## 112TH CONGRESS 1ST SESSION H.R. 2405

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

# 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 Reauthoriza-6 tion Act of 2011".

7 (b) TABLE OF CONTENTS.—The table of contents for8 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. Coordination by Assistant Secretary for Preparedness and Response.
- Sec. 4. Eliminating duplicative Project Bioshield reports.
- Sec. 5. Accelerate countermeasure development by strengthening FDA's role in reviewing products for national security priorities.

#### 1 SEC. 2. REAUTHORIZATION OF CERTAIN PROVISIONS RE-

2

## LATING TO PUBLIC HEALTH PREPAREDNESS.

3 (a) VACCINE TRACKING AND DISTRIBUTION.—Sub-4 section (e) of section 319A of the Public Health Service 5 Act (42 U.S.C. 247d–1) is amended by striking "such 6 sums for each of fiscal years 2007 through 2011" and 7 inserting "\$30,800,000 for each of fiscal years 2012 8 through 2016".

9 (b) IMPROVING STATE AND LOCAL PUBLIC HEALTH
10 SECURITY.—Effective on October 1, 2011, section 319C–
11 1 of the Public Health Service Act (42 U.S.C. 247d–3a)
12 is amended—

- 13 (1) in subsection (f)—
- 14 (A) in paragraph (2), by inserting "and"15 at the end;
- 16 (B) in paragraph (3), by striking "; and"
- 17 and inserting a period; and
- 18 (C) by striking paragraph (4);
- 19 (2) by striking subsection (h); and
- 20 (3) in subsection (i)—
- (A) in paragraph (1) -

1	(i) by amending subparagraph (A) to
2	read as follows:
3	"(A) IN GENERAL.—For the purpose of
4	carrying out this section, there is authorized to
5	be appropriated \$632,900,000 for each of fiscal
6	years 2012 through 2016."; and
7	(ii) by striking subparagraph (B); and
8	(B) in subparagraphs (C) and (D) of para-
9	graph (3), by striking "(1)(A)(i)(I)" each place
10	it appears and inserting "(1)(A)".
11	(c) Partnerships for State and Regional Hos-
12	PITAL PREPAREDNESS TO IMPROVE SURGE CAPACITY.—
13	Paragraph (1) of section $319C-2(j)$ of the Public Health
14	Service Act (42 U.S.C. 247d–3b(j)) is amended to read
15	as follows:
16	"(1) IN GENERAL.—For purposes of carrying
17	out this section, there is authorized to be appro-
18	priated \$378,000,000 for each of fiscal years 2012
19	through 2016.".
20	(d) CDC PROGRAMS FOR COMBATING PUBLIC
21	HEALTH THREATS.—Section 319D of the Public Health
22	Service Act (42 U.S.C. 247d–4) is amended—
23	(1) by striking subsection (c); and
24	(2) in subsection (g), by striking "such sums as
25	may be necessary in each of fiscal years 2007

	4
1	through $2011$ " and inserting " $$160,121,000$ for
2	each of fiscal years 2012 through 2016".
3	(e) Dental Emergency Responders: Public
4	HEALTH AND MEDICAL RESPONSE.—
5	(1) All-hazards public health and med-
6	ICAL RESPONSE CURRICULA AND TRAINING.—Sec-
7	tion $319F(a)(5)(B)$ of the Public Health Service Act
8	(42 U.S.C. 247d– $6(a)(5)(B)$ ) is amended by striking
9	"public health or medical" and inserting "public
10	health, medical, or dental".
11	(2) NATIONAL HEALTH SECURITY STRATEGY.—
12	Section 2802(b)(3) of the Public Health Service Act
13	(42 U.S.C. 300hh–1(b)(3)) is amended—
14	(A) in the matter preceding subparagraph
15	(A), by inserting "and which may include den-
16	tal health facilities" after "mental health facili-
17	ties"; and
18	(B) in subparagraph (D), by inserting
19	"(which may include such dental health as-
20	sets)" after "medical assets".
21	(f) PROCUREMENT OF COUNTERMEASURES.—
22	(1) Contract terms.—Clause (ii) of section
23	319F-2(c)(7)(C) of the Public Health Service Act
24	(42 U.S.C. 247d– $6b(c)(7)(C)$ ) is amended by adding
25	at the end the following:

1	"(X) GOVERNMENT PURPOSE.—
2	The contract shall provide a clear
3	statement of defined Government pur-
4	pose limited to uses related to a secu-
5	rity countermeasure, as defined in
6	paragraph (1)(B).".
7	(2) Reauthorization of the special re-
8	SERVE FUND.—Section 319F–2 of the Public Health
9	Service Act (42 U.S.C. 247d–6b) is amended—
10	(A) in subsection (c)—
11	(i) by striking "special reserve fund
12	under paragraph (10)" each place it ap-
13	pears and inserting "special reserve fund
14	as defined in subsection $(g)(5)$ '; and
15	(ii) by striking paragraphs (9) and
16	(10); and
17	(B) by adding at the end the following:
18	"(g) Special Reserve Fund.—
19	"(1) Authorization of appropriations.—In
20	addition to amounts appropriated to the special re-
21	serve fund prior to the date of the enactment of this
22	subsection, there is authorized to be appropriated,
23	for the procurement of security countermeasures
24	under subsection (c) and for carrying out section
25	319L (relating to the Biomedical Advanced Research

and Development Authority), \$2,800,000,000 for the
 period of fiscal years 2014 through 2018. Amounts
 appropriated pursuant to the preceding sentence are
 authorized to remain available until September 30,
 2019.

6 "(2) NOTICE OF INSUFFICIENT FUNDS.—Not 7 later than 15 days after any date on which the Sec-8 retary determines that the amount of funds in the 9 special reserve fund available for procurement is less 10 than \$1,500,000,000, the Secretary shall submit to 11 the relevant committees of Congress a report detail-12 ing the amount of such funds available for procure-13 ment and the impact such funding will have—

14 "(A) in meeting the security counter15 measure needs identified under this section; and
16 "(B) on the annual Public Health Emer17 gency Medical Countermeasure Enterprise Im18 plementation Plan under section 319F-5(b).

"(3) USE OF SPECIAL RESERVE FUND FOR ADVANCED RESEARCH AND DEVELOPMENT.—The Secretary, acting through the Director of the Biomedical Advanced Research and Development Authority, may utilize not more than 30 percent of the
amounts authorized to be appropriated under paragraph (1) to carry out section 319L (related to the

1	Biomedical Advanced Research and Development
2	Authority). Amounts authorized to be appropriated
3	under this subsection to carry out section 319L are
4	in addition to amounts otherwise authorized to be
5	appropriated to carry out such section.
6	"(4) Restrictions on use of funds.—
7	Amounts in the special reserve fund shall not be
8	used to pay—
9	"(A) costs other than payments made by
10	the Secretary to a vendor for advanced research
11	and development or procurement of a security
12	countermeasure under subsection $(c)(7)$ ; and
13	"(B) any administrative expenses, includ-
14	ing salaries.
15	"(5) DEFINITION.—In this section, the term
16	'special reserve fund' means the 'Biodefense Coun-
17	termeasures' appropriations account, any appropria-
18	tion made available pursuant to section 521(a) of
19	the Homeland Security Act of 2002, and any appro-
20	priation made available pursuant to paragraph (1) of
21	this paragraph.".
22	(g) BIOMEDICAL ADVANCED RESEARCH AND DEVEL-
23	OPMENT AUTHORITY.—
24	
24	(1) TRANSACTION AUTHORITIES.—Section

U.S.C. 247d-7e(c)(5)) is amended by adding at the
 end the following:

3 "(G) GOVERNMENT PURPOSE.—In award-4 ing contracts, grants, and cooperative agree-5 ments under this section, the Secretary shall 6 provide a clear statement of defined Govern-7 ment purpose related to activities included in subsection (a)(6)(B) for a qualified counter-8 9 measure or qualified pandemic or epidemic 10 product.".

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

15 "(2) FUNDING.—To carry out the purposes of
16 this section, there is authorized to be appropriated
17 to the Fund \$415,000,000 for each of fiscal years
18 2012 through 2016, the amounts to remain available
19 until expended.".

20 (3) CONTINUED INAPPLICABILITY OF CERTAIN
21 PROVISIONS.—Section 319L(e)(1)(C) of the Public
22 Health Service Act (42 U.S.C. 247d–7e(e)(1)(C)) is
23 amended by striking "7 years" and inserting "10
24 years".

1	(h) NATIONAL DISASTER MEDICAL SYSTEM.—Sec-
2	tion 2812 of the Public Health Service Act (42 U.S.C.
3	300hh–11) is amended—
4	(1) in subsection $(a)(3)$ , by adding at the end
5	the following:
6	"(D) Administration.—The Secretary
7	may determine and pay claims for reimburse-
8	ment for services under subparagraph (A) di-
9	rectly or by contract providing for payment in
10	advance or by way of reimbursement."; and
11	(2) in subsection (g), by striking "such sums as
12	may be necessary for each of the fiscal years 2007
13	through 2011" and inserting "\$56,000,000 for each
14	of fiscal years 2012 through 2016".
15	(i) 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
18	by striking "6-year" and inserting "10-year".
19	SEC. 3. 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–
4	1)'';
5	(2) in subsection $(b)(4)$ , by adding at the end
6	the following:
7	"(D) IDENTIFICATION OF INEFFICIEN-
8	CIES.—Identify gaps, duplication, and other in-
9	efficiencies in public health preparedness activi-
10	ties and the actions necessary to overcome these
11	obstacles.
12	"(E) DEVELOPMENT OF COUNTER-
13	MEASURE IMPLEMENTATION PLAN.—Lead the
14	development of a coordinated Countermeasure
15	Implementation Plan under subsection (d).
16	"(F) Countermeasures budget anal-
17	vsis.—Oversee, in consultation with the Direc-
18	tor of the Office of Management and Budget,
19	the development of a comprehensive, cross-cut-
20	ting 5-year budget analysis with respect to ac-
21	tivities described in paragraph (3)—
22	"(i) to inform prioritization of re-
23	sources; and
24	"(ii) to ensure that challenges are
25	adequately addressed.

1	"(G) GRANT PROGRAMS FOR MEDICAL AND
2	PUBLIC HEALTH PREPAREDNESS CAPABILI-
3	TIES.—Coordinate, in consultation with the
4	Secretary of Homeland Security, grant pro-
5	grams of the Department of Health and
6	Human Services relating to medical and public
7	health preparedness capabilities and the ability
8	of local communities to respond to public health
9	emergencies, including by—
10	"(i) coordinating the program require-
11	ments, timelines, and measurable goals of
12	such grant programs; and
13	"(ii) establishing a system for gath-
14	ering and disseminating best practices
15	among grant recipients.";
16	(3) by amending subsection (c) to read as fol-
17	lows:
18	"(c) FUNCTIONS.—The Assistant Secretary for Pre-
19	paredness and Response shall—
20	"(1) have authority over and responsibility
21	for—
22	"(A) the National Disaster Medical System
23	(in accordance with section 301 of the Pan-
24	demic and All-Hazards Preparedness Act);

1	"(B) the Hospital Preparedness Coopera-
2	tive Agreement Program pursuant to section
3	319C–2;
4	"(C) the Biomedical Advanced Research
5	and Development Authority under section
6	319L;
7	"(D) the Medical Reserve Corps pursuant
8	to section 2813;
9	"(E) the Emergency System for Advance
10	Registration of Volunteer Health Professionals
11	pursuant to section 319I;
12	"(F) the Strategic National Stockpile; and
13	"(G) the Cities Readiness Initiative; and
14	((2) 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
19	this subsection, and annually thereafter, the Assistant
20	Secretary for Preparedness and Response shall submit to
21	the Secretary and relevant congressional committees a
22	Countermeasure Implementation Plan that—
23	((1) describes the chemical, biological, radio-
24	logical, and nuclear threats facing the Nation and
25	the corresponding efforts to develop qualified coun-

1	termeasures (as defined in section 319F–1), secured
2	countermeasures (as defined in section 319F–2), or
3	qualified pandemic or epidemic products (as defined
4	in section 319F–3) for each threat;
5	"(2) evaluates the progress of all activities with
6	respect to such countermeasures or products, includ-
7	ing research, advanced research, development, pro-
8	curement, stockpiling, deployment, and utilization;
9	"(3) identifies and prioritizes near-, mid-, and
10	long-term needs with respect to such counter-
11	measures or products to address chemical, biological,
12	radiological, and nuclear threats;
13	"(4) identifies, with respect to each category of
14	threat, a summary of all advanced development and
15	procurement awards, including the time elapsed
16	from the issuance of the initial solicitation or re-
17	quest for a proposal to the adjudication (such as the
18	award, denial of award, or solicitation termination),
19	and including—
20	"(A) projected timelines for development
21	and procurement of such countermeasures or
22	products;
23	"(B) clearly defined goals, benchmarks,
24	and milestones for each countermeasure or
25	product, including information on the number

1	of doses required, the intended use of the coun-
2	termeasure or product, and the required coun-
3	termeasure or product characteristics; and
	· · · · ·
4	"(C) projected needs with regard to the re-
5	plenishment of the Strategic National Stockpile;
6	"(5) evaluates progress made in meeting the
7	goals, benchmarks, and milestones identified under
8	paragraph (4);
9	"(6) reports on the amount of funds available
10	for procurement in the special reserve fund as de-
11	fined in section $319F-2(g)(5)$ and the impact this
12	funding will have on meeting the requirements under
13	section 319F–2; and
14	"(7) incorporates input from Federal, State,
15	local, and tribal stakeholders.".
16	(b) Consultation in Authorizing Medical
17	PRODUCTS FOR USE IN EMERGENCIES.—Subsection (c)
18	of section 564 of the Federal Food, Drug, and Cosmetic
19	Act (21 U.S.C. 360bbb–3) is amended by striking "con-
20	sultation with the Director of the National Institutes of
21	Health" and inserting "consultation with the Assistant
22	Secretary for Preparedness and Response, the Director of
23	the National Institutes of Health,".

1 SEC. 4. ELIMINATING DUPLICATIVE PROJECT BIOSHIELD 2 **REPORTS.** 3 Section 5 of the Project Bioshield Act of 2004 (42) 4 U.S.C. 247d–6c) is repealed. 5 SEC. 5. ACCELERATE COUNTERMEASURE DEVELOPMENT 6 BY STRENGTHENING FDA'S ROLE IN REVIEW-7 ING PRODUCTS FOR NATIONAL SECURITY 8 **PRIORITIES.** 9 (a) IN GENERAL.—Section 565 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-4) is amend-10 ed to read as follows: 11 12 "SEC. 565. COUNTERMEASURE DEVELOPMENT AND RE-13 VIEW. 14 "(a) Countermeasures and Products.—The countermeasures and products referred to in this sub-15 16 section are— 17 "(1) qualified countermeasures (as defined in 18 section 319F–1 of the Public Health Service Act): 19 "(2) security countermeasures (as defined in 20 section 319F-2 of such Act); and 21 "(3) qualified pandemic or epidemic products 22 (as defined in section 319F–3 of such Act). 23 "(b) IN GENERAL.— 24 "(1) INVOLVEMENT OF FDA PERSONNEL IN 25 INTERAGENCY ACTIVITIES.—The Secretary shall ac-26 celerate the development, stockpiling, approval, and

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2to in subsection (a) by expanding the involvement of3Food and Drug Administration personnel in inter-4agency activities with the Biomedical Advanced Re-5search and Development Authority, the Centers for6Disease Control and Prevention, the National Insti-7tutes of Health, and the Department of Defense.8"(2) TECHNICAL ASSISTANCE.—The Secretary9shall establish within the Food and Drug Adminis-10tration a team of experts on manufacturing and reg-11ulatory activities (including compliance with current12Good Manufacturing Practice) to provide both off-13site and on-site technical assistance to the manufac-14turers of countermeasures and products referred to15in subsection (a).16"(c) AGENCY INTERACTION WITH SECURITY COUN-17TERMEASURE SPONSORS.—18"(1) COUNTERMEASURE DEVELOPMENT PRO-19GRAM.—20"(A) IN GENERAL.—For each security21countermeasure (as defined in section 319F-222of the Public Health Service Act) that is pro-23cured under such section 319F-2, the Secretary24shall initiate, in consultation with the security25countermeasure sponsor (referred to in this sec-	1	licensure of countermeasures and products referred
4agency activities with the Biomedical Advanced Re-5search and Development Authority, the Centers for6Disease Control and Prevention, the National Insti-7tutes of Health, and the Department of Defense.8"(2) TECHNICAL ASSISTANCE.—The Secretary9shall establish within the Food and Drug Adminis-10tration a team of experts on manufacturing and reg-11ulatory activities (including compliance with current12Good Manufacturing Practice) to provide both off-13site and on-site technical assistance to the manufac-14turers of countermeasures and products referred to15in subsection (a).16"(c) AGENCY INTERACTION WITH SECURITY COUN-17TERMEASURE SPONSORS.—18"(1) COUNTERMEASURE DEVELOPMENT PRO-19GRAM.—20"(A) IN GENERAL.—For each security21countermeasure (as defined in section 319F-222of the Public Health Service Act) that is pro-23cured under such section 319F-2, the Secretary24shall initiate, in consultation with the security	2	to in subsection (a) by expanding the involvement of
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<ul> <li>site and on-site technical assistance to the manufac-</li> <li>turers of countermeasures and products referred to</li> <li>in subsection (a).</li> <li>"(c) AGENCY INTERACTION WITH SECURITY COUN-</li> <li>TERMEASURE SPONSORS.—</li> <li>"(1) COUNTERMEASURE DEVELOPMENT PRO-</li> <li>GRAM.—</li> <li>GRAM.—</li> <li>"(A) IN GENERAL.—For each security</li> <li>countermeasure (as defined in section 319F-2</li> <li>of the Public Health Service Act) that is pro-</li> <li>cured under such section 319F-2, the Secretary</li> <li>shall initiate, in consultation with the security</li> </ul>	11	ulatory activities (including compliance with current
<ul> <li>14 turers of countermeasures and products referred to</li> <li>15 in subsection (a).</li> <li>16 "(c) AGENCY INTERACTION WITH SECURITY COUN-</li> <li>17 TERMEASURE SPONSORS.—</li> <li>18 "(1) COUNTERMEASURE DEVELOPMENT PRO-</li> <li>19 GRAM.—</li> <li>20 "(A) IN GENERAL.—For each security</li> <li>21 countermeasure (as defined in section 319F-2</li> <li>22 of the Public Health Service Act) that is pro-</li> <li>23 cured under such section 319F-2, the Secretary</li> <li>24 shall initiate, in consultation with the security</li> </ul>	12	Good Manufacturing Practice) to provide both off-
<ul> <li>15 in subsection (a).</li> <li>16 "(c) AGENCY INTERACTION WITH SECURITY COUN-</li> <li>17 TERMEASURE SPONSORS.—</li> <li>18 "(1) COUNTERMEASURE DEVELOPMENT PRO-</li> <li>19 GRAM.—</li> <li>20 "(A) IN GENERAL.—For each security</li> <li>21 countermeasure (as defined in section 319F-2</li> <li>22 of the Public Health Service Act) that is pro-</li> <li>23 cured under such section 319F-2, the Secretary</li> <li>24 shall initiate, in consultation with the security</li> </ul>	13	site and on-site technical assistance to the manufac-
<ul> <li>16 "(c) AGENCY INTERACTION WITH SECURITY COUN-</li> <li>17 TERMEASURE SPONSORS.—</li> <li>18 "(1) COUNTERMEASURE DEVELOPMENT PRO-</li> <li>19 GRAM.—</li> <li>20 "(A) IN GENERAL.—For each security</li> <li>21 countermeasure (as defined in section 319F-2</li> <li>22 of the Public Health Service Act) that is pro-</li> <li>23 cured under such section 319F-2, the Secretary</li> <li>24 shall initiate, in consultation with the security</li> </ul>	14	turers of countermeasures and products referred to
<ul> <li>17 TERMEASURE SPONSORS.—</li> <li>18 "(1) COUNTERMEASURE DEVELOPMENT PRO-</li> <li>19 GRAM.—</li> <li>20 "(A) IN GENERAL.—For each security</li> <li>21 countermeasure (as defined in section 319F-2</li> <li>22 of the Public Health Service Act) that is pro-</li> <li>23 cured under such section 319F-2, the Secretary</li> <li>24 shall initiate, in consultation with the security</li> </ul>	15	in subsection (a).
<ul> <li>18 "(1) COUNTERMEASURE DEVELOPMENT PRO-</li> <li>19 GRAM.—</li> <li>20 "(A) IN GENERAL.—For each security</li> <li>21 countermeasure (as defined in section 319F-2</li> <li>22 of the Public Health Service Act) that is pro-</li> <li>23 cured under such section 319F-2, the Secretary</li> <li>24 shall initiate, in consultation with the security</li> </ul>	16	"(c) Agency Interaction With Security Coun-
<ul> <li>19 GRAM.—</li> <li>20 "(A) IN GENERAL.—For each security</li> <li>21 countermeasure (as defined in section 319F-2</li> <li>22 of the Public Health Service Act) that is pro-</li> <li>23 cured under such section 319F-2, the Secretary</li> <li>24 shall initiate, in consultation with the security</li> </ul>	17	TERMEASURE SPONSORS.—
<ul> <li>20 "(A) IN GENERAL.—For each security</li> <li>21 countermeasure (as defined in section 319F-2</li> <li>22 of the Public Health Service Act) that is pro-</li> <li>23 cured under such section 319F-2, the Secretary</li> <li>24 shall initiate, in consultation with the security</li> </ul>	18	"(1) Countermeasure development pro-
<ul> <li>countermeasure (as defined in section 319F-2</li> <li>of the Public Health Service Act) that is pro-</li> <li>cured under such section 319F-2, the Secretary</li> <li>shall initiate, in consultation with the security</li> </ul>	19	GRAM.—
22of the Public Health Service Act) that is pro-23cured under such section 319F-2, the Secretary24shall initiate, in consultation with the security	20	"(A) IN GENERAL.—For each security
<ul> <li>cured under such section 319F–2, the Secretary</li> <li>shall initiate, in consultation with the security</li> </ul>	21	countermeasure (as defined in section $319F-2$
24 shall initiate, in consultation with the security	22	of the Public Health Service Act) that is pro-
	23	cured under such section 319F–2, the Secretary
25 countermeasure sponsor (referred to in this sec-	24	shall initiate, in consultation with the security
	25	countermeasure sponsor (referred to in this sec-

1	tion as the 'countermeasure sponsor'), a pro-
2	gram of frequent scientific feedback and inter-
3	actions regarding the process of developing such
4	countermeasure, including—
5	"(i) regular meetings between appro-
6	priate Food and Drug Administration per-
7	sonnel and the countermeasure sponsor
8	during the process of developing the coun-
9	termeasure, to be scheduled within 45 days
10	after attainment of each milestone identi-
11	fied pursuant to subparagraph $(B)(iv)(I)$
12	in the regulatory management plan for the
13	countermeasure;
14	"(ii) written feedback from the Food
15	and Drug Administration within 30 days
16	after submission of a request for feedback
17	pursuant to subparagraph $(B)(iv)(II)$ in
18	the regulatory management plan for the
19	countermeasure;
20	"(iii) written feedback from the Food
21	and Drug Administration within 30 days
22	after submission by the countermeasure
23	sponsor of a study report that is consid-
24	ered to be complete pursuant to subpara-

1	graph (B)(iv)(III) in the regulatory man-
2	agement plan for the countermeasure;
3	"(iv) at the request of the Director of
4	the Biomedical Advanced Research and
5	Development Authority, participation in
6	meetings of such Authority on the develop-
7	ment of the countermeasure; and
8	"(v) other meetings, including on-site
9	meetings, as appropriate.
10	"(B) REGULATORY MANAGEMENT PLAN
11	In carrying out the program under subpara-
12	graph (A), the Secretary shall, in consultation
13	with the countermeasure sponsor, develop a
14	written regulatory management plan for each
15	security countermeasure (as defined in section
16	319F–2 of the Public Health Service Act) that
17	is procured under such section 319F–2. The
18	regulatory management plan shall be completed
19	within 60 days of issuance of a contract for the
20	countermeasure under such section $319F-2$ or,
21	for a countermeasure that was procured under
22	such section $319F-2$ before the date of the en-
23	actment of the Pandemic and All-Hazards Pre-
24	paredness Reauthorization Act of 2011, within
25	60 days after such date of enactment. The reg-

1	ulatory management plan for a security coun-
2	termeasure shall include—
3	"(i) an assessment of the current reg-
4	ulatory status, an assessment of known
5	scientific gaps, and a proposed pathway to
6	approval or licensure of the counter-
7	measure;
8	"(ii) guidance by the Food and Drug
9	Administration regarding the data required
10	to support delivery of the countermeasure
11	to the Strategic National Stockpile;
12	"(iii) guidance by the Food and Drug
13	Administration regarding data required to
14	support submission of a proposed agree-
15	ment on the design and size of clinical
16	trials for review under section
17	505(b)(5)(B); and
18	"(iv) an agreement between the Food
19	and Drug Administration and the counter-
20	measure sponsor to identify—
21	"(I) developmental milestones
22	that will trigger meetings between the
23	Administration and the sponsor;

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1	"(II) the process for requesting
2	and receiving written or oral feedback
3	from the Administration; and
4	"(III) the type study reports that
5	will be considered by the Administra-
6	tion to be complete.
7	"(C) Applicability to certain quali-
8	FIED PANDEMIC OR EPIDEMIC PRODUCTS.—The
9	Secretary may, with respect to qualified pan-
10	demic or epidemic products (as defined in sec-
11	tion 319F–3 of the Public Health Service Act)
12	for which a contract for advanced research and
13	development is entered into under section 319L
14	of such Act, choose to apply the provisions of
15	subparagraphs (A) and (B) to the same extent
16	and in the same manner as such provisions
17	apply with respect to security countermeasures.
18	"(d) Final Guidance on Development of Ani-
19	MAL MODELS.—Not later than 180 days after the date
20	of the enactment of the Pandemic and All-Hazards Pre-
21	paredness Reauthorization Act of 2011, the Secretary
22	shall provide final guidance to industry regarding the de-
23	velopment of animal models to support approval or licen-
24	sure of countermeasures and products referred to in sub-

section (a) when human efficacy studies are not ethical
 or feasible.

3 "(e) ANNUAL REPORT.—Not later than January 1, 4 2012, and every January 1 thereafter, the Secretary shall 5 submit a report to the Committee on Energy and Com-6 merce of the House of Representatives and the Committee 7 on Health, Education, Labor, and Pensions of the Senate 8 that, with respect to the preceding fiscal year, includes— 9 "(1) the number of full-time equivalent employ-10 ees of the Food and Drug Administration who di-11 rectly support the review of countermeasures and 12 products referred to in subsection (a); 13 "(2) estimates of funds obligated by the Food 14 and Drug Administration for development of such countermeasures and products: 15 "(3) the number of regulatory teams at the 16 17 Food and Drug Administration specific to such 18 countermeasures and products and, for each such 19 team, the assigned products, classes of products, or 20 technologies; "(4) the length of time between each request by 21

the sponsor of such a countermeasure or product for
information and the provision of such information by
the Food and Drug Administration;

1	"(5) the number, type, and frequency of official
2	interactions between the Food and Drug Adminis-
3	tration and—
4	"(A) sponsors of a countermeasure or
5	product referred to in subsection (a); or
6	"(B) another agency engaged in develop-
7	ment or management of portfolios for such
8	countermeasures or products, including the
9	Centers for Disease Control and Prevention, the
10	Biomedical Advanced Research and Develop-
11	ment Authority, the National Institutes of
12	Health, and the appropriate agencies of the De-
13	partment of Defense;
14	"(6) any other measure to determine the effi-
15	ciency of the regulatory teams described in para-
16	graph (3); and
17	"(7) the regulatory science priorities which the
18	Food and Drug Administration is addressing and
19	the progress made on these priorities.".
20	(b) Discussions Between FDA and Sponsor on
21	Design and Size of Animal and Clinical Trials In-
22	TENDED TO FORM THE PRIMARY BASIS OF AN EFFEC-
23	TIVENESS CLAIM WHEN HUMAN EFFICACY STUDIES ARE
24	NOT ETHICAL OR FEASIBLE.—Subparagraph (B) of sec-

1 tion 505(b)(5) of the Federal Food, Drug, and Cosmetic 2 Act (21 U.S.C. 355(b)(5)) is amended to read as follows: 3 "(B)(i) The Secretary shall meet with a sponsor of 4 an investigation or an applicant for approval for a drug 5 under this subsection or section 351 of the Public Health 6 Service Act if the sponsor or applicant makes a reasonable 7 written request for a meeting for the purpose of reaching 8 agreement on the design and size of— 9 "(I) clinical trials intended to form the primary 10 basis of an effectiveness claim; or 11 "(II) animal and clinical trials intended to form the primary basis of an effectiveness claim when 12 13 human efficacy studies are not ethical or feasible. 14 "(ii) The sponsor or applicant shall provide informa-15 tion necessary for discussion and agreement on the design 16 and size of the clinical trials. Minutes of any such meeting 17 shall be prepared by the Secretary and made available to the sponsor or applicant upon request.". 18