

***In the Senate of the United States,***

*February 27, 2013.*

*Resolved*, That the bill from the House of Representatives (H.R. 307) entitled “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.”, do pass with the following

**AMENDMENT:**

Strike out all after the enacting clause and insert:

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

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

5       (b) *TABLE OF CONTENTS.*—*The table of contents of this*  
6 *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

1           *surge capacity for events without notice” after*  
2           *“exercises”; and*

3                   *(B) in paragraph (3)—*

4                           *(i) in the matter preceding subpara-*  
5                           *graph (A)—*

6                                   *(I) by striking “facilities), and*  
7                                   *trauma care” and inserting “and am-*  
8                                   *bulatory care facilities and which may*  
9                                   *include dental health facilities), and*  
10                                   *trauma care, critical care,”; and*

11                                   *(II) by inserting “(including re-*  
12                                   *lated availability, accessibility, and co-*  
13                                   *ordination)” after “public health emer-*  
14                                   *gencies”;*

15                           *(ii) in subparagraph (A), by inserting*  
16                           *“and trauma” after “medical”;*

17                           *(iii) in subparagraph (B), by striking*  
18                           *“Medical evacuation and fatality manage-*  
19                           *ment” and inserting “Fatality manage-*  
20                           *ment”;*

21                           *(iv) by redesignating subparagraphs*  
22                           *(C), (D), and (E) as subparagraphs (D),*  
23                           *(E), and (F), respectively;*

24                           *(v) by inserting after subparagraph*  
25                           *(B), the following the new subparagraph:*

1           “(C) Coordinated medical triage and evacu-  
2           ation to appropriate medical institutions based  
3           on patient medical need, taking into account re-  
4           gionalized systems of care.”;

5                   (vi) in subparagraph (E), as redesign-  
6                   ated by clause (iv), by inserting “(which  
7                   may include such dental health assets)”  
8                   after “medical assets”; and

9                   (vii) by adding at the end the fol-  
10                  lowing:

11           “(G) Optimizing a coordinated and flexible  
12           approach to the medical surge capacity of hos-  
13           pitals, other health care facilities, critical care,  
14           trauma care (which may include trauma cen-  
15           ters), and emergency medical systems.”;

16           (C) in paragraph (4)—

17                   (i) in subparagraph (A), by inserting  
18                   “, including the unique needs and consider-  
19                   ations of individuals with disabilities,”  
20                   after “medical needs of at-risk individuals”;  
21                   and

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

25           “(7) COUNTERMEASURES.—

1           “(A) *Promoting strategic initiatives to ad-*  
2           *vance countermeasures to diagnose, mitigate,*  
3           *prevent, or treat harm from any biological agent*  
4           *or toxin, chemical, radiological, or nuclear agent*  
5           *or agents, whether naturally occurring, uninten-*  
6           *tional, or deliberate.*

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

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

19                 “(A) *optimizing alignment and integration*  
20                 *of medical and public health preparedness and*  
21                 *response planning and capabilities with and*  
22                 *into routine daily activities; and*

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

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

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

4           *(2) in paragraph (4), by striking*  
5 *“2811(b)(3)(B)” and inserting “2802(b)(4)(B)”;*

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

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

10           *“(1) monitor emerging issues and concerns as*  
11 *they relate to medical and public health preparedness*  
12 *and response for at-risk individuals in the event of a*  
13 *public health emergency declared by the Secretary*  
14 *under section 319;”;*

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

17           *“(2) oversee the implementation of the prepared-*  
18 *ness goals described in section 2802(b) with respect to*  
19 *the public health and medical needs of at-risk indi-*  
20 *viduals in the event of a public health emergency, as*  
21 *described in section 2802(b)(4);”;* and

22           *(6) by inserting after paragraph (6), the fol-*  
23 *lowing:*

24           *“(7) disseminate and, as appropriate, update*  
25 *novel and best practices of outreach to and care of at-*

1 *risk individuals before, during, and following public*  
2 *health emergencies in as timely a manner as is prac-*  
3 *ticable, including from the time a public health threat*  
4 *is identified; and*

5 *“(8) ensure that public health and medical infor-*  
6 *mation distributed by the Department of Health and*  
7 *Human Services during a public health emergency is*  
8 *delivered in a manner that takes into account the*  
9 *range of communication needs of the intended recipi-*  
10 *ents, including at-risk individuals.”.*

11 **SEC. 102. ASSISTANT SECRETARY FOR PREPAREDNESS AND**  
12 **RESPONSE.**

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

15 *(1) in subsection (b)—*

16 *(A) in paragraph (3), by inserting “, secu-*  
17 *rity countermeasures (as defined in section*  
18 *319F–2),” after “qualified countermeasures (as*  
19 *defined in section 319F–1)”;*

20 *(B) in paragraph (4), by adding at the end*  
21 *the following:*

22 *“(D) POLICY COORDINATION AND STRA-*  
23 *TEGIC DIRECTION.—Provide integrated policy co-*  
24 *ordination and strategic direction with respect to*  
25 *all matters related to Federal public health and*

1           *medical preparedness and execution and deploy-*  
2           *ment of the Federal response for public health*  
3           *emergencies and incidents covered by the Na-*  
4           *tional Response Plan developed pursuant to sec-*  
5           *tion 504(6) of the Homeland Security Act of*  
6           *2002, or any successor plan, before, during, and*  
7           *following public health emergencies.*

8           “(E)   IDENTIFICATION OF INEFFICIEN-

9           CIES.—Identify and minimize gaps, duplication,

10          and other inefficiencies in medical and public

11          health preparedness and response activities and

12          the actions necessary to overcome these obstacles.

13          “(F)   COORDINATION OF GRANTS AND

14          AGREEMENTS.—Align and coordinate medical

15          and public health grants and cooperative agree-

16          ments as applicable to preparedness and re-

17          sponse activities authorized under this Act, to the

18          extent possible, including program requirements,

19          timelines, and measurable goals, and in con-

20          sultation with the Secretary of Homeland Secu-

21          rity, to—

22                 “(i) optimize and streamline medical

23                 and public health preparedness and re-

24                 sponse capabilities and the ability of local



1            *communities to respond to public health*  
2            *emergencies; and*

3            *“(ii) gather and disseminate best prac-*  
4            *tices among grant and cooperative agree-*  
5            *ment recipients, as appropriate.*

6            *“(G) DRILL AND OPERATIONAL EXER-*  
7            *CISES.—Carry out drills and operational exer-*  
8            *cises, in consultation with the Department of*  
9            *Homeland Security, the Department of Defense,*  
10           *the Department of Veterans Affairs, and other*  
11           *applicable Federal departments and agencies, as*  
12           *necessary and appropriate, to identify, inform,*  
13           *and address gaps in and policies related to all-*  
14           *hazards medical and public health preparedness*  
15           *and response, including exercises based on—*

16           *“(i) identified threats for which coun-*  
17           *termeasures are available and for which no*  
18           *countermeasures are available; and*

19           *“(ii) unknown threats for which no*  
20           *countermeasures are available.*

21           *“(H) NATIONAL SECURITY PRIORITY.—On a*  
22           *periodic basis consult with, as applicable and*  
23           *appropriate, the Assistant to the President for*  
24           *National Security Affairs, to provide an update*  
25           *on, and discuss, medical and public health pre-*

1            *paredness and response activities pursuant to*  
2            *this Act and the Federal Food, Drug, and Cos-*  
3            *metic Act, including progress on the develop-*  
4            *ment, approval, clearance, and licensure of med-*  
5            *ical countermeasures.”; and*

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

7            *“(7) COUNTERMEASURES BUDGET PLAN.—De-*  
8            *velop, and update on an annual basis, a coordinated*  
9            *5-year budget plan based on the medical counter-*  
10           *measure priorities described in subsection (d). Each*  
11           *such plan shall—*

12           *“(A) include consideration of the entire*  
13           *medical countermeasures enterprise, including—*

14           *“(i) basic research and advanced re-*  
15           *search and development;*

16           *“(ii) approval, clearance, licensure,*  
17           *and authorized uses of products; and*

18           *“(iii) procurement, stockpiling, main-*  
19           *tenance, and replenishment of all products*  
20           *in the Strategic National Stockpile;*

21           *“(B) inform prioritization of resources and*  
22           *include measurable outputs and outcomes to*  
23           *allow for the tracking of the progress made to-*  
24           *ward identified priorities;*

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

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

8           (2) by striking subsection (c) and inserting the  
9           following:

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

12           “(1) have lead responsibility within the Depart-  
13           ment of Health and Human Services for emergency  
14           preparedness and response policy coordination and  
15           strategic direction;

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

17           “(A) the National Disaster Medical System  
18           pursuant to section 2812;

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

21           “(C) the Biomedical Advanced Research  
22           and Development Authority pursuant to section  
23           319L;

24           “(D) the Medical Reserve Corps pursuant to  
25           section 2813;

1           “(E) *the Emergency System for Advance*  
 2           *Registration of Volunteer Health Professionals*  
 3           *pursuant to section 319I; and*

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

10          “(3) *exercise the responsibilities and authorities*  
 11          *of the Secretary with respect to the coordination of—*

12           “(A) *the Public Health Emergency Pre-*  
 13           *paredness Cooperative Agreement Program pur-*  
 14           *suant to section 319C–1;*

15           “(B) *the Strategic National Stockpile pur-*  
 16           *suant to section 319F–2; and*

17           “(C) *the Cities Readiness Initiative; and*

18          “(4) *assume other duties as determined appro-*  
 19          *priate by the Secretary.”; and*

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

21          “(d) *PUBLIC HEALTH EMERGENCY MEDICAL COUN-*  
 22          *TERMEASURES ENTERPRISE STRATEGY AND IMPLEMENTA-*  
 23          *TION PLAN.—*

24           “(1) *IN GENERAL.—Not later than 180 days*  
 25           *after the date of enactment of this subsection, and*

1 every year thereafter, the Assistant Secretary for Pre-  
2 paredness and Response shall develop and submit to  
3 the appropriate committees of Congress a coordinated  
4 strategy and accompanying implementation plan for  
5 medical countermeasures to address chemical, biologi-  
6 cal, radiological, and nuclear threats. In developing  
7 such a plan, the Assistant Secretary for Preparedness  
8 and Response shall consult with the Director of the  
9 Biomedical Advanced Research and Development Au-  
10 thority, the Director of the National Institutes of  
11 Health, the Director of the Centers for Disease Control  
12 and Prevention, and the Commissioner of Food and  
13 Drugs. Such strategy and plan shall be known as the  
14 ‘Public Health Emergency Medical Countermeasures  
15 Enterprise Strategy and Implementation Plan’.

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

18 “(A) describe the chemical, biological, radio-  
19 logical, and nuclear agent or agents that may  
20 present a threat to the Nation and the cor-  
21 responding efforts to develop qualified counter-  
22 measures (as defined in section 319F–1), secu-  
23 rity countermeasures (as defined in section  
24 319F–2), or qualified pandemic or epidemic

1           *products (as defined in section 319F-3) for each*  
2           *threat;*

3           “(B) *evaluate the progress of all activities*  
4           *with respect to such countermeasures or prod-*  
5           *ucts, including research, advanced research, de-*  
6           *velopment, procurement, stockpiling, deployment,*  
7           *distribution, and utilization;*

8           “(C) *identify and prioritize near-, mid-,*  
9           *and long-term needs with respect to such coun-*  
10           *termeasures or products to address a chemical,*  
11           *biological, radiological, and nuclear threat or*  
12           *threats;*

13           “(D) *identify, with respect to each category*  
14           *of threat, a summary of all awards and con-*  
15           *tracts, including advanced research and develop-*  
16           *ment and procurement, that includes—*

17           “(i) *the time elapsed from the issuance*  
18           *of the initial solicitation or request for a*  
19           *proposal to the adjudication (such as the*  
20           *award, denial of award, or solicitation ter-*  
21           *mination); and*

22           “(ii) *an identification of projected*  
23           *timelines, anticipated funding allocations,*  
24           *benchmarks, and milestones for each med-*  
25           *ical countermeasure priority under sub-*

1           *paragraph (C), including projected needs*  
2           *with regard to replenishment of the Stra-*  
3           *tegic National Stockpile;*

4           *“(E) be informed by the recommendations of*  
5           *the National Biodefense Science Board pursuant*  
6           *to section 319M;*

7           *“(F) evaluate progress made in meeting*  
8           *timelines, allocations, benchmarks, and mile-*  
9           *stones identified under subparagraph (D)(ii);*

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

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

17           *“(I) identify the progress made in meeting*  
18           *the medical countermeasure priorities for at-risk*  
19           *individuals (as defined in 2802(b)(4)(B)), as ap-*  
20           *licable under subparagraph (C), including with*  
21           *regard to the projected needs for related stock-*  
22           *piling and replenishment of the Strategic Na-*  
23           *tional Stockpile, including by addressing the*  
24           *needs of pediatric populations with respect to*

1           *such countermeasures and products in the Stra-*  
2           *tegic National Stockpile, including—*

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

6                     *“(ii) a description of measures taken to*  
7                     *coordinate with the Office of Pediatric*  
8                     *Therapeutics of the Food and Drug Admin-*  
9                     *istration to maximize the labeling, dosages,*  
10                    *and formulations of such countermeasures*  
11                    *and products for pediatric populations;*

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

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

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



1           of section 564 of the Federal Food, Drug, and  
2           Cosmetic Act, by 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 considered  
12                  and rejected with respect to the use of such  
13                  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 and  
19                  entities that were considered and rejected  
20                  for such a grant, cooperative agreement, or  
21                  contract, except that the report need not dis-  
22                  close the identity of any such person or en-  
23                  tity;

24                  “(iv) whether, with respect to each pro-  
25                  curement that is approved by the President

1           *under section 319F–2(c)(6), a contract was*  
2           *entered into within one year after such ap-*  
3           *proval by the President; and*

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

11          *“(K) be made publicly available.*

12          *“(3) GAO REPORT.—*

13            *“(A) IN GENERAL.—Not later than 1 year*  
14            *after the date of the submission to the Congress*  
15            *of the first Public Health Emergency Medical*  
16            *Countermeasures Enterprise Strategy and Imple-*  
17            *mentation Plan, the Comptroller General of the*  
18            *United States shall conduct an independent eval-*  
19            *uation, and submit to the appropriate commit-*  
20            *tees of Congress a report, concerning such Strat-*  
21            *egy 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 Gov-*  
2           *ernment pursuant to paragraph (2)(C);*

3           *“(ii) the activities of the Department of*  
4           *Health and Human Services with respect to*  
5           *advanced research and development pursu-*  
6           *ant to section 319L; and*

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

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

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

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

6 (1) the research, advanced research, development,  
7 procurement, stockpiling, and distribution of counter-  
8 measures to meet identified needs; and

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

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

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

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

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

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

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

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

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

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

19          “(d) *MEMBERSHIP.—*

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

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

7           “(A) *the Assistant Secretary for Prepared-*  
8 *ness and Response;*

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

11           “(C) *the Director of the Centers for Disease*  
12 *Control and Prevention;*

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

14           “(E) *the Director of the National Institutes*  
15 *of Health;*

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

18           “(G) *the Administrator of the Federal*  
19 *Emergency Management Agency;*

20           “(H) *at least two non-Federal health care*  
21 *professionals with expertise in pediatric medical*  
22 *disaster planning, preparedness, response, or re-*  
23 *covery;*

24           “(I) *at least two representatives from State,*  
25 *local, territorial, or tribal agencies with expertise*

1           *in pediatric disaster planning, preparedness, re-*  
2           *sponse, or recovery; and*

3           “(J) *representatives from such Federal*  
4           *agencies (such as the Department of Education*  
5           *and the Department of Homeland Security) as*  
6           *determined necessary to fulfill the duties of the*  
7           *Advisory Committee, as established under sub-*  
8           *sections (b) and (c).*

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

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

13          ***SEC. 104. MODERNIZATION OF THE NATIONAL DISASTER***  
14                  ***MEDICAL SYSTEM.***

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

17                  *(1) in subsection (a)(3)—*

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

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

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

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

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

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

19 **SEC. 105. CONTINUING THE ROLE OF THE DEPARTMENT OF**  
20 **VETERANS AFFAIRS.**

21          *Section 8117(g) of title 38, United States Code, is*  
22          *amended by striking “such sums as may be necessary to*  
23          *carry out this section for each of fiscal years 2007 through*  
24          *2011” and inserting “\$155,300,000 for each of fiscal years*  
25          *2014 through 2018 to carry out this section”.*



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

5 **SEC. 201. TEMPORARY REASSIGNMENT OF STATE AND**  
6 **LOCAL PERSONNEL DURING A PUBLIC**  
7 **HEALTH EMERGENCY.**

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

11 *“(e) TEMPORARY REASSIGNMENT OF STATE AND*  
12 *LOCAL PERSONNEL DURING A PUBLIC HEALTH EMER-*  
13 *GENCY.—*

14 *“(1) EMERGENCY REASSIGNMENT OF FEDERALLY*  
15 *FUNDED PERSONNEL.—Notwithstanding any other*  
16 *provision of law, and subject to paragraph (2), upon*  
17 *request by the Governor of a State or a tribal organi-*  
18 *zation or such Governor or tribal organization’s des-*  
19 *ignee, the Secretary may authorize the requesting*  
20 *State or Indian tribe to temporarily reassign, for*  
21 *purposes of immediately addressing a public health*  
22 *emergency in the State or Indian tribe, State and*  
23 *local public health department or agency personnel*  
24 *funded in whole or in part through programs author-*  
25 *ized under this Act, as appropriate.*

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

3           “(A) *PUBLIC HEALTH EMERGENCY.*—*The*  
4           *Secretary may authorize a temporary reassign-*  
5           *ment of personnel under paragraph (1) only dur-*  
6           *ing the period of a public health emergency de-*  
7           *termined pursuant to subsection (a).*

8           “(B) *CONTENTS OF REQUEST.*—*To seek au-*  
9           *thority for a temporary reassignment of per-*  
10           *sonnel under paragraph (1), the Governor of a*  
11           *State or a tribal organization shall submit to the*  
12           *Secretary a request for such reassignment flexi-*  
13           *bility and shall include in the request each of the*  
14           *following:*

15           “(i) *An assurance that the public*  
16           *health emergency in the geographic area of*  
17           *the requesting State or Indian tribe cannot*  
18           *be adequately and appropriately addressed*  
19           *by the public health workforce otherwise*  
20           *available.*

21           “(ii) *An assurance that the public*  
22           *health emergency would be addressed more*  
23           *efficiently and effectively through the re-*  
24           *quested temporary reassignment of State*

1           *and local personnel described in paragraph*  
2           *(1).*

3           “(iii) *An assurance that the requested*  
4           *temporary reassignment of personnel is con-*  
5           *sistent with any applicable All-Hazards*  
6           *Public Health Emergency Preparedness and*  
7           *Response Plan under section 319C-1.*

8           “(iv) *An identification of—*

9                   “(I) *each Federal program from*  
10                   *which personnel would be temporarily*  
11                   *reassigned pursuant to the requested*  
12                   *authority; and*

13                   “(II) *the number of personnel who*  
14                   *would be so reassigned from each such*  
15                   *program.*

16           “(v) *Such other information and as-*  
17           *surances upon which the Secretary and*  
18           *Governor of a State or tribal organization*  
19           *agree.*

20           “(C) *CONSIDERATION.—In reviewing a re-*  
21           *quest for temporary reassignment under para-*  
22           *graph (1), the Secretary shall consider the degree*  
23           *to which the program or programs funded in*  
24           *whole or in part by programs authorized under*

1           *this Act would be adversely affected by the reas-*  
2           *signment.*

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

4           “(i) *TERMINATION.*—*A State or Indian*  
5           *tribe’s temporary reassignment of personnel*  
6           *under paragraph (1) shall terminate upon*  
7           *the earlier of the following:*

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

11           “(II) *Subject to clause (i), the ex-*  
12           *piration of the 30-day period following*  
13           *the date on which the Secretary ap-*  
14           *proved the State or Indian tribe’s re-*  
15           *quest for such reassignment flexibility.*

16           “(ii) *EXTENSION OF REASSIGNMENT*  
17           *FLEXIBILITY.*—*The Secretary may extend*  
18           *reassignment flexibility of personnel under*  
19           *paragraph (1) beyond the date otherwise*  
20           *applicable under clause (i)(II) if the public*  
21           *health emergency still exists as of such date,*  
22           *but only if—*

23           “(I) *the State or Indian tribe that*  
24           *submitted the initial request for a tem-*  
25           *porary reassignment of personnel sub-*

1                   mits a request for an extension of such  
2                   temporary reassignment; and

3                   “(II) the request for an extension  
4                   contains the same information and as-  
5                   surances necessary for the approval of  
6                   an initial request for such temporary  
7                   reassignment pursuant to subpara-  
8                   graph (B).

9                   “(3) VOLUNTARY NATURE OF TEMPORARY REAS-  
10                  SIGNMENT OF STATE AND LOCAL PERSONNEL.—

11                  “(A) IN GENERAL.—Unless otherwise pro-  
12                  vided under the law or regulation of the State or  
13                  Indian tribe that receives authorization for tem-  
14                  porary reassignment of personnel under para-  
15                  graph (1), personnel eligible for reassignment  
16                  pursuant to such authorization—

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

19                         “(ii) shall not be required to agree to  
20                         a temporary reassignment.

21                  “(B) PROHIBITION ON CONDITIONING FED-  
22                  ERAL AWARDS.—The Secretary may not condi-  
23                  tion the award of a grant, contract, or coopera-  
24                  tive agreement under this Act on the requirement  
25                  that a State or Indian tribe require that per-

1           *sonnel eligible for reassignment pursuant to an*  
2           *authorization under paragraph (1) agree to such*  
3           *reassignment.*

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

7                   “(A) *any initial request for temporary reas-*  
8                   *signment of personnel; and*

9                   “(B) *any request for an extension of such*  
10                  *temporary reassignment.*

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

12                   “(A) *not later than 6 months after the en-*  
13                   *actment of this subsection, issue proposed guid-*  
14                   *ance on the temporary reassignment of personnel*  
15                   *under this subsection; and*

16                   “(B) *after providing notice and a 60-day*  
17                   *period for public comment, finalize such guid-*  
18                   *ance.*

19          “(6) *REPORT TO CONGRESS.*—*Not later than 4*  
20           *years after the date of enactment of the Pandemic and*  
21           *All-Hazards Preparedness Reauthorization Act of*  
22           *2013, the Comptroller General of the United States*  
23           *shall conduct an independent evaluation, and submit*  
24           *to the appropriate committees of the Congress a re-*

1       *port, on temporary reassignment under this sub-*  
2       *section, including—*

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

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

9               “(C) *an evaluation of how such temporary*  
10              *reassignment has improved operational effi-*  
11              *ciencies in responding to public health emer-*  
12              *gencies;*

13              “(D) *an analysis of the extent to which, if*  
14              *any, Federal programs from which personnel*  
15              *have been temporarily reassigned have been ad-*  
16              *versely affected by the reassignment; and*

17              “(E) *recommendations on how medical*  
18              *surge capacity could be improved in responding*  
19              *to public health emergencies and the impact of*  
20              *the reassignment flexibility under this section on*  
21              *such surge capacity.*

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

23                      “(A) *the terms ‘Indian tribe’ and ‘tribal or-*  
24                      *ganization’ have the meanings given such terms*

1           in section 4 of the Indian Self-Determination  
2           and Education Assistance Act; and

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

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

8   **SEC. 202. IMPROVING STATE AND LOCAL PUBLIC HEALTH**  
9           **SECURITY.**

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

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

16                  (2) in subsection (b)(2)—

17                          (A) in subparagraph (A)—

18                                  (i) by striking clauses (i) and (ii) and  
19                                  inserting the following:

20    “(i) a description of the activities such  
21    entity will carry out under the agreement to  
22    meet the goals identified under section 2802,  
23    including with respect to chemical, biologi-  
24    cal, radiological, or nuclear threats, whether



1 naturally occurring, unintentional, or delib-  
2 erate;

3 “(ii) a description of the activities such  
4 entity will carry out with respect to pan-  
5 demic influenza, as a component of the ac-  
6 tivities carried out under clause (i), and  
7 consistent with the requirements of para-  
8 graphs (2) and (5) of subsection (g);”;

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

11 (iii) by adding at the end the fol-  
12 lowing:

13 “(vi) a description of how, as appro-  
14 priate, the entity may partner with relevant  
15 public and private stakeholders in public  
16 health emergency preparedness and re-  
17 sponse;

18 “(vii) a description of how the entity,  
19 as applicable and appropriate, will coordi-  
20 nate with State emergency preparedness  
21 and response plans in public health emer-  
22 gency preparedness, including State edu-  
23 cational agencies (as defined in section  
24 9101(41) of the Elementary and Secondary  
25 Education Act of 1965) and State child care

1           *lead agencies (designated under section*  
2           *658D of the Child Care and Development*  
3           *Block Grant Act of 1990);*

4           *“(viii) in the case of entities that oper-*  
5           *ate on the United States-Mexico border or*  
6           *the United States-Canada border, a descrip-*  
7           *tion of the activities such entity will carry*  
8           *out under the agreement that are specific to*  
9           *the border area including disease detection,*  
10           *identification, investigation, and prepared-*  
11           *ness and response activities related to*  
12           *emerging diseases and infectious disease*  
13           *outbreaks whether naturally occurring or*  
14           *due to bioterrorism, consistent with the re-*  
15           *quirements of this section; and*

16           *“(ix) a description of any activities*  
17           *that such entity will use to analyze real-*  
18           *time clinical specimens for pathogens of*  
19           *public health or bioterrorism significance,*  
20           *including any utilization of poison control*  
21           *centers;”;* and

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

25           *(3) in subsection (f)—*

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

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

5           (C) by striking paragraph (4);

6           (4) in subsection (g)—

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

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

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

22           (5) by striking subsection (h);

23           (6) by redesignating subsections (i), (j), and (k)  
24           as subsections (h), (i), and (j), respectively;

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

1           (A) in paragraph (1)—

2               (i) in subparagraph (A)—

3                   (I) by striking “\$824,000,000 for  
4                   fiscal year 2007, of which \$35,000,000  
5                   shall be used to carry out subsection  
6                   (h),” and inserting “\$641,900,000 for  
7                   fiscal year 2014”; and

8                   (II) by striking “such sums as  
9                   may be necessary for each of fiscal  
10                   years 2008 through 2011” and insert-  
11                   ing “\$641,900,000 for each of fiscal  
12                   years 2015 through 2018”;

13               (ii) by striking subparagraph (B);

14               (iii) by redesignating subparagraphs  
15               (C) and (D) as subparagraphs (B) and (C),  
16               respectively; and

17               (iv) in subparagraph (C), as so reded-  
18               ignated, by striking “subparagraph (C)”  
19               and inserting “subparagraph (B)”;

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

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

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

1           “(7) *AVAILABILITY OF COOPERATIVE AGREEMENT*  
2           *FUNDS.*—

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

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

17           (8) *in subsection (i), as so redesignated—*

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

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

21           (b) *VACCINE TRACKING AND DISTRIBUTION.*—*Section*  
22           *319A(e) of the Public Health Service Act (42 U.S.C. 247d-*  
23           *1(e)) is amended by striking “such sums for each of fiscal*  
24           *years 2007 through 2011” and inserting “\$30,800,000 for*  
25           *each of fiscal years 2014 through 2018”.*

1       (c) *TECHNICAL AND CONFORMING AMENDMENTS.*—

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

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

8                       (A) *in subsection (i), by striking “(j), and*  
 9 *(k)” and inserting “(i), and (j)”;* and

10                      (B) *in subsection (j)(3), by striking “319C–*  
 11 *1(i)” and inserting “319C–1(h)”.*

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

14       (a) *ALL-HAZARDS PUBLIC HEALTH AND MEDICAL*  
 15 *RESPONSE CURRICULA AND TRAINING.*—*Section*  
 16 *319F(a)(5)(B) of the Public Health Service Act (42 U.S.C.*  
 17 *247d–6(a)(5)(B)) is amended by striking “public health or*  
 18 *medical” and inserting “public health, medical, 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 Serv-*  
 24 *ice Act (42 U.S.C. 247d–7b(k)) is amended by strik-*  
 25 *ing “\$2,000,000 for fiscal year 2002, and such sums*

1       *as may be necessary for each of the fiscal years 2003*  
2       *through 2011” and inserting “\$5,000,000 for each of*  
3       *fiscal years 2014 through 2018”.*

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

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

12                      (B) *in subsection (i), by striking*  
13       *“\$22,000,000 for fiscal year 2007, and such sums*  
14       *as may be necessary for each of fiscal years 2008*  
15       *through 2011” and inserting “\$11,200,000 for*  
16       *each of fiscal years 2014 through 2018”.*

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

21                      (1) *in subsection (a), by inserting “, including,*  
22       *as appropriate, capacity and preparedness to address*  
23       *the needs of children and other at-risk individuals”*  
24       *before the period at the end;*

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

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

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

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

13           “(g) *COORDINATION.—*

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

21           “(2) *NATIONAL COLLABORATION.—Partnerships*  
22           *consisting of one or more eligible entities under this*  
23           *section may, to the extent practicable, collaborate*  
24           *with other partnerships consisting of one or more eli-*  
25           *gible entities under this section for purposes of na-*



1 *tional coordination and collaboration with respect to*  
2 *activities to achieve the preparedness goals described*  
3 *under paragraphs (1), (3), (4), (5), and (6) of section*  
4 *2802(b).”;*

5 *(5) in subsection (i)—*

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

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

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

10 *“(2) MEETING GOALS OF NATIONAL HEALTH SE-*  
11 *CURITY STRATEGY.—The Secretary shall implement*  
12 *objective, evidence-based metrics to ensure that enti-*  
13 *ties receiving awards under this section are meeting,*  
14 *to the extent practicable, the applicable goals of the*  
15 *National Health Security Strategy under section*  
16 *2802.”; and*

17 *(6) in subsection (j)—*

18 *(A) by amending paragraph (1) to read as*  
19 *follows:*

20 *“(1) IN GENERAL.—For purposes of carrying out*  
21 *this section, there is authorized to be appropriated*  
22 *\$374,700,000 for each of fiscal years 2014 through*  
23 *2018.”; and*

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

1           “(4) *AVAILABILITY OF COOPERATIVE AGREEMENT*  
2     *FUNDS.—*—

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

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

17     **SEC. 204. ENHANCING SITUATIONAL AWARENESS AND BIO-**  
18                     **SURVEILLANCE.**

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

21           (1) in subsection (b)—

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

24                     (B) in paragraph (2), by inserting before  
25     the period at the end the following: “, allowing

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

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

7           (2) by striking subsection (c);

8           (3) by redesignating subsections (d) through (g)  
9           as subsections (c) through (f), respectively;

10          (4) in subsection (c), as so redesignated—

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

16          (B) in paragraph (1)—

17           (i) by striking “Pandemic and All-  
18           Hazards Preparedness Act” and inserting  
19           “Pandemic and All-Hazards Preparedness  
20           Reauthorization Act of 2013”; and

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

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

1           “(2) *STRATEGY AND IMPLEMENTATION PLAN.*—  
2           *Not later than 180 days after the date of enactment*  
3           *of the Pandemic and All-Hazards Preparedness Reau-*  
4           *thorization Act of 2013, the Secretary shall submit to*  
5           *the appropriate committees of Congress a coordinated*  
6           *strategy and an accompanying implementation plan*  
7           *that identifies and demonstrates the measurable steps*  
8           *the Secretary will carry out to—*

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

12                  “(B) *modernize and enhance biosurveillance*  
13                  *activities; and*

14                  “(C) *improve information sharing, coordi-*  
15                  *nation, and communication among disparate*  
16                  *biosurveillance systems supported by the Depart-*  
17                  *ment of Health and Human Services.”;*

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

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

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

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

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

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

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

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

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

19 (5) in subsection (d), as so redesignated—

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

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

24           (C) in paragraph (5)—

1                   (i) by striking “4 years after the date  
2                   of enactment of the Pandemic and All-Haz-  
3                   ards Preparedness Act” and inserting “3  
4                   years after the date of enactment of the  
5                   Pandemic and All-Hazards Preparedness  
6                   Reauthorization Act of 2013”; and

7                   (ii) by striking “subsection (d)” and  
8                   inserting “subsection (c)”; and

9                   (6) in subsection (f), as so redesignated, by strik-  
10                  ing “such sums as may be necessary in each of fiscal  
11                  years 2007 through 2011” and inserting  
12                  “\$138,300,000 for each of fiscal years 2014 through  
13                  2018”; and

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

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

23                  (b) *TECHNICAL AND CONFORMING AMENDMENT.*—Sec-  
24                  tion 319C–1(b)(2)(D) of the Public Health Service Act (42

1 *U.S.C. 247d–3a(b)(2)(D)) is amended by striking “section*  
2 *319D(d)(3)” and inserting “section 319D(c)(3)”.*

3 **SEC. 205. ELIMINATING DUPLICATIVE PROJECT BIOSHIELD**  
4 **REPORTS.**

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

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

9 **SEC. 301. SPECIAL PROTOCOL ASSESSMENT.**

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

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

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

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



1 *The sponsor or applicant”.*

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

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

7 (1) *in subsection (a)*—

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

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

16 (C) *in paragraph (3), by striking “a provi-*  
17 *sion of law referred to in such paragraph” and*  
18 *inserting “a section of this Act or the Public*  
19 *Health Service Act referred to in paragraph*  
20 *(2)(A)”;*

21 (2) *in subsection (b)*—

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

1                   (B) in paragraph (1)—

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

6                   (ii) in subparagraph (A), by striking  
7 “specified”;

8                   (iii) in subparagraph (B)—

9                   (I) by striking “specified”; and

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

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

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

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

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

6           (C) in paragraph (2)—

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

9           “(ii) a change in the approval status of  
10          the product such that the circumstances de-  
11          scribed in subsection (a)(2) have ceased to  
12          exist.”;

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

14          (iii) by redesignating subparagraph  
15          (C) as subparagraph (B);

16          (D) in paragraph (4), by striking “advance  
17          notice of termination, and renewal under this  
18          subsection.” and inserting “, and advance notice  
19          of termination under this subsection.”; and

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

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

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

6            *(3) in subsection (c)—*

7            *(A) in the matter preceding paragraph*

8            *(1)—*

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

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

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

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

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

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

2  
3  
4           (5) in subsection (e)—

5           (A) in paragraph (1)(A), by striking “circumstances of the emergency” and inserting “applicable circumstances described in subsection (b)(1)”;

6  
7  
8  
9           (B) in paragraph (1)(B), by amending clause (iii) to read as follows:

10  
11           “(iii) Appropriate conditions with respect to collection and analysis of information 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.”;

12  
13  
14  
15  
16  
17  
18           (C) in paragraph (2)—

19           (i) in subparagraph (A)—

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

21  
22           (II) by striking “circumstances of the emergency” and inserting “applicable circumstances described in subsection (b)(1)”;

23  
24  
25           and

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

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

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

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

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

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

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

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

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

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

15     *(6) in subsection (g)—*

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

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

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

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

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

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

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

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

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

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

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

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



1        *ation by the Secretary of any application or submis-*  
2        *sion pending before the Food and Drug Administra-*  
3        *tion for a product for which an authorization under*  
4        *this section is issued.”; and*

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

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

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

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

20                *“(B) the known and potential benefits of*  
21        *such categorization under the circumstances of*  
22        *the authorization outweigh the known and poten-*  
23        *tial risks of the categorization.*

24                *“(2) CONDITIONS OF DETERMINATION.—The Sec-*  
25        *retary may establish appropriate conditions on the*

1     *performance of the examination or procedure pursu-*  
2     *ant to such determination.*

3             “(3) *EFFECTIVE PERIOD.*—*A determination*  
4     *under this subsection shall be effective for purposes of*  
5     *section 353 of the Public Health Service Act notwith-*  
6     *standing any other provision of that section during*  
7     *the effective period of the relevant declaration under*  
8     *subsection (b).”.*

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

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

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

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

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

20                     “(B)(i) *is intended for use to prevent, diag-*  
21     *nose, or treat a disease or condition involving a*  
22     *biological, chemical, radiological, or nuclear*  
23     *agent or agents; or*

24                     “(ii) *is intended for use to prevent, diag-*  
25     *nose, or treat a serious or life-threatening disease*

1           or condition caused by a product described in  
2           clause (i); and

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

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

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

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

17           “(b) *EXPIRATION DATING*.—

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

23                           “(A) the expiration date extension is in-  
24                           tended to support the United States ability to  
25                           protect—

1                   “(i) the public health; or

2                   “(ii) military preparedness and effec-  
3                   tiveness; and

4                   “(B) the expiration date extension is sup-  
5                   ported by an appropriate scientific evaluation  
6                   that is conducted or accepted by the Secretary.

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

10                   “(A) each specific lot, batch, or other unit  
11                   of the product for which extended expiration is  
12                   authorized;

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

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

22                   “(3) EFFECT.—Notwithstanding any other pro-  
23                   vision of this Act or the Public Health Service Act,  
24                   an eligible product shall not be considered an unap-  
25                   proved product (as defined in section 564(a)(2)(A))

1     *and shall not be deemed adulterated or misbranded*  
2     *under this Act because, with respect to such product,*  
3     *the Secretary has, under paragraph (1), extended the*  
4     *expiration date and authorized the introduction or*  
5     *delivery for introduction into interstate commerce of*  
6     *such product after the expiration date provided by the*  
7     *manufacturer.*

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

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

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

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

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

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

18            *“(1) the product is dispensed during the cir-*  
19       *cumstances described in subsection (a)(1)(C); and*

20            *“(2) such dispensing without an individual pre-*  
21       *scription occurs—*

22            *“(A) as permitted under the law of the*  
23       *State in which the product is dispensed; or*

24            *“(B) in accordance with an order issued by*  
25       *the Secretary, for the purposes and duration of*

1           *the circumstances described in subsection*  
2           *(a)(1)(C).*

3           “(e) *EMERGENCY USE INSTRUCTIONS.*—

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

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

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

23           “(B) *by a government entity (including a*  
24           *Federal, State, local, or tribal government enti-*  
25           *ty), or a person acting on behalf of such a gov-*

1            *ernment entity, in preparation for an emergency*  
2            *response.”.*

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

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

7            *and*

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

9            *“(k) WAIVER IN PUBLIC HEALTH EMERGENCIES.—*

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

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

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



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

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

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

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

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

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

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

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

1 **SEC. 303. DEFINITIONS.**

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

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

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

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

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

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

19 *“(A) that has been identified by the Depart-*  
20 *ment of Health and Human Services or the De-*  
21 *partment of Defense as receiving funding directly*  
22 *related to addressing chemical, biological, radio-*  
23 *logical, or nuclear threats, including pandemic*  
24 *influenza; or*

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

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

3 **SEC. 304. ENHANCING MEDICAL COUNTERMEASURE ACTIVI-**  
4 **TIES.**

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

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

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

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

21           “(1) *ensure the appropriate involvement of Food*  
22 *and Drug Administration personnel in interagency*  
23 *activities related to countermeasure advanced research*  
24 *and development, consistent with sections 319F,*

1       319F-1, 319F-2, 319F-3, 319L, and 2811 of the  
2       Public Health Service Act;

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

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

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

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

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

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

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

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

18           “(B) improve and advance the science relat-  
19 ing to the development of new tools, standards,  
20 and approaches to assessing and evaluating  
21 countermeasures—

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

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

7                   “(5) establish”; and

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

9                   “(c) *FINAL GUIDANCE ON DEVELOPMENT OF ANIMAL*  
10 *MODELS.*—

11                   “(1) *IN GENERAL.*—Not later than 1 year after  
12                   the date of the enactment of the *Pandemic and All-*  
13                   *Hazards Preparedness Reauthorization Act of 2013,*  
14                   *the Secretary shall provide final guidance to industry*  
15                   *regarding the development of animal models to sup-*  
16                   *port approval, clearance, or licensure of counter-*  
17                   *measures referred to in subsection (a) when human ef-*  
18                   *ficacy studies are not ethical or feasible.*

19                   “(2) *AUTHORITY TO EXTEND DEADLINE.*—*The*  
20                   *Secretary may extend the deadline for providing final*  
21                   *guidance under paragraph (1) by not more than 6*  
22                   *months upon submission by the Secretary of a report*  
23                   *on the status of such guidance to the Committee on*  
24                   *Energy and Commerce of the House of Representa-*

1 *tives and the Committee on Health, Education,*  
2 *Labor, and Pensions of the Senate.*

3 “(d) *DEVELOPMENT AND ANIMAL MODELING PROCE-*  
4 *DURES.—*

5 “(1) *AVAILABILITY OF ANIMAL MODEL MEET-*  
6 *INGS.—To facilitate the timely development of animal*  
7 *models and support the development, stockpiling, li-*  
8 *cence, approval, and clearance of countermeasures,*  
9 *the Secretary shall, not later than 180 days after the*  
10 *enactment of this subsection, establish a procedure by*  
11 *which a sponsor or applicant that is developing a*  
12 *countermeasure for which human efficacy studies are*  
13 *not ethical or practicable, and that has an approved*  
14 *investigational new drug application or investiga-*  
15 *tional device exemption, may request and receive—*

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

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

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

1       “(e) *REVIEW AND APPROVAL OF COUNTER-*  
2 *MEASURES.*—

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

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

18 **SEC. 305. REGULATORY MANAGEMENT PLANS.**

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

22       “(f) *REGULATORY MANAGEMENT PLAN.*—

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



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

5           “(B) a countermeasure with respect to  
6           which the Biomedical Advanced Research and  
7           Development Authority has provided funding  
8           under section 319L of the Public Health Service  
9           Act for advanced research and development.

10          “(2) *REGULATORY MANAGEMENT PLAN PROC-*  
11          *ESS.—The Secretary, in consultation with the Assist-*  
12          *ant Secretary for Preparedness and Response and the*  
13          *Director of the Biomedical Advanced Research and*  
14          *Development Authority, shall establish a formal proc-*  
15          *ess for obtaining scientific feedback and interactions*  
16          *regarding the development and regulatory review of*  
17          *eligible countermeasures by facilitating the develop-*  
18          *ment of written regulatory management plans in ac-*  
19          *cordance with this subsection.*

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

22                 “(A) *IN GENERAL.—A sponsor or applicant*  
23                 *of an eligible countermeasure may initiate the*  
24                 *process described under paragraph (2) upon sub-*  
25                 *mission of a written request to the Secretary.*

1           *Such request shall include a proposed regulatory*  
2           *management plan.*

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

8           “(C) *RESPONSE BY SECRETARY.*—*The Sec-*  
9           *retary shall direct the Food and Drug Adminis-*  
10          *tration, upon submission of a written request by*  
11          *a sponsor or applicant under subparagraph (A),*  
12          *to work with the sponsor or applicant to agree*  
13          *on a regulatory management plan within a rea-*  
14          *sonable time not to exceed 90 days. If the Sec-*  
15          *retary determines that no plan can be agreed*  
16          *upon, the Secretary shall provide to the sponsor*  
17          *or applicant, in writing, the scientific or regu-*  
18          *latory rationale why such agreement cannot be*  
19          *reached.*

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

23                 “(A) *an agreement between the Secretary*  
24                 *and the sponsor or applicant regarding develop-*

1           *mental milestones that will trigger responses by*  
2           *the Secretary as described in subparagraph (B);*

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

11           “(C) *an agreement on how the plan shall be*  
12           *modified, if needed.*

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

17           “(A) *feedback from the Secretary regarding*  
18           *the data required to support the approval, clear-*  
19           *ance, or licensure of the eligible countermeasure*  
20           *involved;*

21           “(B) *feedback from the Secretary regarding*  
22           *the data necessary to inform any authorization*  
23           *under section 564;*

24           “(C) *feedback from the Secretary regarding*  
25           *the data necessary to support the positioning*

1           *and delivery of the eligible countermeasure, in-*  
2           *cluding to the Strategic National Stockpile;*

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

6           “(E) *feedback from the Secretary regarding*  
7           *any gaps in scientific knowledge that will need*  
8           *resolution prior to approval, licensure, or clear-*  
9           *ance of the eligible countermeasure and plans for*  
10          *conducting the necessary scientific research;*

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

16          “(G) *as necessary and appropriate, and to*  
17          *the extent practicable, a plan for demonstrating*  
18          *safety and effectiveness in pediatric populations,*  
19          *and for developing pediatric dosing, formulation,*  
20          *and administration with respect to the eligible*  
21          *countermeasure, provided that such plan would*  
22          *not delay authorization under section 564, ap-*  
23          *proval, licensure, or clearance for adults.*

24          “(6) *PRIORITIZATION.—*

1           “(A) *PLANS FOR SECURITY COUNTER-*  
2           *MEASURES.—The Secretary shall establish regu-*  
3           *latory management plans for all security coun-*  
4           *termeasures for which a request is submitted*  
5           *under paragraph (3)(A).*”

6           “(B) *PLANS FOR OTHER ELIGIBLE COUN-*  
7           *TERMEASURES.—The Secretary shall determine*  
8           *whether resources are available to establish regu-*  
9           *latory management plans for eligible counter-*  
10           *measures that are not security countermeasures.*  
11           *If resources are available to establish regulatory*  
12           *management plans for eligible countermeasures*  
13           *that are not security countermeasures, and if re-*  
14           *sources are not available to establish regulatory*  
15           *management plans for all eligible counter-*  
16           *measures for which requests have been submitted,*  
17           *the Director of the Biomedical Advanced Re-*  
18           *search and Development Authority, in consulta-*  
19           *tion with the Commissioner, shall prioritize*  
20           *which eligible countermeasures may receive regu-*  
21           *latory management plans.”.*”

22 **SEC. 306. REPORT.**

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

1       “(g) *ANNUAL REPORT*.—Not later than 180 days after  
2 the date of enactment of this subsection, and annually there-  
3 after, the Secretary shall make publicly available on the  
4 Web site of the Food and Drug Administration a report  
5 that details the countermeasure development and review ac-  
6 tivities of the Food and Drug Administration, including—

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

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

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

19               “(2) with respect to countermeasures for which a  
20 regulatory management plan has been agreed upon  
21 under subsection (f), the extent to which the perform-  
22 ance targets and goals set forth in subsection (f)(4)(B)  
23 and the regulatory management plan have been met,  
24 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 established  
11          pursuant to subsection (b)(4), the number of products,  
12          classes of products, or technologies assigned to each  
13          such team, and the number of, type of, and any  
14          progress made as a result of consultations carried out  
15          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 em-  
22                 ployees of the Food and Drug Administration  
23                 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 of  
4           remaining submitted applications and submissions,  
5           and the number of each type of authorization issued  
6           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 plans  
10          developed, and the number of such plans developed for  
11          security countermeasures; and

12          “(7) the number, type, and frequency of meetings  
13          between the Food and Drug Administration and—

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

16                 “(B) another agency engaged in develop-  
17                 ment or management of portfolios for such coun-  
18                 termeasures, including the Centers for Disease  
19                 Control and Prevention, the Biomedical Ad-  
20                 vanced Research and Development Authority, the  
21                 National Institutes of Health, and the appro-  
22                 priate agencies of the Department of Defense.”.



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

2       (a) *PEDIATRIC STUDIES OF DRUGS.*—Section 505A of  
3 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a)*  
4 *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 secu-*  
10 *rity countermeasure (as defined in section 319F–2 of*  
11 *the Public Health Service Act), or a qualified pan-*  
12 *dem ic 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 Secretary*  
15 *for Preparedness and Response regarding the need for*  
16 *and, from the Director of the Biomedical Advanced*  
17 *Research and Development Authority regarding the*  
18 *conduct of, pediatric studies under this section.”; and*

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

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

1           319F–3 of such Act), in addition to any action  
2           with respect to such drug under subparagraph  
3           (A) or (B), the Secretary shall notify the Assist-  
4           ant Secretary for Preparedness and Response  
5           and the Director of the Biomedical Advanced Re-  
6           search and Development Authority of all pedi-  
7           atric studies in the written request issued by the  
8           Commissioner of Food and Drugs.”.

9           (b) *ADDITION TO PRIORITY LIST CONSIDERATIONS.*—

10          Section 409I of the Public Health Service Act (42 U.S.C.  
11          284m) is amended—

12                 (1) by striking subsection (a)(2) and inserting  
13          the following:

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

17                         “(A) shall consider—

18                                 “(i) therapeutic gaps in pediatrics that  
19                                 may include developmental pharmacology,  
20                                 pharmacogenetic determinants of drug re-  
21                                 sponse, metabolism of drugs and biologics in  
22                                 children, and pediatric clinical trials;

23                                 “(ii) particular pediatric diseases, dis-  
24                                 orders or conditions where more complete  
25                                 knowledge and testing of therapeutics, in-

1           cluding drugs and biologics, may be bene-  
2           ficial in pediatric populations; and

3                   “(iii) the adequacy of necessary infra-  
4           structure to conduct pediatric pharma-  
5           cological research, including research net-  
6           works and trained pediatric investigators;  
7           and

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

17                   (2) in subsection (b), by striking “subsection (a)”  
18          and inserting “paragraphs (1) and (2)(A) of sub-  
19          section (a)”.

20          (c) *ADVICE AND RECOMMENDATIONS OF THE PEDI-*  
21          *ATRIC ADVISORY COMMITTEE REGARDING COUNTER-*  
22          *MEASURES FOR PEDIATRIC POPULATIONS.*—Subsection  
23          (b)(2) of section 14 of the *Best Pharmaceuticals for Children*  
24          *Act* (42 U.S.C. 284m note) is amended—

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

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

4                   “(D) the development of countermeasures  
5                   (as defined in section 565(a) of the Federal Food,  
6                   Drug, and Cosmetic Act) for pediatric popu-  
7                   lations.”.

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

12 **SEC. 401. BIOSHIELD.**

13           (a) *PROCUREMENT OF COUNTERMEASURES.*—Section  
14 319F–2(c) of the Public Health Service Act (42 U.S.C.  
15 247d–6b(c)) is amended—

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

18                   (2) in paragraph (2)(C), by striking “the des-  
19 igned congressional committees (as defined in para-  
20 graph (10))” and inserting “the appropriate commit-  
21 tees of Congress”;

22                   (3) in paragraph (5)(B)(vi), by striking “eight  
23 years” and inserting “10 years”;

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

1           (A) *in the subparagraph heading, by striking*  
2 *“DESIGNATED CONGRESSIONAL COMMIT-*  
3 *TEES” and inserting “APPROPRIATE CONGRES-*  
4 *SIONAL COMMITTEES”;* and

5           (B) *by striking “the designated congress-*  
6 *sional committees” and inserting “the appro-*  
7 *priate congressional committees”;* and

8 (5) *in paragraph (7)(C)—*

9           (A) *in clause (i)(I), by inserting “including*  
10 *advanced research and development,” after “as*  
11 *may reasonably be required,”;*

12           (B) *in clause (ii)—*

13           (i) *in subclause (III), by striking*  
14 *“eight years” and inserting “10 years”;* and

15           (ii) *by striking subclause (IX) and in-*  
16 *serting the following:*

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

20                           “(aa) *may specify—*

21                                   “(AA) *the dosing and*  
22 *administration requirements*  
23 *for the countermeasure to be*  
24 *developed and procured;*

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

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

12                  “(bb) shall provide a clear  
13                  statement of defined Government  
14                  purpose limited to uses related to  
15                  a security countermeasure, as de-  
16                  fined in paragraph (1)(B).”; and  
17                  (C) by adding at the end the following:

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

1                    *vanced research and development as a rea-*  
 2                    *sonable, allowable, and allocable direct cost*  
 3                    *of the contract involved.”.*

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

7                    *(1) in subsection (c)—*

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

12                           *(B) by striking paragraphs (9) and (10);*  
 13                    *and*

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

15            *“(g) SPECIAL RESERVE FUND.—*

16                    *“(1) AUTHORIZATION OF APPROPRIATIONS.—In*  
 17                    *addition to amounts appropriated to the special re-*  
 18                    *serve fund prior to the date of the enactment of this*  
 19                    *subsection, there is authorized to be appropriated, for*  
 20                    *the procurement of security countermeasures under*  
 21                    *subsection (c) and for carrying out section 319L (re-*  
 22                    *lating to the Biomedical Advanced Research and De-*  
 23                    *velopment Authority), \$2,800,000,000 for the period*  
 24                    *of fiscal years 2014 through 2018. Amounts appro-*  
 25                    *priated pursuant to the preceding sentence are au-*

1 *thorized to remain available until September 30,*  
2 *2019.*

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

13       “(3) *RESTRICTIONS ON USE OF FUNDS.—*  
14 *Amounts in the special reserve fund shall not be used*  
15 *to pay costs other than payments made by the Sec-*  
16 *retary to a vendor for advanced development (under*  
17 *section 319L) or for procurement of a security coun-*  
18 *termeasure under subsection (c)(7).*

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



1 available for procurement and the impact such reduc-  
2 tion in funding will have—

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

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

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

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

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

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

21 (a) *DUTIES.*—Section 319L(c)(4) of the Public Health  
22 Service Act (42 U.S.C. 247d–7e(c)(4)) is amended—

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

1 *Federal Food, Drug, and Cosmetic Act or section 351*  
2 *of this Act)” after “development”; and*

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

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

11 *“(G) GOVERNMENT PURPOSE.—In award-*  
12 *ing contracts, grants, and cooperative agreements*  
13 *under this section, the Secretary shall provide a*  
14 *clear statement of defined Government purpose*  
15 *related to activities included in subsection*  
16 *(a)(6)(B) for a qualified countermeasure or*  
17 *qualified pandemic or epidemic product.”.*

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

21 *“(2) FUNDING.—To carry out the purposes of*  
22 *this section, there is authorized to be appropriated to*  
23 *the Fund \$415,000,000 for each of fiscal years 2014*  
24 *through 2018, such amounts to remain available until*  
25 *expended.”.*

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

5       (e) *EXTENSION OF LIMITED ANTITRUST EXEMP-*  
6 *TION.*—

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

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

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

16       “(f) *INDEPENDENT EVALUATION.*—

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

23           “(2) *REPORT.*—Not later than 1 year after the  
24 date of enactment of this subsection, the Comptroller  
25 General of the United States shall submit to the ap-

1     *appropriate committees of Congress a report concerning*  
2     *the results of the evaluation conducted under para-*  
3     *graph (1). Such report shall review and assess—*

4             *“(A) the extent to which flexible manufac-*  
5             *turing capacity under this section is dedicated to*  
6             *chemical, biological, radiological, and nuclear*  
7             *threats;*

8             *“(B) the activities supported by flexible*  
9             *manufacturing initiatives; and*

10            *“(C) the ability of flexible manufacturing*  
11            *activities carried out under this section to—*

12                    *“(i) secure and leverage leading tech-*  
13                    *nical expertise with respect to counter-*  
14                    *measure advanced research, development,*  
15                    *and manufacturing processes; and*

16                    *“(ii) meet the surge manufacturing ca-*  
17                    *capacity needs presented by novel and emerg-*  
18                    *ing threats, including chemical, biological,*  
19                    *radiological, and nuclear agents.”.*

20     *(g) DEFINITIONS.—*

21             *(1) QUALIFIED COUNTERMEASURE.—Section*  
22             *319F-1(a)(2)(A) of the Public Health Service Act (42*  
23             *U.S.C. 247d-6a(a)(2)(A)) is amended—*

24                    *(A) in the matter preceding clause (i), by*  
25                    *striking “to—” and inserting “—”;*

1 (B) in clause (i)—

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

4 (ii) by striking “; or” and inserting a  
5 semicolon;

6 (C) in clause (ii)—

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

9 (ii) by striking the period at the end  
10 and inserting “; or”; and

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

12 “(iii) is a product or technology in-  
13 tended to enhance the use or effect of a drug,  
14 biological product, or device described in  
15 clause (i) or (ii).”.

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

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

22 (B) in clause (ii), by striking “; and” and  
23 inserting “; or”; and

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

1                   “(iii) a product or technology intended  
2                   to enhance the use or effect of a drug, bio-  
3                   logical product, or device described in clause  
4                   (i) or (ii); and”.

5                   (3) *TECHNICAL AMENDMENTS.*—Section 319F-  
6                   3(i) of the Public Health Service Act (42 U.S.C.  
7                   247d–6d(i)) is amended—

8                   (A) in paragraph (1)(C), by inserting “,  
9                   564A, or 564B” after “564”; and

10                   (B) in paragraph (7)(B)(iii), by inserting  
11                   “, 564A, or 564B” after “564”.

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

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

15                   (1) in subsection (a)—

16                   (A) in paragraph (1)—

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

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

1           *such information does not compromise na-*  
2           *tional security”;* and

3           *(B) in paragraph (2)(D), by inserting be-*  
4           *fore the semicolon at the end the following: “and*  
5           *that the potential depletion of countermeasures*  
6           *currently in the stockpile is identified and ap-*  
7           *propriately addressed, including through nec-*  
8           *essary replenishment”;* and

9           *(2) in subsection (f)(1), by striking*  
10          *“\$640,000,000 for fiscal year 2002, and such sums as*  
11          *may be necessary for each of fiscal years 2003 through*  
12          *2006. Such authorization is in addition to amounts*  
13          *in the special reserve fund referred to in subsection*  
14          *(c)(10)(A).” and inserting “\$533,800,000 for each of*  
15          *fiscal years 2014 through 2018. Such authorization is*  
16          *in addition to amounts in the special reserve fund re-*  
17          *ferred to in subsection (h).”.*

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

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

21                 *(1) in paragraph (2)—*

22                         *(A) in subparagraph (D)—*

23                                 *(i) in clause (i), by striking “and” at*  
24                                 *the end;*

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

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

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

8                   “(iv) one such member shall be a State,  
9                   tribal, territorial, or local public health offi-  
10                  cial.”; and

11                  (B) by adding at the end the following flush  
12                  sentence:

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

16                  (2) in paragraph (5)—

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

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

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

22                                 “(D) provide any recommendation, finding,  
23                                 or report provided to the Secretary under this



1           *paragraph to the appropriate committees of Con-*  
2           *gress.”.*

Attest:

*Secretary.*

113<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

**H.R. 307**

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**AMENDMENT**