

115TH CONGRESS
2D SESSION

S. _____

To reauthorize certain programs under the Pandemic and All-Hazards
Preparedness Reauthorization Act.

IN THE SENATE OF THE UNITED STATES

Mr. BURR (for himself, Mr. CASEY, Mr. ALEXANDER, and Mrs. MURRAY) in-
troduced the following bill; which was read twice and referred to the Com-
mittee on _____

A BILL

To reauthorize certain programs under the Pandemic and
All-Hazards Preparedness Reauthorization Act.

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 and Advancing
6 Innovation Act of 2018”.

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. References in Act.

2

TITLE I—STRENGTHENING THE NATIONAL HEALTH SECURITY STRATEGY

Sec. 101. National Health Security Strategy.

TITLE II—IMPROVING PREPAREDNESS AND RESPONSE

- Sec. 201. Improving benchmarks and standards for preparedness and response.
- Sec. 202. Amendments to preparedness and response programs.
- Sec. 203. Regional health care emergency preparedness and response systems.
- Sec. 204. Public health and health care system situational awareness and bio-surveillance capabilities.
- Sec. 205. Strengthening and supporting the public health emergency rapid response fund.
- Sec. 206. Improving preparedness for and response to all-hazards by public health emergency volunteers.

TITLE III—REACHING ALL COMMUNITIES

- Sec. 301. Strengthening and assessing the emergency response workforce.
- Sec. 302. Health system infrastructure to improve preparedness and response.
- Sec. 303. Considerations for at-risk individuals.
- Sec. 304. Improving emergency preparedness and response considerations for children.
- Sec. 305. Reauthorizing the National Advisory Committee on Children and Disasters.
- Sec. 306. Guidance for participation in exercises and drills.

TITLE IV—PRIORITIZING A THREAT-BASED APPROACH

- Sec. 401. Assistant Secretary for Preparedness and Response.
- Sec. 402. Public Health Emergency Medical Countermeasures Enterprise.
- Sec. 403. Strategic National Stockpile.
- Sec. 404. Preparing for pandemic influenza, antimicrobial resistance, and other significant threats.
- Sec. 405. Reporting on the Federal Select Agent Program.

TITLE V—INCREASING COMMUNICATION IN MEDICAL COUNTERMEASURE ADVANCED RESEARCH AND DEVELOPMENT

- Sec. 501. Medical countermeasure budget plan.
- Sec. 502. Material threat and medical countermeasure notifications.
- Sec. 503. Availability of regulatory management plans.
- Sec. 504. The Biomedical Advanced Research and Development Authority and the BioShield Special Reserve Fund.

TITLE VI—ADVANCING TECHNOLOGIES FOR MEDICAL COUNTERMEASURES

- Sec. 601. Administration of countermeasures.
- Sec. 602. Medical countermeasure master files.
- Sec. 603. Animal rule report.

TITLE VII—MISCELLANEOUS PROVISIONS

- Sec. 701. Reauthorizations and extensions.
- Sec. 702. Technical amendments.

1 **SEC. 2. REFERENCES IN ACT.**

2 Except as otherwise specified, amendments made by
3 this Act to a section or other provision of law are amend-
4 ments to such section or other provision of the Public
5 Health Service Act (42 U.S.C. 201 et seq.).

6 **TITLE I—STRENGTHENING THE**
7 **NATIONAL HEALTH SECURITY**
8 **STRATEGY**

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

10 Section 2802 (42 U.S.C. 300hh-1) is amended—

11 (1) in subsection (a)—

12 (A) in paragraph (1)—

13 (i) by striking “2014” and inserting
14 “2018”; and

15 (ii) by striking the second sentence
16 and inserting the following: “Such Na-
17 tional Health Security Strategy shall de-
18 scribe potential emergency health security
19 threats and identify the process for achiev-
20 ing the preparedness goals described in
21 subsection (b) to be prepared to identify
22 and respond to such threats and shall be
23 consistent with the national preparedness
24 goal (as described in section 504(a)(19) of
25 the Homeland Security Act of 2002), the
26 National Incident Management System (as

1 defined in section 501(7) of such Act), and
2 the National Response Plan developed pur-
3 suant to section 504 of such Act, or any
4 successor plan.”;

5 (B) in paragraph (2), by inserting before
6 the period at the end of the second sentence the
7 following: “, and an analysis of any changes to
8 the evidence-based benchmarks and objective
9 standards under sections 319C–1 and 319C–2”;
10 and

11 (C) in paragraph (3)—

12 (i) by striking “2009” and inserting
13 “2022”;

14 (ii) by inserting “(including gaps in
15 the environmental health workforce), de-
16 scribing the status of such workforce”
17 after “gaps in such workforce”;

18 (iii) by striking “and identifying strat-
19 egies” and inserting “identifying strate-
20 gies”; and

21 (iv) by inserting before the period at
22 the end “, and identifying current capabili-
23 ties to meet the requirements of section
24 2803”; and

25 (2) in subsection (b)—

1 (A) in paragraph (2)—

2 (i) in subparagraph (A), by striking
3 “and investigation” and inserting “investigation,
4 and related information technology activities”;

5
6 (ii) in subparagraph (B), by striking
7 “and decontamination” and inserting “decontamination,
8 relevant health care services and supplies, and transportation and
9 disposal of medical waste”; and
10

11 (iii) by adding at the end the following:
12

13 “(E) Response to environmental hazards.”;

14 (B) in paragraph (3)(F), by inserting “or
15 exposures to agents that could cause a public
16 health emergency” before the period;

17 (C) in paragraph (5), by inserting “and
18 other applicable compacts” after “Compact”;

19 and

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

21 “(9) ZOO NOTIC DISEASE, FOOD, AND AGRICULTURE.—In consultation with the Secretary of
22 Agriculture, improving coordination among Federal,
23 State, local, tribal, and territorial entities to prevent,
24 detect, and respond to outbreaks of plant or animal
25

1 disease (including zoonotic disease) that could com-
2 promise national security resulting from a deliberate
3 attack, a naturally occurring threat, the intentional
4 adulteration of food, or other public health threats,
5 taking into account interactions between animal
6 health, human health, and animals' and humans'
7 shared environment as directly related to public
8 health emergency preparedness and response capa-
9 bilities, as applicable.

10 “(10) GLOBAL HEALTH SECURITY.—Assessing
11 current or potential health security threats from
12 abroad to inform domestic public health prepared-
13 ness and response capabilities.”.

14 **TITLE II—IMPROVING**
15 **PREPAREDNESS AND RESPONSE**
16 **SEC. 201. IMPROVING BENCHMARKS AND STANDARDS FOR**
17 **PREPAREDNESS AND RESPONSE.**

18 (a) EVALUATING MEASURABLE EVIDENCE-BASED
19 BENCHMARKS AND OBJECTIVE STANDARDS.—Section
20 319C–1 (42 U.S.C. 247d–3a) is amended by inserting
21 after subsection (j) the following:

22 “(k) EVALUATION.—

23 “(1) IN GENERAL.—Not later than 2 years
24 after the date of enactment of the Pandemic and
25 All-Hazards Preparedness and Advancing Innovation

1 Act of 2018 and every 2 years thereafter, the Sec-
2 retary shall conduct an evaluation of the evidence-
3 based benchmarks and objective standards required
4 under subsection (g). Such evaluation shall be sub-
5 mitted to the congressional committees of jurisdic-
6 tion together with the National Health Security
7 Strategy under section 2802, at such time as such
8 strategy is submitted.

9 “(2) CONTENT.—The evaluation under this
10 paragraph shall include—

11 “(A) a review of evidence-based bench-
12 marks and objective standards, and associated
13 metrics and targets;

14 “(B) a discussion of changes to any evi-
15 dence-based benchmarks and objective stand-
16 ards, and the effect of such changes on the abil-
17 ity to track whether entities are meeting or
18 making progress toward the goals under this
19 section and, to the extent practicable, the appli-
20 cable goals of the National Health Security
21 Strategy under section 2802;

22 “(C) a description of amounts received by
23 eligible entities, as described in subsection (b)
24 and section 319C–2(b), and amounts received
25 by sub-recipients and the effect of such funding

1 on meeting evidence-based benchmarks and ob-
2 jective standards; and

3 “(D) recommendations, as applicable and
4 appropriate, to improve evidence-based bench-
5 marks and objective standards to more accu-
6 rately assess the ability of entities receiving
7 awards under this section to better achieve the
8 goals under this section and section 2802.”.

9 (b) EVALUATING THE PARTNERSHIP FOR STATE AND
10 REGIONAL HOSPITAL PREPAREDNESS.—Section 319C-
11 2(i)(1) (42 U.S.C. 247-3b(i)(1)) is amended by striking
12 “section 319C-1(g), (i), and (j)” and inserting “section
13 319C-1(g), (i), (j), and (k)”.

14 **SEC. 202. AMENDMENTS TO PREPAREDNESS AND RE-**
15 **SPONSE PROGRAMS.**

16 (a) COOPERATIVE AGREEMENT APPLICATIONS FOR
17 IMPROVING STATE AND LOCAL PUBLIC HEALTH SECU-
18 RITY.—Section 319C-1 (42 U.S.C. 247d-3a) is amend-
19 ed—

20 (1) in subsection (a), by inserting “, acting
21 through the Director of the Centers for Disease
22 Control and Prevention,” after “the Secretary”; and

23 (2) in subsection (b)(2)(A)—

24 (A) in clause (vi), by inserting “, including
25 public health agencies with specific expertise

1 that may be relevant to public health security,
2 such as environmental health agencies,” after
3 “stakeholders”;

4 (B) by redesignating clauses (vii) through
5 (ix) as clauses (viii) through (x); and

6 (C) by inserting after clause (vi) the fol-
7 lowing:

8 “(vii) a description of how, as applica-
9 ble, such entity may integrate information
10 to account for individuals with behavioral
11 health needs following a public health
12 emergency;”.

13 (b) PARTNERSHIP FOR STATE AND REGIONAL HOS-
14 PITAL PREPAREDNESS TO IMPROVE SURGE CAPACITY.—
15 Section 319C–2 (42 U.S.C. 247d–3b) is amended—

16 (1) in subsection (a)—

17 (A) by inserting “, acting through the As-
18 sistant Secretary for Preparedness and Re-
19 sponse,” after “The Secretary”; and

20 (B) by striking “preparedness for public
21 health emergencies” and inserting “prepared-
22 ness for, and response to, public health emer-
23 gencies in accordance with subsection (c)”;

24 (2) in subsection (b)(1)(A)—

1 (A) in clause (iii), by redesignating sub-
2 clauses (I) through (III) as items (aa) through
3 (cc), respectively, and adjusting the margins ac-
4 cordingly;

5 (B) by redesignating clauses (i) through
6 (iii) as subclauses (I) through (III) respectively,
7 and adjusting the margins accordingly;

8 (C) by striking “partnership consisting
9 of—” and inserting “partnership—
10 “(i) consisting of—”; and

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

12 “(ii) that may include one or more
13 emergency medical service organizations or
14 emergency management organizations;
15 and”.

16 (c) PUBLIC HEALTH SECURITY GRANTS AUTHORIZA-
17 TION OF APPROPRIATIONS.—Section 319C–1(h)(1)(A)
18 (42 U.S.C. 247d–3a(h)(1)(A)) is amended by striking
19 “\$641,900,000 for fiscal year 2014” and all that follows
20 through the period at the end and inserting
21 “\$685,000,000 for each of fiscal years 2019 through 2023
22 for awards pursuant to paragraph (3) (subject to the au-
23 thority of the Secretary to make awards pursuant to para-
24 graphs (4) and (5)).”.

1 (d) PARTNERSHIP FOR STATE AND REGIONAL HOS-
2 PITAL PREPAREDNESS AUTHORIZATION OF APPROPRIA-
3 TIONS.—Section 319C–2(j) (42 U.S.C. 247d–3b(j)) is
4 amended—

5 (1) by amending paragraph (1) to read as fol-
6 lows:

7 “(1) IN GENERAL.—

8 “(A) AUTHORIZATION OF APPROPRIA-
9 TIONS.—For purposes of carrying out this sec-
10 tion and section 319C–3, in accordance with
11 subparagraph (B), there is authorized to be ap-
12 propriated \$385,000,000 for each of fiscal years
13 2019 through 2023.

14 “(B) RESERVATIONS OF AMOUNTS FOR RE-
15 GIONAL SYSTEMS.—

16 “(i) IN GENERAL.—Subject to clause
17 (ii), of the amount appropriated under sub-
18 paragraph (A) for a fiscal year, the Sec-
19 retary may reserve up to 5 percent for the
20 purpose of carrying out section 319C–3.

21 “(ii) RESERVATIONS CONTINGENT ON
22 CONTINUED APPROPRIATIONS.—If the
23 amount appropriated under subparagraph
24 (A) for fiscal year 2019 or a subsequent
25 fiscal year is less than or equal the amount

1 so appropriated for the previous fiscal
2 year, the amount that may be reserved
3 under clause (i) shall be reduced such that
4 the amount remaining for the purpose of
5 carrying out this section is not less than
6 the amount available for such purpose for
7 the previous fiscal year.”;

8 (2) in paragraph (2), by striking “paragraph
9 (1) for a fiscal year” and inserting “paragraph
10 (1)(A) for a fiscal year and not reserved for the pur-
11 pose described in paragraph (1)(B)(i)”;

12 (3) in paragraph (3)(A), by striking “paragraph
13 (1) and not reserved under paragraph (2)” and in-
14 serting “paragraph (1)(A) and not reserved under
15 paragraph (1)(B)(i) or (2)”.

16 **SEC. 203. REGIONAL HEALTH CARE EMERGENCY PRE-**
17 **PAREDNESS AND RESPONSE SYSTEMS.**

18 (a) IN GENERAL.—Part B of title III (42 U.S.C. 243
19 et seq.) is amended by inserting after section 319C–2 the
20 following:

21 **“SEC. 319C–3. GUIDELINES FOR REGIONAL HEALTH CARE**
22 **EMERGENCY PREPAREDNESS AND RESPONSE**
23 **SYSTEMS.**

24 “(a) PURPOSE.—It is the purpose of this section to
25 identify and provide guidelines for regional systems of hos-

1 pitals, health care facilities, and other public and private
2 sector entities, with varying levels of capability to treat
3 patients and increase medical surge capacity during, and
4 in advance of, a public health emergency, including threats
5 posed by one or more chemical, biological, radiological,
6 and nuclear agents, including emerging infectious dis-
7 eases.

8 “(b) GUIDELINES.—The Assistant Secretary for Pre-
9 paredness and Response, in consultation with the Director
10 of the Centers for Disease Control and Prevention, the Ad-
11 ministrator of the Centers for Medicare & Medicaid Serv-
12 ices, the Administrator of the Health Resources and Serv-
13 ices Administration, the Commissioner of Food and
14 Drugs, the Assistant Secretary for Mental Health and
15 Substance Use, the Assistant Secretary of Labor for Occu-
16 pational Safety and Health, the Secretary of Veterans Af-
17 fairs, heads of such other Federal agencies as the Sec-
18 retary determines to be appropriate, and State, local, trib-
19 al, and territorial public health officials, shall, not later
20 than 2 years after the date of enactment of this section—

21 “(1) identify and develop a set of guidelines re-
22 lating to practices and protocols for all-hazards pub-
23 lic health emergency preparedness and response for
24 hospitals and health care facilities to provide appro-
25 priate patient care during, in advance of, or imme-

1 diately following, a public health emergency, result-
2 ing from one or more chemical, biological, radio-
3 logical, or nuclear agents, including emerging infec-
4 tious diseases (which may include existing practices,
5 such as trauma care and medical surge capacity and
6 capabilities), with respect to—

7 “(A) a regional approach to identifying
8 hospitals and health care facilities based on
9 varying capabilities and capacity to treat pa-
10 tients affected by such emergency, including—

11 “(i) the manner in which the system
12 will coordinate with and integrate the part-
13 nerships established under section 319C-
14 2(b); and

15 “(ii) informing and educating appro-
16 priate first responders and health care sup-
17 ply chain partners of the regional emer-
18 gency preparedness and response capabili-
19 ties and medical surge capacity of such
20 hospitals and health care facilities in the
21 community;

22 “(B) physical and technological infrastruc-
23 ture, laboratory capacity, staffing, blood supply,
24 and other supply chain needs, taking into ac-

1 count resiliency, geographic considerations, and
2 rural considerations;

3 “(C) protocols or best practices for the
4 safety and personal protection of workers who
5 handle human remains and health care workers
6 (including with respect to protective equipment
7 and supplies, waste management processes, and
8 decontamination), sharing of specialized experi-
9 ence among the health care workforce, behav-
10 ioral health, psychological resilience, and train-
11 ing of the workforce, as applicable;

12 “(D) in a manner that allows for disease
13 containment (within the meaning of section
14 2802(b)(2)(B)), coordinated medical triage,
15 treatment, and transportation of patients, based
16 on patient medical need (including patients in
17 rural areas), to the appropriate hospitals or
18 health care facilities within the regional system
19 or, as applicable and appropriate, between sys-
20 tems in different States or regions; and

21 “(E) the needs of children and other at-
22 risk individuals;

23 “(2) make such guidelines available on the
24 internet website of the Department of Health and

1 Human Services in a manner that does not com-
2 promise national security; and

3 “(3) update such guidelines as appropriate, in-
4 cluding based on input received pursuant to sub-
5 sections (c), (e), and (f), to address new and emerg-
6 ing public health threats.

7 “(c) CONSIDERATIONS.—In identifying, developing,
8 and updating guidelines under subsection (b), the Assist-
9 ant Secretary for Preparedness and Response shall—

10 “(1) include input from hospitals and health
11 care facilities, including health care coalitions under
12 section 319C–2, State, local, tribal, and territorial
13 public health departments, and health care or sub-
14 ject matter experts, including experts with relevant
15 expertise in chemical, biological, radiological, or nu-
16 clear threats, and emerging infectious disease as the
17 Assistant Secretary determines appropriate, to meet
18 the goals under section 2802(b)(3);

19 “(2) consult and engage with appropriate
20 health care providers and professionals, including
21 physicians, nurses, first responders, health care fa-
22 cilities (including hospitals, primary care clinics,
23 community health centers, mental health facilities,
24 ambulatory care facilities, and dental health facili-
25 ties), pharmacies, emergency medical providers,

1 trauma care providers, environmental health agen-
2 cies, public health laboratories, poison control cen-
3 ters, blood banks, and other experts that the Assist-
4 ant Secretary determines appropriate, to meet the
5 goals under section 2802(b)(3);

6 “(3) consider feedback related to financial im-
7 plications for hospitals, health care facilities, public
8 health agencies, laboratories, and other entities en-
9 gaged in regional preparedness planning to imple-
10 ment and follow such guidelines, as applicable; and

11 “(4) consider financial requirements and poten-
12 tial incentives for entities to prepare for, and re-
13 spond to, public health emergencies as part of the
14 regional health care emergency preparedness and re-
15 sponse system.

16 “(d) TECHNICAL ASSISTANCE.—The Assistant Sec-
17 retary for Preparedness and Response, in consultation
18 with the Director of the Centers for Disease Control and
19 Prevention and the Assistant Secretary of Labor for Occu-
20 pational Safety and Health, may provide technical assist-
21 ance and consultation towards meeting the guidelines de-
22 scribed in subsection (b).

23 “(e) DEMONSTRATION PROJECT FOR REGIONAL
24 HEALTH CARE PREPAREDNESS AND RESPONSE SYS-
25 TEMS.—

1 “(1) IN GENERAL.—The Assistant Secretary for
2 Preparedness and Response may establish a dem-
3 onstration project pursuant to the development and
4 implementation of guidelines under subsection (b) to
5 improve medical surge capacity for all hazards, build
6 and integrate regional medical response capabilities,
7 improve specialty care expertise for all-hazards re-
8 sponse, and coordinate medical preparedness and re-
9 sponse across State, local, tribal, territorial, and re-
10 gional jurisdictions.

11 “(2) SUNSET.—The authority under this sub-
12 section shall expire on September 30, 2023.

13 “(f) GAO REPORT TO CONGRESS.—

14 “(1) REPORT.—Not later than 3 years after the
15 date of enactment of this section, the Comptroller
16 General of the United States (referred to in this
17 subsection as the ‘Comptroller General’) shall submit
18 to the Committee on Health, Education, Labor, and
19 Pensions and the Committee on Finance of the Sen-
20 ate and the Committee on Energy and Commerce
21 and the Committee on Ways and Means of the
22 House of Representatives, a report on the extent to
23 which hospitals and health care facilities have imple-
24 mented the recommended guidelines under sub-
25 section (b), including an analysis and evaluation of

1 any challenges hospitals or health care facilities ex-
2 perience in implementing such guidelines.

3 “(2) CONTENT.—The Comptroller General shall
4 include in the report under paragraph (1)—

5 “(A) data on the preparedness and re-
6 sponse capabilities that have been informed by
7 the guidelines under subsection (b) to improve
8 regional emergency health care preparedness
9 and response capability, including hospital and
10 health care facility capacity and medical surge
11 capabilities to prepare for, and respond to, pub-
12 lic health emergencies; and

13 “(B) recommendations to reduce gaps in
14 incentives for regional health partners, includ-
15 ing hospitals and health care facilities to im-
16 prove capacity and medical surge capabilities to
17 prepare for, and respond to, public health emer-
18 gencies, consistent with subsection (a), which
19 may include consideration of facilities partici-
20 pating in programs under section 319C–2, pro-
21 grams under the Centers for Medicare & Med-
22 icaid Services (including innovative health care
23 delivery and payment models), and input from
24 private sector financial institutions.

1 “(3) CONSULTATION.—In carrying out para-
2 graphs (1) and (2), the Comptroller General shall
3 consult with the heads of appropriate Federal agen-
4 cies, including—

5 “(A) the Assistant Secretary for Prepared-
6 ness and Response;

7 “(B) the Director of the Centers for Dis-
8 ease Control and Prevention;

9 “(C) the Administrator of the Centers for
10 Medicare & Medicaid Services;

11 “(D) the Assistant Secretary for Mental
12 Health and Substance Use;

13 “(E) the Assistant Secretary of Labor for
14 Occupational Safety and Health;

15 “(F) the Secretary of Veterans Affairs;
16 and

17 “(G) the heads of such other Federal agen-
18 cies as the Secretary determines appropriate.”.

19 (b) ANNUAL REPORTS.—Section 319C–2(i)(1) (42
20 U.S.C. 247d–3b(i)(1)) is amended by inserting after the
21 first sentence the following “The reports submitted under
22 this paragraph shall also include progress towards the im-
23 plementation of section 319C–3.”.

24 (c) NATIONAL HEALTH SECURITY STRATEGY INCOR-
25 PORATION OF REGIONALIZED EMERGENCY PREPARED-

1 NESS AND RESPONSE.—Section 2802(b)(3) (42 U.S.C.
2 300hh–1(b)(3)) is amended—

3 (1) in the matter preceding subparagraph (A),
4 by striking “including mental health” and inserting
5 “including pharmacies, mental health facilities,”;
6 and

7 (2) by amending subparagraph (G) to read as
8 follows:

9 “(G) Optimizing a coordinated and flexible
10 approach to the emergency response and med-
11 ical surge capacity of hospitals, other health
12 care facilities, critical care, trauma care (which
13 may include trauma centers), and emergency
14 medical systems, which may include the imple-
15 mentation of guidelines for regional health care
16 emergency preparedness and response systems
17 under section 319C–3.”.

18 (d) IMPROVING STATE AND LOCAL PUBLIC HEALTH
19 SECURITY.—

20 (1) STATE AND LOCAL SECURITY.—Section
21 319C–1(e) (42 U.S.C. 247d–3a(e)) is amended by
22 striking “, and local emergency plans.” and inserting
23 “, local emergency plans, and any regional health
24 care emergency preparedness and response system

1 established pursuant to the applicable guidelines
2 under section 319C-3.”.

3 (2) PARTNERSHIPS.—Section 319C-2(d)(1)(A)
4 (42 U.S.C. 247d-3b(d)(1)(A)) is amended—

5 (A) in clause (i), by striking “; and” and
6 inserting “;”

7 (B) by redesignating clause (ii) as clause
8 (iii); and

9 (C) inserting after clause (i), the following:

10 “(ii) among one or more facilities in a
11 regional health care emergency system
12 under section 319C-3; and”.

13 **SEC. 204. PUBLIC HEALTH AND HEALTH CARE SYSTEM SIT-**
14 **UATIONAL AWARENESS AND BIOSURVEIL-**
15 **LANCE CAPABILITIES.**

16 (a) FACILITIES, CAPACITIES, AND BIOSURVEILLANCE
17 CAPABILITIES.—Section 319D (42 U.S.C. 247d-4) is
18 amended—

19 (1) in the section heading, by striking “**REVI-**
20 **TALIZING**” and inserting “**FACILITIES AND CA-**
21 **PACITIES OF**”;

22 (2) in subsection (a)—

23 (A) in the subsection heading, by striking
24 “**FACILITIES; CAPACITIES**” and inserting “**IN**
25 **GENERAL**”;

1 (B) in paragraph (1), by striking “and im-
2 proved” and inserting “, improved, and appro-
3 priately maintained”;

4 (C) in paragraph (3), in the matter pre-
5 ceding subparagraph (A), by striking “expand,
6 enhance, and improve” and inserting “expand,
7 improve, enhance, and appropriately maintain”;
8 and

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

10 “(4) STUDY OF RESOURCES FOR FACILITIES
11 AND CAPACITIES.—Not later than June 1, 2022, the
12 Comptroller General of the United States shall con-
13 duct a study on Federal spending in fiscal years
14 2013 through 2018 for activities authorized under
15 this subsection. Such study shall include a review
16 and assessment of obligations and expenditures di-
17 rectly related to each activity under paragraphs (2)
18 and (3), including a specific accounting of, and de-
19 lineation between, obligations and expenditures in-
20 curred for the construction, renovation, equipping,
21 and security upgrades of facilities and associated
22 contracts under this subsection, and the obligations
23 and expenditures incurred to establish and improve
24 the situational awareness and biosurveillance net-
25 work under subsection (b), and shall identify the

1 agency or agencies incurring such obligations and
2 expenditures.”;

3 (3) in subsection (b)—

4 (A) in the subsection heading, by striking
5 “NATIONAL” and inserting “ESTABLISHMENT
6 OF SYSTEMS OF PUBLIC HEALTH ”;

7 (B) in paragraph (1)(B), by inserting “im-
8 munization information systems,” after “cen-
9 ters,”; and

10 (C) in paragraph (2)—

11 (i) by inserting “develop a plan to,
12 and” after “The Secretary shall”; and

13 (ii) by inserting “and in a form read-
14 ily usable for analytical approaches” after
15 “in a secure manner”; and

16 (D) by amending paragraph (3) to read as
17 follows:

18 “(3) STANDARDS.—

19 “(A) IN GENERAL.—Not later than 1 year
20 after the date of the enactment of the Pan-
21 demic and All-Hazards Preparedness and Ad-
22 vancing Innovation Act of 2018, the Secretary,
23 in cooperation with health care providers, State,
24 local, tribal, and territorial public health offi-
25 cials, and relevant Federal agencies (including

1 the Office of the National Coordinator for
2 Health Information Technology and the Na-
3 tional Institute of Standards and Technology),
4 shall, as necessary, adopt technical and report-
5 ing standards, including standards for inter-
6 operability as defined by section 3000, for net-
7 works under paragraph (1) and update such
8 standards as necessary. Such standards shall be
9 made available on the internet website of the
10 Department of Health and Human Services, in
11 a manner that does not compromise national se-
12 curity.

13 “(B) DEFERENCE TO STANDARDS DEVEL-
14 OPMENT ORGANIZATIONS.—In adopting and im-
15 plementing standards under this subsection and
16 subsection (c), the Secretary shall give def-
17 erence to standards published by standards de-
18 velopment organizations and voluntary con-
19 sensus-based standards entities.”;

20 (4) in subsection (c)—

21 (A) in paragraph (1)—

22 (i) by striking “Not later than 2 years
23 after the date of enactment of the Pan-
24 demic and All-Hazards Preparedness Re-

1 authorization Act of 2013, the Secretary”
2 and inserting “The Secretary”;

3 (ii) by inserting “, and improve as ap-
4 plicable and appropriate,” after “shall es-
5 tablish”;

6 (iii) by striking “of rapid” and insert-
7 ing “of, rapid”; and

8 (iv) by striking “such connectivity”
9 and inserting “such interoperability”;

10 (B) by amending paragraph (2) to read as
11 follows:

12 “(2) COORDINATION AND CONSULTATION.—In
13 establishing and improving the network under para-
14 graph (1) the Secretary shall—

15 “(A) facilitate coordination among agencies
16 within the Department of Health and Human
17 Services that provide or have the potential to
18 provide information and data to, and analyses
19 for, the situational awareness and biosurveil-
20 lance network under paragraph (1), including
21 coordination among relevant agencies related to
22 health care services, the facilitation of health
23 information exchange (including the Office of
24 the National Coordinator for Health Informa-

1 tion Technology), and public health emergency
2 preparedness and response; and

3 “(B) consult with the Secretary of Agri-
4 culture, the Secretary of Commerce (and the
5 Director of the National Institute of Standards
6 and Technology), the Secretary of Defense, the
7 Secretary of Homeland Security, and the Sec-
8 retary of Veterans Affairs, and the heads of
9 other Federal agencies, as the Secretary deter-
10 mines appropriate.”;

11 (C) in paragraph (3)—

12 (i) by redesignating subparagraphs
13 (A) through (E) as clauses (i) through (v),
14 respectively, and adjusting the margins ac-
15 cordingly;

16 (ii) in clause (iv), as so redesign-
17 nated—

18 (I) by inserting “immunization
19 information programs,” after “poison
20 control,”; and

21 (II) by striking “ and clinical
22 laboratories” and inserting “, clinical
23 laboratories, and public environmental
24 health agencies”;

1 (iii) by striking “The network” and
2 inserting the following:

3 “(A) IN GENERAL.—The network”; and

4 (iv) by adding at the end the fol-
5 lowing:

6 “(B) REVIEW.—Not later than 2 years
7 after the date of the enactment of the Pan-
8 demic and All-Hazards Preparedness and Ad-
9 vancing Innovation Act of 2018 and every 6
10 years thereafter, the Secretary shall conduct a
11 review of the elements described in subpara-
12 graph (A). Such review shall include a discus-
13 sion of the addition of any elements pursuant to
14 clause (v), including elements added to advanc-
15 ing new technologies, and identify any chal-
16 lenges in the incorporation of elements under
17 subparagraph (A). The Secretary shall provide
18 such review to the congressional committees of
19 jurisdiction.”;

20 (D) in paragraph (5)—

21 (i) by redesignating subparagraphs
22 (A) through (D) as clauses (i) through
23 (iv), respectively, and adjusting the mar-
24 gins accordingly;

1 (ii) by striking “In establishing” and
2 inserting the following:

3 “(A) IN GENERAL.—In establishing”;

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

6 “(B) PUBLIC MEETING.—

7 “(i) IN GENERAL.—Not later than
8 180 days after the date of enactment of
9 the Pandemic and All-Hazards Prepared-
10 ness and Advancing Innovation Act of
11 2018, the Secretary shall convene a public
12 meeting for purposes of discussing and
13 providing input on the potential goals,
14 functions, and uses of the network de-
15 scribed in paragraph (1) and incorporating
16 the elements described in paragraph
17 (3)(A).

18 “(ii) EXPERTS.—The public meeting
19 shall include representatives of relevant
20 Federal agencies (including representatives
21 from the Office of the National Coordi-
22 nator for Health Information Technology
23 and the National Institute of Standards
24 and Technology), State, local, tribal, and
25 territorial public health officials, stake-

1 holders with expertise in biosurveillance
2 and situational awareness, and stake-
3 holders with expertise in capabilities rel-
4 evant to biosurveillance and situational
5 awareness, such as experts in informatics
6 and data analytics (including experts in
7 prediction and forecasting), and other rep-
8 resentatives as the Secretary determines
9 appropriate.

10 “(iii) TOPICS.—Such public meeting
11 shall include a discussion of—

12 “(I) data elements, including
13 minimal or essential data elements,
14 that are voluntarily provided for such
15 network, which may include elements
16 from public health and public and pri-
17 vate health care entities, to the extent
18 practicable;

19 “(II) standards and implementa-
20 tion specifications that may improve
21 the collection, analysis, and interpre-
22 tation of data during a public health
23 emergency;

1 “(III) strategies to encourage the
2 access, exchange, and use of informa-
3 tion;

4 “(IV) considerations for State,
5 local, tribal, and territorial capabilities
6 and infrastructure related to data ex-
7 change and interoperability;

8 “(V) privacy and security protec-
9 tions provided at the Federal, State,
10 local, tribal, and territorial levels, and
11 by nongovernmental stakeholders; and

12 “(VI) opportunities for the incor-
13 poration of innovative technologies to
14 improve the network.”; and

15 (iv) in subparagraph (A), as so des-
16 ignated by clause (ii)—

17 (I) in clause (i), as so redesign-
18 nated—

19 (aa) by striking “as deter-
20 mined” and inserting “as adopt-
21 ed”; and

22 (bb) by inserting “and the
23 National Institute of Standards
24 and Technology” after “Office of

1 the National Coordinator for
2 Health Information Technology”;

3 (II) in clause (iii), as so redesignated,
4 by striking “; and” and inserting a semicolon;

5
6 (III) in clause (iv), as so redesignated,
7 by striking the period and inserting “; and”;

8 and
9 (IV) by adding at the end the following:
10

11 “(v) pilot test standards and implementation
12 specifications, consistent with the process
13 described in section 3002(b)(3)(C), which State,
14 local, tribal, and territorial public health
15 entities may utilize, on a voluntary basis,
16 as a part of the network.”;

17
18 (E) by redesignating paragraph (6) as
19 paragraph (7);

20 (F) by inserting after paragraph (5) the
21 following:

22 “(6) STRATEGY AND IMPLEMENTATION
23 PLAN.—

24 “(A) IN GENERAL.—Not later than 18
25 months after the date of enactment of the Pan-

1 for pandemics and all-hazards) from
2 public and private entities;

3 “(III) improve information shar-
4 ing, coordination, and communication
5 among disparate biosurveillance sys-
6 tems supported by the Department of
7 Health and Human Services, includ-
8 ing the identification of methods to
9 improve accountability, better utilize
10 resources and workforce capabilities,
11 and incorporate innovative tech-
12 nologies within and across agencies;
13 and

14 “(IV) test and evaluate capabili-
15 ties of the interoperable network of
16 systems to improve situational aware-
17 ness and biosurveillance capabilities;

18 “(iv) includes performance measures
19 and the metrics by which performance
20 measures will be assessed with respect to
21 the measurable steps under clause (iii);
22 and

23 “(v) establishes dates by which each
24 measurable step under clause (iii) will be
25 implemented.”.

1 “(B) ANNUAL BUDGET PLAN.—Not later
2 than 2 years after the date of enactment of the
3 Pandemic and All-Hazards Preparedness and
4 Advancing Innovation Act of 2018 and on an
5 annual basis thereafter, in accordance with the
6 strategy and implementation plan under this
7 paragraph, the Secretary shall, taking into ac-
8 count recommendations provided by the Na-
9 tional Biodefense Science Board, develop a
10 budget plan based on the strategy and imple-
11 mentation plan under this section. Such budget
12 plan shall include—

13 “(i) a summary of resources pre-
14 viously expended to establish, improve, and
15 utilize the nationwide public health situa-
16 tional awareness and biosurveillance net-
17 work under paragraph (1);

18 “(ii) estimates of costs and resources
19 needed to establish and improve the net-
20 work under paragraph (1) according to the
21 strategy and implementation plan under
22 subparagraph (A);

23 “(iii) the identification of gaps and in-
24 efficiencies in nationwide public health sit-
25 uational awareness and biosurveillance ca-

1 pabilities, resources, and authorities need-
2 ed to address such gaps; and
3 “(iv) a strategy to minimize and ad-
4 dress such gaps and improve inefficien-
5 cies.”;
6 (G) in paragraph (7), as so redesignated—
7 (i) in subparagraph (A), by inserting
8 “(taking into account zoonotic disease, in-
9 cluding gaps in scientific understanding of
10 the interactions between human, animal,
11 and environmental health)” after “human
12 health”;
13 (ii) in subparagraph (B)—
14 (I) by inserting “and gaps in sur-
15 veillance programs” after “surveil-
16 lance programs”; and
17 (II) by striking “; and” and in-
18 serting a semicolon;
19 (iii) in subparagraph (C)—
20 (I) by inserting “, animal health
21 organizations related to zoonotic dis-
22 ease,” after “health care entities”;
23 and
24 (II) by striking the period and
25 inserting “; and”; and

1 (iv) by adding at the end the fol-
2 lowing:

3 “(D) provide recommendations to the Sec-
4 retary on policies and procedures to complete
5 the steps described in this paragraph in a man-
6 ner that is consistent with section 2802.”; and

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

8 “(8) SITUATIONAL AWARENESS AND BIO-
9 SURVEILLANCE AS A NATIONAL SECURITY PRI-
10 ORITY.—The Secretary, on a periodic basis as appli-
11 cable and appropriate, shall meet with the Director
12 of National Intelligence to inform the development
13 and capabilities of the nationwide public health situ-
14 ational awareness and biosurveillance network.”;

15 (5) in subsection (d)—

16 (A) in paragraph (1)—

17 (i) by inserting “environmental health
18 agencies,” after “public health agencies,”;

19 and

20 (ii) by inserting “immunization pro-
21 grams,” after “poison control centers,”;

22 and

23 (B) in paragraph (2)—

24 (i) in subparagraph (B), by striking
25 “and” at the end;

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

3 (iii) by adding after subparagraph (C)
4 the following:

5 “(D) an implementation plan that may in-
6 clude measurable steps to achieve the purposes
7 described in paragraph (1).”; and

8 (C) by striking paragraph (5) and insert-
9 ing the following:

10 “(5) TECHNICAL ASSISTANCE.—The Secretary
11 may provide technical assistance to States, localities,
12 tribes, and territories or a consortium of States, lo-
13 calities, tribes, and territories receiving an award
14 under this subsection regarding interoperability and
15 the technical standards set forth by the Secretary.”;

16 (6) by redesignating subsections (f) and (g) as
17 subsections (h) and (i), respectively; and

18 (7) by inserting after subsection (e) the fol-
19 lowing:

20 “(f) TIMELINE.—The Secretary shall accomplish the
21 purposes under subsections (b) and (c) no later than Sep-
22 tember 30, 2023, and shall provide a justification to Con-
23 gress for any missed or delayed implementation of measur-
24 able steps identified under subsection (c)(6)(A)(iii).

1 “(g) INDEPENDENT EVALUATION.—Not later than 3
2 years after the date of enactment of the Pandemic and
3 All-Hazards Preparedness and Advancing Innovation Act
4 of 2018, the Comptroller General of the United States
5 shall conduct an independent evaluation, and submit to
6 the Secretary and the appropriate committees of Congress
7 a report concerning the activities conducted under sub-
8 sections (b) and (c), and provide recommendations, as ap-
9 plicable and appropriate, on necessary improvements to
10 the biosurveillance and situational awareness network.”.

11 (b) AUTHORIZATION OF APPROPRIATIONS.—Sub-
12 section (h) of section 319D (42 U.S.C. 247d–4), as redes-
13 igned by subsection (a)(6), is amended by striking
14 “\$138,300,000 for each of fiscal years 2014 through
15 2018” and inserting “\$161,800,000 for each of fiscal
16 years 2019 through 2023”.

17 **SEC. 205. STRENGTHENING AND SUPPORTING THE PUBLIC**
18 **HEALTH EMERGENCY RAPID RESPONSE**
19 **FUND.**

20 Section 319 of the Public Health Service Act (42
21 U.S.C. 247d) is amended—

22 (1) in subsection (b)—

23 (A) in paragraph (1)—

24 (i) in the first sentence, by inserting

25 “or if the Secretary determines there is the

1 significant potential for a public health
2 emergency, to allow the Secretary to rap-
3 idly respond to the immediate needs result-
4 ing from such public health emergency or
5 potential public health emergency” before
6 the period; and

7 (ii) by inserting “The Secretary shall
8 plan for the expedited distribution of funds
9 to appropriate agencies and entities.” after
10 the first sentence;

11 (B) by redesignating paragraph (2) as
12 paragraph (3);

13 (C) by inserting after paragraph (1) the
14 following:

15 “(2) USES.—The Secretary may use amounts
16 in the Fund established under paragraph (1), to—

17 “(A) facilitate coordination between and
18 among Federal, State, local, tribal, and terri-
19 torial entities and public and private health
20 care entities that the Secretary determines may
21 be affected by a public health emergency or po-
22 tential public health emergency (including com-
23 munication of such entities with relevant inter-
24 national entities, as applicable);

1 “(B) make grants, provide for awards,
2 enter into contracts, and conduct supportive in-
3 vestigations pertaining to a public health emer-
4 gency or potential public health emergency, in-
5 cluding further supporting programs under sec-
6 tion 319C–1 or 319C–2;

7 “(C) facilitate and accelerate, as applica-
8 ble, advanced research and development of secu-
9 rity countermeasures (as defined in section
10 319F–2), qualified countermeasures (as defined
11 in section 319F–1), or qualified pandemic or
12 epidemic products (as defined in section 319F–
13 3), that are applicable to the public health
14 emergency or potential public health emergency
15 under paragraph (1);

16 “(D) strengthen biosurveillance capabilities
17 and laboratory capacity to identify, collect, and
18 analyze information on such public health emer-
19 gency or potential public health emergency, in-
20 cluding the systems under section 319D;

21 “(E) support initial emergency operations
22 and assets related to preparation and deploy-
23 ment of intermittent disaster response per-
24 sonnel expenses under section 2812, and the
25 Medical Reserve Corps under section 2813; and

1 “(F) other activities, as the Secretary de-
2 termines applicable and appropriate.”; and

3 (D) by inserting after paragraph (3), as so
4 redesignated, the following:

5 “(4) REVIEW.—Not later than 2 years after the
6 date of enactment of the Pandemic and All-Hazards
7 Preparedness and Advancing Innovation Act of
8 2018, the Secretary, in coordination with the Assist-
9 ant Secretary for Preparedness and Response, shall
10 conduct a review of the Fund under this section, and
11 provide recommendations to the Committee on
12 Health, Education, Labor, and Pensions and the
13 Committee on Appropriations of the Senate and the
14 Committee on Energy and Commerce and the Com-
15 mittee on Appropriations of the House of Represent-
16 atives on policies to improve such Fund for the uses
17 described in paragraph (2).

18 “(5) GAO REPORT.—Not later than 4 years
19 after the date of enactment of the Pandemic and
20 All-Hazards Preparedness and Advancing Innovation
21 Act of 2018, the Comptroller General of the United
22 States shall conduct a review of the Fund under this
23 section, including the uses and the resources avail-
24 able in the Fund.”; and

25 (2) in subsection (c)—

1 (A) by inserting “rapidly respond to public
2 health emergencies or potential public health
3 emergencies and” after “used to”; and

4 (B) by striking “section.” and inserting
5 “Act or funds otherwise provided for emergency
6 response.”.

7 **SEC. 206. IMPROVING PREPAREDNESS FOR AND RESPONSE**
8 **TO ALL-HAZARDS BY PUBLIC HEALTH EMER-**
9 **GENCY VOLUNTEERS.**

10 Section 319I (42 U.S.C. 247d–7b) is amended:

11 (1) in subsection (a), by adding at the end the
12 following: “Such health care professionals may in-
13 clude members of the National Disaster Medical
14 System, members of the Medical Reserve Corps, and
15 individual health care professionals.”;

16 (2) in subsection (i) by adding at the end “In
17 order to inform the development of such mechanisms
18 by States, the Secretary shall make available infor-
19 mation and material provided by States that have
20 developed mechanisms to waive the application of li-
21 censing requirements to applicable health profes-
22 sionals seeking to provide medical services during a
23 public health emergency. Such information shall be
24 made publicly available in a manner that does not
25 jeopardize national security.”; and

1 (3) in subsection (k) by striking “\$2014
2 through 2018” and inserting “2019 through 2023”.

3 **TITLE III—REACHING ALL**
4 **COMMUNITIES**

5 **SEC. 301. STRENGTHENING AND ASSESSING THE EMER-**
6 **GENCY RESPONSE WORKFORCE.**

7 (a) NATIONAL DISASTER MEDICAL SYSTEM.—Clause
8 (ii) of section 2812(a)(3)(A) (42 U.S.C. 300hh–
9 11(a)(3)(A)) is amended to read as follows:

10 “(ii) be present at locations, and for
11 limited periods of time, specified by the
12 Secretary on the basis that the Secretary
13 has determined that a location is at risk of
14 a public health emergency during the time
15 specified, or there is a significant potential
16 for a public health emergency.”.

17 (b) VOLUNTEER MEDICAL RESERVE CORPS.—Sec-
18 tion 2813(a) (42 U.S.C. 42 U.S.C. 300hh–15(a)) is
19 amended by striking the second sentence and inserting
20 “The Secretary may appoint a Director to head the Corps
21 and oversee the activities of the Corps chapters that exist
22 at the State, local, and tribal levels.”

23 (c) REVIEW OF THE NATIONAL DISASTER MEDICAL
24 SYSTEM.—Section 2812(b)(2) (42 U.S.C. 300hh–
25 11(b)(2)) is amended to read as follows:

1 “(2) JOINT REVIEW AND MEDICAL SURGE CA-
2 PACITY STRATEGIC PLAN.—

3 “(A) REVIEW.—Not later than 180 days
4 after the date of enactment of the Pandemic
5 and All-Hazards Preparedness and Advancing
6 Innovation Act of 2018, the Secretary, in co-
7 ordination with the Secretary of Homeland Se-
8 curity, the Secretary of Defense, and the Sec-
9 retary of Veterans Affairs, shall conduct a joint
10 review of the National Disaster Medical System.
11 Such review shall include—

12 “(i) an evaluation of medical surge ca-
13 pacity, as described in section 2803(a);

14 “(ii) an assessment of the available
15 workforce of the intermittent disaster re-
16 sponse personnel described in subsection
17 (c);

18 “(iii) the capacity of the workforce de-
19 scribed in clause (ii) to respond to all haz-
20 ards, including capacity to simultaneously
21 respond to multiple public health emer-
22 gencies and the capacity to respond to a
23 nationwide public health emergency;

24 “(iv) the effectiveness of efforts to re-
25 cruit, retain, and train such workforce; and

1 “(v) gaps that may exist in such
2 workforce and recommendations for ad-
3 dressing such gaps.

4 “(B) UPDATES.—As part of the National
5 Health Security Strategy under section 2802,
6 the Secretary shall update the findings from the
7 review under subparagraph (A) and provide rec-
8 ommendations to modify the policies of the Na-
9 tional Disaster Medical System as necessary.”.

10 (d) NOTIFICATION OF NDMS SHORTAGE.—Section
11 2812(c) (42 U.S.C. 300hh–11(c)) is amended by adding
12 at the end the following:

13 “(3) SERVICE BENEFIT.—Individuals appointed
14 to serve under this subsection shall be considered
15 public safety officers under part L of title I of the
16 Omnibus Crime Control and Safe Streets Act of
17 1968. The Secretary shall provide notification to eli-
18 gible individuals of any effect such designation may
19 have on other benefits for which such individuals are
20 eligible, including benefits from private entities.

21 “(4) NOTIFICATION.—Not later than 30 days
22 after the date on which the Secretary determines the
23 number of intermittent disaster response personnel
24 of such System is insufficient to address a public
25 health emergency or potential public health emer-

1 agency, the Secretary shall submit to the congress-
2 sional committees of jurisdiction a notification de-
3 tailing the impact such shortage could have on meet-
4 ing public health needs and emergency medical per-
5 sonnel needs during a public health emergency, and
6 any identified measures to address such shortage.

7 “(5) CERTAIN APPOINTMENTS.—

8 “(A) IN GENERAL.—If the Secretary deter-
9 mines that the number of intermittent disaster
10 response personnel within the National Disaster
11 Medical System under this section is insuffi-
12 cient to address a public health emergency or
13 potential public health emergency, the Secretary
14 may appoint candidates directly to personnel
15 positions for intermittent disaster response
16 within such system. The Secretary shall provide
17 updates on the number of vacant or unfilled po-
18 sitions within such system to the congressional
19 committees of jurisdiction each quarter for
20 which this authority is in effect.

21 “(B) SUNSET.—The authority under this
22 paragraph shall expire on September 30,
23 2021.”.

1 (e) PUBLIC SAFETY OFFICER BENEFITS.—Section
2 1204(9) of title I of the Omnibus Crime Control and Safe
3 Streets Act of 1968 (34 U.S.C. 10284(9)) is amended—

4 (1) in subparagraph (C)(ii), by striking “or” at
5 the end;

6 (2) in subparagraph (D), by striking the period
7 and inserting “; or”; and

8 (3) by inserting after subparagraph (D) the fol-
9 lowing:

10 “(E) an individual appointed to the Na-
11 tional Disaster Medical System under section
12 2812 of the Public Health Service Act (42
13 U.S.C. 300hh–11) who is performing official
14 duties of the Department of Health and Human
15 Services, if those official duties are related to
16 responding to a public health emergency or po-
17 tential public health emergency, or other activi-
18 ties for which the Secretary of Health and
19 Human Services has activated such National
20 Disaster Medical System.”.

21 (f) NATIONAL DISASTER MEDICAL SYSTEM AUTHOR-
22 IZATION OF APPROPRIATIONS.—Section 2812(g) (42
23 U.S.C. 300hh–11(g)) is amended by striking
24 “\$52,700,000 for each of fiscal years 2014 through 2018”

1 and inserting “\$57,400,000 for each of fiscal years 2019
2 through 2023”.

3 (g) MEDICAL RESERVE CORPS. AUTHORIZATION OF
4 APPROPRIATIONS.—Section 2813(i) (42 U.S.C. 300hh–
5 15(i)) is amended by striking “2014 through 2018” and
6 inserting “2019 through 2023”.

7 **SEC. 302. HEALTH SYSTEM INFRASTRUCTURE TO IMPROVE**
8 **PREPAREDNESS AND RESPONSE.**

9 (a) COORDINATION OF PREPAREDNESS.—Section
10 2811(b)(5) (42 U.S.C. 300hh–10(b)(5)) is amended by
11 adding at the end the following: “Such logistical support
12 shall include working with other relevant Federal, State,
13 local, tribal, and territorial public health officials and pri-
14 vate sector partners to identify the critical infrastructure
15 assets, systems, and networks needed for the proper func-
16 tioning of the health care and public health sectors that
17 need to be maintained through any emergency or disaster,
18 including entities capable of assisting with, responding to,
19 and mitigating the effect of a public health emergency,
20 including an emergency under section 319, an emergency
21 or major disaster under the Robert T. Stafford Disaster
22 Relief and Emergency Assistance Act, or the National
23 Emergencies Act, including by establishing methods to ex-
24 change critical information and deliver products consumed

1 or used to preserve, protect, or sustain life, health, or safe-
2 ty, and sharing of specialized expertise.”.

3 (b) MANUFACTURING CAPACITY.—Section
4 2811(d)(2)(C) (42 U.S.C. 300hh–10(d)(2)(C)) is amended
5 by inserting “, and ancillary medical supplies to assist
6 with the utilization of such products,” after “products”.

7 **SEC. 303. CONSIDERATIONS FOR AT-RISK INDIVIDUALS.**

8 (a) AT-RISK INDIVIDUALS IN THE NATIONAL
9 HEALTH SECURITY STRATEGY.—Section 2802(b)(4)(B)
10 (42 U.S.C. 300hh–1(b)(4)(B)) is amended—

11 (1) by striking “this section and sections 319C–
12 1, 319F, and 319L,” and inserting “this Act”; and

13 (2) by striking “special” and inserting “access
14 or functional”.

15 (b) COUNTERMEASURE CONSIDERATIONS.—Section
16 319L(c)(6) (42 U.S.C. 247d–7e(e)(6)) is amended—

17 (1) by striking “elderly” and inserting “senior
18 citizens”; and

19 (2) by inserting “with relevant characteristics
20 that warrant consideration during the process of re-
21 searching and developing such countermeasures and
22 products” before the period.

1 **SEC. 304. IMPROVING EMERGENCY PREPAREDNESS AND**
2 **RESPONSE CONSIDERATIONS FOR CHIL-**
3 **DREN.**

4 Part B of title III (42 U.S.C. 243 et seq.) is amended
5 by inserting after section 319D the following:

6 **“SEC. 319D-1. CHILDREN’S PREPAREDNESS UNIT.**

7 “(a) **ENHANCING EMERGENCY PREPAREDNESS FOR**
8 **CHILDREN.**—The Secretary, acting through the Director
9 of the Centers for Disease Control and Prevention (re-
10 ferred to in this subsection as the ‘Director’), shall main-
11 tain an internal team of experts, to be known as the Chil-
12 dren’s Preparedness Unit (referred to in this subsection
13 as the ‘Unit’), to work collaboratively to provide guidance
14 on the considerations for, and the specific needs of, chil-
15 dren before, during, and after public health emergencies.
16 The Unit shall inform the Director regarding emergency
17 preparedness and response efforts pertaining to children
18 at the Centers for Disease Control and Prevention.

19 “(b) **EXPERTISE.**—The team described in subsection
20 (a) shall include one or more pediatricians, which may be
21 a developmental-behavior pediatrician, and may also in-
22 clude behavioral scientists, child psychologists, epidemiolo-
23 gists, biostatisticians, health communications staff, and
24 individuals with other areas of expertise, as the Secretary
25 determines appropriate.

1 “(c) DUTIES.—The team described in subsection (a)
2 may—

3 “(1) assist State, local, tribal, and territorial
4 emergency planning and response activities related
5 to children, which may include developing, identi-
6 fying, and sharing best practices;

7 “(2) provide technical assistance, training, and
8 consultation to Federal, State, local, tribal, and ter-
9 ritorial public health officials to improve prepared-
10 ness and response capabilities with respect to the
11 needs of children, including providing such technical
12 assistance, training, and consultation to eligible enti-
13 ties in order to support the achievement of measur-
14 able evidence-based benchmarks and objective stand-
15 ards applicable to sections 319C–1 and 319C–2 ;

16 “(3) improve the utilization of methods to in-
17 corporate the needs of children in planning for and
18 responding to a public health emergency, including
19 public awareness of such methods;

20 “(4) coordinate with, and improve, public-pri-
21 vate partnerships, such as health care coalitions pur-
22 suant to sections 319C–2 and 319C–3, to address
23 gaps and inefficiencies in emergency preparedness
24 and response efforts for children;

1 “(5) provide expertise and input during the de-
2 velopment of guidance and clinical recommendations
3 to address the needs of children when preparing for,
4 and responding to, public health emergencies; and

5 “(6) carry out other duties related to prepared-
6 ness and response activities for children, as the Sec-
7 retary determines appropriate.”.

8 **SEC. 305. REAUTHORIZING THE NATIONAL ADVISORY COM-**
9 **MITTEE ON CHILDREN AND DISASTERS.**

10 Section 2811A (42 U.S.C. 300hh–10a) is amended—

11 (1) in subsection (b)(2), by inserting “, mental
12 and behavioral,” after “medical”;

13 (2) in subsection (d)—

14 (A) in paragraph (1), by striking “15” and
15 inserting “25”; and

16 (B) by striking paragraph (2) and insert-
17 ing the following:

18 “(2) **REQUIRED NON-FEDERAL MEMBERS.**—The
19 Secretary, in consultation with such other heads of
20 Federal agencies as may be appropriate, shall ap-
21 point to the Advisory Committee under paragraph
22 (1) at least 13 individuals to perform the duties de-
23 scribed in subsections (b) and (c), including—

1 “(A) at least 2 non-Federal professionals
2 with expertise in pediatric medical disaster
3 planning, preparedness, response, or recovery;

4 “(B) at least 2 representatives from State,
5 local, tribal, or territorial agencies with exper-
6 tise in pediatric disaster planning, prepared-
7 ness, response, or recovery;

8 “(C) at least 4 members representing
9 health care professionals, which may include
10 members with expertise in pediatric emergency
11 medicine; pediatric trauma, critical care, or sur-
12 gery; the treatment of pediatric patients af-
13 fected by chemical, biological, radiological, or
14 nuclear agents and emerging infectious dis-
15 eases; pediatric mental or behavioral health re-
16 lated to children affected by a public health
17 emergency; or pediatric primary care; and

18 “(D) other members as the Secretary de-
19 termines appropriate, of whom—

20 “(i) at least one such member shall
21 represent a children’s hospital;

22 “(ii) at least one such member shall
23 be an individual with expertise in schools
24 or child care settings;

1 “(G) The Administrator of the Health Re-
2 sources and Services Administration.

3 “(H) The Administrator of the Federal
4 Emergency Management Agency.

5 “(I) The Administrator of the Administra-
6 tion for Community Living.

7 “(J) The Secretary of Education.

8 “(K) Representatives from such Federal
9 agencies (such as the Substance Abuse and
10 Mental Health Services Administration and the
11 Department of Homeland Security) as the Sec-
12 retary determines appropriate to fulfill the du-
13 ties of the Advisory Committee under sub-
14 sections (b) and (c).”.

15 “(4) TERM OF APPOINTMENT.—Each member
16 of the Advisory Committee appointed under para-
17 graph (2) shall serve for a term of 3 years, except
18 that the Secretary may adjust the terms of the Advi-
19 sory Committee appointees serving on the date of
20 enactment of the Pandemic and All-Hazards Pre-
21 paredness and Advancing Innovation Act of 2018, or
22 appointees who are initially appointed after such
23 date of enactment, in order to provide for a stag-
24 gered term of appointment for all members.

1 “(5) CONSECUTIVE APPOINTMENTS; MAXIMUM
2 TERMS.—A member appointed under paragraph (2)
3 may serve not more than 3 terms on the Advisory
4 Committee, and not more than 2 of which may be
5 served consecutively.”;

6 (3) in subsection (e), by adding at the end “At
7 least one meeting per year shall be an in-person
8 meeting.”; and

9 (4) in subsection (f) by striking “2018” and in-
10 serting “2023”.

11 **SEC. 306. GUIDANCE FOR PARTICIPATION IN EXERCISES**
12 **AND DRILLS.**

13 Not later than 2 years after the date of enactment
14 of this Act, the Secretary of Health and Human Services
15 shall issue final guidance regarding the participation of
16 State, local, tribal, and territorial public health depart-
17 ment or agency personnel funded in whole or in part
18 through programs authorized under this Act in drills and
19 operational exercises in order to identify, inform, and ad-
20 dress the gaps in and policies related to all-hazards med-
21 ical and public health preparedness and response, which
22 may include drills and operational exercises that incor-
23 porate medical surge capacity planning, medical counter-
24 measure distribution and administration, and preparing
25 for and responding to identified threats for that region.

1 The Secretary shall consult with the Department of
2 Homeland Security, the Department of Defense, the De-
3 partment of Veterans Affairs, and other applicable Fed-
4 eral departments and agencies as necessary and appro-
5 priate in the development of such guidance. The Secretary
6 shall make the guidance available on the internet website
7 of the Department of Health and Human Services.

8 **TITLE IV—PRIORITIZING A**
9 **THREAT-BASED APPROACH**

10 **SEC. 401. ASSISTANT SECRETARY FOR PREPAREDNESS AND**
11 **RESPONSE.**

12 Section 2811(b) (42 U.S.C. 300hh–10(b)) is amend-
13 ed—

14 (1) in the matter preceding paragraph (1) by
15 inserting “utilize experience related to public health
16 emergency preparedness and response, biodefense,
17 medical countermeasures, and other relevant topics
18 to” after “shall”; and

19 (2) in paragraph (4) by adding at the end the
20 following:

21 “(I) **THREAT AWARENESS.**—Coordinate
22 with the Director of the Centers for Disease
23 Control and Prevention, the Director of Na-
24 tional Intelligence, the Secretary of Homeland
25 Security, the Assistant to the President for Na-

1 tional Security Affairs, the Secretary of De-
2 fense, and other relevant Federal officials, to
3 maintain a current assessment of national secu-
4 rity threats and inform preparedness and re-
5 sponse capabilities based on the range of the
6 threats that have the potential to result in a
7 public health emergency.”.

8 **SEC. 402. PUBLIC HEALTH EMERGENCY MEDICAL COUN-**
9 **TERMEASURES ENTERPRISE.**

10 (a) IN GENERAL.—Title XXVIII is amended by in-
11 serting after section 2811 (42 U.S.C. 300hh–10) the fol-
12 lowing:

13 **“SEC. 2811–1. PUBLIC HEALTH EMERGENCY MEDICAL**
14 **COUNTERMEASURES ENTERPRISE.**

15 “(a) IN GENERAL.—The Secretary shall establish the
16 Public Health Emergency Medical Countermeasures En-
17 terprise (referred to in this section as the ‘PHEMCE’).
18 The Assistant Secretary for Preparedness and Response
19 shall serve as chair of the PHEMCE.

20 “(b) MEMBERS.—The PHEMCE shall include each
21 of the following members, or the designee of such mem-
22 bers:

23 “(1) The Assistant Secretary for Preparedness
24 and Response.

1 “(2) The Director of the Centers for Disease
2 Control and Prevention.

3 “(3) The Director of the National Institutes of
4 Health.

5 “(4) The Commissioner of Food and Drugs.

6 “(5) The Secretary of Defense.

7 “(6) The Secretary of Homeland Security.

8 “(7) The Secretary of Agriculture.

9 “(8) The Secretary of Veterans Affairs.

10 “(9) Representatives of any other Federal agen-
11 cy, which may include the Director of the Bio-
12 medical Advanced Research and Development Au-
13 thority, and the Director of the Strategic National
14 Stockpile, as the Secretary determines appropriate.

15 “(c) FUNCTIONS.—

16 “(1) IN GENERAL.—The functions of the
17 PHEMCE shall include the following:

18 “(A) Establish a process pursuant to sec-
19 tion 2811(d)(2)(B) to make recommendations
20 to the Secretary regarding the prioritization of
21 research, development, and procurement of
22 countermeasures, as defined in section 319F-
23 2(e), based on the health security needs of the
24 United States. Such recommendations shall be
25 informed by the National Health Security

1 Strategy pursuant to section 2802, the Stra-
2 tegic National Stockpile review required under
3 section 319F-2(a)(2), the countermeasures
4 budget plan pursuant to section 2811(b)(7),
5 and an assessment of current national security
6 threats, including chemical, biological, radio-
7 logical and nuclear threats, including emerging
8 infectious diseases. In the event that members
9 of the PHEMCE do not agree upon a rec-
10 ommendation, the Secretary shall provide a de-
11 termination regarding such recommendation.

12 “(B) Identify national health security
13 needs, including gaps in public health prepared-
14 ness and response related to countermeasures
15 and challenges to addressing such needs (in-
16 cluding any regulatory challenges), and provide
17 for alignment of countermeasure procurement
18 with recommendations under subparagraph (A).

19 “(C) Develop strategies related to logistics,
20 deployment, distribution, dispensing, and use of
21 countermeasures that may be applicable to the
22 activities of the strategic national stockpile
23 under section 319F-2(a).

1 “(D) Provide consultation for the develop-
2 ment of the strategy and implementation plan
3 under section 2811(d).

4 “(2) INPUT.—In carrying out subparagraphs
5 (B) and (C) of paragraph (1), the PHEMCE shall
6 solicit and consider input from State, local, tribal,
7 and territorial public health departments, as appro-
8 priate.”.

9 (b) PUBLIC HEALTH EMERGENCY MEDICAL COUN-
10 TERMEASURES ENTERPRISE STRATEGY AND IMPLEMEN-
11 TATION PLAN.—Section 2811(d)(1) (42 U.S.C. 300hh-
12 10(d)(1)) is amended—

13 (1) by striking “Not later than 180 days after
14 the date of enactment of this subsection, and every
15 year thereafter” and inserting “Not later than
16 March 15, 2020, and biennially thereafter”; and

17 (2) by striking “Director of Biomedical” and all
18 that follows through “Food and Drugs” and insert-
19 ing “Public Health Emergency Medical Counter-
20 measures Enterprise established under section
21 2811-1”.

22 **SEC. 403. STRATEGIC NATIONAL STOCKPILE.**

23 (a) Section 319F-2(a) (42 U.S.C. 247d-6b(a)) is
24 amended—

1 (1) by redesignating paragraphs (2) and (3) as
2 paragraphs (3) and (4), respectively; and

3 (2) in paragraph (1)—

4 (A) by inserting “and optimize” after
5 “provide for”;

6 (B) by inserting “and, as informed by ex-
7 isting recommendations of, or consultations
8 with, the Public Health Emergency Medical
9 Countermeasure Enterprise established under
10 section 2811–1, make necessary additions or
11 modifications to the contents of such stockpile
12 or stockpiles based on the review conducted
13 under paragraph (2)” before the period of the
14 first sentence; and

15 (C) by striking the second sentence;

16 (3) by inserting after paragraph (1) the fol-
17 lowing:

18 “(2) THREAT-BASED REVIEW.—

19 “(A) IN GENERAL.—The Secretary shall
20 conduct a biennial threat-based review (taking
21 into account at-risk individuals) of the contents
22 of the stockpile under paragraph (1), including
23 non-pharmaceutical supplies, and, in consulta-
24 tion with the Public Health Emergency Medical
25 Countermeasures Enterprise established under

1 section 2811–1, review contents within the
2 stockpile and assess whether such contents are
3 consistent with the recommendations made pur-
4 suant to section 2811–1(c)(1)(A). Such review
5 shall be submitted biennially, beginning on
6 March 15, 2019, to the Committee on Health,
7 Education, Labor, and Pensions and the Com-
8 mittee on Appropriations of the Senate and the
9 Committee on Energy and Commerce and the
10 Committee on Appropriations of the House of
11 Representatives, in a manner that does not
12 compromise national security.

13 “(B) ADDITIONS, MODIFICATIONS, AND
14 REPLENISHMENTS.—Each biennial threat-based
15 review under subparagraph (A) shall, for each
16 new or modified countermeasure procurement
17 or replenishment, provide—

18 “(i) information regarding—

19 “(I) the quantities of the addi-
20 tional or modified countermeasure
21 procured for, or contracted to be pro-
22 cured for, the stockpile;

23 “(II) planning considerations for
24 appropriate manufacturing capacity
25 and capability to meet the goals of

1 such additions or modifications (with-
2 out disclosing proprietary informa-
3 tion), including consideration of the
4 effect such additions or modifications
5 may have on the availability of such
6 products and ancillary medical sup-
7 plies in the health care system;

8 “(III) the presence or lack of a
9 commercial market for the counter-
10 measure at the time of procurement;

11 “(IV) the emergency health secu-
12 rity threat or threats such counter-
13 measure procurement is intended to
14 address, including whether such pro-
15 curement is consistent with meeting
16 emergency health security needs asso-
17 ciated with such threat or threats;

18 “(V) an assessment of whether
19 the emergency health security threat
20 or threats described in subclause (IV)
21 could be addressed in a manner that
22 better utilizes the resources of the
23 stockpile and permits the greatest
24 possible increase in the level of emer-

1 agency preparedness to address such
2 threats;

3 “(VI) whether such counter-
4 measure is replenishing an expired
5 countermeasure, is a different coun-
6 termeasure with the same indication
7 that is replacing an expired counter-
8 measure, or is a new addition to the
9 stockpile;

10 “(VII) a description of how such
11 additions or modifications align with
12 the countermeasures budget plan as
13 required under section 2811(b)(7), in-
14 cluding expected life-cycle costs, ex-
15 penditures related to countermeasure
16 procurement to address the threat or
17 threats described in subclause (IV),
18 replenishment dates (including the
19 ability to extend the maximum shelf
20 life of a countermeasure), and the
21 manufacturing capacity required to
22 replenish such countermeasure; and

23 “(VIII) appropriate protocols and
24 processes for the deployment, distribu-
25 tion, or dispensing of the counter-

1 measure at the State and local level,
2 including plans for relevant capabili-
3 ties of State and local entities to dis-
4 pense, distribute, and administer the
5 countermeasure; and

6 “(ii) an assurance that for each coun-
7 termeasure produced or replenished under
8 this subsection, the Secretary completed a
9 review addressing each item listed under
10 this subsection in advance of such procure-
11 ment or replenishment, which need not be
12 provided in advance of procurement.”;

13 (4) in paragraph (3), as so redesignated—

14 (A) in subparagraph (A), by inserting
15 “and the Public Health Emergency Medical
16 Countermeasures Enterprise established under
17 section 2811–1” before the semicolon;

18 (B) in subparagraph (C), by inserting “,
19 and the availability, deployment, dispensing,
20 and administration of countermeasures” before
21 the semicolon; and

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

24 “(E) devise plans for effective and timely
25 supply-chain management of the stockpile, in

1 consultation with the Director of the Centers
2 for Disease Control and Prevention, the Assist-
3 ant Secretary for Preparedness and Response,
4 the Secretary of Transportation, the Secretary
5 of Homeland Security, the Secretary of Vet-
6 erans Affairs, and the heads of other appro-
7 priate Federal agencies, State, local, tribal, and
8 territorial agencies, and the public and private
9 health care infrastructure, as applicable, taking
10 into account the manufacturing capacity and
11 other available sources of products and appro-
12 priate alternatives to supplies in the stockpile;”
13 and

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

15 “(5) GAO REPORT.—

16 “(A) IN GENERAL.—Not later than 3 years
17 after the date of enactment of the Pandemic
18 and All-Hazards Preparedness and Advancing
19 Innovation Act of 2018, and every 5 years
20 thereafter, the Comptroller General of the
21 United States shall conduct a review of any
22 changes to the contents or management of the
23 stockpile since January 1, 2015. Such review
24 shall include—

1 “(i) an assessment of the comprehen-
2 siveness and completeness of each biennial
3 threat-based review under paragraph (2),
4 including whether all newly procured or re-
5 plenished countermeasures within the
6 stockpile were described in each annual re-
7 view, and whether, consistent with para-
8 graph (2)(B), the Secretary conducted the
9 necessary internal review in advance of
10 such procurement or replenishment;

11 “(ii) an assessment of whether the
12 Secretary established health security and
13 science-based justifications, and a descrip-
14 tion of such justifications for procurement
15 decisions related to health security needs
16 with respect to the identified threat, for
17 additions or modifications to the stockpile
18 based on the information provided in such
19 reviews under paragraph (2)(B), including
20 whether such review was conducted prior
21 to procurement, modification, or replenish-
22 ment;

23 “(iii) an assessment of the plans de-
24 veloped by the Secretary for the deploy-
25 ment, distribution, and dispensing of coun-

1 countermeasures procured, modified, or replen-
2 ished under paragraph (1), including
3 whether such plans were developed prior to
4 procurement, modification, or replenish-
5 ment;

6 “(iv) an accounting of counter-
7 measures procured, modified, or replen-
8 ished under paragraph (1) that received
9 advanced research and development fund-
10 ing from the Biomedical Advanced Re-
11 search and Development Authority;

12 “(v) an analysis of how such procure-
13 ment decisions made progress towards
14 meeting emergency health security needs
15 related to the identified threats for coun-
16 termeasures added, modified, or replen-
17 ished under paragraph (1);

18 “(vi) a description of the resources ex-
19 pended related to the procurement of coun-
20 termeasures (including additions, modifica-
21 tions, and replenishments) in the stockpile,
22 and how such expenditures relate to the
23 emergency health security needs of the
24 stockpile;

1 “(vii) an assessment of the extent to
2 which additions, modifications, and replen-
3 ishments reviewed under paragraph (2)
4 align with previous relevant reports or re-
5 views by the Secretary or the Comptroller
6 General; and

7 “(viii) with respect to any change in
8 the Federal organizational management of
9 the stockpile, an assessment and compari-
10 son of the processes affected by such
11 change, including planning for potential
12 countermeasure deployment, distribution,
13 or dispensing capabilities and processes re-
14 lated to procurement decisions, use of
15 stockpiled countermeasures, and use of re-
16 sources for such activities.

17 “(B) SUBMISSION.—Not later than 6
18 months after completing a classified version of
19 the review under subparagraph (A), the Comp-
20 troller General shall submit an unclassified
21 version of the review to the appropriate commit-
22 tees of Congress.”.

23 (b) AUTHORIZATION OF APPROPRIATIONS, STRA-
24 TEGIC NATIONAL STOCKPILE.—Section 319F-2(f)(1) (42
25 U.S.C. 247d-6b(f)(1)) is amended by striking

1 “\$533,800,000 for each of fiscal years 2014 through
2 2018” and inserting “\$610,000,000 for each of fiscal
3 years 2019 through 2023”.

4 **SEC. 404. PREPARING FOR PANDEMIC INFLUENZA, ANTI-**
5 **MICROBIAL RESISTANCE, AND OTHER SIG-**
6 **NIFICANT THREATS.**

7 Section 319L(c)(4) (247d–7e(c)(4)) is amended by
8 adding at the end the following:

9 “(F) STRATEGIC INITIATIVES.—The Sec-
10 retary, acting through the Director of BARDA,
11 may implement strategic initiatives, including
12 by building on existing programs, supporting
13 innovative candidate products in preclinical and
14 clinical development, to address priority, natu-
15 rally occurring and man-made threats that, as
16 determined by the Secretary, pose a significant
17 level of risk to national security based on the
18 characteristics of a chemical, biological, radio-
19 logical or nuclear threat, or existing capabilities
20 to respond to such a threat (including medical
21 response and treatment capabilities and manu-
22 facturing infrastructure). Such initiatives shall
23 accelerate and support the advanced research,
24 development, and procurement of, counter-

1 measures and products, as applicable, to ad-
2 dress areas including—

3 “(i) chemical, biological, radiological,
4 or nuclear threats, including emerging in-
5 fectionous diseases, for which insufficient ap-
6 proved, licensed, or authorized counter-
7 measures exist, or for which such threat,
8 or the result of an exposure to such threat,
9 may become resistant to countermeasures
10 or existing countermeasures may be ren-
11 dered ineffective;

12 “(ii) threats that consistently exist or
13 continually circulate and have significant
14 potential to become a pandemic, such as
15 pandemic influenza, which may include the
16 advanced research and development, manu-
17 facturing, and appropriate stockpiling of
18 qualified pandemic or epidemic products,
19 and products, technologies, or processes to
20 support the advanced research and devel-
21 opment of such countermeasures (including
22 multiuse platform technologies for
23 diagnostics, vaccines, and therapeutics;
24 virus seeds; clinical trial lots; novel virus

1 strains; and antigen and adjuvant mate-
2 rial); and

3 “(iii) threats that may result pri-
4 marily or secondarily from a chemical, bio-
5 logical, radiological, or nuclear agent, or
6 emerging infectious disease, and which
7 may present increased treatment complica-
8 tions such as the occurrence of resistance
9 to available countermeasures or potential
10 countermeasures, including antimicrobial
11 resistant pathogens.”.

12 **SEC. 405. REPORTING ON THE FEDERAL SELECT AGENT**
13 **PROGRAM.**

14 Section 351A(k) (42 U.S.C. 262a) is amended—

15 (1) by striking “The Secretary” and inserting
16 the following:

17 “(1) IN GENERAL.—The Secretary”; and

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

19 “(2) IMPLEMENTATION OF RECOMMENDATIONS
20 OF THE FEDERAL EXPERTS SECURITY ADVISORY
21 PANEL AND THE FAST TRACK ACTION COMMITTEE
22 ON SELECT AGENT REGULATIONS.—

23 “(A) IN GENERAL.—Not later than 1 year
24 after the date of the enactment of the Pan-
25 demic and All-Hazards Preparedness and Ad-

1 vancing Innovation Act of 2018, the Secretary
2 shall provide an update to the appropriate com-
3 mittees of Congress on the implementation of
4 recommendations of the Federal Experts Secu-
5 rity Advisory Panel concerning the select agent
6 program.

7 “(B) CONTINUED UPDATES.—The Sec-
8 retary shall provide status updates at 6 month
9 intervals following the submission of the update
10 under subparagraph (A) until the recommenda-
11 tions described in such subparagraph are fully
12 implemented, or a justification is provided for
13 the delay in, or lack of, implementation.”.

14 **TITLE V—INCREASING COMMU-**
15 **NICATION IN MEDICAL COUN-**
16 **TERMEASURE ADVANCED RE-**
17 **SEARCH AND DEVELOPMENT**

18 **SEC. 501. MEDICAL COUNTERMEASURE BUDGET PLAN.**

19 Section 2811(b)(7) (42 U.S.C. 300hh–10(b)(7)) is
20 amended—

21 (1) in the matter preceding subparagraph (A),
22 by striking “March 1 of each year” and inserting
23 “March 15, 2020 and every 2 years thereafter”;

24 (2) by striking subparagraph (A) and inserting
25 the following:

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

4 “(i) basic research and advanced re-
5 search and development;

6 “(ii) approval, clearance, licensure,
7 and authorized uses of products;

8 “(iii) procurement, stockpiling, main-
9 tenance, and potential replenishment (in-
10 cluding manufacturing capabilities) of all
11 products in the Strategic National Stock-
12 pile; and

13 “(iv) the availability of technologies
14 that may assist in the advanced research
15 and development of countermeasures and
16 opportunities to use such technologies to
17 accelerate and navigate challenges unique
18 to countermeasure research and develop-
19 ment;”.

20 (3) by redesignating subparagraphs (D) and
21 (E) as subparagraphs (E) and (F), respectively;

22 (4) by inserting after subparagraph (C), the fol-
23 lowing:

24 “(D) identify the full range of anticipated
25 medical countermeasure needs related to re-

1 search and development, procurement, and
2 stockpiling, including the potential need for in-
3 dications, dosing, and administration tech-
4 nologies, and other countermeasure needs as
5 applicable and appropriate;” and

6 (5) in subparagraph (E), as so redesignated, by
7 striking “March 15 of each year” and inserting
8 “March 15, 2020, and every 2 years thereafter”.

9 **SEC. 502. MATERIAL THREAT AND MEDICAL COUNTER-**
10 **MEASURE NOTIFICATIONS.**

11 (a) CONGRESSIONAL NOTIFICATION OF MATERIAL
12 THREAT DETERMINATION.—Section 319F–2(c)(2)(C) (42
13 U.S.C. 247d-6b(c)(2)(C)) is amended by striking “The
14 Secretary and the Homeland Security Secretary shall
15 promptly notify the appropriate committees of Congress”
16 and inserting “The Secretary and the Secretary of Home-
17 land Security shall send to Congress, on an annual basis,
18 all current material threat determinations and shall
19 promptly notify the Committee on Health, Education,
20 Labor, and Pensions and the Committee on Homeland Se-
21 curity and Government Affairs of the Senate and the Com-
22 mittee on Energy and Commerce and the Committee on
23 Homeland Security of the House of Representatives”.

24 (b) CONTRACTING COMMUNICATIONS.—

1 (1) CONTRACT DURATION.—Section 319F–
2 2(c)(7)(B)(ii)(III) (42 U.S.C. 247d–
3 6b(c)(7)(B)(ii)(III)) is amended by adding at the
4 end the following: “The Secretary shall notify the
5 vendor within 90 days of a determination by the
6 Secretary to renew such contract.”.

7 (2) EXPEDITED AUTHORITIES.—Section
8 319L(c)(5)(B)(i) (42 U.S.C. 247d–7e(c)(5)(B)(i)) is
9 amended by adding at the end the following: “Upon
10 award, extension, or termination of any such con-
11 tract, grant, cooperative agreement, and other trans-
12 action, the Secretary shall provide a written notifica-
13 tion to the receiving entity that includes a justifica-
14 tion for such award, extension, or termination.”.

15 **SEC. 503. AVAILABILITY OF REGULATORY MANAGEMENT**
16 **PLANS.**

17 Section 565(f) of the Federal Food, Drug and Cos-
18 metic Act (21 U.S.C. 360bbb–4(f)) is amended—

19 (1) by redesignating paragraphs (3) through
20 (6) as paragraphs (4) through (7), respectively;

21 (2) by inserting after paragraph (2) the fol-
22 lowing:

23 “(3) PUBLICATION.—The Secretary shall make
24 available on the internet website of the Food and

1 Drug Administration information regarding regu-
2 latory management plans, including—

3 “(A) the process by which an applicant
4 may submit a request for a regulatory manage-
5 ment plan;

6 “(B) the timeframe by which the Secretary
7 is required to respond to such request;

8 “(C) the information required for the sub-
9 mission of such request;

10 “(D) a description of the types of develop-
11 ment milestones and performance targets that
12 could be discussed and included in such plans;
13 and

14 “(E) contact information for beginning the
15 regulatory management plan process.”;

16 (3) in paragraph (6), as so redesignated, in the
17 matter preceding subparagraph (A)—

18 (A) by striking “paragraph (4)(A)” and in-
19 serting “paragraph (5)(A)”; and

20 (B) by striking “paragraph (4)(B)” and
21 inserting “paragraph (5)(B)”; and

22 (4) in paragraph (7)(A), as so redesignated, by
23 striking “paragraph (3)(A)” and inserting “para-
24 graph (4)(A)”.

1 **SEC. 504. THE BIOMEDICAL ADVANCED RESEARCH AND DE-**
2 **VELOPMENT AUTHORITY AND THE BIO-**
3 **SHIELD SPECIAL RESERVE FUND.**

4 (a) BIOSHIELD SPECIAL RESERVE FUND.—Section
5 319F–2(g)(1) (42 U.S.C. 247d–6b(g)(1)) is amended—

6 (1) by striking “\$2,800,000,000 for the period
7 of fiscal years 2014 through 2018” and inserting
8 “\$3,500,000,000 for the period of fiscal years 2019
9 through 2023, to remain available until expended”;
10 and

11 (2) by striking the second sentence.

12 (b) THE BIOMEDICAL ADVANCED RESEARCH AND
13 DEVELOPMENT AUTHORITY.—Section 319L(d)(2) (42
14 U.S.C. 247d–7e(d)(2)) is amended by striking
15 “\$415,000,000 for each of fiscal years 2014 through
16 2018” and inserting “\$611,700,000 for each of fiscal
17 years 2019 through 2023”.

18 **TITLE VI—ADVANCING TECH-**
19 **NOLOGIES FOR MEDICAL**
20 **COUNTERMEASURES**

21 **SEC. 601. ADMINISTRATION OF COUNTERMEASURES.**

22 Section 319L(c)(4)(D)(iii) (42 U.S.C. 247d–
23 7e(c)(4)(D)(iii)) is amended by striking “and platform
24 technologies” inserting “platform technologies, tech-
25 nologies to administer countermeasures, technologies to
26 improve storage, and transportation of countermeasures”.

1 **SEC. 602. MEDICAL COUNTERMEASURE MASTER FILES.**

2 (a) IN GENERAL.—Chapter V of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
4 ed by inserting after section 565A the following:

5 **“SEC. 565B. MEDICAL COUNTERMEASURE MASTER FILES.**

6 “(a) PURPOSE.—The purpose of this section is to
7 support and accelerate the development or manufacture
8 of security countermeasures, qualified countermeasures,
9 and qualified pandemic or epidemic products by facili-
10 tating and encouraging submission of data and informa-
11 tion to support such products to master files, and through
12 clarifying the authority to cross-reference to data and in-
13 formation previously submitted to the Secretary.

14 “(b) APPLICABILITY OF REFERENCE.—

15 “(1) IN GENERAL.—A person may submit data
16 and information to the Secretary with the intent to
17 reference, or to authorize, in writing, another person
18 to reference, such data or information, in accordance
19 with subsections (d) and (e) of section 314.420 of
20 title 21, Code of Federal Regulations (or any suc-
21 cessor regulations), to support a medical counter-
22 measure submission (including a supplement or
23 amendment to any such submission), without requir-
24 ing the master file holder to disclose the data and
25 information to any such persons authorized to ref-
26 erence the master file.

1 “(2) MASTER FILE HOLDER.—In this section,
2 the term ‘master file holder’ means a person who
3 submits data and information to the Secretary with
4 the intent to reference or authorize to reference such
5 data or information to support a medical counter-
6 measure submission, as described in paragraph (1).

7 “(c) MEDICAL COUNTERMEASURE MASTER FILE
8 CONTENT.—

9 “(1) IN GENERAL.—A master file under this
10 section may include information to support and ac-
11 celerate—

12 “(A) the development of medical counter-
13 measure submissions to support the approval,
14 licensure, classification, clearance, conditional
15 approval, or authorization of one or more secu-
16 rity countermeasures, qualified counter-
17 measures, or qualified pandemic or epidemic
18 products; and

19 “(B) the manufacture of security counter-
20 measures, qualified countermeasures, or quali-
21 fied pandemic or epidemic products.

22 “(2) REQUIRED UPDATES.—The Secretary may
23 require, as appropriate, that the master file holder
24 ensure that the contents of such master file are up-

1 dated during the time such master file is referenced
2 for a medical countermeasure submission.

3 “(d) SPONSOR REFERENCE.—

4 “(1) IN GENERAL.—Each incorporation of in-
5 formation or data contained in a master file by ref-
6 erence shall describe the incorporated material in a
7 manner in which the Secretary determines appro-
8 priate and that permits the review of such informa-
9 tion without necessitating resubmission of such in-
10 formation or data. Master files shall be submitted in
11 an electronic format in accordance with section
12 745A and as specified in applicable guidance.

13 “(2) REFERENCE BY A MASTER FILE HOLD-
14 ER.—A master file holder that is the sponsor of a
15 medical countermeasure submission shall notify the
16 Secretary in writing of the intent to reference the
17 medical countermeasure master file as a part of the
18 submission.

19 “(3) REFERENCE BY AN AUTHORIZED PER-
20 SON.—A sponsor of a medical countermeasure sub-
21 mission may, where the Secretary determines appro-
22 priate, incorporate by reference all or part of the
23 contents of a medical countermeasure master file, if
24 the master file holder authorizes the incorporation in
25 writing.

1 “(e) ACKNOWLEDGEMENT OF MASTER FILE BY THE
2 SECRETARY.—The Secretary shall provide the master file
3 holder with a written notification indicating that the Sec-
4 retary has reviewed and relied upon specified information
5 or data within a master file and the purposes for which
6 such information or data was incorporated by reference
7 if the Secretary has reviewed and relied upon such speci-
8 fied information or data to support the approval, classi-
9 fication, conditional approval, clearance, licensure, or au-
10 thorization of a security countermeasure, qualified coun-
11 termeasure, or qualified pandemic or epidemic product.
12 The Secretary may rely upon the data and information
13 within the medical countermeasure master file for which
14 such written notification was provided in additional appli-
15 cations, as applicable and appropriate and upon the re-
16 quest of the master file holder so notified in writing or
17 by an authorized person of such holder.

18 “(f) RULES OF CONSTRUCTION.—Nothing in this
19 section shall be construed to—

20 “(1) alter the authority of the Secretary to ap-
21 prove, license, classify, clear, conditionally approve,
22 or authorize drugs, biological products, or devices
23 pursuant to this Act or section 351 of the Public
24 Health Service Act (as authorized prior to the date
25 of enactment of the Pandemic and All-Hazards Pre-

1 paredness and Advancing Innovation Act of 2018),
2 including the standards of evidence, and applicable
3 conditions, for approval under the applicable Act; or

4 “(2) alter the authority of the Secretary under
5 this Act or the Public Health Service Act to deter-
6 mine the types of information or data previously
7 submitted by a sponsor or any other person that
8 may be incorporated by reference in an application,
9 request, or notification for a drug, biological prod-
10 uct, or device submitted under sections 505(i),
11 505(b), 505(j), 512(b)(1), 512(b)(2), 564, 571,
12 520(g), 515(e), 513(f)(2), or 510(k) of this Act, or
13 subsection (a) or (k) of section 351 of the Public
14 Health Service Act, including a supplement or
15 amendment to any such submission, and the require-
16 ments associated with such reference.

17 “(g) DEFINITIONS.—In this section:

18 “(1) The term ‘medical countermeasure submis-
19 sion’ means an investigational new drug application
20 under section 505(i), a new drug application under
21 section 505(b), or an abbreviated new drug applica-
22 tion under section 505(j) of this Act, a biological
23 product license application under section 351(a) of
24 the Public Health Service Act or a biosimilar biologi-
25 cal product license application under section 351(k)

1 of the Public Health Service Act, a new animal drug
2 application under section 512(b)(1) or abbreviated
3 new animal drug application under section
4 512(b)(2), an application for conditional approval of
5 a new animal drug under 571, an investigational de-
6 vice application under section 520(g), an application
7 with respect to a device under section 515(c), a re-
8 quest for classification of a device under section
9 513(f)(2), a notification with respect to a device
10 under section 510(k), or request for an emergency
11 use authorization under section 564 to support—

12 “(A) the approval, licensure, classification,
13 clearance, conditional approval, or authorization
14 of a security countermeasure, qualified counter-
15 measure, or qualified pandemic or epidemic
16 product; or

17 “(B) a new indication to an approved secu-
18 rity countermeasure, qualified countermeasure,
19 or qualified pandemic or epidemic product.

20 “(2) The terms ‘qualified countermeasure’, ‘se-
21 curity countermeasure’, and ‘qualified pandemic or
22 epidemic product’ have the meanings given such
23 terms in sections 319F–1, 319F–2, and 319F–3, re-
24 spectively, of the Public Health Service Act.”.

1 (b) STAKEHOLDER INPUT.—Not later than 18
2 months after the date of enactment of this Act, the Sec-
3 retary of Health and Human Services (referred to in this
4 section as the “Secretary”), acting through the Commis-
5 sioner of Food and Drugs and in consultation with the
6 Assistant Secretary for Preparedness and Response, shall
7 solicit input from stakeholders, including stakeholders de-
8 veloping security countermeasures, qualified counter-
9 measures, or qualified pandemic or epidemic products, and
10 stakeholders developing technologies to assist in the devel-
11 opment of such countermeasures with respect to how the
12 Food and Drug Administration can advance the use of
13 tools and technologies to support and accelerate the devel-
14 opment or manufacture of security countermeasures,
15 qualified countermeasures, and qualified pandemic or epi-
16 demic products, including through the reliance on cross-
17 referenced data and information contained within master
18 files and submissions previously submitted to the Sec-
19 retary as set forth in section 565B of the Federal Food,
20 Drug, and Cosmetic Act, as added by subsection (a).

21 (c) GUIDANCE.—Not later than 2 years after the
22 after the date of enactment of this Act, the Secretary, act-
23 ing through the Commissioner of Food and Drugs, shall
24 publish draft guidance about how reliance on cross-ref-
25 erenced data and information contained within master

1 files under section 565B of the Federal Food, Drug, and
2 Cosmetic Act, as added by subsection (a) or submissions
3 otherwise submitted to the Secretary may be used for spe-
4 cific tools or technologies (including platform technologies)
5 that have the potential to support and accelerate the devel-
6 opment or manufacture of security countermeasures,
7 qualified countermeasures, qualified pandemic or epidemic
8 products. The Secretary, acting through the Commissioner
9 of Food and Drugs, shall publish the final guidance not
10 later than 3 years after the enactment of this Act.

11 **SEC. 603. ANIMAL RULE REPORT.**

12 (a) STUDY.—The Comptroller General of the United
13 States shall conduct a study on the application of the re-
14 quirements under section 565(d) of the of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4(d))
16 (referred to in this section as the “animal rule”) as a com-
17 ponent of medical countermeasure advanced development
18 under the Biomedical Advanced Research and Develop-
19 ment Authority and regulatory review by the Food and
20 Drug Administration. In conducting such study, the
21 Comptroller General shall examine the following:

22 (1) The extent to which advanced development
23 and review of a medical countermeasure are coordi-
24 nated between the Biomedical Advanced Research
25 and Development Authority and the Food and Drug

1 Administration, including activities facilitate appro-
2 priate and efficient design of studies to support ap-
3 proval, licensure, and authorization under the ani-
4 mal rule, consistent with the recommendations in the
5 animal rule guidance, issued pursuant to section
6 565(c) of the Federal Food Drug and Cosmetic Act
7 (21 U.S.C. 360bbb-4(c)) and entitled “Product De-
8 velopment Under the Animal Rule Guidance for In-
9 dustry” (issued in October 2015), to resolve discrep-
10 ancies in the design of adequate and well-controlled
11 efficacy studies conducted in animal models related
12 to the provision of substantial evidence of effective-
13 ness for the product approved, licensed, or author-
14 ized under the animal rule.

15 (2) The consistency of the application of the
16 animal rule among and between review divisions
17 within the Food and Drug Administration.

18 (3) The flexibilities pursuant to the animal rule
19 to address variations in countermeasure development
20 and review processes, including the extent to which
21 qualified animal models are adopted and used within
22 the Food and Drug Administration in regulatory de-
23 cisionmaking with respect to medical counter-
24 measures.

1 (4) The extent to which the guidance issued
2 under section 565(c) of the Federal Food Drug and
3 Cosmetic Act (21 U.S.C. 360bbb–4(c)), entitled,
4 “Product Development Under the Animal Rule
5 Guidance for Industry” (issued in October 2015),
6 has assisted in achieving the purposes described in
7 paragraphs (1), (2), and (3).

8 (b) CONSULTATIONS.—In conducting the study under
9 subsection (a), the Comptroller General of the United
10 States shall consult with—

11 (1) the Federal agencies responsible for advanc-
12 ing, reviewing, and procuring medical counter-
13 measures, including the Office of the Assistant Sec-
14 retary for Preparedness and Response, the Bio-
15 medical Advanced Research and Development Au-
16 thority, the Food and Drug Administration, and the
17 Department of Defense;

18 (2) manufacturers involved in the research and
19 development of medical countermeasures to address
20 biological, chemical, radiological, and nuclear
21 threats; and

22 (3) other biodefense stakeholders, as applicable.

23 (c) REPORT.—Not later than 3 years after the date
24 of enactment of this Act, the Comptroller General of the
25 United States shall submit to the Committee on Health,

1 Education, Labor, and Pensions of the Senate and the
2 Committee on Energy and Commerce of the House of
3 Representatives a report containing the results of the
4 study conducted under subsection (a) and recommenda-
5 tions to improve the application and consistency of the re-
6 quirements under subsections (c) and (d) of section 565
7 of the Federal Food, Drug and Cosmetic Act (21 U.S.C.
8 360bbb-4) to support and expedite the research and devel-
9 opment of medical countermeasures, as applicable.

10 (d) PROTECTION OF NATIONAL SECURITY.—The
11 Comptroller General of the United States shall conduct
12 the study and issue the assessment and report under this
13 section in a manner that does not compromise national
14 security.

15 **TITLE VII—MISCELLANEOUS** 16 **PROVISIONS**

17 **SEC. 701. REAUTHORIZATIONS AND EXTENSIONS.**

18 (a) VETERANS AFFAIRS.—Section 8117(g) of title
19 38, United States Code, is amended by striking “2014
20 through 2018” and inserting “2019 through 2023”.

21 (b) VACCINE TRACKING AND DISTRIBUTION.—Sec-
22 tion 319A(e) (42 U.S.C. 247d-1(e)) is amended by strik-
23 ing “2014 through 2018” and inserting “2019 through
24 2023”.

1 (c) TEMPORARY REASSIGNMENT.—Section 319(e)(8)
2 (42 U.S.C. 247d(e)(8)) is amended by striking “2018”
3 and inserting “2023”.

4 (d) STRATEGIC INNOVATION PARTNER.—Section
5 319L(c)(4)(E)(ix) (42 U.S.C. 247d–7e(c)(4)(E)(ix)) is
6 amended by striking “2022” and inserting “2023”.

7 (e) PUBLIC DISCLOSURE EXEMPTION.—Section
8 319L(e)(1)(C) (42 U.S.C. 247d–7e(e)(1)(C)) is amended
9 by striking “12” and inserting “17”.

10 (f) LIMITED ANTITRUST EXEMPTION.—

11 (1) IN GENERAL.—Section 405 of the Pandemic
12 and All-Hazards Preparedness Act (42 U.S.C.
13 247d–6a note) is amended—

14 (A) by redesignating such section as sec-
15 tion 319L–1;

16 (B) transferring such section to the Public
17 Health Service Act (42 U.S.C. 201 et seq.), to
18 appear after section 319L of such Act (42
19 U.S.C. 247d–7e);

20 (C) in subsection (a)(1)—

21 (i) by striking “Secretary of Health
22 and Human Services (referred to in this
23 subsection as the ‘Secretary’)” and insert-
24 ing “Secretary”;

1 (ii) by striking “of the Public Health
2 Service Act (42 U.S.C. 247d–6b)) (as
3 amended by this Act”;

4 (iii) by striking “of the Public Health
5 Service Act (42 U.S.C. 247d– 6a)) (as
6 amended by this Act”; and

7 (iv) by striking “of the Public Health
8 Service Act (42 U.S.C. 247d–6d)”;

9 (D) in subsection (b), by striking “12-
10 year” and inserting “17-year”.

11 (2) EFFECTIVE DATE.—The amendment made
12 by paragraph (1)(D) shall take effect as if enacted
13 on December 17, 2012.

14 (3) CONFORMING AMENDMENT.—The table of
15 contents in section 1(b) of the Pandemic and All-
16 Hazards Preparedness Act (Public Law 109–417) is
17 amended by striking the item related to section 405.

18 **SEC. 702. TECHNICAL AMENDMENTS.**

19 (a) PUBLIC HEALTH SERVICE ACT.—Title III (42
20 U.S.C. 241 et seq.) is amended—

21 (1) in paragraphs (1) and (5) of section 319F–
22 1(a) (42 U.S.C. 247d–6a(a)), by striking “section
23 319F(h)” each place such term appears and insert-
24 ing “section 319F(e)”; and

1 (2) in section 319K(a) (42 U.S.C. 247d–7d(a)),
2 by striking “section 319F(h)(4)” and inserting “sec-
3 tion 319F(e)(4)”.

4 (b) PUBLIC HEALTH SECURITY GRANTS.—Section
5 319C–1(b)(2) (42 U.S.C. 247d–3a(b)(2)) is amended—

6 (1) in subparagraph (C), by striking “individ-
7 uals,” and inserting “individuals,”; and

8 (2) in subparagraph (F), by striking “make sat-
9 isfactory annual improvement and describe” and in-
10 serting “makes satisfactory annual improvement and
11 describes”.

12 (c) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—
13 The Federal Food, Drug, and Cosmetic Act is amended—

14 (1) in section 564A(e)(2)(A) (21 U.S.C.
15 360bbb–3a(e)(2)(A)), by striking “subsection
16 (a)(1)(C)(i)” and inserting “subsection (a)(1)(C)”;
17 and

18 (2) in section 564B(2)(C) (21 U.S.C. 360bbb–
19 3b(2)(C)), by inserting “or section 564A”.