

112TH CONGRESS
1ST SESSION

H. R. 2405

AN ACT

To reauthorize certain provisions of the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act relating to public health preparedness and countermeasure development, 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 2011”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Reauthorization of certain provisions relating to public health preparedness.
- Sec. 3. Temporary redeployment of personnel during a public health emergency.
- Sec. 4. Coordination by Assistant Secretary for Preparedness and Response.
- Sec. 5. Eliminating duplicative Project Bioshield reports.
- Sec. 6. Authorization for medical products for use in emergencies.
- Sec. 7. Additional provisions related to medical products for emergency use.
- Sec. 8. Products held for emergency use.
- Sec. 9. Accelerate countermeasure development by strengthening FDA’s role in reviewing products for national security priorities.

7 **SEC. 2. REAUTHORIZATION OF CERTAIN PROVISIONS RE-**
8 **LATING TO PUBLIC HEALTH PREPAREDNESS.**

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

15 (b) **IMPROVING STATE AND LOCAL PUBLIC HEALTH**
16 **SECURITY.**—Effective on October 1, 2011, section 319C–
17 1 of the Public Health Service Act (42 U.S.C. 247d–3a)
18 is amended—

19 (1) in subsection (b)(2)(A)—

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

3 (B) in clause (v), by adding “and” at the
4 end; and

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

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

12 (2) in subsection (f)—

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

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

17 (C) by striking paragraph (4);

18 (3) by striking subsection (h); and

19 (4) in subsection (i)—

20 (A) in paragraph (1)—

21 (i) by amending subparagraph (A) to
22 read as follows:

23 “(A) IN GENERAL.—For the purpose of
24 carrying out this section, there is authorized to

1 be appropriated \$632,900,000 for each of fiscal
2 years 2012 through 2016.”; and

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

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

11 (1) in subsection (a), by inserting “, including
12 capacity and preparedness to address the needs of
13 pediatric and other at-risk populations” before the
14 period at the end;

15 (2) in subsection (i)—

16 (A) by striking “The requirements of” and
17 inserting the following:

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

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

20 “(2) MEETING GOALS OF NATIONAL HEALTH
21 SECURITY STRATEGY.—The Secretary shall imple-
22 ment objective, evidence-based metrics to ensure that
23 entities receiving awards under this section are
24 meeting, to the extent practicable, the goals of the

1 National Health Security Strategy under section
2 2802.”; and

3 (3) by amending subsection (j)(1) to read as
4 follows:

5 “(1) IN GENERAL.—For purposes of carrying
6 out this section, there is authorized to be appro-
7 priated \$378,000,000 for each of fiscal years 2012
8 through 2016.”.

9 (d) CDC PROGRAMS FOR COMBATING PUBLIC
10 HEALTH THREATS.—Section 319D of the Public Health
11 Service Act (42 U.S.C. 247d–4) is amended—

12 (1) by striking subsection (e); and

13 (2) in subsection (g), by striking “such sums as
14 may be necessary in each of fiscal years 2007
15 through 2011” and inserting “\$160,121,000 for
16 each of fiscal years 2012 through 2016”.

17 (e) DENTAL EMERGENCY RESPONDERS: PUBLIC
18 HEALTH AND MEDICAL RESPONSE.—

19 (1) ALL-HAZARDS PUBLIC HEALTH AND MED-
20 ICAL RESPONSE CURRICULA AND TRAINING.—Sec-
21 tion 319F(a)(5)(B) of the Public Health Service Act
22 (42 U.S.C. 247d–6(a)(5)(B)) is amended by striking
23 “public health or medical” and inserting “public
24 health, medical, or dental”.

1 (2) NATIONAL HEALTH SECURITY STRATEGY.—
2 Section 2802(b)(3) of the Public Health Service Act
3 (42 U.S.C. 300hh–1(b)(3)) is amended—

4 (A) in the matter preceding subparagraph
5 (A), by inserting “and which may include den-
6 tal health facilities” after “mental health facili-
7 ties”; and

8 (B) in subparagraph (D), by inserting
9 “(which may include dental health assets)”
10 after “medical assets”.

11 (f) PROCUREMENT OF COUNTERMEASURES.—

12 (1) CONTRACT TERMS.—Subclause (IX) of sec-
13 tion 319F–2(c)(7)(C)(ii) of the Public Health Serv-
14 ice Act (42 U.S.C. 247d–6b(c)(7)(C)(ii)) is amended
15 to read as follows:

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

19 “(aa) may specify—

20 “(AA) the dosing and
21 administration requirements
22 for countermeasures to be
23 developed and procured;

24 “(BB) the amount of
25 funding that will be dedi-

1 cated by the Secretary for
2 development and acquisition
3 of the countermeasure; and

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

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

14 (2) REAUTHORIZATION OF THE SPECIAL RE-
15 SERVE FUND.—Section 319F–2 of the Public Health
16 Service Act (42 U.S.C. 247d–6b) is amended—

17 (A) in subsection (c)—

18 (i) by striking “special reserve fund
19 under paragraph (10)” each place it ap-
20 pears and inserting “special reserve fund
21 as defined in subsection (g)(5)”; and

22 (ii) by striking paragraphs (9) and
23 (10); and

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

25 “(g) SPECIAL RESERVE FUND.—

1 “(1) AUTHORIZATION OF APPROPRIATIONS.—In
2 addition to amounts appropriated to the special re-
3 serve fund prior to the date of the enactment of this
4 subsection, there is authorized to be appropriated,
5 for the procurement of security countermeasures
6 under subsection (c) and for carrying out section
7 319L (relating to the Biomedical Advanced Research
8 and Development Authority), \$2,800,000,000 for the
9 period of fiscal years 2014 through 2018. Amounts
10 appropriated pursuant to the preceding sentence are
11 authorized to remain available until September 30,
12 2019.

13 “(2) NOTICE OF INSUFFICIENT FUNDS.—Not
14 later than 15 days after any date on which the Sec-
15 retary determines that the amount of funds in the
16 special reserve fund available for procurement is less
17 than \$1,500,000,000, the Secretary shall submit to
18 the Committee on Energy and Commerce of the
19 House of Representatives and the Committee on
20 Health, Education, Labor, and Pensions of the Sen-
21 ate a report detailing the amount of such funds
22 available for procurement and the impact such fund-
23 ing will have—

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

1 “(B) on the annual Countermeasure Imple-
2 mentation Plan under section 2811(d).

3 “(3) USE OF SPECIAL RESERVE FUND FOR AD-
4 VANCED RESEARCH AND DEVELOPMENT.—The Sec-
5 retary may utilize not more than 30 percent of the
6 amounts authorized to be appropriated under para-
7 graph (1) to carry out section 319L (related to the
8 Biomedical Advanced Research and Development
9 Authority). Amounts authorized to be appropriated
10 under this subsection to carry out section 319L are
11 in addition to amounts otherwise authorized to be
12 appropriated to carry out such section.

13 “(4) RESTRICTIONS ON USE OF FUNDS.—
14 Amounts in the special reserve fund shall not be
15 used to pay—

16 “(A) costs other than payments made by
17 the Secretary to a vendor for advanced develop-
18 ment (under section 319L) or for procurement
19 of a security countermeasure under subsection
20 (c)(7); and

21 “(B) any administrative expenses, includ-
22 ing salaries.

23 “(5) DEFINITION.—In this section, the term
24 ‘special reserve fund’ means the ‘Biodefense Coun-
25 termeasures’ appropriations account, any appropria-

1 tion made available pursuant to section 521(a) of
2 the Homeland Security Act of 2002, and any appro-
3 priation made available pursuant to paragraph (1) of
4 this paragraph.”.

5 (g) EMERGENCY SYSTEM FOR ADVANCE REGISTRA-
6 TION OF VOLUNTEER HEALTH PROFESSIONALS.—Section
7 319I(k) of the Public Health Service Act (42 U.S.C.
8 247d–7b(k)) is amended by striking “are authorized to be
9 appropriated \$2,000,000 for fiscal year 2002, and such
10 sums as may be necessary for each of the fiscal years 2003
11 through 2011” and inserting “is authorized to be appro-
12 priated \$5,900,000 for each of fiscal years 2012 through
13 2016”.

14 (h) BIOMEDICAL ADVANCED RESEARCH AND DEVEL-
15 OPMENT AUTHORITY.—

16 (1) TRANSACTION AUTHORITIES.—Section
17 319L(c)(5) of the Public Health Service Act (42
18 U.S.C. 247d–7e(c)(5)) is amended by adding at the
19 end the following:

20 “(G) GOVERNMENT PURPOSE.—In award-
21 ing contracts, grants, and cooperative agree-
22 ments under this section, the Secretary shall
23 provide a clear statement of defined Govern-
24 ment purpose related to activities included in
25 subsection (a)(6)(B) for a qualified counter-

1 measure or qualified pandemic or epidemic
2 product.”.

3 (2) BIODEFENSE MEDICAL COUNTERMEASURE
4 DEVELOPMENT FUND.—Paragraph (2) of section
5 319L(d) of the Public Health Service Act (42 U.S.C.
6 247d–7e(d)) is amended to read as follows:

7 “(2) FUNDING.—To carry out the purposes of
8 this section, there is authorized to be appropriated
9 to the Fund \$415,000,000 for each of fiscal years
10 2012 through 2016, the amounts to remain available
11 until expended.”.

12 (3) CONTINUED INAPPLICABILITY OF CERTAIN
13 PROVISIONS.—Section 319L(e)(1)(C) of the Public
14 Health Service Act (42 U.S.C. 247d–7e(e)(1)(C)) is
15 amended by striking “the date that is 7 years after
16 the date of enactment of the Pandemic and All-Haz-
17 ards Preparedness Act” and inserting “September
18 30, 2016”.

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

22 (1) in subsection (a)(3), by adding at the end
23 the following:

24 “(D) ADMINISTRATION.—The Secretary
25 may determine and pay claims for reimburse-

1 ment for services under subparagraph (A) di-
2 rectly or by contract providing for payment in
3 advance or by way of reimbursement.”; and

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

8 (j) NATIONAL HEALTH SECURITY STRATEGY
9 TIMELINE.—Section 2802(a)(1) of the Public Health
10 Service Act (42 U.S.C. 300hh–1(a)(1)) is amended by
11 striking “2009” and inserting “2014”.

12 (k) ENHANCING SURGE CAPACITY.—Section 2802(b)
13 of the Public Health Service Act (42 U.S.C. 300hh–
14 1(b)(3)) is amended—

15 (1) in paragraph (1)(A), by inserting “, includ-
16 ing drills and exercises to ensure medical surge ca-
17 pacity for events without notice” after “exercises”;
18 and

19 (2) in paragraph (3)—

20 (A) in the matter preceding subparagraph
21 (A), as amended by subsection (e)(2) of this
22 section—

23 (i) by inserting “availability, coordina-
24 tion, accessibility,” after “response capa-
25 bilities,”;

1 (ii) by striking “including mental
2 health facilities” and inserting “including
3 mental health and ambulatory care facili-
4 ties”; and

5 (iii) by striking “trauma care and
6 emergency medical service systems” and
7 inserting “trauma care, critical care, and
8 emergency medical service systems”; and

9 (B) in subparagraph (B), by striking
10 “Medical evacuation and fatality management”
11 and inserting “Fatality management, and co-
12 ordinated medical triage and evacuation to the
13 appropriate medical institution based on patient
14 medical need as part of regional systems”.

15 (l) VOLUNTEER MEDICAL RESERVE CORPS.—Section
16 2813(i) of the Public Health Service Act (42 U.S.C.
17 300hh–15(i)) is amended by striking “\$22,000,000 for fis-
18 cal year 2007, and such sums as may be necessary for
19 each of fiscal years 2008 through 2011” and inserting
20 “\$11,900,000 for each of fiscal years 2012 through
21 2016”.

22 (m) EXTENSION OF LIMITED ANTITRUST EXEMP-
23 TION.—Section 405(b) of the Pandemic and All-Hazard
24 Preparedness Act (42 U.S.C. 247d–6a note) is amended
25 by striking “at the end of the 6-year period that begins

1 on the date of enactment of this Act” and inserting “on
2 September 30, 2016”.

3 **SEC. 3. TEMPORARY REDEPLOYMENT OF PERSONNEL DUR-**
4 **ING A PUBLIC HEALTH EMERGENCY.**

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

8 “(e) TEMPORARY REDEPLOYMENT OF PERSONNEL
9 DURING A PUBLIC HEALTH EMERGENCY.—

10 “(1) EMERGENCY REDEPLOYMENT OF FEDER-
11 ALLY FUNDED PERSONNEL.—Notwithstanding any
12 other provision of law, and subject to paragraph (2),
13 upon a request that is from a State, locality, terri-
14 tory, tribe, or the Freely Associated States and that
15 includes such information and assurances as the
16 Secretary may require, the Secretary may authorize
17 the requesting entity to temporarily redeploy to im-
18 mediately address a public health emergency non-
19 Federal personnel funded in whole or in part
20 through—

21 “(A) any program under this Act; or

22 “(B) at the discretion of the Secretary,
23 any other program funded in whole or in part
24 by the Department of Health and Human Serv-
25 ices.

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

3 “(A) PUBLIC HEALTH EMERGENCY.—The
4 Secretary may exercise the authority vested by
5 paragraph (1) only during the period of a pub-
6 lic health emergency determined pursuant to
7 subsection (a).

8 “(B) CONSIDERATIONS.—In authorizing a
9 temporary redeployment under paragraph (1),
10 the Secretary shall consider each of the fol-
11 lowing:

12 “(i) The degree to which the emer-
13 gency cannot be adequately and appro-
14 priately addressed by the public health
15 workforce.

16 “(ii) The degree to which the emer-
17 gency requires or would otherwise benefit
18 from supplemental staffing from those
19 funded through nonpreparedness Federal
20 programs.

21 “(iii) The degree to which such pro-
22 grams would be adversely affected by the
23 redeployment.

24 “(iv) Such other factors as the Sec-
25 retary may deem appropriate.

1 “(C) TERMINATION AND EXTENSION.—

2 “(i) TERMINATION.—The authority to
3 authorize a temporary redeployment of
4 personnel under paragraph (1) shall termi-
5 nate upon the earlier of the following:

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

9 “(II) Subject to clause (ii), 30
10 days after the activation of the Sec-
11 retary’s authority pursuant to sub-
12 paragraph (A).

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

20 “(I) the extension is requested by
21 the entity that requested authority to
22 authorize a temporary redeployment;
23 and

1 “(II) the Secretary gives notice
2 to the Congress in conjunction with
3 the extension.”.

4 **SEC. 4. COORDINATION BY ASSISTANT SECRETARY FOR**
5 **PREPAREDNESS AND RESPONSE.**

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

8 (1) in subsection (b)(3)—

9 (A) by inserting “stockpiling, distribution,”
10 before “and procurement”; and

11 (B) by inserting “, security measures (as
12 defined in section 319F–2,” after “qualified
13 countermeasures (as defined in section 319F–
14 1)”;

15 (2) in subsection (b)(4), by adding at the end
16 the following:

17 “(D) IDENTIFICATION OF INEFFICIEN-
18 CIES.—Identify gaps, duplication, and other in-
19 efficiencies in public health preparedness activi-
20 ties and the actions necessary to overcome these
21 obstacles.

22 “(E) DEVELOPMENT OF COUNTER-
23 MEASURE IMPLEMENTATION PLAN.—Lead the
24 development of a coordinated Countermeasure
25 Implementation Plan under subsection (d).

1 “(F) COUNTERMEASURES BUDGET ANAL-
2 YSIS.—Oversee the development of a com-
3 prehensive, cross-cutting 5-year budget analysis
4 with respect to activities described in paragraph
5 (3)—

6 “(i) to inform prioritization of re-
7 sources; and

8 “(ii) to ensure that challenges to such
9 activities are adequately addressed.

10 “(G) GRANT PROGRAMS FOR MEDICAL AND
11 PUBLIC HEALTH PREPAREDNESS CAPABILI-
12 TIES.—Coordinate, in consultation with the
13 Secretary of Homeland Security, grant pro-
14 grams of the Department of Health and
15 Human Services relating to medical and public
16 health preparedness capabilities and the activi-
17 ties of local communities to respond to public
18 health emergencies, including the—

19 “(i) coordination of relevant program
20 requirements, timelines, and measurable
21 goals of such grant programs; and

22 “(ii) establishment of a system for
23 gathering and disseminating best practices
24 among grant recipients.”;

1 (3) by amending subsection (c) to read as fol-
2 lows:

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

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

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

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

13 “(B) the Hospital Preparedness Coopera-
14 tive Agreement Program pursuant to section
15 319C-2;

16 “(C) the Biomedical Advanced Research
17 and Development Authority under section
18 319L; and

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

22 “(3) provide policy coordination and oversight
23 of—

24 “(A) the Strategic National Stockpile
25 under section 319F-2;

1 “(B) the Cities Readiness Initiative; and

2 “(C) the Medical Reserve Corps pursuant

3 to section 2813; and

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

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

7 “(d) COUNTERMEASURE IMPLEMENTATION PLAN.—

8 Not later than 6 months after the date of enactment of

9 this subsection, and annually thereafter, the Assistant

10 Secretary for Preparedness and Response shall submit

11 through the Secretary to the Committee on Energy and

12 Commerce of the House of Representatives and the Com-

13 mittee on Health, Education, Labor, and Pensions of the

14 Senate a Countermeasure Implementation Plan that—

15 “(1) describes the chemical, biological, radio-

16 logical, and nuclear threats facing the Nation and

17 the corresponding efforts to develop qualified coun-

18 termeasures (as defined in section 319F–1), security

19 countermeasures (as defined in section 319F–2), or

20 qualified pandemic or epidemic products (as defined

21 in section 319F–3) for each threat;

22 “(2) evaluates the progress of all activities with

23 respect to such countermeasures or products, includ-

24 ing research, advanced research, development, pro-

25 curement, stockpiling, deployment, and utilization;

1 “(3) identifies and prioritizes near-, mid-, and
2 long-term needs with respect to such counter-
3 measures or products to address chemical, biological,
4 radiological, and nuclear threats;

5 “(4) identifies, with respect to each category of
6 threat, a summary of all advanced development and
7 procurement awards, including—

8 “(A) the time elapsed from the issuance of
9 the initial solicitation or request for a proposal
10 to the adjudication (such as the award, denial
11 of award, or solicitation termination);

12 “(B) projected timelines for development
13 and procurement of such countermeasures or
14 products;

15 “(C) clearly defined goals, benchmarks,
16 and milestones for each such countermeasure or
17 product, including information on the number
18 of doses required, the intended use of the coun-
19 termeasure or product, and the required coun-
20 termeasure or product characteristics; and

21 “(D) projected needs with regard to the re-
22 plenishment of the Strategic National Stockpile;

23 “(5) evaluates progress made in meeting the
24 goals, benchmarks, and milestones identified under
25 paragraph (4)(C);

1 “(6) reports on the amount of funds available
2 for procurement in the special reserve fund as de-
3 fined in section 319F-2(g)(5) and the impact this
4 funding will have on meeting the requirements under
5 section 319F-2;

6 “(7) incorporates input from Federal, State,
7 local, and tribal stakeholders; and

8 “(8) addresses the needs of pediatric popu-
9 lations with respect to such countermeasures and
10 products in the Strategic National Stockpile and in-
11 cludes—

12 “(A) a list of such countermeasures and
13 products necessary to address the needs of pedi-
14 atric populations;

15 “(B) a description of measures taken to
16 coordinate with Office of Pediatric Therapeutics
17 of the Food and Drug Administration to maxi-
18 mize the labeling, dosages, and formulations of
19 such countermeasures and products for pedi-
20 atric populations;

21 “(C) a description of existing gaps in the
22 Strategic National Stockpile and the develop-
23 ment of such countermeasures and products to
24 address the needs of pediatric populations; and

1 “(D) an evaluation of the progress made in
2 addressing gaps identified pursuant to subpara-
3 graph (C).

4 Notwithstanding any other provision of this subsection,
5 the Plan shall not include any confidential commercial in-
6 formation, proprietary information, or information that
7 could reveal vulnerabilities of the Nation in the prepara-
8 tion for or ability to respond to chemical, biological, radio-
9 logical, or nuclear threats.”.

10 (b) CONSULTATION IN AUTHORIZING MEDICAL
11 PRODUCTS FOR USE IN EMERGENCIES.—Subsection (c)
12 of section 564 of the Federal Food, Drug, and Cosmetic
13 Act (21 U.S.C. 360bbb–3) is amended by striking “con-
14 sultation with the Director of the National Institutes of
15 Health” and inserting “consultation with the Assistant
16 Secretary for Preparedness and Response, the Director of
17 the National Institutes of Health,”.

18 (c) BIOSURVEILLANCE PLAN.—Not later than one
19 year after the date of the enactment of this Act, the Sec-
20 retary of Health and Human Services shall prepare and
21 submit to the Committee on Energy and Commerce of the
22 House of Representatives and the Committee on Health,
23 Education, Labor, and Pensions of the Senate a plan to
24 improve information sharing, coordination, and commu-

1 nications among disparate biosurveillance systems sup-
2 ported by the Department of Health and Human Services.

3 **SEC. 5. ELIMINATING DUPLICATIVE PROJECT BIOSHIELD**
4 **REPORTS.**

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

7 **SEC. 6. AUTHORIZATION FOR MEDICAL PRODUCTS FOR**
8 **USE IN EMERGENCIES.**

9 Section 564 of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 360bbb–3) is amended—

11 (1) in subsection (a)—

12 (A) in paragraph (1), by striking “sections
13 505, 510(k), and 515 of this Act” and inserting
14 “any provision of this Act”;

15 (B) in paragraph (2)(A), by striking
16 “under a provision of law referred to in such
17 paragraph” and inserting “under a provision of
18 law in section 505, 510(k), or 515 of this Act
19 or section 351 of the Public Health Service
20 Act”; and

21 (C) in paragraph (3), by striking “a provi-
22 sion of law referred to in such paragraph” and
23 inserting “a provision of law referred to in
24 paragraph (2)(A)”;

25 (2) in subsection (b)—

1 (A) in the subsection heading, by striking
2 “DECLARATION OF EMERGENCY” and inserting
3 “DECLARATION SUPPORTING EMERGENCY USE
4 AUTHORIZATION”;

5 (B) in paragraph (1)—

6 (i) in the matter preceding subpara-
7 graph (A), by striking “an emergency jus-
8 tifying” and inserting “that circumstances
9 exist justifying”;

10 (ii) in subparagraph (A), by striking
11 “specified”;

12 (iii) in subparagraph (B), by striking
13 “specified”; and

14 (iv) by amending subparagraph (C) to
15 read as follows:

16 “(C) a determination by the Secretary that
17 there is a public health emergency, or a signifi-
18 cant potential for a public health emergency, in-
19 volving a heightened risk to national security or
20 the health and security of United States citi-
21 zens abroad, and involving a biological, chem-
22 ical, radiological, or nuclear agent or agents, or
23 a disease or condition that may be attributable
24 to such agent or agents.”;

25 (C) in paragraph (2)—

1 (i) by amending subparagraph (A) to
2 read as follows:

3 “(A) IN GENERAL.—A declaration under
4 this subsection shall terminate upon a deter-
5 mination by the Secretary, in consultation with,
6 as appropriate, the Secretary of Homeland Se-
7 curity or the Secretary of Defense, that the cir-
8 cumstances described in paragraph (1) have
9 ceased to exist.”;

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

11 (iii) by redesignating subparagraph
12 (C) as subparagraph (B); and

13 (D) in paragraph (4), by striking “advance
14 notice of termination, and renewal” and insert-
15 ing “and advance notice of termination”;

16 (3) in subsection (c)(1), by striking “specified
17 in” and insert “covered by”;

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

21 (5) in subsection (e)—

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

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

1 formation concerning the safety and effec-
2 tiveness of the product with respect to the
3 actual use of such product pursuant to an
4 authorization under this section.”;

5 (B) in paragraph (2)—

6 (i) in subparagraph (A)—

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

10 (II) by inserting “or in para-
11 graph (1)(B)” before the period at the
12 end;

13 (ii) in subparagraph (B)(i), by insert-
14 ing “, with the exception of extensions of
15 a product’s expiration date authorized
16 under section 564A(b)” before the period
17 at the end; and

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

20 “(C) In establishing conditions under this
21 paragraph with respect to the distribution and
22 administration of a product, the Secretary shall
23 not impose conditions that would restrict dis-
24 tribution or administration of the product that
25 is solely for the approved uses.”;

1 (C) by amending paragraph (3) to read as
2 follows:

3 “(3) GOOD MANUFACTURING PRACTICE; PRE-
4 SCRIPTION; PRACTITIONER’S AUTHORIZATION.—With
5 respect to the emergency use of a product for which
6 an authorization under this section is issued (wheth-
7 er for an unapproved product or an unapproved use
8 of an approved product), the Secretary may waive or
9 limit, to the extent appropriate given the cir-
10 cumstances of the emergency—

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

20 “(B) requirements established under sec-
21 tion 503(b); and

22 “(C) requirements established under sec-
23 tion 520(e).”; and

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

1 “(5) EXISTING AUTHORITIES.—Nothing in this
2 section restricts any authority vested in the Sec-
3 retary by any other provision of this Act or the Pub-
4 lic Health Service Act for establishing conditions of
5 authorization for a product.”; and

6 (6) in subsection (g)—

7 (A) in the heading, by striking “REVOCA-
8 TION OF AUTHORIZATION” and inserting “RE-
9 VIEW, MODIFICATION, AND REVOCATION OF
10 AUTHORIZATION”;

11 (B) in paragraph (1), by striking “periodi-
12 cally review” and inserting “review not less
13 than every three years”; and

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

15 “(3) MODIFICATION.—The Secretary may mod-
16 ify an authorization under this section or the condi-
17 tions of such an authorization, at any time, based on
18 a review of the authorization or new information
19 that is otherwise obtained, including information ob-
20 tained during an emergency.”.

21 **SEC. 7. ADDITIONAL PROVISIONS RELATED TO MEDICAL**
22 **PRODUCTS FOR EMERGENCY USE.**

23 (a) IN GENERAL.—The Federal Food, Drug, and
24 Cosmetic Act is amended by inserting after section 564
25 (21 U.S.C. 360bbb–3) the following:

1 **“SEC. 564A. ADDITIONAL PROVISIONS RELATED TO MED-**
2 **ICAL PRODUCTS FOR EMERGENCY USE.**

3 “(a) DEFINITIONS.—For purposes of this section:

4 “(1) The term ‘product’ means a drug, device,
5 or biological product.

6 “(2) The term ‘eligible product’ means a prod-
7 uct that is—

8 “(A) approved or cleared under this chap-
9 ter or licensed under section 351 of the Public
10 Health Service Act; and

11 “(B) intended to be used to diagnose, pre-
12 vent, or treat a disease or condition involving a
13 biological, chemical, radiological, or nuclear
14 agent or agents during—

15 “(i) a domestic emergency or military
16 emergency involving heightened risk of at-
17 tack with such an agent or agents; or

18 “(ii) a public health emergency affect-
19 ing national security or the health and se-
20 curity of United States citizens abroad.

21 “(b) EXPIRATION DATING.—

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

1 “(A) the eligible product is intended to be
2 held for use for a domestic, military, or public
3 health emergency described in subsection
4 (a)(2)(B);

5 “(B) the expiration date extension is in-
6 tended to support the United States’ ability to
7 protect—

8 “(i) the public health; or

9 “(ii) military preparedness and effec-
10 tiveness; and

11 “(C) the expiration date extension is sup-
12 ported by an appropriate scientific evaluation
13 that is conducted or accepted by the Secretary.

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

17 “(A) each specific lot, batch, or other unit
18 of the product for which extended expiration is
19 authorized;

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

21 “(C) any other requirements or conditions
22 as the Secretary may deem appropriate for the
23 protection of the public health, which may in-
24 clude requirements for, or conditions on, prod-
25 uct sampling, storage, packaging or repack-

1 aging, transport, labeling, notice to product re-
2 ipients, recordkeeping, periodic testing or re-
3 testing, or product disposition.

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

15 “(c) CURRENT GOOD MANUFACTURING PRAC-
16 TICES.—

17 “(1) IN GENERAL.—The Secretary may, when
18 the circumstances of a domestic, military, or public
19 health emergency described in subsection (a)(2)(B)
20 so warrant, authorize, with respect to an eligible
21 product, deviations from current good manufac-
22 turing practice requirements otherwise applicable to
23 the manufacture, processing, packing, or holding of
24 products subject to regulation under this Act, in-
25 cluding requirements under section 501 or 520(f)(1)

1 or applicable conditions prescribed with respect to
2 the eligible product by an order under section
3 520(f)(2).

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

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

20 “(1) the product is dispensed during an actual
21 emergency described in subsection (a)(2)(B); and

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

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

1 “(B) in accordance with an order issued by
2 the Secretary.

3 “(e) EMERGENCY USE INSTRUCTIONS.—

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

12 “(2) EFFECT.—Notwithstanding any other pro-
13 visions of this Act or the Public Health Service Act,
14 a product shall not be considered an unapproved
15 product (as defined in section 564(a)(2)(A)) and
16 shall not be deemed adulterated or misbranded
17 under this Act because of—

18 “(A) the issuance of emergency use in-
19 structions under paragraph (1) with respect to
20 such product; or

21 “(B) the introduction or delivery for intro-
22 duction of such product into interstate com-
23 merce accompanied by such instructions during
24 an emergency response to an actual emergency
25 described in subsection (a)(2)(B).”.

1 (b) 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, an actual or potential domestic emergency or military
15 emergency involving heightened risk of attack with a bio-
16 logical, chemical, radiological, or nuclear agent, or an ac-
17 tual or potential public health emergency affecting na-
18 tional security or the health and security of United States
19 citizens abroad.”.

20 **SEC. 8. PRODUCTS HELD FOR EMERGENCY USE.**

21 The Federal Food, Drug, and Cosmetic Act (21
22 U.S.C. 301 et seq.) is amended by inserting after section
23 564A, as added by section 7, the following:

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

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

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

10 “(2) is held and not used, unless and until that
11 product—

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

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

18 “(C) is authorized for use under section
19 564.”.

20 **SEC. 9. ACCELERATE COUNTERMEASURE DEVELOPMENT**
21 **BY STRENGTHENING FDA’S ROLE IN REVIEW-**
22 **ING PRODUCTS FOR NATIONAL SECURITY**
23 **PRIORITIES.**

24 (a) IN GENERAL.—Section 565 of the Federal Food,
25 Drug, and Cosmetic Act (21 U.S.C. 360bbb–4) is amend-
26 ed to read as follows:

1 **“SEC. 565. COUNTERMEASURE DEVELOPMENT AND RE-**
2 **VIEW.**

3 “(a) COUNTERMEASURES AND PRODUCTS.—The
4 countermeasures and products referred to in this sub-
5 section are—

6 “(1) qualified countermeasures (as defined in
7 section 319F–1 of the Public Health Service Act);

8 “(2) security countermeasures (as defined in
9 section 319F–2 of such Act); and

10 “(3) qualified pandemic or epidemic products
11 (as defined in section 319F–3 of such Act) that the
12 Secretary determines to be a priority.

13 “(b) IN GENERAL.—

14 “(1) INVOLVEMENT OF FDA PERSONNEL IN
15 INTERAGENCY ACTIVITIES.—For the purpose of ac-
16 celerating the development, stockpiling, approval,
17 clearance, and licensure of countermeasures and
18 products referred to in subsection (a), the Secretary
19 shall expand the involvement of Food and Drug Ad-
20 ministration personnel in interagency activities with
21 the Assistant Secretary for Preparedness and Re-
22 sponse (including the Biomedical Advanced Research
23 and Development Authority), the Centers for Dis-
24 ease Control and Prevention, the National Institutes
25 of Health, and the Department of Defense.

1 “(2) TECHNICAL ASSISTANCE.—The Secretary
2 shall establish within the Food and Drug Adminis-
3 tration a team of experts on manufacturing and reg-
4 ulatory activities (including compliance with current
5 Good Manufacturing Practices) to provide both off-
6 site and on-site technical assistance to the manufac-
7 turers of countermeasures and products referred to
8 in subsection (a). On-site technical assistance shall
9 be provided upon the request of the manufacturer
10 and at the discretion of the Secretary if the Sec-
11 retary determines that the provision of such assist-
12 ance would accelerate the development, manufac-
13 turing, or approval, clearance, or licensure of coun-
14 termeasures and products referred to in subsection
15 (a).

16 “(c) AGENCY INTERACTION WITH SECURITY COUN-
17 TERMEASURE SPONSORS.—

18 “(1) IN GENERAL.—For security counter-
19 measures (as defined in section 319F-2 of the Pub-
20 lic Health Service Act) that are procured under such
21 section 319F-2—

22 “(A) the Secretary shall establish a process
23 for frequent scientific feedback and interactions
24 between the Food and Drug Administration and
25 the security countermeasure sponsor (referred

1 to in this subsection as the ‘sponsor’), designed
2 to facilitate the approval, clearance, and licen-
3 sure of the security countermeasures;

4 “(B) such feedback and interactions shall
5 include meetings and, in accordance with sub-
6 section (b)(2), on-site technical assistance; and

7 “(C) at the request of the Secretary, the
8 process under this paragraph shall include par-
9 ticipation by the Food and Drug Administration
10 in meetings between the Biomedical Advanced
11 Research and Development Authority and spon-
12 sors on the development of such counter-
13 measures.

14 “(2) REGULATORY MANAGEMENT PLAN.—

15 “(A) IN GENERAL.—The process estab-
16 lished under paragraph (1) shall allow for the
17 development of a written regulatory manage-
18 ment plan (in this paragraph referred to as the
19 ‘plan’) for a security countermeasure (as de-
20 fined in paragraph (1)) in accordance with this
21 paragraph.

22 “(B) PROPOSAL AND FINALIZATION OF
23 PLAN.—In carrying out the process under para-
24 graph (1), the Secretary shall direct the Food
25 and Drug Administration, upon submission of a

1 written request by the sponsor that includes a
2 proposed plan and relevant data and future
3 planning detail to support such a plan, to work
4 with the sponsor to agree on a final plan within
5 a reasonable time not to exceed 90 days. The
6 basis for this agreement shall be the proposed
7 plan submitted by the sponsor. Notwithstanding
8 the preceding sentence, the Secretary shall re-
9 tain full discretion to determine the contents of
10 the final plan or to determine that no such plan
11 can be agreed upon. If the Secretary determines
12 that no final plan can be agreed upon, the Sec-
13 retary shall provide to the sponsor, in writing,
14 the scientific or regulatory rationale why such
15 agreement cannot be reached. If a final plan is
16 agreed upon, it shall be shared with the sponsor
17 in writing.

18 “(C) CONTENTS.—The plan shall include
19 an agreement on the nature of, and timelines
20 for, feedback and interactions between the
21 sponsor and the Food and Drug Administra-
22 tion, shall provide reasonable flexibility in im-
23 plementing and adjusting the agreement under
24 this paragraph as warranted during the coun-

1 termeasure development process, and shall iden-
2 tify—

3 “(i) the current regulatory status of
4 the countermeasure, an assessment of
5 known scientific gaps relevant to approval,
6 clearance, or licensure of the counter-
7 measure, and a proposed pathway to ap-
8 proval, clearance, or licensure of the coun-
9 termeasure;

10 “(ii) developmental milestones whose
11 completion will result in meetings to be
12 scheduled within a reasonable time be-
13 tween the applicable review division of the
14 Food and Drug Administration and the
15 sponsor;

16 “(iii) sponsor submissions that will re-
17 sult in written feedback from the review di-
18 vision within a reasonable time;

19 “(iv) feedback by the Food and Drug
20 Administration regarding the data required
21 to support delivery of the countermeasure
22 to the Strategic National Stockpile under
23 section 319F-2 of the Public Health Serv-
24 ice Act;

1 “(v) feedback by the Food and Drug
2 Administration regarding data required to
3 support submission of a proposed agree-
4 ment on the design and size of clinical
5 trials for review under section
6 505(b)(5)(B); and

7 “(vi) other issues that have the poten-
8 tial to delay approval, clearance, or licen-
9 sure.

10 “(D) CHANGES.—Changes to the plan
11 shall be made by subsequent agreement between
12 the Secretary and the sponsor. If after reason-
13 able attempts to negotiate changes to the plan
14 the Secretary and the sponsor are unable to fi-
15 nalize such changes, the Secretary shall provide
16 to the sponsor, in writing, the scientific or regu-
17 latory rationale why such changes are required
18 or cannot be included in the plan.

19 “(3) APPLICABILITY TO CERTAIN QUALIFIED
20 PANDEMIC OR EPIDEMIC PRODUCTS.—The Secretary
21 may, with respect to qualified pandemic or epidemic
22 products (as defined in section 319F–3 of the Public
23 Health Service Act) for which a contract for ad-
24 vanced research and development is entered into
25 under section 319L of such Act, choose to apply the

1 provisions of paragraphs (1) and (2) to the same ex-
2 tent and in the same manner as such provisions
3 apply with respect to security countermeasures.

4 “(d) FINAL GUIDANCE ON DEVELOPMENT OF ANI-
5 MAL MODELS.—

6 “(1) IN GENERAL.—Not later than 1 year after
7 the date of the enactment of the Pandemic and All-
8 Hazards Preparedness Reauthorization Act of 2011,
9 the Secretary shall provide final guidance to indus-
10 try regarding the development of animal models to
11 support approval, clearance, or licensure of counter-
12 measures and products referred to in subsection (a)
13 when human efficacy studies are not ethical or fea-
14 sible.

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

23 “(e) BIENNIAL REPORT.—Not later than January 1,
24 2013, and every 2 years thereafter, the Secretary shall
25 submit a report to the Committee on Energy and Com-

1 merce of the House of Representatives and the Committee
2 on Health, Education, Labor, and Pensions of the Senate,
3 that, with respect to the preceding 2 fiscal years, in-
4 cludes—

5 “(1) the number of full-time equivalent employ-
6 ees of the Food and Drug Administration who di-
7 rectly support the review of countermeasures and
8 products referred to in subsection (a);

9 “(2) estimates of funds obligated by the Food
10 and Drug Administration for review of such counter-
11 measures and products;

12 “(3) the number of regulatory teams at the
13 Food and Drug Administration specific to such
14 countermeasures and products and, for each such
15 team, the assigned products, classes of products, or
16 technologies;

17 “(4) the length of time between each request by
18 the sponsor of such a countermeasure or product for
19 information and the provision of such information by
20 the Food and Drug Administration;

21 “(5) the number, type, and frequency of official
22 interactions between the Food and Drug Adminis-
23 tration and—

24 “(A) sponsors of a countermeasure or
25 product referred to in subsection (a); or

1 “(B) another agency engaged in develop-
2 ment or management of portfolios for such
3 countermeasures or products, including the
4 Centers for Disease Control and Prevention, the
5 Biomedical Advanced Research and Develop-
6 ment Authority, the National Institutes of
7 Health, and the appropriate agencies of the De-
8 partment of Defense;

9 “(6) a description of other measures that, as
10 determined by the Secretary, are appropriate to de-
11 termine the efficiency of the regulatory teams de-
12 scribed in paragraph (3); and

13 “(7) the regulatory science priorities that relate
14 to countermeasures or products referred to in sub-
15 section (a) and which the Food and Drug Adminis-
16 tration is addressing and the progress made on these
17 priorities.”.

18 (b) SPECIAL PROTOCOL ASSESSMENT.—Subpara-
19 graph (B) of section 505(b)(5) of the Federal Food, Drug,
20 and Cosmetic Act (21 U.S.C. 355(b)(5)) is amended to
21 read as follows:

22 “(B)(i) The Secretary shall meet with a sponsor of
23 an investigation or an applicant for approval for a drug
24 under this subsection or section 351 of the Public Health
25 Service Act if the sponsor or applicant makes a reasonable

1 written request for a meeting for the purpose of reaching
2 agreement on the design and size of—

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

5 “(II) animal efficacy trials and any associated
6 clinical trials that in combination are intended to
7 form the primary basis of an effectiveness claim for
8 a countermeasure or product referred to in section
9 565(a) when human efficacy studies are not ethical
10 or feasible.

11 “(ii) The sponsor or applicant shall provide informa-
12 tion necessary for discussion and agreement on the design
13 and size of the clinical trials. Minutes of any such meeting
14 shall be prepared by the Secretary and made available to
15 the sponsor or applicant upon request.”.

Passed the House of Representatives December 6,
2011.

Attest:

Clerk.

112TH CONGRESS
1ST SESSION

H. R. 2405

AN ACT

To reauthorize certain provisions of the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act relating to public health preparedness and countermeasure development, and for other purposes.