

112TH CONGRESS  
2D SESSION

# H. R. 6672

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## AN ACT

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

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

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 Reauthoriza-  
 4 tion Act of 2012”.

5 (b) **TABLE OF CONTENTS.**—The table of contents of  
 6 this Act is as follows:

Sec. 1. Short title; table of contents.

**TITLE I—STRENGTHENING NATIONAL PREPAREDNESS AND  
 RESPONSE FOR PUBLIC HEALTH EMERGENCIES**

- Sec. 101. National Health Security Strategy.
- Sec. 102. Assistant Secretary for Preparedness and Response.
- Sec. 103. National Advisory Committee on Children and Disasters.
- Sec. 104. Modernization of the National Disaster Medical System.
- Sec. 105. Continuing the role of the Department of Veterans Affairs.

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

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

**TITLE III—ENHANCING MEDICAL COUNTERMEASURE REVIEW**

- Sec. 301. Special protocol assessment.
- Sec. 302. Authorization for medical products for use in emergencies.
- Sec. 303. Definitions.
- Sec. 304. Enhancing medical countermeasure activities.
- Sec. 305. Regulatory management plans.
- Sec. 306. Report.
- Sec. 307. Pediatric medical countermeasures.

**TITLE IV—ACCELERATING MEDICAL COUNTERMEASURE  
 ADVANCED RESEARCH AND DEVELOPMENT**

- Sec. 401. BioShield.
- Sec. 402. Biomedical Advanced Research and Development Authority.
- Sec. 403. Strategic National Stockpile.
- Sec. 404. National Biodefense Science Board.

1 **TITLE I—STRENGTHENING NA-**  
2 **TIONAL PREPAREDNESS AND**  
3 **RESPONSE FOR PUBLIC**  
4 **HEALTH EMERGENCIES**

5 **SEC. 101. NATIONAL HEALTH SECURITY STRATEGY.**

6 (a) IN GENERAL.—Section 2802 of the Public Health  
7 Service Act (42 U.S.C. 300hh–1) is amended—

8 (1) in subsection (a)(1), by striking “2009” and  
9 inserting “2014”; and

10 (2) in subsection (b)—

11 (A) in paragraph (1)(A), by inserting “,  
12 including drills and exercises to ensure medical  
13 surge capacity for events without notice” after  
14 “exercises”; and

15 (B) in paragraph (3)—

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

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

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

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

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

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

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

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

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

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

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

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

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

4           (C) in paragraph (4)—

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

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

13          “(7) COUNTERMEASURES.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 (1) in subsection (b)—

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11                  “(C) the Cities Readiness Initiative; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

11          “(K) be made publicly available.

12          “(3) GAO REPORT.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 “(d) MEMBERSHIP.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15 “(f) SUNSET.—The Advisory Committee shall termi-  
16 nate on the date that is 5 years after the date of enact-  
17 ment of the Pandemic and All-Hazards Preparedness Re-  
18 authorization Act of 2012.”.

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

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

23 (1) in subsection (a)(3)—

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



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

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

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

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

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

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

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

3 Section 8117(g) of title 38, United States Code, is  
4 amended by striking “such sums as may be necessary to  
5 carry out this section for each of fiscal years 2007 through  
6 2011” and inserting “\$155,300,000 for each of fiscal  
7 years 2013 through 2017 to carry out this section”.

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

12 **SEC. 201. TEMPORARY REDEPLOYMENT OF FEDERALLY**  
13 **FUNDED PERSONNEL DURING A PUBLIC**  
14 **HEALTH EMERGENCY.**

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

18 “(e) TEMPORARY REDEPLOYMENT OF FEDERALLY  
19 FUNDED PERSONNEL DURING A PUBLIC HEALTH EMER-  
20 GENCY.—

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

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

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

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

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

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

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

6           “(iii) An assurance that the requested  
7 temporary redeployment of personnel is  
8 consistent with the any applicable All-Haz-  
9 ards Public Health Emergency Prepared-  
10 ness and Response Plan under section  
11 319C–1.

12           “(iv) An identification of—

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

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

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

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

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

3 “(D) TERMINATION AND EXTENSION.—

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

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

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

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

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

1 for a temporary redeployment of per-  
2 sonnel submits a request for an exten-  
3 sion of such authority; and

4 “(II) the request for an extension  
5 contains the same type of information  
6 and assurances necessary for the ap-  
7 proval of an initial request for such  
8 authority.

9 “(3) NOTICE TO PERSONNEL OF POSSIBILITY  
10 OF REDEPLOYMENT.—The Secretary shall ensure  
11 that, if a State or tribe receives Federal funds for  
12 personnel who are subject to the Secretary’s rede-  
13 ployment authority under this subsection, the State  
14 or tribe gives notice to such personnel of the possi-  
15 bility of redeployment—

16 “(A) at the time of hiring; or

17 “(B) in the case of personnel hired before  
18 the date of the enactment of this subsection, as  
19 soon as practicable.

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

23 “(A) any initial request for authority for a  
24 temporary redeployment of personnel; and

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

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

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

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

11           “(6) REPORT TO CONGRESS.—Not later than 4  
12 years after the date of enactment of the Pandemic  
13 and All-Hazards Preparedness Reauthorization Act  
14 of 2012, the Comptroller General of the United  
15 States shall conduct an independent evaluation, and  
16 submit to the appropriate committees of the Con-  
17 gress a report, on the Secretary’s authority under  
18 this subsection, including—

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

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

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

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

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

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

16          “(8) SUNSET.—The authority under this sub-  
17          section shall terminate on the date that is 5 years  
18          after the date of enactment of the Pandemic and  
19          All-Hazards Preparedness Reauthorization Act of  
20          2012.”.

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

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



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

4           (2) in subsection (b)(2)—

5                 (A) in subparagraph (A)—

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

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

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

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

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

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

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

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

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

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

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

13 (3) in subsection (f)—

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

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

18 (C) by striking paragraph (4);

19 (4) in subsection (g)—

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

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

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

3 (B) in paragraph (2)(A), by adding at the  
4 end the following: “The Secretary shall periodically  
5 update, as necessary and appropriate,  
6 such pandemic influenza plan criteria and shall  
7 require the integration of such criteria into the  
8 benchmarks and standards described in paragraph  
9 (1).”;

10 (5) by striking subsection (h);

11 (6) in subsection (i)—

12 (A) in paragraph (1)—

13 (i) in subparagraph (A)—

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

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

25 (ii) by striking subparagraph (B);

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

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

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

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

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

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

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

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

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

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

5 (b) VACCINE TRACKING AND DISTRIBUTION.—Sec-  
6 tion 319A(e) of the Public Health Service Act (42 U.S.C.  
7 247d–1(e)) is amended by striking “such sums for each  
8 of fiscal years 2007 through 2011” and inserting  
9 “\$30,800,000 for each of fiscal years 2013 through  
10 2017”.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16 “(g) COORDINATION.—

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

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



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

8 (5) in subsection (i)—

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

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

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

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

20 (6) in subsection (j)—

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

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

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

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

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

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

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

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

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

24                (1) in subsection (b)—

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

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

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

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

13 (3) in subsection (d)—

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

19 (B) in paragraph (1)—

20 (i) by striking “Pandemic and All-  
21 Hazards Preparedness Act” and inserting  
22 “Pandemic and All-Hazards Preparedness  
23 Reauthorization Act of 2012”; and

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

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

3 “(2) STRATEGY AND IMPLEMENTATION  
4 PLAN.—Not later than 180 days after the date of  
5 enactment of the Pandemic and All-Hazards Pre-  
6 paredness Reauthorization Act of 2012, the Sec-  
7 retary shall submit to the appropriate committees of  
8 Congress a coordinated strategy and an accom-  
9 panying implementation plan that identifies and  
10 demonstrates the measurable steps the Secretary will  
11 carry out to—

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

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

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

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

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

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

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

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

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

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

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

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

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

1 and All-Hazards Preparedness Reauthorization Act  
2 of 2012”;

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

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

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

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

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

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

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

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

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

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

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

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

14 The sponsor or applicant”.

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

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

20 (1) in subsection (a)—

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

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



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

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

9 (2) in subsection (b)—

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

14 (B) in paragraph (1)—

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

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

21 (iii) in subparagraph (B)—

22 (I) by striking “specified”; and

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

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

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

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

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

19 (C) in paragraph (2)—

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

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

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

2 (iii) by redesignating subparagraph

3 (C) as subparagraph (B);

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

5 notice of termination, and renewal under this

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

7 tice of termination under this subsection.”; and

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

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

19 (3) in subsection (c)—

20 (A) in the matter preceding paragraph

21 (1)—

22 (i) by inserting “the Assistant Sec-

23 retary for Preparedness and Response,”

24 after “consultation with”;

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

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

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

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

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

17 (5) in subsection (e)—

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

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

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

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

6           (C) in paragraph (2)—

7                 (i) in subparagraph (A)—

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

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

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

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

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

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

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

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

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

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

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

3           “(C) requirements established under sec-  
4           tion 520(e).”;

5           (6) in subsection (g)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

6 “(a) DEFINITIONS.—In this section:

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

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

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

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

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

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

1 of Homeland Security, the Secretary of  
2 Defense, or the Secretary, respectively; or

3 “(ii) the identification of a material  
4 threat described in subparagraph (D) of  
5 section 564(b)(1) has been made pursuant  
6 to section 319F–2 of the Public Health  
7 Service Act.

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

10 “(b) EXPIRATION DATING.—

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

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

19 “(i) the public health; or

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

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

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

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

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

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

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

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

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

10 “(c) CURRENT GOOD MANUFACTURING PRACTICE.—

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

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

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

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

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

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

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

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

24 “(e) EMERGENCY USE INSTRUCTIONS.—

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

22 **SEC. 303. DEFINITIONS.**

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

1 “(a) DEFINITIONS.—In this section—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 “(5) establish”; and

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

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

8 “(1) IN GENERAL.—Not later than 1 year after  
9 the date of the enactment of the Pandemic and All-  
10 Hazards Preparedness Reauthorization Act of 2012,  
11 the Secretary shall provide final guidance to indus-  
12 try regarding the development of animal models to  
13 support approval, clearance, or licensure of counter-  
14 measures referred to in subsection (a) when human  
15 efficacy studies are not ethical or feasible.

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

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

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

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

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

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

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

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

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

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

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

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

18 “(f) REGULATORY MANAGEMENT PLAN.—

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23 “(6) PRIORITIZATION.—

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

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

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

21 **SEC. 306. REPORT.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

19                         “(A) shall consider—

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

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

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

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

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

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

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

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

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

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

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

14 **SEC. 401. BIOSHIELD.**

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

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

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

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

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

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

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

9 (5) in paragraph (7)(C)—

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

13 (B) in clause (ii)—

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

17 (ii) by striking subclause (IX) and in-  
18 sserting the following:

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

22 “(aa) may specify—

23 “(AA) the dosing and  
24 administration requirements

1 for the countermeasure to be  
2 developed and procured;

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

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

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

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

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

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

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

9 (1) in subsection (c)—

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

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

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

17 “(g) SPECIAL RESERVE FUND.—

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

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

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

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

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



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

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

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

10 “(h) DEFINITIONS.—In this section:

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

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

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

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

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

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

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

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

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

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

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

10          (e) EXTENSION OF LIMITED ANTITRUST EXEMP-  
11          TION.—Section 405(b) of the Pandemic and All-Hazards  
12          Preparedness Act (42 U.S.C. 247d–6a note) is amended  
13          by striking “6-year” and inserting “11-year”.

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

17           “(f) INDEPENDENT EVALUATION.—

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

24           “(2) REPORT.—Not later than 1 year after the  
25           date of enactment of this subsection, the Comp-

1 troller General of the United States shall submit to  
2 the appropriate committees of Congress a report  
3 concerning the results of the evaluation conducted  
4 under paragraph (1). Such report shall review and  
5 assess—

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

10 “(B) the activities supported by flexible  
11 manufacturing initiatives; and

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

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

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

22 (g) DEFINITIONS.—

23 (1) QUALIFIED COUNTERMEASURE.—Section  
24 319F–1(a)(2)(A) of the Public Health Service Act  
25 (42 U.S.C. 247d–6a(a)(2)(A)) is amended—

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

3 (B) in clause (i)—

4 (i) by striking “diagnose” and insert-  
5 ing “to diagnose”; and

6 (ii) by striking “; or” and inserting a  
7 semicolon;

8 (C) in clause (ii)—

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

11 (ii) by striking the period at the end  
12 and inserting “; or”; and

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

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

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

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

24 (B) in clause (ii), by striking “; and” and  
25 inserting “; or”; and

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

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

6 (3) TECHNICAL AMENDMENTS.—Section 319F–  
7 3(i) of the Public Health Service Act (42 U.S.C.  
8 247d–6d(i)) is amended—

9 (A) in paragraph (1)(C), by inserting “,  
10 564A, or 564B” after “564”; and

11 (B) in paragraph (7)(B)(iii), by inserting  
12 “, 564A, or 564B” after “564”.

13 **SEC. 403. STRATEGIC NATIONAL STOCKPILE.**

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

16 (1) in subsection (a)—

17 (A) in paragraph (1)—

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

21 (ii) by inserting before the period at  
22 the end of the second sentence the fol-  
23 lowing: “and shall submit such review an-  
24 nually to the appropriate congressional  
25 committees of jurisdiction to the extent

1           that disclosure of such information does  
2           not compromise national security”; and

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

9           (2) in subsection (f)(1), by striking  
10          “\$640,000,000 for fiscal year 2002, and such sums  
11          as may be necessary for each of fiscal years 2003  
12          through 2006. Such authorization is in addition to  
13          amounts in the special reserve fund referred to in  
14          subsection (c)(10)(A).” and inserting “\$533,800,000  
15          for each of fiscal years 2013 through 2017. Such  
16          authorization is in addition to amounts in the special  
17          reserve fund referred 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  
9 State, tribal, territorial, or local public  
10 health official.”; and

11 (B) by adding at the end the following  
12 flush 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  
18 “and” 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  
2 Congress.”.

Passed the House of Representatives December 19,  
2012.

Attest:

*Clerk.*

112<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 6672

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## 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.