention, the Biomedical Ad-*
16 *vanced Research and Development Authority, the*
17 *National Institutes of Health, and the appro-*
18 *priate agencies of the Department of Defense.”.*

19 **SEC. 307. PEDIATRIC MEDICAL COUNTERMEASURES.**

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

23 *(1) in subsection (d), by adding at the end the*
24 *following:*

1 “(5) *CONSULTATION.*—*With respect to a drug*
2 *that is a qualified countermeasure (as defined in sec-*
3 *tion 319F–1 of the Public Health Service Act), a secu-*
4 *urity countermeasure (as defined in section 319F–2 of*
5 *the Public Health Service Act), or a qualified pan-*
6 *demic or epidemic product (as defined in section*
7 *319F–3 of the Public Health Service Act), the Sec-*
8 *retary shall solicit input from the Assistant Secretary*
9 *for Preparedness and Response regarding the need for*
10 *and, from the Director of the Biomedical Advanced*
11 *Research and Development Authority regarding the*
12 *conduct of, pediatric studies under this section.”; and*
13 *(2) in subsection (n)(1), by adding at the end the*
14 *following:*

15 “(C) *For a drug that is a qualified counter-*
16 *measure (as defined in section 319F–1 of the*
17 *Public Health Service Act), a security counter-*
18 *measure (as defined in section 319F–2 of the*
19 *Public Health Service Act), or a qualified pan-*
20 *demic or epidemic product (as defined in section*
21 *319F–3 of such Act), in addition to any action*
22 *with respect to such drug under subparagraph*
23 *(A) or (B), the Secretary shall notify the Assist-*
24 *ant Secretary for Preparedness and Response*
25 *and the Director of the Biomedical Advanced Re-*

1 *search and Development Authority of all pedi-*
2 *atric studies in the written request issued by the*
3 *Commissioner of Food and Drugs.”.*

4 *(b) ADDITION TO PRIORITY LIST CONSIDERATIONS.—*
5 *Section 409I of the Public Health Service Act (42 U.S.C.*
6 *284m) is amended—*

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

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

12 *“(A) shall consider—*

13 *“(i) therapeutic gaps in pediatrics that*
14 *may include developmental pharmacology,*
15 *pharmacogenetic determinants of drug re-*
16 *sponse, metabolism of drugs and biologics in*
17 *children, and pediatric clinical 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 in*

6 *section 319F–2), and qualified pandemic or epi-*

7 *demic products (as defined in section 319F–3) to*

8 *address the needs of pediatric populations, in*

9 *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 (a)”*

13 *and inserting “paragraphs (1) and (2)(A) of sub-*

14 *section (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 Children*

19 *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 Food,*

1 *Drug, and Cosmetic Act) for pediatric popu-*
2 *lations.”.*

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.—Section*
9 *319F–2(c) of the Public Health Service Act (42 U.S.C.*
10 *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 para-*
15 *graph (10))” and inserting “the appropriate commit-*
16 *tees 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*

(B) by striking “the designated congressional committees” and inserting “the appropriate congressional committees”; and

(5) in paragraph (7)(C)—

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

(B) in clause (ii)—

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

(ii) by striking subclause (IX) and inserting the following:

“(IX) CONTRACT TERMS.—The Secretary, in any contract for procurement under this section—

“(aa) may specify—

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

“(BB) the amount of funding that will be dedicated by the Secretary for advanced research, develop-

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, for*
17 *the procurement of security countermeasures under*
18 *subsection (c) and for carrying out section 319L (re-*
19 *lating to the Biomedical Advanced Research and De-*
20 *velopment Authority), \$2,800,000,000 for the period*
21 *of fiscal years 2014 through 2018. Amounts appro-*
22 *priated pursuant to the preceding sentence are au-*
23 *thorized 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 Au-*
7 *thority). Amounts authorized to be appropriated*
8 *under this subsection to carry out section 319L are in*
9 *addition to amounts otherwise authorized to be ap-*
10 *propriated to carry out such section.*

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

17 “(4) *REPORT.*—*Not later than 30 days after any*
18 *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 Sec-*
21 *retary shall submit to the appropriate committees of*
22 *Congress a report detailing the amount of such funds*
23 *available for procurement and the impact such reduc-*
24 *tion in funding will have—*

1 “(A) *in meeting the security countermeasure*
2 *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 account,*
13 *any appropriation made available pursuant to sec-*
14 *tion 521(a) of the Homeland Security Act of 2002,*
15 *and any appropriation made available pursuant to*
16 *subsection (g)(1).”.*

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

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

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

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

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

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

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

19 “(2) FUNDING.—To carry out the purposes of
20 this section, there is authorized to be appropriated to
21 the Fund \$415,000,000 for each of fiscal years 2014
22 through 2018, such amounts to remain available until
23 expended.”.

24 (d) CONTINUED INAPPLICABILITY OF CERTAIN PROVI-
25 SIONS.—Section 319L(e)(1)(C) of the Public Health Service

1 *Act (42 U.S.C. 247d–7e(e)(1)(C)) is amended by striking*
2 *“7 years” and inserting “12 years”.*

3 *(e) EXTENSION OF LIMITED ANTITRUST EXEMP-*
4 *TION.—*

5 *(1) IN GENERAL.—Section 405(b) of the Pan-*
6 *demic and All-Hazards Preparedness Act (42 U.S.C.*
7 *247d–6a note) is amended by striking “6-year” and*
8 *inserting “12-year”.*

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

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

14 *“(f) INDEPENDENT EVALUATION.—*

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

21 *“(2) REPORT.—Not later than 1 year after the*
22 *date of enactment of this subsection, the Comptroller*
23 *General of the United States shall submit to the ap-*
24 *propriate committees of Congress a report concerning*

1 *the results of the evaluation conducted under para-*
2 *graph (1). Such report shall review and assess—*

3 *“(A) the extent to which flexible manufac-*
4 *turing capacity under this section is dedicated to*
5 *chemical, biological, radiological, and nuclear*
6 *threats;*

7 *“(B) the activities supported by flexible*
8 *manufacturing initiatives; and*

9 *“(C) the ability of flexible manufacturing*
10 *activities carried out under this section to—*

11 *“(i) secure and leverage leading tech-*
12 *nical expertise with respect to counter-*
13 *measure advanced research, development,*
14 *and manufacturing processes; and*

15 *“(ii) meet the surge manufacturing ca-*
16 *capacity needs presented by novel and emerg-*
17 *ing threats, including chemical, biological,*
18 *radiological, and nuclear agents.”.*

19 *(g) DEFINITIONS.—*

20 *(1) QUALIFIED COUNTERMEASURE.—Section*
21 *319F–1(a)(2)(A) of the Public Health Service Act (42*
22 *U.S.C. 247d–6a(a)(2)(A)) is amended—*

23 *(A) in the matter preceding clause (i), by*
24 *striking “to—” and inserting “—”;*

25 *(B) in clause (i)—*

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

3 (ii) by striking “; or” and inserting a
4 semicolon;

5 (C) in clause (ii)—

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

8 (ii) by striking the period at the end
9 and inserting “; or”; and

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

11 “(iii) is a product or technology in-
12 tended to enhance the use or effect of a drug,
13 biological product, or device described in
14 clause (i) or (ii).”.

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

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

21 (B) in clause (ii), by striking “; and” and
22 inserting “; or”; and

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

24 “(iii) a product or technology intended
25 to enhance the use or effect of a drug, bio-

1 *logical product, or device described in clause*
2 *(i) or (ii); and”.*

3 (3) *TECHNICAL AMENDMENTS.—Section 319F–*
4 *3(i) of the Public Health Service Act (42 U.S.C.*
5 *247d–6d(i)) is amended—*

6 (A) *in paragraph (1)(C), by inserting “,*
7 *564A, or 564B” after “564”; and*

8 (B) *in paragraph (7)(B)(iii), by inserting*
9 *“, 564A, or 564B” after “564”.*

10 ***SEC. 403. STRATEGIC NATIONAL STOCKPILE.***

11 *Section 319F–2 of the Public Health Service Act (42*
12 *U.S.C. 247d–6b) is amended—*

13 (1) *in subsection (a)—*

14 (A) *in paragraph (1)—*

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

18 (ii) *by inserting before the period at*
19 *the end of the second sentence the following:*
20 *“and shall submit such review annually to*
21 *the appropriate congressional committees of*
22 *jurisdiction to the extent that disclosure of*
23 *such information does not compromise na-*
24 *tional security”; and*

1 (B) in paragraph (2)(D), by inserting be-
2 fore the semicolon at the end the following: “and
3 that the potential depletion of countermeasures
4 currently in the stockpile is identified and ap-
5 propriately addressed, including through nec-
6 essary replenishment”; and

7 (2) in subsection (f)(1), by striking
8 “\$640,000,000 for fiscal year 2002, and such sums as
9 may be necessary for each of fiscal years 2003 through
10 2006. Such authorization is in addition to amounts
11 in the special reserve fund referred to in subsection
12 (c)(10)(A).” and inserting “\$533,800,000 for each of
13 fiscal years 2014 through 2018. Such authorization is
14 in addition to amounts in the special reserve fund re-
15 ferred to in subsection (h).”.

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

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

19 (1) in paragraph (2)—

20 (A) in subparagraph (D)—

21 (i) in clause (i), by striking “and” at
22 the end;

(ii) in clause (ii), by striking the period and inserting a semicolon; and

1 (iii) by adding at the end the fol-
2 lowing:

3 “(iii) one such member shall be an in-
4 dividual with pediatric subject matter ex-
5 pertise; and

6 “(iv) one such member shall be a State,
7 tribal, territorial, or local public health offi-
8 cial.”; and

9 (B) by adding at the end the following flush
10 sentence:

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

14 (2) in paragraph (5)—

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

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

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

20 “(D) provide any recommendation, finding,
21 or report provided to the Secretary under this
22 paragraph to the appropriate committees of Con-
23 gress.”.