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112TH CONGRESS
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H. R. 2405

[Report No. 112-286]

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.

IN THE HOUSE OF REPRESENTATIVES

JUNE 28, 2011

Mr. ROGERS of Michigan (for himself, Mrs. MYRICK, and Mr. GENE GREEN of Texas) introduced the following bill; which was referred to the Committee on Energy and Commerce

NOVEMBER 16, 2011

Additional sponsors: Mr. BURGESS and Ms. ESHOO

NOVEMBER 16, 2011

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

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

[For text of introduced bill, see copy of bill as introduced on June 28, 2011]

A BILL

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,*

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

4 (a) *SHORT TITLE.*—*This Act may be cited as the*
 5 *“Pandemic and All-Hazards Preparedness Reauthorization*
 6 *Act of 2011”.*

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

Sec. 1. Short title; table of contents.

Sec. 2. Reauthorization of certain provisions relating to public health prepared-
ness.

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 re-
viewing products for national security priorities.

9 **SEC. 2. REAUTHORIZATION OF CERTAIN PROVISIONS RE-**
 10 **LATING TO PUBLIC HEALTH PREPAREDNESS.**

11 (a) *VACCINE TRACKING AND DISTRIBUTION.*—*Sub-*
 12 *section (e) of section 319A of the Public Health Service Act*
 13 *(42 U.S.C. 247d–1) is amended by striking “such sums for*
 14 *each of fiscal years 2007 through 2011” and inserting*
 15 *“\$30,800,000 for each of fiscal years 2012 through 2016”.*

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

20 (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” at
14 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 car-
24 rying out this section, there is authorized to be

1 *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 U.S.C.*
10 *247d–3b) is amended—*

11 *(1) in subsection (a), by inserting “, including*
12 *capacity and preparedness to address the needs of pe-*
13 *diatric and other at-risk populations” before the pe-*
14 *riod 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 SE-*
21 *CURITY STRATEGY.—The Secretary shall implement*
22 *objective, evidence-based metrics to ensure that enti-*
23 *ties receiving awards under this section are meeting,*
24 *to the extent practicable, the goals of the National*
25 *Health Security Strategy under section 2802.”; and*

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

3 “(1) *IN GENERAL.*—For purposes of carrying out
4 this section, there is authorized to be appropriated
5 \$378,000,000 for each of fiscal years 2012 through
6 2016.”.

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

10 (1) by striking subsection (c); and

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

15 (e) *DENTAL EMERGENCY RESPONDERS: PUBLIC*
16 *HEALTH AND MEDICAL RESPONSE.*—

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

23 (2) *NATIONAL HEALTH SECURITY STRATEGY.*—
24 Section 2802(b)(3) of the Public Health Service Act
25 (42 U.S.C. 300hh–1(b)(3)) is amended—

1 (A) in the matter preceding subparagraph
 2 (A), by inserting “and which may include dental
 3 health facilities” after “mental health facilities”;
 4 and

5 (B) in subparagraph (D), by inserting
 6 “(which may include dental health assets)” after
 7 “medical assets”.

8 (f) *PROCUREMENT OF COUNTERMEASURES.*—

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

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

16 “(aa) may specify—

17 “(AA) the dosing and
 18 administration requirements
 19 for countermeasures to be de-
 20 veloped and procured;

21 “(BB) the amount of
 22 funding that will be dedi-
 23 cated by the Secretary for de-
 24 velopment and acquisition of
 25 the countermeasure; and

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

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

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

14 (A) in subsection (c)—

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

19 (ii) by striking paragraphs (9) and
20 (10); and

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

22 “(g) *SPECIAL RESERVE FUND.*—

23 “(1) *AUTHORIZATION OF APPROPRIATIONS.*—In
24 addition to amounts appropriated to the special re-
25 serve fund prior to the date of the enactment of this

1 subsection, there is authorized to be appropriated, for
2 the procurement of security countermeasures under
3 subsection (c) and for carrying out section 319L (re-
4 lating to the Biomedical Advanced Research and De-
5 velopment Authority), \$2,800,000,000 for the period
6 of fiscal years 2014 through 2018. Amounts appro-
7 priated pursuant to the preceding sentence are au-
8 thorized to remain available until September 30,
9 2019.

10 “(2) NOTICE OF INSUFFICIENT FUNDS.—Not
11 later than 15 days after any date on which the Sec-
12 retary determines that the amount of funds in the
13 special reserve fund available for procurement is less
14 than \$1,500,000,000, the Secretary shall submit to the
15 Committee on Energy and Commerce of the House of
16 Representatives and the Committee on Health, Edu-
17 cation, Labor, and Pensions of the Senate a report de-
18 tailing the amount of such funds available for pro-
19 curement and the impact such funding will have—

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

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

24 “(3) USE OF SPECIAL RESERVE FUND FOR AD-
25 VANCED RESEARCH AND DEVELOPMENT.—The Sec-

1 *retary may utilize not more than 30 percent of the*
2 *amounts authorized to be appropriated under para-*
3 *graph (1) to carry out section 319L (related to the*
4 *Biomedical Advanced Research and Development Au-*
5 *thority). Amounts authorized to be appropriated*
6 *under this subsection to carry out section 319L are in*
7 *addition to amounts otherwise authorized to be ap-*
8 *propriated to carry out such section.*

9 *“(4) RESTRICTIONS ON USE OF FUNDS.—*
10 *Amounts in the special reserve fund shall not be used*
11 *to pay—*

12 *“(A) costs other than payments made by the*
13 *Secretary to a vendor for advanced development*
14 *(under section 319L) or for procurement of a se-*
15 *curity countermeasure under subsection (c)(7);*
16 *and*

17 *“(B) any administrative expenses, includ-*
18 *ing salaries.*

19 *“(5) DEFINITION.—In this section, the term ‘spe-*
20 *cial reserve fund’ means the ‘Biodefense Counter-*
21 *measures’ appropriations account, any appropriation*
22 *made available pursuant to section 521(a) of the*
23 *Homeland Security Act of 2002, and any appropria-*
24 *tion made available pursuant to paragraph (1) of this*
25 *paragraph.”.*

1 (g) *EMERGENCY SYSTEM FOR ADVANCE REGISTRATION*
2 *OF VOLUNTEER HEALTH PROFESSIONALS.*—Section
3 *319I(k) of the Public Health Service Act (42 U.S.C. 247d–*
4 *7b(k)) is amended by striking “are authorized to be appro-*
5 *priated \$2,000,000 for fiscal year 2002, and such sums as*
6 *may be necessary for each of the fiscal years 2003 through*
7 *2011” and inserting “is authorized to be appropriated*
8 *\$5,900,000 for each of fiscal years 2012 through 2016”.*

9 (h) *BIOMEDICAL ADVANCED RESEARCH AND DEVEL-*
10 *OPMENT AUTHORITY.*—

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

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

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

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

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

13 (i) *NATIONAL DISASTER MEDICAL SYSTEM.*—*Section*
14 *2812 of the Public Health Service Act (42 U.S.C. 300hh–*
15 *11) is amended—*

16 (1) *in subsection (a)(3), by adding at the end the*
17 *following:*

18 “(D) *ADMINISTRATION.*—*The Secretary*
19 *may determine and pay claims for reimburse-*
20 *ment for services under subparagraph (A) di-*
21 *rectly or by contract providing for payment in*
22 *advance or by way of reimbursement.”; and*

23 (2) *in subsection (g), by striking “such sums as*
24 *may be necessary for each of the fiscal years 2007*

1 *through 2011” and inserting “\$56,000,000 for each of*
2 *fiscal years 2012 through 2016”.*

3 (j) *NATIONAL HEALTH SECURITY STRATEGY*
4 *TIMELINE.—Section 2802(a)(1) of the Public Health Serv-*
5 *ice Act (42 U.S.C. 300hh–1(a)(1)) is amended by striking*
6 *“2009” and inserting “2014”.*

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

10 (1) *in paragraph (1)(A), by inserting “, includ-*
11 *ing drills and exercises to ensure medical surge capac-*
12 *ity for events without notice” after “exercises”; and*

13 (2) *in paragraph (3)—*

14 (A) *in the matter preceding subparagraph*
15 *(A), as amended by subsection (e)(2) of this sec-*
16 *tion—*

17 (i) *by inserting “availability, coordi-*
18 *nation, accessibility,” after “response capa-*
19 *bilities,”;*

20 (ii) *by striking “including mental*
21 *health facilities” and inserting “including*
22 *mental health and ambulatory care facili-*
23 *ties”; and*

24 (iii) *by striking “trauma care and*
25 *emergency medical service systems” and in-*

1 serting “trauma care, critical care, and
2 emergency medical service systems”; and

3 (B) in subparagraph (B), by striking “Med-
4 ical evacuation and fatality management” and
5 inserting “Fatality management, and coordi-
6 nated medical triage and evacuation to the ap-
7 propriate medical institution based on patient
8 medical need as part of regional systems”.

9 (l) *VOLUNTEER MEDICAL RESERVE CORPS.*—Section
10 *2813(i) of the Public Health Service Act (42 U.S.C. 300hh–*
11 *15(i)) is amended by striking “\$22,000,000 for fiscal year*
12 *2007, and such sums as may be necessary for each of fiscal*
13 *years 2008 through 2011” and inserting “\$11,900,000 for*
14 *each of fiscal years 2012 through 2016”.*

15 (m) *EXTENSION OF LIMITED ANTITRUST EXEMP-*
16 *TION.*—Section 405(b) of the *Pandemic and All-Hazard*
17 *Preparedness Act (42 U.S.C. 247d–6a note) is amended by*
18 *striking “at the end of the 6-year period that begins on the*
19 *date of enactment of this Act” and inserting “on September*
20 *30, 2016”.*

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

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

1 “(e) *TEMPORARY REDEPLOYMENT OF PERSONNEL*
2 *DURING A PUBLIC HEALTH EMERGENCY.*—

3 “(1) *EMERGENCY REDEPLOYMENT OF FEDER-*
4 *ALLY FUNDED PERSONNEL.*—*Notwithstanding any*
5 *other provision of law, and subject to paragraph (2),*
6 *upon a request that is from a State, locality, terri-*
7 *tory, tribe, or the Freely Associated States and that*
8 *includes such information and assurances as the Sec-*
9 *retary may require, the Secretary may authorize the*
10 *requesting entity to temporarily redeploy to imme-*
11 *diately address a public health emergency non-Fed-*
12 *eral personnel funded in whole or in part through—*

13 “(A) *any program under this Act; or*

14 “(B) *at the discretion of the Secretary, any*
15 *other program funded in whole or in part by the*
16 *Department of Health and Human Services.*

17 “(2) *ACTIVATION OF EMERGENCY REDEPLOY-*
18 *MENT.*—

19 “(A) *PUBLIC HEALTH EMERGENCY.*—*The*
20 *Secretary may exercise the authority vested by*
21 *paragraph (1) only during the period of a public*
22 *health emergency determined pursuant to sub-*
23 *section (a).*

1 “(B) *CONSIDERATIONS.*—*In authorizing a*
2 *temporary redeployment under paragraph (1),*
3 *the Secretary shall consider each of the following:*

4 “(i) *The degree to which the emergency*
5 *cannot be adequately and appropriately ad-*
6 *ressed by the public health workforce.*

7 “(ii) *The degree to which the emer-*
8 *gency requires or would otherwise benefit*
9 *from supplemental staffing from those fund-*
10 *ed through nonpreparedness Federal pro-*
11 *grams.*

12 “(iii) *The degree to which such pro-*
13 *grams would be adversely affected by the re-*
14 *deployment.*

15 “(iv) *Such other factors as the Sec-*
16 *retary may deem appropriate.*

17 “(C) *TERMINATION AND EXTENSION.*—

18 “(i) *TERMINATION.*—*The authority to*
19 *authorize a temporary redeployment of per-*
20 *sonnel under paragraph (1) shall terminate*
21 *upon the earlier of the following:*

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

1 “(II) Subject to clause (ii), 30
2 days after the activation of the Sec-
3 retary’s authority pursuant to sub-
4 paragraph (A).

5 “(ii) *EXTENSION AUTHORITY.*—The
6 Secretary may extend the authority to au-
7 thorize a temporary redeployment of per-
8 sonnel under paragraph (1) beyond the date
9 otherwise applicable under clause (i)(II) if
10 the public health emergency still exists, but
11 only if—

12 “(I) the extension is requested by
13 the entity that requested authority to
14 authorize a temporary redeployment;
15 and

16 “(II) the Secretary gives notice to
17 the Congress in conjunction with the
18 extension.”.

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

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

23 (1) *in subsection (b)(3)—*

24 (A) *by inserting “stockpiling, distribution,”*
25 *before “and procurement”; and*

1 (B) by inserting “, security measures (as
2 defined in section 319F-2,” after “qualified
3 countermeasures (as defined in section 319F-1)”;
4 (2) in subsection (b)(4), by adding at the end the
5 following:

6 “(D) IDENTIFICATION OF INEFFICIEN-
7 CIES.—Identify gaps, duplication, and other in-
8 efficiencies in public health preparedness activi-
9 ties and the actions necessary to overcome these
10 obstacles.

11 “(E) DEVELOPMENT OF COUNTERMEASURE
12 IMPLEMENTATION PLAN.—Lead the development
13 of a coordinated Countermeasure Implementa-
14 tion Plan under subsection (d).

15 “(F) COUNTERMEASURES BUDGET ANAL-
16 YSIS.—Oversee the development of a comprehen-
17 sive, cross-cutting 5-year budget analysis with
18 respect to activities described in paragraph (3)—

19 “(i) to inform prioritization of re-
20 sources; and

21 “(ii) to ensure that challenges to such
22 activities are adequately addressed.

23 “(G) GRANT PROGRAMS FOR MEDICAL AND
24 PUBLIC HEALTH PREPAREDNESS CAPABILI-
25 TIES.—Coordinate, in consultation with the Sec-

1 *retary of Homeland Security, grant programs of*
2 *the Department of Health and Human Services*
3 *relating to medical and public health prepared-*
4 *ness capabilities and the activities of local com-*
5 *munities to respond to public health emergencies,*
6 *including the—*

7 *“(i) coordination of relevant program*
8 *requirements, timelines, and measurable*
9 *goals of such grant programs; and*

10 *“(ii) establishment of a system for*
11 *gathering and disseminating best practices*
12 *among grant recipients.”;*

13 *(3) by amending subsection (c) to read as fol-*
14 *lows:*

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

17 *“(1) have lead responsibility within the Depart-*
18 *ment of Health and Human Services for emergency*
19 *preparedness and response policy and coordination;*

20 *“(2) have authority over and responsibility for—*

21 *“(A) the National Disaster Medical System*
22 *(in accordance with section 301 of the Pandemic*
23 *and All-Hazards Preparedness Act);*

24 *“(B) the Hospital Preparedness Cooperative*
25 *Agreement Program pursuant to section 319C–2;*

1 “(C) the Biomedical Advanced Research
2 and Development Authority under section 319L;
3 and

4 “(D) the Emergency System for Advance
5 Registration of Volunteer Health Professionals
6 pursuant to section 319I;

7 “(3) provide policy coordination and oversight
8 of—

9 “(A) the Strategic National Stockpile under
10 section 319F-2;

11 “(B) the Cities Readiness Initiative; and

12 “(C) the Medical Reserve Corps pursuant to
13 section 2813; and

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

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

17 “(d) COUNTERMEASURE IMPLEMENTATION PLAN.—

18 Not later than 6 months after the date of enactment of this
19 subsection, and annually thereafter, the Assistant Secretary
20 for Preparedness and Response shall submit through the
21 Secretary to the Committee on Energy and Commerce of
22 the House of Representatives and the Committee on Health,
23 Education, Labor, and Pensions of the Senate a Counter-
24 measure Implementation Plan that—

1 “(1) describes the chemical, biological, radio-
2 logical, and nuclear threats facing the Nation and the
3 corresponding efforts to develop qualified counter-
4 measures (as defined in section 319F-1), security
5 countermeasures (as defined in section 319F-2), or
6 qualified pandemic or epidemic products (as defined
7 in section 319F-3) for each threat;

8 “(2) evaluates the progress of all activities with
9 respect to such countermeasures or products, includ-
10 ing research, advanced research, development, pro-
11 curement, stockpiling, deployment, and utilization;

12 “(3) identifies and prioritizes near-, mid-, and
13 long-term needs with respect to such countermeasures
14 or products to address chemical, biological, radio-
15 logical, and nuclear threats;

16 “(4) identifies, with respect to each category of
17 threat, a summary of all advanced development and
18 procurement awards, including—

19 “(A) the time elapsed from the issuance of
20 the initial solicitation or request for a proposal
21 to the adjudication (such as the award, denial of
22 award, or solicitation termination);

23 “(B) projected timelines for development
24 and procurement of such countermeasures or
25 products;

1 “(C) clearly defined goals, benchmarks, and
2 milestones for each such countermeasure or prod-
3 uct, including information on the number of
4 doses required, the intended use of the counter-
5 measure or product, and the required counter-
6 measure or product characteristics; and

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

9 “(5) evaluates progress made in meeting the
10 goals, benchmarks, and milestones identified under
11 paragraph (4)(C);

12 “(6) reports on the amount of funds available for
13 procurement in the special reserve fund as defined in
14 section 319F-2(g)(5) and the impact this funding
15 will have on meeting the requirements under section
16 319F-2;

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

19 “(8) addresses the needs of pediatric populations
20 with respect to such countermeasures and products in
21 the Strategic National Stockpile and includes—

22 “(A) a list of such countermeasures and
23 products necessary to address the needs of pedi-
24 atric populations;

1 “(B) a description of measures taken to co-
2 ordinate with Office of Pediatric Therapeutics of
3 the Food and Drug Administration to maximize
4 the labeling, dosages, and formulations of such
5 countermeasures and products for pediatric pop-
6 ulations;

7 “(C) a description of existing gaps in the
8 Strategic National Stockpile and the develop-
9 ment of such countermeasures and products to
10 address the needs of pediatric populations; and

11 “(D) an evaluation of the progress made in
12 addressing gaps identified pursuant to subpara-
13 graph (C).

14 Notwithstanding any other provision of this subsection, the
15 Plan shall not include any confidential commercial infor-
16 mation, proprietary information, or information that could
17 reveal vulnerabilities of the Nation in the preparation for
18 or ability to respond to chemical, biological, radiological,
19 or nuclear threats.”.

20 (b) *CONSULTATION IN AUTHORIZING MEDICAL PROD-*
21 *UCTS FOR USE IN EMERGENCIES.*—Subsection (c) of section
22 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 360bbb–3) is amended by striking “consultation with the
24 Director of the National Institutes of Health” and inserting
25 “consultation with the Assistant Secretary for Preparedness

1 *and Response, the Director of the National Institutes of*
2 *Health,”.*

3 (c) *BIOSURVEILLANCE PLAN.*—Not later than one year
4 *after the date of the enactment of this Act, the Secretary*
5 *of Health and Human Services shall prepare and submit*
6 *to the Committee on Energy and Commerce of the House*
7 *of Representatives and the Committee on Health, Edu-*
8 *cation, Labor, and Pensions of the Senate a plan to improve*
9 *information sharing, coordination, and communications*
10 *among disparate biosurveillance systems supported by the*
11 *Department of Health and Human Services.*

12 **SEC. 5. ELIMINATING DUPLICATIVE PROJECT BIOSHIELD**
13 **REPORTS.**

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

16 **SEC. 6. AUTHORIZATION FOR MEDICAL PRODUCTS FOR USE**
17 **IN EMERGENCIES.**

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

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 a provision of*
2 *law in section 505, 510(k), or 515 of this Act or*
3 *section 351 of the Public Health Service Act”;*
4 *and*

5 *(C) in paragraph (3), by striking “a provi-*
6 *sion of law referred to in such paragraph” and*
7 *inserting “a provision of law referred to in para-*
8 *graph (2)(A)”;*

9 *(2) in subsection (b)—*

10 *(A) in the subsection heading, by striking*
11 *“DECLARATION OF EMERGENCY” and inserting*
12 *“DECLARATION SUPPORTING EMERGENCY USE*
13 *AUTHORIZATION”;*

14 *(B) in paragraph (1)—*

15 *(i) in the matter preceding subpara-*
16 *graph (A), by striking “an emergency justi-*
17 *fying” and inserting “that circumstances*
18 *exist justifying”;*

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

21 *(iii) in subparagraph (B), by striking*
22 *“specified”; and*

23 *(iv) by amending subparagraph (C) to*
24 *read as follows:*

1 “(C) a determination by the Secretary that
2 there is a public health emergency, or a signifi-
3 cant potential for a public health emergency, in-
4 volving a heightened risk to national security or
5 the health and security of United States citizens
6 abroad, and involving a biological, chemical, ra-
7 diological, or nuclear agent or agents, or a dis-
8 ease or condition that may be attributable to
9 such agent or agents.”;

10 (C) in paragraph (2)—

11 (i) by amending subparagraph (A) to
12 read as follows:

13 “(A) *IN GENERAL.*—A declaration under
14 this subsection shall terminate upon a deter-
15 mination by the Secretary, in consultation with,
16 as appropriate, the Secretary of Homeland Secu-
17 rity or the Secretary of Defense, that the cir-
18 cumstances described in paragraph (1) have
19 ceased to exist.”;

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

21 (iii) by redesignating subparagraph
22 (C) as subparagraph (B); and

23 (D) in paragraph (4), by striking “advance
24 notice of termination, and renewal” and insert-
25 ing “and advance notice of termination”;

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

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

6 (5) in subsection (e)—

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

9 “(iii) Appropriate conditions with re-
10 spect to the collection and analysis of infor-
11 mation concerning the safety and effective-
12 ness of the product with respect to the ac-
13 tual use of such product pursuant to an au-
14 thorization under this section.”;

15 (B) in paragraph (2)—

16 (i) in subparagraph (A)—

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

20 (II) by inserting “or in para-
21 graph (1)(B)” before the period at the
22 end;

23 (ii) in subparagraph (B)(i), by insert-
24 ing “, with the exception of extensions of a
25 product’s expiration date authorized under

1 *section 564A(b)” before the period at the*
2 *end; and*

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

5 *“(C) In establishing conditions under this*
6 *paragraph with respect to the distribution and*
7 *administration of a product, the Secretary shall*
8 *not impose conditions that would restrict dis-*
9 *tribution or administration of the product that*
10 *is solely for the approved uses.”;*

11 *(C) by amending paragraph (3) to read as*
12 *follows:*

13 *“(3) GOOD MANUFACTURING PRACTICE; PRE-*
14 *SCRIPTION; PRACTITIONER’S AUTHORIZATION.—With*
15 *respect to the emergency use of a product for which*
16 *an authorization under this section is issued (whether*
17 *for an unapproved product or an unapproved use of*
18 *an approved product), the Secretary may waive or*
19 *limit, to the extent appropriate given the cir-*
20 *cumstances of the emergency—*

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

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

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

6 *“(C) requirements established under section*
7 *520(e).”;* and

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

9 *“(5) EXISTING AUTHORITIES.—Nothing in this*
10 *section restricts any authority vested in the Secretary*
11 *by any other provision of this Act or the Public*
12 *Health Service Act for establishing conditions of au-*
13 *thorization for a product.”;* and

14 *(6) in subsection (g)—*

15 *(A) in the heading, by striking “REVOCA-*
16 *TION OF AUTHORIZATION” and inserting “RE-*
17 *VIEW, MODIFICATION, AND REVOCATION OF AU-*
18 *THORIZATION”;*

19 *(B) in paragraph (1), by striking “periodi-*
20 *cally review” and inserting “review not less than*
21 *every three years”;* and

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

23 *“(3) MODIFICATION.—The Secretary may modify*
24 *an authorization under this section or the conditions*
25 *of such an authorization, at any time, based on a re-*

1 *view of the authorization or new information that is*
2 *otherwise obtained, including information obtained*
3 *during an emergency.”.*

4 **SEC. 7. ADDITIONAL PROVISIONS RELATED TO MEDICAL**
5 **PRODUCTS FOR EMERGENCY USE.**

6 *(a) IN GENERAL.—The Federal Food, Drug, and Cos-*
7 *metic Act is amended by inserting after section 564 (21*
8 *U.S.C. 360bbb–3) the following:*

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

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

12 *“(1) The term ‘product’ means a drug, device, or*
13 *biological product.*

14 *“(2) The term ‘eligible product’ means a product*
15 *that is—*

16 *“(A) approved or cleared under this chapter*
17 *or licensed under section 351 of the Public*
18 *Health Service Act; and*

19 *“(B) intended to be used to diagnose, pre-*
20 *vent, or treat a disease or condition involving a*
21 *biological, chemical, radiological, or nuclear*
22 *agent or agents during—*

23 *“(i) a domestic emergency or military*
24 *emergency involving heightened risk of at-*
25 *tack with such an agent or agents; or*

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

4 “(b) EXPIRATION DATING.—

5 “(1) IN GENERAL.—The Secretary may extend
6 the expiration date and authorize the introduction or
7 delivery for introduction into interstate commerce of
8 an eligible product after the expiration date provided
9 by the manufacturer if—

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

14 “(B) the expiration date extension is in-
15 tended to support the United States’ ability to
16 protect—

17 “(i) the public health; or

18 “(ii) military preparedness and effec-
19 tiveness; and

20 “(C) the expiration date extension is sup-
21 ported by an appropriate scientific evaluation
22 that is conducted or accepted by the Secretary.

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

1 “(A) each specific lot, batch, or other unit
2 of the product for which extended expiration is
3 authorized;

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

5 “(C) any other requirements or conditions
6 as the Secretary may deem appropriate for the
7 protection of the public health, which may in-
8 clude requirements for, or conditions on, product
9 sampling, storage, packaging or repackaging,
10 transport, labeling, notice to product recipients,
11 recordkeeping, periodic testing or retesting, or
12 product disposition.

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

24 “(c) *CURRENT GOOD MANUFACTURING PRACTICES.*—

1 “(1) *IN GENERAL.*—*The Secretary may, when*
2 *the circumstances of a domestic, military, or public*
3 *health emergency described in subsection (a)(2)(B) so*
4 *warrant, authorize, with respect to an eligible prod-*
5 *uct, deviations from current good manufacturing*
6 *practice requirements otherwise applicable to the*
7 *manufacture, processing, packing, or holding of prod-*
8 *ucts subject to regulation under this Act, including re-*
9 *quirements under section 501 or 520(f)(1) or applica-*
10 *ble conditions prescribed with respect to the eligible*
11 *product by an order under section 520(f)(2).*

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

20 “(d) *MASS DISPENSING.*—*The requirements of section*
21 *503(b) and 520(e) shall not apply to an eligible product,*
22 *and the product shall not be considered an unapproved*
23 *product (as defined in section 564(a)(2)(A)) and shall not*
24 *be deemed adulterated or misbranded under this Act because*
25 *it is dispensed without an individual prescription, if—*

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

3 “(2) *such dispensing without an individual pre-*
4 *scription occurs—*

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

7 “(B) *in accordance with an order issued by*
8 *the Secretary.*

9 “(e) *EMERGENCY USE INSTRUCTIONS.—*

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

17 “(2) *EFFECT.—Notwithstanding any other pro-*
18 *visions of this Act or the Public Health Service Act,*
19 *a product shall not be considered an unapproved*
20 *product (as defined in section 564(a)(2)(A)) and shall*
21 *not be deemed adulterated or misbranded under this*
22 *Act because of—*

23 “(A) *the issuance of emergency use instruc-*
24 *tions under paragraph (1) with respect to such*
25 *product; or*

1 “(B) the introduction or delivery for intro-
2 duction of such product into interstate commerce
3 accompanied by such instructions during an
4 emergency response to an actual emergency de-
5 scribed in subsection (a)(2)(B).”.

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

9 (1) in subsection (f), by striking paragraph (7);
10 and

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

12 “(k) *WAIVER IN PUBLIC HEALTH EMERGENCIES.—*
13 *The Secretary may waive any requirement of this section*
14 *with respect to a qualified countermeasure (as defined in*
15 *section 319F–1(a)(2) of the Public Health Service Act) to*
16 *which a requirement under this section has been applied,*
17 *if the Secretary determines that such waiver is required to*
18 *mitigate the effects of, or reduce the severity of, an actual*
19 *or potential domestic emergency or military emergency in-*
20 *volving heightened risk of attack with a biological, chemical,*
21 *radiological, or nuclear agent, or an actual or potential*
22 *public health emergency affecting national security or the*
23 *health and security of United States citizens abroad.”.*

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

2 *The Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
3 *301 et seq.) is amended by inserting after section 564A, as*
4 *added by section 7, the following:*

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

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

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

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

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

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

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

1 **SEC. 9. ACCELERATE COUNTERMEASURE DEVELOPMENT BY**
2 **STRENGTHENING FDA'S ROLE IN REVIEWING**
3 **PRODUCTS FOR NATIONAL SECURITY PRIOR-**
4 **ITIES.**

5 (a) *IN GENERAL.*—Section 565 of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 360bbb–4) is amended
7 to read as follows:

8 **“SEC. 565. COUNTERMEASURE DEVELOPMENT AND REVIEW.**

9 “(a) *COUNTERMEASURES AND PRODUCTS.*—The coun-
10 termeasures and products referred to in this subsection
11 are—

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

14 “(2) *security countermeasures (as defined in sec-*
15 *tion 319F–2 of such Act); and*

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

19 “(b) *IN GENERAL.*—

20 “(1) *INVOLVEMENT OF FDA PERSONNEL IN*
21 *INTERAGENCY ACTIVITIES.*—*For the purpose of accel-*
22 *erating the development, stockpiling, approval, clear-*
23 *ance, and licensure of countermeasures and products*
24 *referred to in subsection (a), the Secretary shall ex-*
25 *pend the involvement of Food and Drug Administra-*
26 *tion personnel in interagency activities with the As-*

1 *Assistant Secretary for Preparedness and Response (in-*
2 *cluding the Biomedical Advanced Research and De-*
3 *velopment Authority), the Centers for Disease Control*
4 *and Prevention, the National Institutes of Health,*
5 *and the Department of Defense.*

6 “(2) *TECHNICAL ASSISTANCE.—The Secretary*
7 *shall establish within the Food and Drug Administra-*
8 *tion a team of experts on manufacturing and regu-*
9 *latory activities (including compliance with current*
10 *Good Manufacturing Practices) to provide both off-*
11 *site and on-site technical assistance to the manufac-*
12 *turers of countermeasures and products referred to in*
13 *subsection (a). On-site technical assistance shall be*
14 *provided upon the request of the manufacturer and at*
15 *the discretion of the Secretary if the Secretary deter-*
16 *mines that the provision of such assistance would ac-*
17 *celerate the development, manufacturing, or approval,*
18 *clearance, or licensure of countermeasures and prod-*
19 *ucts referred to in subsection (a).*

20 “(c) *AGENCY INTERACTION WITH SECURITY COUNTER-*
21 *MEASURE SPONSORS.—*

22 “(1) *IN GENERAL.—For security counter-*
23 *measures (as defined in section 319F–2 of the Public*
24 *Health Service Act) that are procured under such sec-*
25 *tion 319F–2—*

1 “(A) the Secretary shall establish a process
2 for frequent scientific feedback and interactions
3 between the Food and Drug Administration and
4 the security countermeasure sponsor (referred to
5 in this subsection as the ‘sponsor’), designed to
6 facilitate the approval, clearance, and licensure
7 of the security countermeasures;

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

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

17 “(2) REGULATORY MANAGEMENT PLAN.—

18 “(A) IN GENERAL.—The process established
19 under paragraph (1) shall allow for the develop-
20 ment of a written regulatory management plan
21 (in this paragraph referred to as the ‘plan’) for
22 a security countermeasure (as defined in para-
23 graph (1)) in accordance with this paragraph.

24 “(B) PROPOSAL AND FINALIZATION OF
25 PLAN.—In carrying out the process under para-

1 *graph (1), the Secretary shall direct the Food*
2 *and Drug Administration, upon submission of a*
3 *written request by the sponsor that includes a*
4 *proposed plan and relevant data and future*
5 *planning detail to support such a plan, to work*
6 *with the sponsor to agree on a final plan within*
7 *a reasonable time not to exceed 90 days. The*
8 *basis for this agreement shall be the proposed*
9 *plan submitted by the sponsor. Notwithstanding*
10 *the preceding sentence, the Secretary shall retain*
11 *full discretion to determine the contents of the*
12 *final plan or to determine that no such plan can*
13 *be agreed upon. If the Secretary determines that*
14 *no final plan can be agreed upon, the Secretary*
15 *shall provide to the sponsor, in writing, the sci-*
16 *entific or regulatory rationale why such agree-*
17 *ment cannot be reached. If a final plan is agreed*
18 *upon, it shall be shared with the sponsor in writ-*
19 *ing.*

20 “(C) *CONTENTS.*—*The plan shall include an*
21 *agreement on the nature of, and timelines for,*
22 *feedback and interactions between the sponsor*
23 *and the Food and Drug Administration, shall*
24 *provide reasonable flexibility in implementing*
25 *and adjusting the agreement under this para-*

1 *graph as warranted during the countermeasure*
2 *development process, and shall identify—*

3 *“(i) the current regulatory status of the*
4 *countermeasure, an assessment of known*
5 *scientific gaps relevant to approval, clear-*
6 *ance, or licensure of the countermeasure,*
7 *and a proposed pathway to approval, clear-*
8 *ance, or licensure of the countermeasure;*

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

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

17 *“(iv) feedback by the Food and Drug*
18 *Administration regarding the data required*
19 *to support delivery of the countermeasure to*
20 *the Strategic National Stockpile under sec-*
21 *tion 319F-2 of the Public Health Service*
22 *Act;*

23 *“(v) feedback by the Food and Drug*
24 *Administration regarding data required to*
25 *support submission of a proposed agreement*

1 *on the design and size of clinical trials for*
2 *review under section 505(b)(5)(B); and*

3 *“(vi) other issues that have the poten-*
4 *tial to delay approval, clearance, or licen-*
5 *sure.*

6 *“(D) CHANGES.—Changes to the plan shall*
7 *be made by subsequent agreement between the*
8 *Secretary and the sponsor. If after reasonable at-*
9 *tempts to negotiate changes to the plan the Sec-*
10 *retary and the sponsor are unable to finalize*
11 *such changes, the Secretary shall provide to the*
12 *sponsor, in writing, the scientific or regulatory*
13 *rationale why such changes are required or can-*
14 *not be included in the plan.*

15 *“(3) APPLICABILITY TO CERTAIN QUALIFIED*
16 *PANDEMIC OR EPIDEMIC PRODUCTS.—The Secretary*
17 *may, with respect to qualified pandemic or epidemic*
18 *products (as defined in section 319F–3 of the Public*
19 *Health Service Act) for which a contract for advanced*
20 *research and development is entered into under sec-*
21 *tion 319L of such Act, choose to apply the provisions*
22 *of paragraphs (1) and (2) to the same extent and in*
23 *the same manner as such provisions apply with re-*
24 *spect to security countermeasures.*

1 “(d) *FINAL GUIDANCE ON DEVELOPMENT OF ANIMAL*
2 *MODELS.*—

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

12 “(2) *AUTHORITY TO EXTEND DEADLINE.*—*The*
13 *Secretary may extend the deadline for providing final*
14 *guidance under paragraph (1) by not more than 6*
15 *months upon submission by the Secretary of a report*
16 *on the status of such guidance to the Committee on*
17 *Energy and Commerce of the House of Representa-*
18 *tives and the Committee on Health, Education,*
19 *Labor, and Pensions of the Senate.*

20 “(e) *BIENNIAL REPORT.*—Not later than January 1,
21 2013, and every 2 years thereafter, the Secretary shall sub-
22 mit a report to the Committee on Energy and Commerce
23 of the House of Representatives and the Committee on
24 Health, Education, Labor, and Pensions of the Senate, that,
25 with respect to the preceding 2 fiscal years, includes—

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

5 “(2) estimates of funds obligated by the Food
6 and Drug Administration for review of such counter-
7 measures and products;

8 “(3) the number of regulatory teams at the Food
9 and Drug Administration specific to such counter-
10 measures and products and, for each such team, the
11 assigned products, classes of products, or technologies;

12 “(4) the length of time between each request by
13 the sponsor of such a countermeasure or product for
14 information and the provision of such information by
15 the Food and Drug Administration;

16 “(5) the number, type, and frequency of official
17 interactions between the Food and Drug Administra-
18 tion and—

19 “(A) sponsors of a countermeasure or prod-
20 uct referred to in subsection (a); or

21 “(B) another agency engaged in develop-
22 ment or management of portfolios for such coun-
23 termeasures or products, including the Centers
24 for Disease Control and Prevention, the Bio-
25 medical Advanced Research and Development

1 *Authority, the National Institutes of Health, and*
2 *the appropriate agencies of the Department of*
3 *Defense;*

4 “(6) a description of other measures that, as de-
5 *termined by the Secretary, are appropriate to deter-*
6 *mine the efficiency of the regulatory teams described*
7 *in paragraph (3); and*

8 “(7) the regulatory science priorities that relate
9 *to countermeasures or products referred to in sub-*
10 *section (a) and which the Food and Drug Adminis-*
11 *tration is addressing and the progress made on these*
12 *priorities.”.*

13 ***(b) SPECIAL PROTOCOL ASSESSMENT.***—Subparagraph
14 ***(B)*** of section 505(b)(5) of the Federal Food, Drug, and Cos-
15 *metic Act (21 U.S.C. 355(b)(5)) is amended to read as fol-*
16 *lows:*

17 “(B)(i) *The Secretary shall meet with a sponsor of an*
18 *investigation or an applicant for approval for a drug under*
19 *this subsection or section 351 of the Public Health Service*
20 *Act if the sponsor or applicant makes a reasonable written*
21 *request for a meeting for the purpose of reaching agreement*
22 *on the design and size of—*

23 “(I) *clinical trials intended to form the primary*
24 *basis of an effectiveness claim; or*

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

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

Union Calendar No. 189

112TH CONGRESS
1ST Session

H. R. 2405

[Report No. 112-286]

A BILL

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.

NOVEMBER 16, 2011

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed