

Suspend the Rules And Pass the Bill, H.R. 6378, With Amendments

(The amendments strike all after the enacting clause and insert a new text and a new title)

115TH CONGRESS
2D SESSION

H. R. 6378

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

IN THE HOUSE OF REPRESENTATIVES

JULY 16, 2018

Mrs. BROOKS of Indiana (for herself, Ms. ESHOO, Mr. WALDEN, and Mr. PALLONE) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on the Judiciary, Veterans' Affairs, and Homeland Security, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

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

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

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

2 (a) SHORT TITLE.—This Act may be cited as the
3 “Pandemic and All-Hazards Preparedness and Advancing
4 Innovation Act of 2018”.

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

Sec. 1. Short title; table of contents.

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. Military and civilian partnership for trauma readiness.
- Sec. 205. Public health and health care system situational awareness and bio-surveillance capabilities.
- Sec. 206. Strengthening and supporting the public health emergency rapid response fund.
- Sec. 207. Improving all-hazards preparedness and response by public health emergency volunteers.
- Sec. 208. Clarifying State liability law for volunteer health care professionals.
- Sec. 209. Report on adequate national blood supply.
- Sec. 210. Report on the public health preparedness and response capabilities and capacities of hospitals, long-term care facilities, and other health care facilities.

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. National advisory committees on 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.
Sec. 505. Additional strategies for combating antibiotic resistance.

TITLE VI—ADVANCING TECHNOLOGIES FOR MEDICAL
COUNTERMEASURES

- Sec. 601. Administration of countermeasures.
Sec. 602. Updating definitions of other transactions.
Sec. 603. Medical countermeasure master files.
Sec. 604. Animal rule report.
Sec. 605. Review of the benefits of genomic engineering technologies and their
potential role in national security.
Sec. 606. Report on vaccines development.
Sec. 607. Strengthening mosquito abatement for safety and health.

TITLE VII—MISCELLANEOUS PROVISIONS

- Sec. 701. Reauthorizations and extensions.
Sec. 702. Location of materials in the stockpile.
Sec. 703. Cybersecurity.
Sec. 704. Technical amendments.
Sec. 705. Formal strategy relating to children separated from parents and
guardians as a result of zero tolerance policy.
Sec. 706. Reporting relating to children separated from parents and guardians
as a result of zero tolerance policy.
Sec. 707. Technical correction.
Sec. 708. Savings clause.

1 TITLE I—STRENGTHENING THE
2 NATIONAL HEALTH SECURITY
3 STRATEGY

4 SEC. 101. NATIONAL HEALTH SECURITY STRATEGY.

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

7 (1) in subsection (a)—

8 (A) in paragraph (1)—

9 (i) by striking “2014” and inserting

10 “2018”; and

1 (ii) by striking the second sentence
2 and inserting the following: “Such Na-
3 tional Health Security Strategy shall de-
4 scribe potential emergency health security
5 threats and identify the process for achiev-
6 ing the preparedness goals described in
7 subsection (b) to be prepared to identify
8 and respond to such threats and shall be
9 consistent with the national preparedness
10 goal (as described in section 504(a)(19) of
11 the Homeland Security Act of 2002), the
12 National Incident Management System (as
13 defined in section 501(7) of such Act), and
14 the National Response Plan developed pur-
15 suant to section 504 of such Act, or any
16 successor plan.”;

17 (B) in paragraph (2), by inserting before
18 the period at the end of the second sentence the
19 following: “, and an analysis of any changes to
20 the evidence-based benchmarks and objective
21 standards under sections 319C–1 and 319C–2”;
22 and

23 (C) in paragraph (3)—

24 (i) by striking “2009” and inserting
25 “2022”;

1 (ii) by inserting “(including gaps in
2 the environmental health and animal
3 health workforces, as applicable), describ-
4 ing the status of such workforce” after
5 “gaps in such workforce”;

6 (iii) by striking “and identifying strat-
7 egies” and inserting “identifying strate-
8 gies”; and

9 (iv) by inserting before the period at
10 the end “, and identifying current capabili-
11 ties to meet the requirements of section
12 2803”; and

13 (2) in subsection (b)—

14 (A) in paragraph (2)—

15 (i) in subparagraph (A), by striking
16 “and investigation” and inserting “inves-
17 tigation, and related information tech-
18 nology activities”;

19 (ii) in subparagraph (B), by striking
20 “and decontamination” and inserting “de-
21 contamination, relevant health care serv-
22 ices and supplies, and transportation and
23 disposal of medical waste”; and

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

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

2 (B) in paragraph (3)—

3 (i) in the matter preceding subpara-
4 graph (A), by striking “including mental
5 health” and inserting “including phar-
6 macies, mental health facilities,”; and

7 (ii) in subparagraph (F), by inserting
8 “or exposures to agents that could cause a
9 public health emergency” before the pe-
10 riod;

11 (C) in paragraph (5), by inserting “and
12 other applicable compacts” after “Compact”;
13 and

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

15 “(9) ZOONOTIC DISEASE, FOOD, AND AGRI-
16 CULTURE.—Improving coordination among Federal,
17 State, local, tribal, and territorial entities (including
18 through consultation with the Secretary of Agri-
19 culture) to prevent, detect, and respond to outbreaks
20 of plant or animal disease (including zoonotic dis-
21 ease) that could compromise national security result-
22 ing from a deliberate attack, a naturally occurring
23 threat, the intentional adulteration of food, or other
24 public health threats, taking into account inter-
25 actions between animal health, human health, and

1 animals’ and humans’ shared environment as di-
2 rectly related to public health emergency prepared-
3 ness and response capabilities, as applicable.

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

8 **TITLE II—IMPROVING**
9 **PREPAREDNESS AND RESPONSE**

10 **SEC. 201. IMPROVING BENCHMARKS AND STANDARDS FOR**
11 **PREPAREDNESS AND RESPONSE.**

12 (a) EVALUATING MEASURABLE EVIDENCE-BASED
13 BENCHMARKS AND OBJECTIVE STANDARDS.—Section
14 319C–1 of the Public Health Service Act (42 U.S.C.
15 247d–3a) is amended by inserting after subsection (j) the
16 following:

17 “(k) EVALUATION.—

18 “(1) IN GENERAL.—Not later than 2 years
19 after the date of enactment of the Pandemic and
20 All-Hazards Preparedness and Advancing Innovation
21 Act of 2018 and every 2 years thereafter, the Sec-
22 retary shall conduct an evaluation of the evidence-
23 based benchmarks and objective standards required
24 under subsection (g). Such evaluation shall be sub-
25 mitted to the congressional committees of jurisdic-

1 tion together with the National Health Security
2 Strategy under section 2802, at such time as such
3 strategy is submitted.

4 “(2) CONTENT.—The evaluation under this
5 paragraph shall include—

6 “(A) a review of evidence-based bench-
7 marks and objective standards, and associated
8 metrics and targets;

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

17 “(C) a description of amounts received by
18 eligible entities described in subsection (b) and
19 section 319C–2(b), and amounts received by
20 subrecipients and the effect of such funding on
21 meeting evidence-based benchmarks and objec-
22 tive standards; and

23 “(D) recommendations, as applicable and
24 appropriate, to improve evidence-based bench-
25 marks and objective standards to more accu-

1 rately assess the ability of entities receiving
2 awards under this section to better achieve the
3 goals under this section and section 2802.”.

4 (b) EVALUATING THE PARTNERSHIP FOR STATE AND
5 REGIONAL HOSPITAL PREPAREDNESS.—Section 319C–
6 2(i)(1) of the Public Health Service Act (42 U.S.C. 247–
7 3b(i)(1)) is amended by striking “section 319C–1(g), (i),
8 and (j)” and inserting “section 319C–1(g), (i), (j), and
9 (k)”.

10 **SEC. 202. AMENDMENTS TO PREPAREDNESS AND RE-**
11 **SPONSE PROGRAMS.**

12 (a) COOPERATIVE AGREEMENT APPLICATIONS FOR
13 IMPROVING STATE AND LOCAL PUBLIC HEALTH SECU-
14 RITY.—Section 319C–1 of the Public Health Service Act
15 (42 U.S.C. 247d–3a) is amended—

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

19 (2) in subsection (b)(2)(A)—

20 (A) in clause (vi), by inserting “, including
21 public health agencies with specific expertise
22 that may be relevant to public health security,
23 such as environmental health agencies,” after
24 “stakeholders”;

1 (B) by redesignating clauses (vii) through
2 (ix) as clauses (viii) through (x);

3 (C) by inserting after clause (vi) the fol-
4 lowing:

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

10 (D) in clause (ix), as so redesignated, by
11 striking “; and” and inserting a semicolon;

12 (E) in clause (x), as so redesignated, by in-
13 serting “and” after the semicolon; and

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

15 “(xi) a description of how the entity
16 will partner with health care facilities, in-
17 cluding hospitals and nursing homes and
18 other long-term care facilities, to promote
19 and improve public health preparedness
20 and response; and

21 “(xii) a description of how, as appro-
22 priate and practicable, the entity will in-
23 clude critical infrastructure partners, such
24 as utility companies within the entity’s ju-
25 risdiction, in planning pursuant to this

1 subparagraph to help ensure that critical
2 infrastructure will remain functioning dur-
3 ing, or return to function as soon as prac-
4 ticable after, a public health emergency.”.

5 (b) EXCEPTION RELATING TO APPLICATION OF CER-
6 TAIN REQUIREMENTS.—Section 319C–1(g) of the Public
7 Health Service Act (42 U.S.C. 247d–3a(g)) is amended—

8 (1) in paragraph (5)—

9 (A) by striking “Beginning with fiscal year
10 2009” and inserting “Beginning with fiscal
11 year 2019”;

12 (B) by striking “for the immediately pre-
13 ceding fiscal year” and inserting “for either of
14 the two immediately preceding fiscal years”;
15 and

16 (C) by striking “2008” and inserting
17 “2019”; and

18 (2) by amending subparagraph (A) of para-
19 graph (6) to read as follows:

20 “(A) IN GENERAL.—The amounts de-
21 scribed in this paragraph are the following
22 amounts that are payable to an entity for ac-
23 tivities described in section 319C–1 or 319C–2:

24 “(i) For one (but not both) of the
25 first two fiscal years immediately following

1 a fiscal year in which an entity experienced
2 a failure described in subparagraph (A) or
3 (B) of paragraph (5) by the entity, an
4 amount equal to 10 percent of the amount
5 the entity was eligible to receive for the re-
6 spective fiscal year.

7 “(ii) For one (but not both) of the
8 first two fiscal years immediately following
9 the third consecutive fiscal year in which
10 an entity experienced such a failure, in lieu
11 of applying clause (i), an amount equal to
12 15 percent of the amount the entity was el-
13 igible to receive for the respective fiscal
14 year.”.

15 (b) PARTNERSHIP FOR STATE AND REGIONAL HOS-
16 PITAL PREPAREDNESS TO IMPROVE SURGE CAPACITY.—
17 Section 319C–2 of the Public Health Service Act (42
18 U.S.C. 247d–3b) is amended—

19 (1) in subsection (a)—

20 (A) by inserting “, acting through the As-
21 sistant Secretary for Preparedness and Re-
22 sponse,” after “The Secretary”; and

23 (B) by striking “preparedness for public
24 health emergencies” and inserting “prepared-

1 ness for, and response to, public health emer-
2 gencies in accordance with subsection (c)”;

3 (2) in subsection (b)(1)(A)—

4 (A) by striking “partnership consisting of”
5 and inserting “coalition that includes”;

6 (B) in clause (ii), by striking “; and” and
7 inserting a semicolon; and

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

9 “(iv) one or more emergency medical serv-
10 ice organizations or emergency management or-
11 ganizations; and”;

12 (3) in subsection (d)—

13 (A) in paragraph (1)(B), by striking “part-
14 nership” each place it appears and inserting
15 “coalition”; and

16 (B) in paragraph (2)(C), by striking “med-
17 ical preparedness” and inserting “preparedness
18 and response”;

19 (4) in subsection (f), by striking “partnership”
20 and inserting “coalition”;

21 (5) in subsection (g)(2)—

22 (A) by striking “Partnerships” and insert-
23 ing “Coalitions”;

24 (B) by striking “partnerships” and insert-
25 ing “coalitions”; and

1 (C) by inserting “and response” after
2 “preparedness”; and
3 (6) in subsection (i)(1)—
4 (A) by striking “An entity” and inserting
5 “A coalition”; and
6 (B) by striking “such partnership” and in-
7 serting “such coalition”.

8 (c) PUBLIC HEALTH SECURITY GRANTS AUTHORIZA-
9 TION OF APPROPRIATIONS.—Section 319C–1(h)(1)(A) of
10 the Public Health Service Act (42 U.S.C. 247d–
11 3a(h)(1)(A)) is amended by striking “\$641,900,000 for
12 fiscal year 2014” and all that follows through the period
13 at the end and inserting “\$685,000,000 for each of fiscal
14 years 2019 through 2023 for awards pursuant to para-
15 graph (3) (subject to the authority of the Secretary to
16 make awards pursuant to paragraphs (4) and (5)).”.

17 (d) PARTNERSHIP FOR STATE AND REGIONAL HOS-
18 PITAL PREPAREDNESS AUTHORIZATION OF APPROPRIA-
19 TIONS.—Section 319C–2(j) of the Public Health Service
20 Act (42 U.S.C. 247d–3b(j)) is amended—

21 (1) by amending paragraph (1) to read as fol-
22 lows:

23 “(1) IN GENERAL.—

24 “(A) AUTHORIZATION OF APPROPRIA-
25 TIONS.—For purposes of carrying out this sec-

1 tion and section 319C–3, in accordance with
2 subparagraph (B), there is authorized to be ap-
3 propriated \$385,000,000 for each of fiscal years
4 2019 through 2023.

5 “(B) RESERVATION OF AMOUNTS FOR RE-
6 GIONAL SYSTEMS.—

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

12 “(ii) RESERVATION CONTINGENT ON
13 CONTINUED APPROPRIATIONS FOR THIS
14 SECTION.—If for fiscal year 2019 or a sub-
15 sequent fiscal year, the amount appro-
16 priated under subparagraph (A) is such
17 that, after application of clause (i), the
18 amount remaining for the purpose of car-
19 rying out this section would be less than
20 the amount available for such purpose for
21 the previous fiscal year, the amount that
22 may be reserved under clause (i) shall be
23 reduced such that the amount remaining
24 for the purpose of carrying out this section

1 is not less than the amount available for
2 such purpose for the previous fiscal year.

3 “(iii) SUNSET.—The authority to re-
4 serve amounts under clause (i) shall expire
5 on September 30, 2023.”;

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

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

14 **SEC. 203. REGIONAL HEALTH CARE EMERGENCY PRE-**
15 **PAREDNESS AND RESPONSE SYSTEMS.**

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

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

22 “(a) PURPOSE.—It is the purpose of this section to
23 identify and provide guidelines for regional systems of hos-
24 pitals, health care facilities, and other public and private
25 sector entities, with varying levels of capability to treat

1 patients and increase medical surge capacity during, in ad-
2 vance of, and immediately following a public health emer-
3 gency, including threats posed by one or more chemical,
4 biological, radiological, or nuclear agents, including emerg-
5 ing infectious diseases.

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

19 “(1) identify and develop a set of guidelines re-
20 lating to practices and protocols for all-hazards pub-
21 lic health emergency preparedness and response for
22 hospitals and health care facilities to provide appro-
23 priate patient care during, in advance of, or imme-
24 diately following, a public health emergency, result-
25 ing from one or more chemical, biological, radio-

1 logical, or nuclear agents, including emerging infec-
2 tious diseases (which may include existing practices,
3 such as trauma care and medical surge capacity and
4 capabilities), with respect to—

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

9 “(i) the manner in which the system
10 will coordinate with and integrate the part-
11 nerships and health care coalitions estab-
12 lished under section 319C–2(b); and

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

20 “(B) physical and technological infrastruc-
21 ture, laboratory capacity, staffing, blood supply,
22 and other supply chain needs, taking into ac-
23 count resiliency, geographic considerations, and
24 rural considerations;

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

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

19 “(E) the needs of children and other at-
20 risk individuals;

21 “(2) make such guidelines available on the
22 internet website of the Department of Health and
23 Human Services in a manner that does not com-
24 promise national security; and

1 “(3) update such guidelines as appropriate, in-
2 cluding based on input received pursuant to sub-
3 sections (c) and (e) and information resulting from
4 applicable reports required under the Pandemic and
5 All-Hazards Preparedness and Advancing Innovation
6 Act of 2018 (including any amendments made by
7 such Act), to address new and emerging public
8 health threats.

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

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

21 “(2) consult and engage with appropriate
22 health care providers and professionals, including
23 physicians, nurses, first responders, health care fa-
24 cilities (including hospitals, primary care clinics,
25 community health centers, mental health facilities,

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

8 “(3) consider feedback related to financial im-
9 plications for hospitals, health care facilities, public
10 health agencies, laboratories, blood banks, and other
11 entities engaged in regional preparedness planning
12 to implement and follow such guidelines, as applica-
13 ble; and

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

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

1 “(e) DEMONSTRATION PROJECT FOR REGIONAL
2 HEALTH CARE PREPAREDNESS AND RESPONSE SYS-
3 TEMS.—

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

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

16 (b) GAO REPORT TO CONGRESS.—

17 (1) REPORT.—Not later than 3 years after the
18 date of enactment of this Act, the Comptroller Gen-
19 eral of the United States (referred to in this sub-
20 section as the “Comptroller General”) shall submit
21 to the Committee on Health, Education, Labor, and
22 Pensions and the Committee on Finance of the Sen-
23 ate and the Committee on Energy and Commerce
24 and the Committee on Ways and Means of the
25 House of Representatives, a report on the extent to

1 which hospitals and health care facilities have imple-
2 mented the recommended guidelines under section
3 319C–3(b) of the Public Health Service Act (as
4 added by subsection (a)), including an analysis and
5 evaluation of any challenges hospitals or health care
6 facilities experienced in implementing such guide-
7 lines.

8 (2) CONTENT.—The Comptroller General shall
9 include in the report under paragraph (1)—

10 (A) data on the preparedness and response
11 capabilities that have been informed by the
12 guidelines under section 319C–3(b) of the Pub-
13 lic Health Service Act to improve regional emer-
14 gency health care preparedness and response
15 capability, including hospital and health care
16 facility capacity and medical surge capabilities
17 to prepare for, and respond to, public health
18 emergencies; and

19 (B) recommendations to reduce gaps in in-
20 centives for regional health partners, including
21 hospitals and health care facilities, to improve
22 capacity and medical surge capabilities to pre-
23 pare for, and respond to, public health emer-
24 gencies, consistent with subsection (a), which
25 may include consideration of facilities partici-

1 pating in programs under section 319C–2 of
2 the Public Health Service Act (42 U.S.C.
3 247d–3b) or in programs under the Centers for
4 Medicare & Medicaid Services (including inno-
5 vative health care delivery and payment mod-
6 els), and input from private sector financial in-
7 stitutions.

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

12 (A) the Assistant Secretary for Prepared-
13 ness and Response;

14 (B) the Director of the Centers for Disease
15 Control and Prevention;

16 (C) the Administrator of the Centers for
17 Medicare & Medicaid Services;

18 (D) the Assistant Secretary for Mental
19 Health and Substance Use;

20 (E) the Assistant Secretary of Labor for
21 Occupational Safety and Health; and

22 (F) the Secretary of Veterans Affairs.

23 (c) ANNUAL REPORTS.—Section 319C–2(i)(1) of the
24 Public Health Service Act (42 U.S.C. 247d–3b(i)(1)) is
25 amended by inserting after the first sentence the following

1 “In submitting reports under this paragraph an entity
2 shall include information on the progress that the entity
3 has made toward the implementation of section 319C–3
4 (or barriers to progress, if any).”.

5 (d) NATIONAL HEALTH SECURITY STRATEGY INCOR-
6 PORATION OF REGIONALIZED EMERGENCY PREPARED-
7 NESS AND RESPONSE.—Subparagraph (G) of section
8 2802(b)(3) of the Public Health Service Act (42 U.S.C.
9 300hh–1(b)(3)) is amended to read as follows:

10 “(G) Optimizing a coordinated and flexible
11 approach to the emergency response and med-
12 ical surge capacity of hospitals, other health
13 care facilities, critical care, trauma care (which
14 may include trauma centers), and emergency
15 medical systems.”.

16 (e) IMPROVING STATE AND LOCAL PUBLIC HEALTH
17 SECURITY.—

18 (1) STATE AND LOCAL SECURITY.—Section
19 319C–1(e) of the Public Health Service Act (42
20 U.S.C. 247d–3a(e)) is amended by striking “, and
21 local emergency plans.” and inserting “, local emer-
22 gency plans, and any regional health care emergency
23 preparedness and response system established pursu-
24 ant to the applicable guidelines under section 319C–
25 3.”.

1 (2) PARTNERSHIPS.—Section 319C–2(d)(1)(A)
2 of the Public Health Service Act (42 U.S.C. 247d-
3 3b(d)(1)(A)) is amended—

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

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

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

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

12 **SEC. 204. MILITARY AND CIVILIAN PARTNERSHIP FOR**
13 **TRAUMA READINESS.**

14 Title XII of the Public Health Service Act (42 U.S.C.
15 300d et seq.) is amended by adding at the end the fol-
16 lowing new part:

17 **“PART I—MILITARY AND CIVILIAN PARTNERSHIP**
18 **FOR TRAUMA READINESS GRANT PROGRAM**

19 **“SEC. 1291. MILITARY AND CIVILIAN PARTNERSHIP FOR**
20 **TRAUMA READINESS GRANT PROGRAM.**

21 “(a) MILITARY TRAUMA TEAM PLACEMENT PRO-
22 GRAM.—

23 “(1) IN GENERAL.—The Secretary, acting
24 through the Assistant Secretary for Preparedness
25 and Response and in consultation with the Secretary

1 of Defense, shall award grants to not more than 20
2 eligible high acuity trauma centers to enable military
3 trauma teams to provide, on a full-time basis, trauma
4 care and related acute care at such trauma centers.
5

6 “(2) LIMITATIONS.—In the case of a grant
7 awarded under paragraph (1) to an eligible high
8 acuity trauma center, such grant—

9 “(A) shall be for a period of at least 3
10 years and not more than 5 years (and may be
11 renewed at the end of such period); and

12 “(B) shall be in an amount that does not
13 exceed \$1,000,000 per year.

14 “(3) AVAILABILITY OF FUNDS.—Notwith-
15 standing section 1552 of title 31, United States
16 Code, or any other provision of law, funds available
17 to the Secretary for obligation for a grant under this
18 subsection shall remain available for expenditure for
19 100 days after the last day of the performance pe-
20 riod of such grant.

21 “(b) MILITARY TRAUMA CARE PROVIDER PLACE-
22 MENT PROGRAM.—

23 “(1) IN GENERAL.—The Secretary, acting
24 through the Assistant Secretary for Preparedness
25 and Response and in consultation with the Secretary

1 of Defense, shall award grants to eligible trauma
2 centers to enable military trauma care providers to
3 provide trauma care and related acute care at such
4 trauma centers.

5 “(2) LIMITATIONS.—In the case of a grant
6 awarded under paragraph (1) to an eligible trauma
7 center, such grant—

8 “(A) shall be for a period of at least 1 year
9 and not more than 3 years (and may be re-
10 newed at the end of such period); and

11 “(B) shall be in an amount that does not
12 exceed, in a year—

13 “(i) \$100,000 for each military trau-
14 ma care provider that is a physician at
15 such eligible trauma center; and

16 “(ii) \$50,000 for each other military
17 trauma care provider at such eligible trau-
18 ma center.

19 “(c) GRANT REQUIREMENTS.—

20 “(1) DEPLOYMENT AND PUBLIC HEALTH EMER-
21 GENCIES.—As a condition of receipt of a grant
22 under this section, a grant recipient shall agree to
23 allow military trauma care providers providing care
24 pursuant to such grant to—

1 “(A) be deployed by the Secretary of De-
2 fense for military operations, for training, or
3 for response to a mass casualty incident; and

4 “(B) be deployed by the Secretary of De-
5 fense, in consultation with the Secretary of
6 Health and Human Services, for response to a
7 public health emergency pursuant to section
8 319.

9 “(2) USE OF FUNDS.—Grants awarded under
10 this section to an eligible trauma center may be used
11 to train and incorporate military trauma care pro-
12 viders into such trauma center, including incorpora-
13 tion into operational exercises and training drills re-
14 lated to public health emergencies, expenditures for
15 malpractice insurance, office space, information
16 technology, specialty education and supervision,
17 trauma programs, research, and applicable license
18 fees for such military trauma care providers.

19 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
20 tion shall be construed to affect any other provision of law
21 that preempts State licensing requirements for health care
22 professionals, including with respect to military trauma
23 care providers.

24 “(e) REPORTING REQUIREMENTS.—

1 “(1) REPORT TO THE SECRETARY AND THE
2 SECRETARY OF DEFENSE.—Each eligible trauma
3 center or eligible high acuity trauma center awarded
4 a grant under subsection (a) or (b) for a year shall
5 submit to the Secretary and the Secretary of De-
6 fense a report for such year that includes informa-
7 tion on—

8 “(A) the number and types of trauma
9 cases managed by military trauma teams or
10 military trauma care providers pursuant to such
11 grant during such year;

12 “(B) the ability to maintain the integration
13 of the military trauma providers or teams of
14 providers as part of the trauma center, includ-
15 ing the financial effect of such grant on the
16 trauma center;

17 “(C) the educational effect on resident
18 trainees in centers where military trauma teams
19 are assigned;

20 “(D) any research conducted during such
21 year supported by such grant; and

22 “(E) any other information required by the
23 Secretaries for the purpose of evaluating the ef-
24 fect of such grant.

1 “(2) REPORT TO CONGRESS.—Not less than
2 once every 2 years, the Secretary, in consultation
3 with the Secretary of Defense, shall submit a report
4 to the congressional committees of jurisdiction that
5 includes information on the effect of placing military
6 trauma care providers in trauma centers awarded
7 grants under this section on—

8 “(A) maintaining military trauma care
9 providers’ readiness and ability to respond to
10 and treat battlefield injuries;

11 “(B) providing health care to civilian trau-
12 ma patients in urban and rural settings;

13 “(C) the capability of trauma centers and
14 military trauma care providers to increase med-
15 ical surge capacity, including as a result of a
16 large scale event;

17 “(D) the ability of grant recipients to
18 maintain the integration of the military trauma
19 providers or teams of providers as part of the
20 trauma center;

21 “(E) efforts to incorporate military trauma
22 care providers into operational exercises and
23 training and drills for public health emer-
24 gencies; and

1 “(F) the capability of military trauma care
2 providers to participate as part of a medical re-
3 sponse during or in advance of a public health
4 emergency, as determined by the Secretary, or
5 a mass casualty incident.

6 “(f) DEFINITIONS.—For purposes of this part:

7 “(1) ELIGIBLE TRAUMA CENTER.—The term
8 ‘eligible trauma center’ means a Level I, II, or III
9 trauma center that satisfies each of the following:

10 “(A) Such trauma center has an agree-
11 ment with the Secretary of Defense to enable
12 military trauma care providers to provide trau-
13 ma care and related acute care at such trauma
14 center.

15 “(B) Such trauma center utilizes a risk-ad-
16 justed benchmarking system and metrics to
17 measure performance, quality, and patient out-
18 comes.

19 “(C) Such trauma center demonstrates a
20 need for integrated military trauma care pro-
21 viders to maintain or improve the trauma clin-
22 ical capability of such trauma center.

23 “(2) ELIGIBLE HIGH ACUITY TRAUMA CEN-
24 TER.—The term ‘eligible high acuity trauma center’

1 means a Level I trauma center that satisfies each of
2 the following:

3 “(A) Such trauma center has an agree-
4 ment with the Secretary of Defense to enable
5 military trauma teams to provide trauma care
6 and related acute care at such trauma center.

7 “(B) At least 20 percent of patients treat-
8 ed at such trauma center in the most recent 3-
9 month period for which data are available are
10 treated for a major trauma at such trauma cen-
11 ter.

12 “(C) Such trauma center utilizes a risk-ad-
13 justed benchmarking system and metrics to
14 measure performance, quality, and patient out-
15 comes.

16 “(D) Such trauma center is an academic
17 training center—

18 “(i) affiliated with a medical school;

19 “(ii) that maintains residency pro-
20 grams and fellowships in critical trauma
21 specialties and subspecialties, and provides
22 education and supervision of military trau-
23 ma team members according to those spe-
24 cialties and subspecialties; and

1 “(iii) that undertakes research in the
2 prevention and treatment of traumatic in-
3 jury.

4 “(E) Such trauma center serves as a med-
5 ical and public health preparedness and re-
6 sponse leader for its community, such as by
7 participating in a partnership for State and re-
8 gional hospital preparedness established under
9 section 319C-2 or 319C-3.

10 “(3) MAJOR TRAUMA.—The term ‘major trau-
11 ma’ means an injury that is greater than or equal
12 to 15 on the injury severity score.

13 “(4) MILITARY TRAUMA TEAM.—The term
14 ‘military trauma team’ means a complete military
15 trauma team consisting of military trauma care pro-
16 viders.

17 “(5) MILITARY TRAUMA CARE PROVIDER.—The
18 term ‘military trauma care provider’ means a mem-
19 ber of the Armed Forces who furnishes emergency,
20 critical care, and other trauma acute care services
21 (including a physician, surgeon, physician assistant,
22 nurse, nurse practitioner, respiratory therapist,
23 flight paramedic, combat medic, or enlisted medical
24 technician), or other military trauma care provider
25 as the Secretary determines appropriate.

1 “(g) AUTHORIZATION OF APPROPRIATIONS.—To
2 carry out this section, there are authorized to be appro-
3 priated \$15,000,000 for each of fiscal years 2019 through
4 2023, of which—

5 “(1) $\frac{2}{3}$ of the amount made available each fis-
6 cal year shall be made available for grants under
7 subsection (a); and

8 “(2) $\frac{1}{3}$ of the amount made available each fis-
9 cal year shall be made available for grants under
10 subsection (b).”.

11 **SEC. 205. PUBLIC HEALTH AND HEALTH CARE SYSTEM SIT-**
12 **UATIONAL AWARENESS AND BIOSURVEIL-**
13 **LANCE CAPABILITIES.**

14 (a) FACILITIES, CAPACITIES, AND BIOSURVEILLANCE
15 CAPABILITIES.—Section 319D of the Public Health Serv-
16 ice Act (42 U.S.C. 247d–4) is amended—

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

20 (2) in subsection (a)—

21 (A) in the subsection heading, by striking
22 “FACILITIES; CAPACITIES” and inserting “IN
23 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, the Secretary
8 of Veterans Affairs, and the heads of other
9 Federal agencies, as the Secretary determines
10 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 ated—

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

21 (II) by striking “and clinical lab-
22 oratories” 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; stakeholders
3 with expertise in capabilities relevant to
4 biosurveillance and situational awareness,
5 such as experts in informatics and data
6 analytics (including experts in prediction,
7 modeling, or 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 redesign-
4 nated, by striking “; and” and insert-
5 ing a semicolon;

6 (III) in clause (iv), as so redesign-
7 nated, by striking the period and in-
8 serting “; and”; and

9 (IV) by adding at the end the fol-
10 lowing:

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

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 demic and All-Hazards Preparedness and Ad-
2 vancing Innovation Act of 2018, the Secretary
3 shall submit to the congressional committees of
4 jurisdiction a coordinated strategy and an ac-
5 companying implementation plan that—

6 “(i) is informed by the public meeting
7 under paragraph (5)(B);

8 “(ii) includes a review and assessment
9 of existing capabilities of the network and
10 related infrastructure, including input pro-
11 vided by the public meeting under para-
12 graph (5)(B);

13 “(iii) identifies and demonstrates the
14 measurable steps the Secretary will carry
15 out to—

16 “(I) develop, implement, and
17 evaluate the network described in
18 paragraph (1), utilizing elements de-
19 scribed in paragraph (3)(A);

20 “(II) modernize and enhance bio-
21 surveillance activities, including strat-
22 egies to include innovative tech-
23 nologies and analytical approaches
24 (including prediction and forecasting

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 (i) and (j), respectively; and

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

20 “(f) PERSONNEL AUTHORITIES.—

21 “(1) SPECIALLY QUALIFIED PERSONNEL.—In
22 addition to any other personnel authorities, to carry
23 out subsections (b) and (c), the Secretary may—

24 “(A) appoint highly qualified individuals to
25 scientific or professional positions at the Cen-

1 ters for Disease Control and Prevention, not to
2 exceed 30 such employees at any time (specific
3 to positions authorized by this subsection), with
4 expertise in capabilities relevant to biosurveil-
5 lance and situational awareness, such as experts
6 in informatics and data analytics (including ex-
7 perts in prediction, modeling, or forecasting),
8 and other related scientific or technical fields;
9 and

10 “(B) compensate individuals appointed
11 under subparagraph (A) in the same manner
12 and subject to the same terms and conditions in
13 which individuals appointed under 9903 of title
14 5, United States Code, are compensated, with-
15 out regard to the provisions of chapter 51 and
16 subchapter III of chapter 53 of such title relat-
17 ing to classification and General Schedule pay
18 rates.

19 “(2) LIMITATIONS.—The Secretary shall exer-
20 cise the authority under paragraph (1) in a manner
21 that is consistent with the limitations described in
22 section 319F–1(e)(2).

23 “(g) TIMELINE.—The Secretary shall accomplish the
24 purposes under subsections (b) and (c) no later than Sep-
25 tember 30, 2023, and shall provide a justification to the

1 congressional committees of jurisdiction for any missed or
2 delayed implementation of measurable steps identified
3 under subsection (c)(6)(A)(iii).

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

14 (b) AUTHORIZATION OF APPROPRIATIONS.—Sub-
15 section (i) of section 319D of the Public Health Service
16 Act (42 U.S.C. 247d–4), as redesignated by subsection
17 (a)(6), is amended by striking “\$138,300,000 for each of
18 fiscal years 2014 through 2018” and inserting
19 “\$161,800,000 for each of fiscal years 2019 through
20 2023”.

21 (c) BIOLOGICAL THREAT DETECTION REPORT.—The
22 Secretary of Health and Human Services shall, in coordi-
23 nation with the Secretary of Defense and the Secretary
24 of Homeland Security, not later than 180 days after the
25 date of enactment of this Act, report to the Committee

1 on Energy and Commerce, the Committee on Armed Serv-
2 ices, and the Committee on Homeland Security of the
3 House of Representatives and the Committee on Health,
4 Education, Labor, and Pensions, the Committee on Armed
5 Services, and the Committee on Homeland Security and
6 Governmental Affairs of the Senate on the state of Fed-
7 eral biological threat detection efforts, including the fol-
8 lowing—

9 (1) an identification of technological, oper-
10 ational, and programmatic successes and failures of
11 domestic detection programs supported by Federal
12 departments and agencies for intentionally-intro-
13 duced or accidentally-released biological threat
14 agents and naturally occurring infectious diseases;

15 (2) a description of Federal efforts to facilitate
16 the exchange of information related to the informa-
17 tion described in paragraph (1) among Federal de-
18 partments and agencies that utilize biological threat
19 detection technology;

20 (3) a description of the capabilities of detection
21 systems in use by Federal departments and agencies
22 including the capability to—

23 (A) rapidly detect, identify, characterize,
24 and confirm the presence of biological threat
25 agents;

1 (B) recover live biological agents from col-
2 lection devices;

3 (C) determine the geographical distribution
4 of biological agents;

5 (D) determine the extent of environmental
6 contamination and persistence of biological
7 agents; and

8 (E) provide advanced molecular diagnostics
9 to State, local, tribal, and territorial public
10 health and other laboratories that support bio-
11 logical threat detection activities;

12 (4) a description of Federal interagency coordi-
13 nation related to biological threat detection;

14 (5) a description of efforts by Federal depart-
15 ments and agencies that utilize biological threat de-
16 tection technology to collaborate with State, local,
17 tribal, and territorial public health laboratories and
18 other users of biological threat detection systems, in-
19 cluding collaboration regarding the development of—

20 (A) biological threat detection require-
21 ments or standards;

22 (B) a standardized integration strategy;

23 (C) training requirements or guidelines;

24 (D) guidelines for a coordinated public
25 health response, including preparedness capa-

1 bilities, and, as applicable, for coordination with
2 public health surveillance systems; and

3 (E) a coordinated environmental remedi-
4 ation plan, as applicable; and

5 (6) recommendations related to research, ad-
6 vanced research, development, and procurement for
7 Federal departments and agencies to improve and
8 enhance biological threat detection systems, includ-
9 ing recommendations on the transfer of biological
10 threat detection technology among Federal depart-
11 ments and agencies, as necessary and appropriate.

12 **SEC. 206. STRENGTHENING AND SUPPORTING THE PUBLIC**
13 **HEALTH EMERGENCY RAPID RESPONSE**
14 **FUND.**

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

17 (1) in subsection (b)—

18 (A) in paragraph (1)—

19 (i) in the first sentence, by inserting
20 “or if the Secretary determines there is the
21 significant potential for a public health
22 emergency, to allow the Secretary to rap-
23 idly respond to the immediate needs result-
24 ing from such public health emergency or

1 potential public health emergency” before
2 the period; and

3 (ii) by inserting “The Secretary shall
4 plan for the expedited distribution of funds
5 to appropriate agencies and entities.” after
6 the first sentence;

7 (B) by redesignating paragraph (2) as
8 paragraph (3);

9 (C) by inserting after paragraph (1) the
10 following:

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

13 “(A) facilitate coordination between and
14 among Federal, State, local, tribal, and terri-
15 torial entities and public and private health
16 care entities that the Secretary determines may
17 be affected by a public health emergency or po-
18 tential public health emergency referred to in
19 paragraph (1) (including communication of
20 such entities with relevant international enti-
21 ties, as applicable);

22 “(B) make grants, provide for awards,
23 enter into contracts, and conduct supportive in-
24 vestigations pertaining to a public health emer-
25 gency or potential public health emergency, in-

1 including further supporting programs under sec-
2 tion 319C–1, 319C–2, or 319C–3;

3 “(C) facilitate and accelerate, as applica-
4 ble, advanced research and development of secu-
5 rity countermeasures (as defined in section
6 319F–2), qualified countermeasures (as defined
7 in section 319F–1), or qualified pandemic or
8 epidemic products (as defined in section 319F–
9 3), that are applicable to the public health
10 emergency or potential public health emergency
11 under paragraph (1);

12 “(D) strengthen biosurveillance capabilities
13 and laboratory capacity to identify, collect, and
14 analyze information regarding such public
15 health emergency or potential public health
16 emergency, including the systems under section
17 319D;

18 “(E) support initial emergency operations
19 and assets related to preparation and deploy-
20 ment of intermittent disaster response per-
21 sonnel under section 2812, and the Medical Re-
22 serve Corps under section 2813; and

23 “(F) carry out other activities, as the Sec-
24 retary determines applicable and appropriate.”;
25 and

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

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

16 “(5) GAO REPORT.—Not later than 4 years
17 after the date of enactment of the Pandemic and
18 All-Hazards Preparedness and Advancing Innovation
19 Act of 2018, the Comptroller General of the United
20 States shall—

21 “(A) conduct a review of the Fund under
22 this section, including its uses and the re-
23 sources available in the Fund; and

24 “(B) submit to the Committee on Health,
25 Education, Labor, and Pensions of the Senate

1 and the Committee on Energy and Commerce
2 of the House of Representatives a report on
3 such review, including recommendations related
4 to such review, as applicable.”; and
5 (2) in subsection (c)—

6 (A) by inserting “rapidly respond to public
7 health emergencies or potential public health
8 emergencies and” after “used to”; and

9 (B) by striking “section.” and inserting
10 “Act or funds otherwise provided for emergency
11 response.”.

12 **SEC. 207. IMPROVING ALL-HAZARDS PREPAREDNESS AND**
13 **RESPONSE BY PUBLIC HEALTH EMERGENCY**
14 **VOLUNTEERS.**

15 (a) IN GENERAL.—Section 319I of the Public Health
16 Service Act (42 U.S.C. 247d–7b) is amended—

17 (1) in the section heading, by striking
18 “**HEALTH PROFESSIONS VOLUNTEERS**” and in-
19 serting “**VOLUNTEER HEALTH PROFESSIONAL**”;

20 (2) in subsection (a), by adding at the end the
21 following: “Such health care professionals may in-
22 clude members of the National Disaster Medical
23 System, members of the Medical Reserve Corps, and
24 individual health care professionals.”;

1 (3) in subsection (i) by adding at the end “In
2 order to inform the development of such mechanisms
3 by States, the Secretary shall make available infor-
4 mation and material provided by States that have
5 developed mechanisms to waive the application of li-
6 censing requirements to applicable health profes-
7 sionals seeking to provide medical services during a
8 public health emergency. Such information shall be
9 made publicly available in a manner that does not
10 compromise national security.”; and

11 (4) in subsection (k) by striking “2014 through
12 2018” and inserting “2019 through 2023”.

13 (b) ALL-HAZARDS PUBLIC HEALTH EMERGENCY
14 PREPAREDNESS AND RESPONSE PLAN.—Section 319C–
15 1(b)(2)(A)(iv) of the Public Health Service Act (42 U.S.C.
16 247d–3a(b)(2)(A)(iv)) is amended to read as follows:

17 “(iv) a description of the mechanism the
18 entity will implement to utilize the Emergency
19 Management Assistance Compact, or other mu-
20 tual aid agreement, for medical and public
21 health mutual aid, and, as appropriate, the ac-
22 tivities such entity will implement pursuant to
23 section 319I to improve enrollment and coordi-
24 nation of volunteer health care professionals

1 seeking to provide medical services during a
2 public health emergency, which may include—

3 “(I) providing a public method of
4 communication for purposes of volunteer
5 coordination (such as a phone number);

6 “(II) providing for optional registra-
7 tion to participate in volunteer services
8 during processes related to State medical
9 licensing, registration, or certification or
10 renewal of such licensing, registration or
11 certification; or

12 “(III) other mechanisms as the State
13 determines appropriate;”.

14 **SEC. 208. CLARIFYING STATE LIABILITY LAW FOR VOLUN-**
15 **TEER HEALTH CARE PROFESSIONALS.**

16 (a) IN GENERAL.—Title II of the Public Health Serv-
17 ice Act (42 U.S.C. 202 et seq.) is amended by inserting
18 after section 224 the following:

19 **“SEC. 225. HEALTH CARE PROFESSIONALS ASSISTING DUR-**
20 **ING A PUBLIC HEALTH EMERGENCY.**

21 “(a) LIMITATION ON LIABILITY.—Notwithstanding
22 any other provision of law, a health care professional who
23 is a member of the Medical Reserve Corps under section
24 2813 or who is included in the Emergency System for Ad-

1 vance Registration of Volunteer Health Professionals
2 under section 319I and who—

3 “(1) is responding—

4 “(A) to a public health emergency deter-
5 mined under section 319(a), during the initial
6 period of not more than 90 days (as determined
7 by the Secretary) of the public health emer-
8 gency determination (excluding any period cov-
9 ered by a renewal of such determination); or

10 “(B) to a major disaster or an emergency
11 as declared by the President under section 401
12 of the Robert T. Stafford Disaster Relief and
13 Emergency Assistance Act (42 U.S.C. 5170) or
14 under section 201 of the National Emergencies
15 Act (50 U.S.C.1621) during the initial period of
16 such declaration; and

17 “(2) is alleged to be liable for an act or omis-
18 sion—

19 “(A) during the initial period of a deter-
20 mination or declaration described in paragraph
21 (1) and related to the treatment of individuals
22 in need of health care services due to such pub-
23 lic health emergency, major disaster, or emer-
24 gency;

1 “(B) in the State or States for which such
2 determination or declaration is made;

3 “(C) in the health care professional’s ca-
4 pacity as a member of the Medical Reserve
5 Corps or a professional included in the Emer-
6 gency System for Advance Registration of Vol-
7 unteer Health Professionals under section 319I;
8 and

9 “(D) in the course of providing services
10 that are within the scope of the license, reg-
11 istration, or certification of the professional, as
12 defined by the State of licensure, registration,
13 or certification; and

14 “(3) prior to the rendering of such act or omis-
15 sion, was authorized by the State’s authorization of
16 deploying such State’s Emergency System for Ad-
17 vance Registration of Volunteer Health Professionals
18 described in section 319I or the Medical Reserve
19 Corps established under section 2813, to provide
20 health care services,

21 shall be subject only to the State liability laws of the State
22 in which such act or omission occurred, in the same man-
23 ner and to the same extent as a similar health care profes-
24 sional who is a resident of such State would be subject

1 to such State laws, except with respect to the licensure,
2 registration, and certification of such individual.

3 “(b) VOLUNTEER PROTECTION ACT.—Nothing in
4 this section shall be construed to affect an individual’s
5 right to protections under the Volunteer Protection Act
6 of 1997.

7 “(c) PREEMPTION.—This section shall supercede the
8 laws of any State that would subject a health care profes-
9 sional described in subsection (a) to the liability laws of
10 any State other than the State liability laws to which such
11 individual is subject pursuant to such subsection.

12 “(d) DEFINITIONS.—In this section:

13 “(1) The term ‘health care professional’ means
14 an individual licensed, registered, or certified under
15 Federal or State laws or regulations to provide
16 health care services.

17 “(2) The term ‘health care services’ means any
18 services provided by a health care professional, or by
19 any individual working under the supervision of a
20 health care professional, that relate to—

21 “(A) the diagnosis, prevention, or treat-
22 ment of any human disease or impairment; or

23 “(B) the assessment or care of the health
24 of human beings.

25 “(e) EFFECTIVE DATE.—

1 “(1) IN GENERAL.—This section shall take ef-
2 fect 90 days after the date of the enactment of the
3 Pandemic and All-Hazards Preparedness and Ad-
4 vancing Innovation Act of 2018.

5 “(2) APPLICATION.—This section shall apply to
6 a claim for harm only if the act or omission that
7 caused such harm occurred on or after the effective
8 date described in paragraph (1).”.

9 (b) GAO STUDY.—Not later than one year after the
10 date of enactment of this Act, the Comptroller General
11 of the United States shall conduct a review of—

12 (1) the number of health care providers who
13 register under the Emergency System for Advance
14 Registration of Volunteer Health Professionals
15 under section 319I of the Public Health Service Act
16 (42 U.S.C. 247d–7b) in advance to provide services
17 during a public health emergency;

18 (2) the number of health care providers who are
19 credentialed to provide services during the period of
20 a public health emergency declaration, including
21 those who are credentialed through programs estab-
22 lished in the Emergency System for Advance Reg-
23 istration of Volunteer Health Professionals under
24 such section 319I and those credentialed by authori-

1 ties within the State in which the emergency oc-
2 curred;

3 (3) the average time to verify the credentials of
4 a health care provider during the period of a public
5 health emergency declaration, including the average
6 time pursuant to the Emergency System for Ad-
7 vance Registration of Volunteer Health Professionals
8 under such section 319I and for an individual's cre-
9 dentials to be verified by an authority within the
10 State; and

11 (4) the Emergency System for Advance Reg-
12 istration of Volunteer Health Professionals program
13 in States, including whether physician or medical
14 groups, associations, or other relevant provider orga-
15 nizations utilize such program for purposes of volun-
16 teering during public health emergencies.

17 **SEC. 209. REPORT ON ADEQUATE NATIONAL BLOOD SUP-**
18 **PLY.**

19 Not later than 1 year after the date of the enactment
20 of this Act, the Secretary of Health and Human Services
21 shall submit to Congress a report containing recommenda-
22 tions related to maintaining an adequate national blood
23 supply, including—

1 (1) challenges associated with the continuous
2 recruitment of blood donors (including those newly
3 eligible to donate);

4 (2) ensuring the adequacy of the blood supply
5 in the case of public health emergencies;

6 (3) implementation of the transfusion trans-
7 mission monitoring system; and

8 (4) other measures to promote safety and inno-
9 vation, such as the development, use, or implementa-
10 tion of new technologies, processes, and procedures
11 to improve the safety and reliability of the blood
12 supply.

13 **SEC. 210. REPORT ON THE PUBLIC HEALTH PREPARED-**
14 **NESS AND RESPONSE CAPABILITIES AND CA-**
15 **PACITIES OF HOSPITALS, LONG-TERM CARE**
16 **FACILITIES, AND OTHER HEALTH CARE FA-**
17 **CILITIES.**

18 (a) STUDY.—

19 (1) IN GENERAL.—Not later than one year
20 after the date of enactment of this Act, the Sec-
21 retary of Health and Human Services shall enter
22 into an agreement with an appropriate entity to con-
23 duct a study regarding the public health prepared-
24 ness and response capabilities and medical surge ca-
25 pacities of hospitals, long-term care facilities, and

1 other health care facilities to prepare for, and re-
2 spond to, public health emergencies, including nat-
3 ural disasters.

4 (2) CONSULTATION.—In conducting the study
5 under paragraph (1), the entity shall consult with
6 Federal, State, local, tribal, and territorial public
7 health officials (as appropriate), and health care
8 providers and facilities with experience in public
9 health preparedness and response activities.

10 (3) EVALUATION.—The study under paragraph
11 (1) shall include—

12 (A) an evaluation of the current bench-
13 marks and objective standards, as applicable,
14 related to programs that support hospitals,
15 long-term care facilities, and other health care
16 facilities, and their effect on improving public
17 health preparedness and response capabilities
18 and medical surge capacities, including the
19 Hospital Preparedness Program, the Public
20 Health Emergency Preparedness cooperative
21 agreements, and the Regional Health Care
22 Emergency Preparedness and Response Sys-
23 tems under section 319C–3 of the Public
24 Health Service Act (as added by section 203);

1 (B) the identification of gaps in prepared-
2 ness, including with respect to such benchmarks
3 and objective standards, such as those identified
4 during recent public health emergencies, for
5 hospitals, long-term care facilities, and other
6 health care facilities to address future potential
7 public health threats;

8 (C) an evaluation of coordination efforts
9 between the recipients of Federal funding for
10 programs described in subparagraph (A) and
11 entities with expertise in emergency power sys-
12 tems and other critical infrastructure partners
13 during a public health emergency, to ensure a
14 functioning critical infrastructure, to the great-
15 est extent practicable, during a public health
16 emergency;

17 (D) an evaluation of coordination efforts
18 between the recipients of Federal funding for
19 programs described in subparagraph (A) and
20 environmental health agencies with expertise in
21 emergency preparedness and response planning
22 for hospitals, long-term care facilities and other
23 health care facilities; and

24 (E) an evaluation of current public health
25 preparedness and response capabilities and

1 medical surge capacities related to at-risk indi-
2 viduals during public health emergencies, in-
3 cluding an identification of gaps in such pre-
4 paredness as they relate to such individuals.

5 (b) REPORT.—

6 (1) IN GENERAL.—The agreement under sub-
7 section (a) shall require the entity to submit to the
8 Secretary of Health and Human Services and the
9 congressional committees of jurisdiction, not later
10 than 3 years after the date of enactment of this Act,
11 a report on the results of the study conducted pur-
12 suant to this section.

13 (2) CONTENTS.—The report under paragraph
14 (1) shall—

15 (A) describe the findings and conclusions
16 of the evaluation conducted pursuant to sub-
17 section (a); and

18 (B) provide recommendations for improv-
19 ing public health preparedness and response ca-
20 pability and medical surge capacity for hos-
21 pitals, long-term care facilities, and other health
22 care facilities, including—

23 (i) improving the existing benchmarks
24 and objective standards for the Federal
25 grant programs described in subsection

1 (a)(3)(A) or developing new benchmarks
2 and standards for such programs; and
3 (ii) identifying best practices for im-
4 proving public health preparedness and re-
5 sponse programs and medical surge capac-
6 ity at hospitals, long-term care facilities,
7 and other health care facilities, including
8 recommendations for the evaluation under
9 subparagraphs (C) and (D) of subsection
10 (a)(3).

11 **TITLE III—REACHING ALL** 12 **COMMUNITIES**

13 **SEC. 301. STRENGTHENING AND ASSESSING THE EMER-** 14 **GENCY RESPONSE WORKFORCE.**

15 (a) NATIONAL DISASTER MEDICAL SYSTEM.—

16 (1) STRENGTHENING THE NATIONAL DISASTER
17 MEDICAL SYSTEM.—Clause (ii) of section
18 2812(a)(3)(A) of the Public Health Service Act (42
19 U.S.C. 300hh–11(a)(3)(A)) is amended to read as
20 follows:

21 “(ii) be present at locations, and for
22 limited periods of time, specified by the
23 Secretary on the basis that the Secretary
24 has determined that a location is at risk of
25 a public health emergency during the time

1 specified, or there is a significant potential
2 for a public health emergency.”.

3 (2) REVIEW OF THE NATIONAL DISASTER MED-
4 ICAL SYSTEM.—Section 2812(b)(2) of the Public
5 Health Service Act (42 U.S.C. 300hh–11(b)(2)) is
6 amended to read as follows:

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

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

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

20 “(ii) an assessment of the available
21 workforce of the intermittent disaster re-
22 sponse personnel described in subsection
23 (c);

24 “(iii) the capacity of the workforce de-
25 scribed in clause (ii) to respond to all haz-

1 ards, including capacity to simultaneously
2 respond to multiple public health emer-
3 gencies and the capacity to respond to a
4 nationwide public health emergency;

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

7 “(v) gaps that may exist in such
8 workforce and recommendations for ad-
9 dressing such gaps.

10 “(B) UPDATES.—As part of the National
11 Health Security Strategy under section 2802,
12 the Secretary shall update the findings from the
13 review under subparagraph (A) and provide rec-
14 ommendations to modify the policies of the Na-
15 tional Disaster Medical System as necessary.”.

16 (3) NOTIFICATION OF SHORTAGE.—Section
17 2812(c) of the Public Health Service Act (42 U.S.C.
18 300hh–11(c)) is amended by adding at the end the
19 following:

20 “(3) NOTIFICATION.—Not later than 30 days
21 after the date on which the Secretary determines the
22 number of intermittent disaster-response personnel
23 of the National Disaster Medical System is insuffi-
24 cient to address a public health emergency or poten-
25 tial public health emergency, the Secretary shall sub-

1 mit to the congressional committees of jurisdiction a
2 notification detailing—

3 “(A) the impact such shortage could have
4 on meeting public health needs and emergency
5 medical personnel needs during a public health
6 emergency; and

7 “(B) any identified measures to address
8 such shortage.

9 “(4) CERTAIN APPOINTMENTS.—

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

23 “(B) SUNSET.—The authority under this
24 paragraph shall expire on September 30,
25 2021.”.

1 (4) AUTHORIZATION OF APPROPRIATIONS.—

2 Section 2812(g) of the Public Health Service Act
3 (42 U.S.C. 300hh–11(g)) is amended by striking
4 “\$52,700,000 for each of fiscal years 2014 through
5 2018” and inserting “\$57,400,000 for each of fiscal
6 years 2019 through 2023”.

7 (b) VOLUNTEER MEDICAL RESERVE CORPS.—

8 (1) IN GENERAL.—Section 2813(a) of the Pub-
9 lic Health Service Act (42 U.S.C. 42 U.S.C. 300hh–
10 15(a)) is amended by striking the second sentence
11 and inserting “The Secretary may appoint a Direc-
12 tor to head the Corps and oversee the activities of
13 the Corps chapters that exist at the State, local,
14 tribal, and territorial levels.”.

15 (2) AUTHORIZATION OF APPROPRIATIONS.—

16 Section 2813(i) of the Public Health Service Act (42
17 U.S.C. 300hh–15(i)) is amended by striking “2014
18 through 2018” and inserting “2019 through 2023”.

19 (c) STRENGTHENING THE EPIDEMIC INTELLIGENCE
20 SERVICE.—Section 317F of the Public Health Service Act
21 (42 U.S.C. Sec. 247b–7) is amended—

22 (1) in subsection (a)—

23 (A) in paragraph (1)—

24 (i) by inserting “or preparedness and
25 response activities, including rapid re-

1 sponse to public health emergencies and
2 significant public health threats” after
3 “conduct prevention activities”; and

4 (ii) by striking “\$35,000” and insert-
5 ing “\$50,000”; and

6 (B) in paragraph (2)(B), by striking “3
7 years” and inserting “2 years”; and
8 (2) in subsection (c)—

9 (A) by striking “For the purpose of car-
10 rying out this section” and inserting the fol-
11 lowing:

12 “(1) IN GENERAL.—For the purpose of car-
13 rying out this section, except as described in para-
14 graph (2)”; and

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

16 “(2) EPIDEMIC INTELLIGENCE SERVICE PRO-
17 GRAM.—For purposes of carrying out this section
18 with respect to qualified health professionals serving
19 in the Epidemic Intelligence Service, as authorized
20 under section 317G, there are authorized to be ap-
21 propriated \$1,000,000 for each of fiscal years 2019
22 through 2023.”.

23 (d) SERVICE BENEFIT FOR NATIONAL DISASTER
24 MEDICAL SYSTEM VOLUNTEERS.—

1 (1) IN GENERAL.—Section 2812(c) of the Pub-
2 lic Health Service Act (42 U.S.C. 300hh–11(c)), as
3 amended by subsection (a)(3), is further amended by
4 adding at the end the following:

5 “(5) SERVICE BENEFIT.—Individuals appointed
6 to serve under this subsection shall be considered eli-
7 gible for benefits under part L of title I of the Om-
8 nibus Crime Control and Safe Streets Act of 1968.
9 The Secretary shall provide notification to eligible
10 individuals of any effect such designation may have
11 on other benefits for which such individual are eligi-
12 ble, including benefits from private entities.”.

13 (2) PUBLIC SAFETY OFFICER BENEFITS.—Sec-
14 tion 1204(9) of title I of the Omnibus Crime Control
15 and Safe Streets Act of 1968 (34 U.S.C. 10284(9))
16 is amended—

17 (A) in subparagraph (C)(ii), by striking
18 “or” at the end;

19 (B) in subparagraph (D), by striking the
20 period and inserting “; or”; and

21 (C) by inserting after subparagraph (D)
22 the following:

23 “(E) an individual appointed to the Na-
24 tional Disaster Medical System under section
25 2812 of the Public Health Service Act (42

1 U.S.C. 300hh–11) who is performing official
2 duties of the Department of Health and Human
3 Services, if those official duties are—

4 “(i) related to responding to a public
5 health emergency or potential public health
6 emergency, or other activities for which the
7 Secretary of Health and Human Services
8 has activated such National Disaster Med-
9 ical System; and

10 “(ii) determined by the Secretary of
11 Health and Human Services to be haz-
12 ardous.”.

13 (3) SUNSET.—The amendments made by para-
14 graphs (1) and (2) shall cease to have force or effect
15 on October 1, 2021.

16 (e) MISSION READINESS REPORT TO CONGRESS.—

17 (1) REPORT.—Not later than one year after the
18 date of enactment of this section, the Comptroller
19 General of the United States (referred to in this
20 subsection as the “Comptroller General”) shall sub-
21 mit to the Committee on Health, Education, Labor,
22 and Pensions of the Senate and the Committee on
23 Energy and Commerce of the House of Representa-
24 tives, a report on the medical surge capacity of the
25 United States in the event of a public health emer-

1 agency, including the capacity and capability of the
2 current health care workforce to prepare for, and re-
3 spond to the full range of public health emergencies
4 or potential public health emergencies, and rec-
5 ommendations to address any gaps identified in such
6 workforce.

7 (2) CONTENTS.—The Comptroller General shall
8 include in the report under paragraph (1)—

9 (A) the number of health care providers
10 who have volunteered to provide health care
11 services during a public health emergency, in-
12 cluding members of the National Disaster Med-
13 ical System, the Disaster Medical Assistant
14 Teams, the Medical Reserve Corps, and other
15 volunteer health care professionals in the
16 verification network pursuant to section 319I of
17 the Public Health Service Act (42 U.S.C.
18 247d–7b);

19 (B) the capacity of the workforce described
20 in subparagraph (A) to respond to a public
21 health emergency or potential public health
22 emergency, including the capacity to respond to
23 multiple concurrent public health emergencies
24 and the capacity to respond to a nationwide
25 public health emergency;

1 (C) the preparedness and response capa-
2 bilities and mission readiness of the workforce
3 described in subparagraph (A) taking into ac-
4 count areas of health care expertise and consid-
5 erations for at-risk individuals (as defined in
6 section 2802(b)(4)(B) of the Public Health
7 Service Act (42 U.S.C. 300hh–1(b)(4)(B));

8 (D) an assessment of the effectiveness of
9 efforts to recruit, retain, and train such work-
10 force; and

11 (E) identification of gaps that may exist in
12 such workforce and recommendations for ad-
13 dressing such gaps, the extent to which the As-
14 sistant Secretary for Preparedness and Re-
15 sponse plans to address such gaps, and any rec-
16 ommendations from the Comptroller General to
17 address such gaps.

18 **SEC. 302. HEALTH SYSTEM INFRASTRUCTURE TO IMPROVE**
19 **PREPAREDNESS AND RESPONSE.**

20 (a) COORDINATION OF PREPAREDNESS.—Section
21 2811(b)(5) of the Public Health Service Act (42 U.S.C.
22 300hh–10(b)(5)) is amended by adding at the end the fol-
23 lowing: “Such logistical support shall include working with
24 other relevant Federal, State, local, tribal, and territorial
25 public health officials and private sector entities to identify

1 the critical infrastructure assets, systems, and networks
2 needed for the proper functioning of the health care and
3 public health sectors that need to be maintained through
4 any emergency or disaster, including entities capable of
5 assisting with, responding to, and mitigating the effect of
6 a public health emergency, including a public health emer-
7 gency determined by the Secretary pursuant to section
8 319(a), an emergency or major disaster declared by the
9 President under the Robert T. Stafford Disaster Relief
10 and Emergency Assistance Act, or the National Emer-
11 gencies Act, including by establishing methods to exchange
12 critical information and deliver products consumed or used
13 to preserve, protect, or sustain life, health, or safety, and
14 sharing of specialized expertise.”.

15 (b) MANUFACTURING CAPACITY.—Section
16 2811(d)(2)(C) of the Public Health Service Act (42
17 U.S.C. 300hh–10(d)(2)(C)) is amended by inserting “,
18 and ancillary medical supplies to assist with the utilization
19 of such countermeasures or products,” after “products”.

20 (c) EVALUATION OF BARRIERS TO RAPID DELIVERY
21 OF MEDICAL COUNTERMEASURES.—

22 (1) RAPID DELIVERY STUDY.—The Assistant
23 Secretary for Preparedness and Response may con-
24 duct a study on issues that have the potential to ad-
25 versely affect the handling and rapid delivery of

1 medical countermeasures to individuals during public
2 health emergencies occurring in the United States.

3 (2) NOTICE TO CONGRESS.—Not later than 9
4 months after the date of the enactment of this Act,
5 the Assistant Secretary for Preparedness and Re-
6 sponse shall notify the Committee on Energy and
7 Commerce of the House of Representatives and the
8 Committee on Health, Education, Labor, and Pen-
9 sions of the Senate if the Assistant Secretary for
10 Preparedness and Response does not plan to conduct
11 the study under paragraph (1) and shall provide
12 such committees a summary explanation for such de-
13 cision.

14 (3) REPORT TO CONGRESS.—Not later than 1
15 year after the Assistant Secretary for Preparedness
16 and Response conducts the study under paragraph
17 (1), such Assistant Secretary shall submit a report
18 to the Committee on Energy and Commerce of the
19 House of Representatives and the Committee on
20 Health, Education, Labor, and Pensions of the Sen-
21 ate containing the findings of such study.

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

23 (a) AT-RISK INDIVIDUALS IN THE NATIONAL
24 HEALTH SECURITY STRATEGY.—Section 2802(b)(4)(B)

1 of the Public Health Service Act (42 U.S.C. 300hh–
2 1(b)(4)(B)) is amended—

3 (1) by striking “this section and sections 319C–
4 1, 319F, and 319L,” and inserting “this Act,”; and
5 (2) by striking “special” and inserting “access
6 or functional”.

7 (b) COUNTERMEASURE CONSIDERATIONS.—Section
8 319L(c)(6) of the Public Health Service Act (42 U.S.C.
9 247d–7e(c)(6)) is amended—

10 (1) by striking “elderly” and inserting “senior
11 citizens”; and

12 (2) by inserting “with relevant characteristics
13 that warrant consideration during the process of re-
14 searching and developing such countermeasures and
15 products” before the period.

16 (c) BIOSURVEILLANCE OF EMERGING PUBLIC
17 HEALTH THREATS.—Section 2814 is amended—

18 (1) in paragraph (7), by striking “; and” and
19 inserting a semicolon;

20 (2) in paragraph (8), by striking the period and
21 inserting “; and”; and

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

23 “(9) facilitate coordination to ensure that, in
24 implementing the situational awareness and bio-
25 surveillance network under section 319D, the Sec-

1 retary considers incorporating data and information
2 from Federal, State, local, tribal, and territorial
3 public health officials and entities relevant to detect-
4 ing emerging public health threats that may affect
5 at-risk individuals, such as pregnant and postpartum
6 women and infants, including adverse health out-
7 comes of such populations related to such emerging
8 public health threats.”.

9 **SEC. 304. IMPROVING EMERGENCY PREPAREDNESS AND**
10 **RESPONSE CONSIDERATIONS FOR CHIL-**
11 **DREN.**

12 Part B of title III of the Public Health Service Act
13 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
14 tion 319D the following:

15 **“SEC. 319D–1. CHILDREN’S PREPAREDNESS UNIT.**

16 “(a) ENHANCING EMERGENCY PREPAREDNESS FOR
17 CHILDREN.—The Secretary, acting through the Director
18 of the Centers for Disease Control and Prevention (re-
19 ferred to in this subsection as the ‘Director’), shall main-
20 tain an internal team of experts, to be known as the Chil-
21 dren’s Preparedness Unit (referred to in this subsection
22 as the ‘Unit’), to work collaboratively to provide guidance
23 on the considerations for, and the specific needs of, chil-
24 dren before, during, and after public health emergencies.
25 The Unit shall inform the Director regarding emergency

1 preparedness and response efforts pertaining to children
2 at the Centers for Disease Control and Prevention.

3 “(b) EXPERTISE.—The team described in subsection
4 (a) shall include one or more pediatricians, which may be
5 a developmental-behavioral pediatrician, and may also in-
6 clude behavioral scientists, child psychologists, epidemiolo-
7 gists, biostatisticians, health communications staff, and
8 individuals with other areas of expertise, as the Secretary
9 determines appropriate.

10 “(c) DUTIES.—The team described in subsection (a)
11 may—

12 “(1) assist State, local, tribal, and territorial
13 emergency planning and response activities related
14 to children, which may include developing, identi-
15 fying, and sharing best practices;

16 “(2) provide technical assistance, training, and
17 consultation to Federal, State, local, tribal, and ter-
18 ritorial public health officials to improve prepared-
19 ness and response capabilities with respect to the
20 needs of children, including providing such technical
21 assistance, training, and consultation to eligible enti-
22 ties in order to support the achievement of measur-
23 able evidence-based benchmarks and objective stand-
24 ards applicable to sections 319C–1 and 319C–2;

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

5 “(4) coordinate with, and improve, public-pri-
6 vate partnerships, such as health care coalitions pur-
7 suant to sections 319C–2 and 319C–3, to address
8 gaps and inefficiencies in emergency preparedness
9 and response efforts for children;

10 “(5) provide expertise and input during the de-
11 velopment of guidance and clinical recommendations
12 to address the needs of children when preparing for,
13 and responding to, public health emergencies, includ-
14 ing pursuant to section 319C–3; and

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

18 **SEC. 305. NATIONAL ADVISORY COMMITTEES ON DISAS-**
19 **TERS.**

20 (a) REAUTHORIZING THE NATIONAL ADVISORY COM-
21 MITTEE ON CHILDREN AND DISASTERS.—Section 2811A
22 of the Public Health Service Act (42 U.S.C. 300hh–10a)
23 is amended—

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

1 (2) in subsection (d)—

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

4 (B) by striking paragraph (2) and insert-
5 ing the following:

6 “(2) REQUIRED NON-FEDERAL MEMBERS.—The
7 Secretary, in consultation with such other heads of
8 Federal agencies as may be appropriate, shall ap-
9 point to the Advisory Committee under paragraph
10 (1) at least 13 individuals, including—

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

14 “(B) at least 2 representatives from State,
15 local, tribal, or territorial agencies with exper-
16 tise in pediatric disaster planning, prepared-
17 ness, response, or recovery;

18 “(C) at least 4 members representing
19 health care professionals, which may include
20 members with expertise in pediatric emergency
21 medicine; pediatric trauma, critical care, or sur-
22 gery; the treatment of pediatric patients af-
23 fected by chemical, biological, radiological, or
24 nuclear agents, including emerging infectious
25 diseases; pediatric mental or behavioral health

1 related to children affected by a public health
2 emergency; or pediatric primary care; and

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

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

7 “(ii) at least one such member shall
8 be an individual with expertise in schools
9 or child care settings;

10 “(iii) at least one such member shall
11 be an individual with expertise in children
12 and youth with special health care needs;
13 and

14 “(iv) at least one such member shall
15 be an individual with expertise in the needs
16 of parents or family caregivers, including
17 the parents or caregivers of children with
18 disabilities.”.

19 “(3) FEDERAL MEMBERS.—The Advisory Com-
20 mittee under paragraph (1) shall include the fol-
21 lowing Federal members or their designees (who
22 may be non-voting members, as determined by the
23 Secretary):

24 “(A) The Assistant Secretary for Pre-
25 paredness and Response.

1 “(B) The Director of the Biomedical Ad-
2 vanced Research and Development Authority.

3 “(C) The Director of the Centers for Dis-
4 ease Control and Prevention.

5 “(D) The Commissioner of Food and
6 Drugs.

7 “(E) The Director of the National Insti-
8 tutes of Health.

9 “(F) The Assistant Secretary of the Ad-
10 ministration for Children and Families.

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

13 “(H) The Administrator of the Federal
14 Emergency Management Agency.

15 “(I) The Administrator of the Administra-
16 tion for Community Living.

17 “(J) The Secretary of Education.

18 “(K) Representatives from such Federal
19 agencies (such as the Substance Abuse and
20 Mental Health Services Administration and the
21 Department of Homeland Security) as the Sec-
22 retary determines appropriate to fulfill the du-
23 ties of the Advisory Committee under sub-
24 sections (b) and (c).”.

1 “(4) TERM OF APPOINTMENT.—Each member
2 of the Advisory Committee appointed under para-
3 graph (2) shall serve for a term of 3 years, except
4 that the Secretary may adjust the terms of the Advi-
5 sory Committee appointees serving on the date of
6 enactment of the Pandemic and All-Hazards Pre-
7 paredness and Advancing Innovation Act of 2018, or
8 appointees who are initially appointed after such
9 date of enactment, in order to provide for a stag-
10 gered term of appointment for all members.

11 “(5) CONSECUTIVE APPOINTMENTS; MAXIMUM
12 TERMS.—A member appointed under paragraph (2)
13 may serve not more than 3 terms on the Advisory
14 Committee, and not more than 2 of such terms may
15 be served consecutively.”;

16 (3) in subsection (e), by adding at the end “At
17 least one meeting per year shall be an in-person
18 meeting.”;

19 (4) by redesignating subsection (f) as sub-
20 section (g);

21 (5) by inserting after subsection (e) the fol-
22 lowing:

23 “(f) COORDINATION.—The Secretary shall coordinate
24 duties and activities authorized under this section in ac-
25 cordance with section 2811D.”; and

1 (6) in subsection (g), as so redesignated, by
2 striking “2018” and inserting “2023”.

3 (b) AUTHORIZING THE NATIONAL ADVISORY COM-
4 MITTEE ON SENIORS AND DISASTERS.—Subtitle B of title
5 XXVIII of the Public Health Service Act (42 U.S.C.
6 300hh et seq.) is amended by inserting after section
7 2811A the following:

8 **“SEC. 2811B. NATIONAL ADVISORY COMMITTEE ON SEN-**
9 **IORS AND DISASTERS.**

10 “(a) ESTABLISHMENT.—The Secretary, in consulta-
11 tion with the Secretary of Homeland Security and the Sec-
12 retary of Veterans Affairs, shall establish an advisory com-
13 mittee to be known as the National Advisory Committee
14 on Seniors and Disasters (referred to in this section as
15 the ‘Advisory Committee’).

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

17 “(1) provide advice and consultation with re-
18 spect to the activities carried out pursuant to section
19 2814, as applicable and appropriate;

20 “(2) evaluate and provide input with respect to
21 the medical and public health needs of seniors re-
22 lated to preparation for, response to, and recovery
23 from all-hazards emergencies; and

24 “(3) provide advice and consultation with re-
25 spect to State emergency preparedness and response

1 activities relating to seniors, including related drills
2 and exercises pursuant to the preparedness goals
3 under section 2802(b).

4 “(c) ADDITIONAL DUTIES.—The Advisory Committee
5 may provide advice and recommendations to the Secretary
6 with respect to seniors and the medical and public health
7 grants and cooperative agreements as applicable to pre-
8 paredness and response activities under this title and title
9 III.

10 “(d) MEMBERSHIP.—

11 “(1) IN GENERAL.—The Secretary, in consulta-
12 tion with such other heads of agencies as appro-
13 priate, shall appoint not more than 17 members to
14 the Advisory Committee. In appointing such mem-
15 bers, the Secretary shall ensure that the total mem-
16 bership of the Advisory Committee is an odd num-
17 ber.

18 “(2) REQUIRED MEMBERS.—The Advisory
19 Committee shall include Federal members or their
20 designees (who may be non-voting members, as de-
21 termined by the Secretary) and non-Federal mem-
22 bers, as follows:

23 “(A) The Assistant Secretary for Pre-
24 paredness and Response.

1 “(B) The Director of the Biomedical Ad-
2 vanced Research and Development Authority.

3 “(C) The Director of the Centers for Dis-
4 ease Control and Prevention.

5 “(D) The Commissioner of Food and
6 Drugs.

7 “(E) The Director of the National Insti-
8 tutes of Health.

9 “(F) The Administrator of the Centers for
10 Medicare & Medicaid Services.

11 “(G) The Administrator of the Administra-
12 tion for Community Living.

13 “(H) The Administrator of the Federal
14 Emergency Management Agency.

15 “(I) The Under Secretary for Health of
16 the Department of Veterans Affairs.

17 “(J) At least 2 non-Federal health care
18 professionals with expertise in geriatric medical
19 disaster planning, preparedness, response, or
20 recovery.

21 “(K) At least 2 representatives of State,
22 local, territorial, or tribal agencies with exper-
23 tise in geriatric disaster planning, preparedness,
24 response, or recovery.

1 “(L) Representatives of such other Federal
2 agencies (such as the Department of Energy
3 and the Department of Homeland Security) as
4 the Secretary determines necessary to fulfill the
5 duties of the Advisory Committee.

6 “(e) MEETINGS.—The Advisory Committee shall
7 meet not less frequently than biannually. At least one
8 meeting per year shall be an in-person meeting.

9 “(f) COORDINATION.—The Secretary shall coordinate
10 duties and activities authorized under this section in ac-
11 cordance with section 2811D.

12 “(g) SUNSET.—

13 “(1) IN GENERAL.—The Advisory Committee
14 shall terminate on September 30, 2023.

15 “(2) EXTENSION OF COMMITTEE.—Not later
16 than October 1, 2022, the Secretary shall submit to
17 Congress a recommendation on whether the Advisory
18 Committee should be extended.”.

19 (c) NATIONAL ADVISORY COMMITTEE ON INDIVID-
20 UALS WITH DISABILITIES AND DISASTERS.—Subtitle B
21 of title XXVIII of the Public Health Service Act (42
22 U.S.C. 300hh et seq.), as amended by subsection (b), is
23 further amended by inserting after section 2811B the fol-
24 lowing:

1 **“SEC. 2811C. NATIONAL ADVISORY COMMITTEE ON INDIVID-**
2 **UALS WITH DISABILITIES AND DISASTERS.**

3 “(a) ESTABLISHMENT.—The Secretary, in consulta-
4 tion with the Secretary of Homeland Security, shall estab-
5 lish a national advisory committee to be known as the Na-
6 tional Advisory Committee on Individuals with Disabilities
7 and Disasters (referred to in this section as the ‘Advisory
8 Committee’).

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

10 “(1) provide advice and consultation with re-
11 spect to activities carried out pursuant to section
12 2814, as applicable and appropriate;

13 “(2) evaluate and provide input with respect to
14 the medical, public health, and accessibility needs of
15 individuals with disabilities related to preparation
16 for, response to, and recovery from all-hazards emer-
17 gencies; and

18 “(3) provide advice and consultation with re-
19 spect to State emergency preparedness and response
20 activities, including related drills and exercises pur-
21 suant to the preparedness goals under section
22 2802(b).

23 “(c) MEMBERSHIP.—

24 “(1) IN GENERAL.—The Secretary, in consulta-
25 tion with such other heads of agencies and depart-
26 ments as appropriate, shall appoint not more than

1 17 members to the Advisory Committee. In appoint-
2 ing such members, the Secretary shall ensure that
3 the total membership of the Advisory Committee is
4 an odd number.

5 “(2) REQUIRED MEMBERS.—The Advisory
6 Committee shall include Federal members or their
7 designees (who may be non-voting members, as de-
8 termined by the Secretary) and non-Federal mem-
9 bers, as follows:

10 “(A) The Assistant Secretary for Pre-
11 paredness and Response.

12 “(B) The Administrator of the Administra-
13 tion for Community Living.

14 “(C) The Director of the Biomedical Ad-
15 vanced Research and Development Authority.

16 “(D) The Director of the Centers for Dis-
17 ease Control and Prevention.

18 “(E) The Commissioner of Food and
19 Drugs.

20 “(F) The Director of the National Insti-
21 tutes of Health.

22 “(G) The Administrator of the Federal
23 Emergency Management Agency.

24 “(H) The Chair of the National Council on
25 Disability.

1 “(I) The Chair of the United States Access
2 Board.

3 “(J) The Under Secretary for Health of
4 the Department of Veterans Affairs.

5 “(K) At least 2 non-Federal health care
6 professionals with expertise in disability accessi-
7 bility before, during, and after disasters, med-
8 ical and mass care disaster planning, prepared-
9 ness, response, or recovery.

10 “(L) At least 2 representatives from State,
11 local, territorial, or tribal agencies with exper-
12 tise in disaster planning, preparedness, re-
13 sponse, or recovery for individuals with disabil-
14 ities.

15 “(M) At least 2 individuals with a dis-
16 ability with expertise in disaster planning, pre-
17 paredness, response, or recovery for individuals
18 with disabilities.

19 “(d) MEETINGS.—The Advisory Committee shall
20 meet not less frequently than biannually. At least one
21 meeting per year shall be an in-person meeting.

22 “(e) DISABILITY DEFINED.—For purposes of this
23 section, the term ‘disability’ has the meaning given such
24 term in section 3 of the Americans with Disabilities Act
25 of 1990.

1 “(f) COORDINATION.—The Secretary shall coordinate
2 duties and activities authorized under this section in ac-
3 cordance with section 2811D.

4 “(g) SUNSET.—

5 “(1) IN GENERAL.—The Advisory Committee
6 shall terminate on September 30, 2023.

7 “(2) RECOMMENDATION.—Not later than Octo-
8 ber 1, 2022, the Secretary shall submit to Congress
9 a recommendation on whether the Advisory Com-
10 mittee should be extended.”.

11 (d) ADVISORY COMMITTEE COORDINATION.—Sub-
12 title B of title XXVIII of the Public Health Service Act
13 (42 U.S.C. 300hh et seq.), as amended by subsection (c),
14 is further amended by inserting after section 2811C the
15 following:

16 **“SEC. 2811D. ADVISORY COMMITTEE COORDINATION.**

17 “(a) IN GENERAL.—The Secretary shall coordinate
18 duties and activities authorized under sections 2811A,
19 2811B, and 2811C, and make efforts to reduce unneces-
20 sary or duplicative reporting, or unnecessary duplicative
21 meetings and recommendations under such sections, as
22 practicable. Members of the advisory committees author-
23 ized under such sections, or their designees, shall annually
24 meet to coordinate any recommendations, as appropriate,
25 that may be similar, duplicative, or overlapping with re-

1 spect to addressing the needs of children, seniors, and in-
2 dividuals with disabilities during public health emer-
3 gencies. If such coordination occurs through an in-person
4 meeting, it shall not be considered the required in-person
5 meetings under any of sections 2811A(e), 2811B(e), or
6 2811C(d).

7 “(b) COORDINATION AND ALIGNMENT.—The Sec-
8 retary, acting through the employee designated pursuant
9 to section 2814, shall align preparedness and response
10 programs or activities to address similar, dual, or overlap-
11 ping needs of children, seniors, and individuals with dis-
12 abilities, and any challenges in preparing for and respond-
13 ing to such needs.

14 “(c) NOTIFICATION.—The Secretary shall annually
15 notify the congressional committees of jurisdiction regard-
16 ing the steps taken to coordinate, as appropriate, the rec-
17 ommendations under this section, and provide a summary
18 description of such coordination.”.

19 **SEC. 306. GUIDANCE FOR PARTICIPATION IN EXERCISES**
20 **AND DRILLS.**

21 Not later than 2 years after the date of enactment
22 of this Act, the Secretary of Health and Human Services
23 shall issue final guidance regarding the ability of per-
24 sonnel funded by programs authorized under this Act (in-
25 cluding the amendments made by this Act) to participate

1 in drills and operational exercises related to all-hazards
2 medical and public health preparedness and response.
3 Such drills and operational exercises may include activities
4 that incorporate medical surge capacity planning, medical
5 countermeasure distribution and administration, and pre-
6 paring for and responding to identified threats for that
7 region. Such personnel may include State, local, tribal,
8 and territorial public health department or agency per-
9 sonnel funded under this Act (including the amendments
10 made by this Act). The Secretary shall consult with the
11 Department of Homeland Security, the Department of
12 Defense, the Department of Veterans Affairs, and other
13 applicable Federal departments and agencies as necessary
14 and appropriate in the development of such guidance. The
15 Secretary shall make the guidance available on the inter-
16 net website of the Department of Health and Human
17 Services.

18 **TITLE IV—PRIORITIZING A**
19 **THREAT-BASED APPROACH**

20 **SEC. 401. ASSISTANT SECRETARY FOR PREPAREDNESS AND**
21 **RESPONSE.**

22 Section 2811 of the Public Health Service Act (42
23 U.S.C. 300hh–10) is amended—
24 (1) in subsection (b)—

1 (A) in the matter preceding paragraph (1)
2 by inserting “utilize experience related to public
3 health emergency preparedness and response,
4 biodefense, medical countermeasures, and other
5 relevant topics to” after “shall”; and

6 (B) in paragraph (4) by adding at the end
7 the following:

8 “(I) THREAT AWARENESS.—Coordinate
9 with the Director of the Centers for Disease
10 Control and Prevention, the Director of Na-
11 tional Intelligence, the Secretary of Homeland
12 Security, the Assistant to the President for Na-
13 tional Security Affairs, the Secretary of De-
14 fense, and other relevant Federal officials, such
15 as the Secretary of Agriculture, to maintain a
16 current assessment of national security threats
17 and inform preparedness and response capabili-
18 ties based on the range of the threats that have
19 the potential to result in a public health emer-
20 gency.”; and

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

22 “(f) PROTECTION OF NATIONAL SECURITY FROM
23 THREATS.—

24 “(1) IN GENERAL.—In carrying out the duties
25 under subsection (b)(3), the Assistant Secretary for

1 Preparedness and Response shall implement stra-
2 tegic initiatives or activities to address threats, in-
3 cluding pandemic influenza, that pose a significant
4 level of risk to public health and national security
5 based on the characteristics of such threat, which
6 may also include a chemical, biological, radiological,
7 or nuclear agent, including threats with a significant
8 potential to become a pandemic. Such initiatives
9 shall include activities to accelerate and support the
10 advanced research, development, manufacturing ca-
11 pacity, procurement, and stockpiling of counter-
12 measures, including initiatives under section
13 319L(c)(4)(F). Such activities shall ensure activities
14 related to readiness to respond to pandemic influ-
15 enza threats by supporting the development and
16 manufacturing of influenza virus seeds, clinical trial
17 lots, and stockpiles of novel influenza strains.

18 “(2) AUTHORIZATION OF APPROPRIATIONS.—

19 “(A) IN GENERAL.—For purposes of car-
20 rying out this subsection, there is authorized to
21 be appropriated \$250,000,000 for each of fiscal
22 years 2019 through 2023.

23 “(B) SUPPLEMENT, NOT SUPPLANT.—

24 Funds appropriated under this subsection shall
25 be used to supplement and not supplant funds

1 provided under section 319L(f) and section
2 319F–2(g).

3 “(C) DOCUMENTATION REQUIRED.—The
4 Assistant Secretary for Preparedness and Re-
5 sponse shall, as required under subsection
6 (b)(7), document amounts expended for pur-
7 poses of carrying out this subsection, including
8 amounts appropriated to the Public Health and
9 Social Services Emergency Fund under title II
10 of Division H of the Consolidated Appropria-
11 tions Act, 2018 (Public Law 115–141), as ap-
12 plicable to section 319L(c)(4)(F).”.

13 **SEC. 402. PUBLIC HEALTH EMERGENCY MEDICAL COUN-**
14 **TERMEASURES ENTERPRISE.**

15 (a) IN GENERAL.—Title XXVIII is amended by in-
16 serting after section 2811 of the Public Health Service
17 Act (42 U.S.C. 300hh–10) the following:

18 **“SEC. 2811–1. PUBLIC HEALTH EMERGENCY MEDICAL**
19 **COUNTERMEASURES ENTERPRISE.**

20 “(a) IN GENERAL.—The Secretary shall establish the
21 Public Health Emergency Medical Countermeasures En-
22 terprise (referred to in this section as the ‘PHEMCE’).
23 The Assistant Secretary for Preparedness and Response
24 shall serve as chair of the PHEMCE.

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

4 “(1) The Assistant Secretary for Preparedness
5 and Response.

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

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

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

11 “(5) The Secretary of Defense.

12 “(6) The Secretary of Homeland Security.

13 “(7) The Secretary of Agriculture.

14 “(8) The Secretary of Veterans Affairs.

15 “(9) The Director of National Intelligence.

16 “(10) Representatives of any other Federal
17 agency, which may include the Director of the Bio-
18 medical Advanced Research and Development Au-
19 thority, the Director of the Strategic National Stock-
20 pile, the Director of the National Institute of Allergy
21 and Infectious Diseases, and the Director of the Of-
22 fice of Public Health Preparedness and Response, as
23 the Secretary determines appropriate.

24 “(c) FUNCTIONS.—

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

3 “(A) Utilize a process to make rec-
4 ommendations to the Secretary regarding re-
5 search, advanced research, development, pro-
6 curement, stockpiling, deployment, distribution,
7 and utilization with respect to countermeasures,
8 as defined in section 319F–2(c), including
9 prioritization based on the health security needs
10 of the United States. Such recommendations
11 shall be informed by, when available and prac-
12 ticable, the National Health Security Strategy
13 pursuant to section 2802, the Strategic Na-
14 tional Stockpile needs pursuant to section
15 319F–2, and assessments of current national
16 security threats, including chemical, biological,
17 radiological and nuclear threats, including
18 emerging infectious diseases. In the event that
19 members of the PHEMCE do not agree upon a
20 recommendation, the Secretary shall provide a
21 determination regarding such recommendation.

22 “(B) Identify national health security
23 needs, including gaps in public health prepared-
24 ness and response related to countermeasures
25 and challenges to addressing such needs (in-

1 including any regulatory challenges), and support
2 alignment of countermeasure procurement with
3 recommendations to address such needs under
4 subparagraph (A).

5 “(C) Assist the Secretary in developing
6 strategies related to logistics, deployment, dis-
7 tribution, dispensing, and use of counter-
8 measures that may be applicable to the activi-
9 ties of the strategic national stockpile under
10 section 319F–2(a).

11 “(D) Provide consultation for the develop-
12 ment of the strategy and implementation plan
13 under section 2811(d).

14 “(2) INPUT.—In carrying out subparagraphs
15 (B) and (C) of paragraph (1), the PHEMCE shall
16 solicit and consider input from State, local, tribal,
17 and territorial public health departments or officials,
18 as appropriate.”.

19 (b) PUBLIC HEALTH EMERGENCY MEDICAL COUN-
20 TERMEASURES ENTERPRISE STRATEGY AND IMPLEMEN-
21 TATION PLAN.—Section 2811(d) of the Public Health
22 Service Act (42 U.S.C. 300hh–10(d)) is amended—

23 (1) in paragraph (1)—

24 (A) by striking “Not later than 180 days
25 after the date of enactment of this subsection,

1 and every year thereafter” and inserting “Not
2 later than March 15, 2020, and biennially
3 thereafter”; and

4 (B) by striking “Director of Biomedical”
5 and all that follows through “Food and Drugs”
6 and inserting “Public Health Emergency Med-
7 ical Countermeasures Enterprise established
8 under section 2811–1”; and

9 (2) in paragraph (2)(J)(v), by striking “one-
10 year period” and inserting “2-year period”.

11 **SEC. 403. STRATEGIC NATIONAL STOCKPILE.**

12 (a) IN GENERAL.—Section 319F–2(a) of the Public
13 Health Service Act (42 U.S.C. 247d–6b(a)) is amended—

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

16 (2) in paragraph (1)—

17 (A) by inserting “the Assistant Secretary
18 for Preparedness and Response and” after “col-
19 laboration with”;

20 (B) by inserting “and optimize” after
21 “provide for”;

22 (C) by inserting “and, as informed by ex-
23 isting recommendations of, or consultations
24 with, the Public Health Emergency Medical
25 Countermeasure Enterprise established under

1 section 2811–1, make necessary additions or
2 modifications to the contents of such stockpile
3 or stockpiles based on the review conducted
4 under paragraph (2)” before the period of the
5 first sentence; and

6 (D) by striking the second sentence;

7 (3) by inserting after paragraph (1) the fol-
8 lowing:

9 “(2) THREAT-BASED REVIEW.—

10 “(A) IN GENERAL.—The Secretary shall
11 conduct an annual threat-based review (taking
12 into account at-risk individuals) of the contents
13 of the stockpile under paragraph (1), including
14 non-pharmaceutical supplies, and, in consulta-
15 tion with the Public Health Emergency Medical
16 Countermeasures Enterprise established under
17 section 2811–1, review contents within the
18 stockpile and assess whether such contents are
19 consistent with the recommendations made pur-
20 suant to section 2811–1(c)(1)(A). Such review
21 shall be submitted annually, beginning on
22 March 15, 2019, to the Committee on Health,
23 Education, Labor, and Pensions and the Com-
24 mittee on Appropriations of the Senate and the
25 Committee on Energy and Commerce and the

1 Committee on Appropriations of the House of
2 Representatives, in a manner that does not
3 compromise national security.

4 “(B) ADDITIONS, MODIFICATIONS, AND
5 REPLENISHMENTS.—Each annual threat-based
6 review under subparagraph (A) shall, for each
7 new or modified countermeasure procurement
8 or replenishment, provide—

9 “(i) information regarding—

10 “(I) the quantities of the addi-
11 tional or modified countermeasure
12 procured for, or contracted to be pro-
13 cured for, the stockpile;

14 “(II) planning considerations for
15 appropriate manufacturing capacity
16 and capability to meet the goals of
17 such additions or modifications (with-
18 out disclosing proprietary informa-
19 tion), including consideration of the
20 effect such additions or modifications
21 may have on the availability of such
22 products and ancillary medical sup-
23 plies in the health care system;

1 “(III) the presence or lack of a
2 commercial market for the counter-
3 measure at the time of procurement;

4 “(IV) the emergency health secu-
5 rity threat or threats such counter-
6 measure procurement is intended to
7 address, including whether such pro-
8 curement is consistent with meeting
9 emergency health security needs asso-
10 ciated with such threat or threats;

11 “(V) an assessment of whether
12 the emergency health security threat
13 or threats described in subclause (IV)
14 could be addressed in a manner that
15 better utilizes the resources of the
16 stockpile and permits the greatest
17 possible increase in the level of emer-
18 gency preparedness to address such
19 threats;

20 “(VI) whether such counter-
21 measure is replenishing an expiring or
22 expired countermeasure, is a different
23 countermeasure with the same indica-
24 tion that is replacing an expiring or

1 expired countermeasure, or is a new
2 addition to the stockpile;

3 “(VII) a description of how such
4 additions or modifications align with
5 projected investments under previous
6 countermeasures budget plans under
7 section 2811(b)(7), including expected
8 life-cycle costs, expenditures related to
9 countermeasure procurement to ad-
10 dress the threat or threats described
11 in subclause (IV), replenishment dates
12 (including the ability to extend the
13 maximum shelf life of a counter-
14 measure), and the manufacturing ca-
15 pacity required to replenish such
16 countermeasure; and

17 “(VIII) appropriate protocols and
18 processes for the deployment, distribu-
19 tion, or dispensing of the counter-
20 measure at the State and local level,
21 including plans for relevant capabili-
22 ties of State and local entities to dis-
23 pense, distribute, and administer the
24 countermeasure; and

1 “(ii) an assurance, which need not be
2 provided in advance of procurement, that
3 for each countermeasure procured or re-
4 plenished under this subsection, the Sec-
5 retary completed a review addressing each
6 item listed under this subsection in ad-
7 vance of such procurement or replenish-
8 ment.”;

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

10 (A) in subparagraph (A), by inserting
11 “and the Public Health Emergency Medical
12 Countermeasures Enterprise established under
13 section 2811–1” before the semicolon;

14 (B) in subparagraph (C), by inserting “,
15 and the availability, deployment, dispensing,
16 and administration of countermeasures” before
17 the semicolon;

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

20 “(E) devise plans for effective and timely
21 supply-chain management of the stockpile, in
22 consultation with the Director of the Centers
23 for Disease Control and Prevention, the Assist-
24 ant Secretary for Preparedness and Response,
25 the Secretary of Transportation, the Secretary

1 of Homeland Security, the Secretary of Vet-
2 erans Affairs, and the heads of other appro-
3 priate Federal agencies; State, local, tribal, and
4 territorial agencies; and the public and private
5 health care infrastructure, as applicable, taking
6 into account the manufacturing capacity and
7 other available sources of products and appro-
8 priate alternatives to supplies in the stockpile;”;

9 (D) in subparagraph (G), by striking “;
10 and” and inserting a semicolon;

11 (E) in subparagraph (H), by striking the
12 period and inserting a semicolon; and

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

14 “(I) ensure that each countermeasure or
15 product under consideration for procurement
16 pursuant to this subsection receives the same
17 consideration regardless of whether such coun-
18 termeasure or product receives or had received
19 funding under section 319L, including with re-
20 spect to whether the countermeasure or product
21 is most appropriate to meet the emergency
22 health security needs of the United States; and

23 “(J) provide assistance, including technical
24 assistance, to maintain and improve State and
25 local public health preparedness capabilities to

1 distribute and dispense medical counter-
2 measures and products from the stockpile, as
3 appropriate.”; and

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

5 “(5) GAO REPORT.—

6 “(A) IN GENERAL.—Not later than 3 years
7 after the date of enactment of the Pandemic
8 and All-Hazards Preparedness and Advancing
9 Innovation Act of 2018, and every 5 years
10 thereafter, the Comptroller General of the
11 United States shall conduct a review of any
12 changes to the contents or management of the
13 stockpile since January 1, 2015. Such review
14 shall include—

15 “(i) an assessment of the comprehen-
16 siveness and completeness of each annual
17 threat-based review under paragraph (2),
18 including whether all newly procured or re-
19 plenished countermeasures within the
20 stockpile were described in each annual re-
21 view, and whether, consistent with para-
22 graph (2)(B), the Secretary conducted the
23 necessary internal review in advance of
24 such procurement or replenishment;

1 “(ii) an assessment of whether the
2 Secretary established health security and
3 science-based justifications, and a descrip-
4 tion of such justifications for procurement
5 decisions related to health security needs
6 with respect to the identified threat, for
7 additions or modifications to the stockpile
8 based on the information provided in such
9 reviews under paragraph (2)(B), including
10 whether such review was conducted prior
11 to procurement, modification, or replenish-
12 ment;

13 “(iii) an assessment of the plans de-
14 veloped by the Secretary for the deploy-
15 ment, distribution, and dispensing of coun-
16 termeasures procured, modified, or replen-
17 ished under paragraph (1), including
18 whether such plans were developed prior to
19 procurement, modification, or replenish-
20 ment;

21 “(iv) an accounting of counter-
22 measures procured, modified, or replen-
23 ished under paragraph (1) that received
24 advanced research and development fund-

1 ing from the Biomedical Advanced Re-
2 search and Development Authority;

3 “(v) an analysis of how such procure-
4 ment decisions made progress toward
5 meeting emergency health security needs
6 related to the identified threats for coun-
7 termeasures added, modified, or replen-
8 ished under paragraph (1);

9 “(vi) a description of the resources ex-
10 pended related to the procurement of coun-
11 termeasures (including additions, modifica-
12 tions, and replenishments) in the stockpile,
13 and how such expenditures relate to the
14 ability of the stockpile to meet emergency
15 health security needs;

16 “(vii) an assessment of the extent to
17 which additions, modifications, and replen-
18 ishments reviewed under paragraph (2)
19 align with previous relevant reports or re-
20 views by the Secretary or the Comptroller
21 General;

22 “(viii) with respect to any change in
23 the Federal organizational management of
24 the stockpile, an assessment and compari-
25 son of the processes affected by such

1 change, including planning for potential
2 countermeasure deployment, distribution,
3 or dispensing capabilities and processes re-
4 lated to procurement decisions, use of
5 stockpiled countermeasures, and use of re-
6 sources for such activities; and

7 “(ix) an assessment of whether the
8 processes and procedures described by the
9 Secretary pursuant to section 403(b) of
10 the Pandemic and All-Hazards Prepared-
11 ness and Advancing Innovation Act of
12 2018 are sufficient to ensure counter-
13 measures and products under consideration
14 for procurement pursuant to subsection (a)
15 receive the same consideration regardless
16 of whether such countermeasures and
17 products receive or had received funding
18 under section 319L, including with respect
19 to whether such countermeasures and
20 products are most appropriate to meet the
21 emergency health security needs of the
22 United States.

23 “(B) SUBMISSION.—Not later than 6
24 months after completing a classified version of
25 the review under subparagraph (A), the Comp-

1 troller General shall submit an unclassified
2 version of the review to the congressional com-
3 mittees of jurisdiction.”.

4 (b) ADDITIONAL REPORTING.—In the first threat-
5 based review submitted after the date of enactment of this
6 Act pursuant to paragraph (2) of section 319F–2(a) of
7 the Public Health Service Act (42 U.S.C. 247d–6b(a)), as
8 amended by subsection (a), the Secretary shall include a
9 description of the processes and procedures through which
10 the Director of Strategic National Stockpile and the Di-
11 rector of the Biomedical Advanced Research and Develop-
12 ment Authority coordinate with respect to counter-
13 measures and products procured under such section
14 319F–2(a), including such processes and procedures in
15 place to ensure countermeasures and products under con-
16 sideration for procurement pursuant to such section
17 319F–2(a) receive the same consideration regardless of
18 whether such countermeasures and products receive or
19 had received funding under section 319L of the Public
20 Health Service Act (42 U.S.C. 247d–7e), or whether such
21 countermeasures and products are the most appropriate
22 to meet the emergency health security needs of the United
23 States.

24 (c) AUTHORIZATION OF APPROPRIATIONS, STRA-
25 TEGIC NATIONAL STOCKPILE.—Section 319F–2(f)(1) of

1 the Public Health Service Act (42 U.S.C. 247d–6b(f)(1))
2 is amended by striking “\$533,800,000 for each of fiscal
3 years 2014 through 2018” and inserting “\$610,000,000
4 for each of fiscal years 2019 through 2023, to remain
5 available until expended”.

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

9 (a) STRATEGIC INITIATIVES.—Section 319L(c)(4)
10 (247d–7e(c)(4)) is amended by adding at the end the fol-
11 lowing:

12 “(F) STRATEGIC INITIATIVES.—The Sec-
13 retary, acting through the Director of BARDA,
14 may implement strategic initiatives, including
15 by building on existing programs and by award-
16 ing contracts, grants, and cooperative agree-
17 ments, or entering into other transactions, to
18 support innovative candidate products in pre-
19 clinical and clinical development that address
20 priority, naturally occurring and man-made
21 threats that, as determined by the Secretary,
22 pose a significant level of risk to national secu-
23 rity based on the characteristics of a chemical,
24 biological, radiological or nuclear threat, or ex-
25 isting capabilities to respond to such a threat

1 (including medical response and treatment ca-
2 pabilities and manufacturing infrastructure).
3 Such initiatives shall accelerate and support the
4 advanced research, development, and procure-
5 ment of, countermeasures and products, as ap-
6 plicable, to address areas including—

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

16 “(ii) threats that consistently exist or
17 continually circulate and have significant
18 potential to become a pandemic, such as
19 pandemic influenza, which may include the
20 advanced research and development, manu-
21 facturing, and appropriate stockpiling of
22 qualified pandemic or epidemic products,
23 and products, technologies, or processes to
24 support the advanced research and devel-
25 opment of such countermeasures (including

1 multiuse platform technologies for
2 diagnostics, vaccines, and therapeutics;
3 virus seeds; clinical trial lots; novel virus
4 strains; and antigen and adjuvant mate-
5 rial); and

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

15 (b) EMERGING INFECTIOUS DISEASE PROGRAM.—
16 Section 319L of the Public Health Service Act (42 U.S.C.
17 247d–7e) is amended—

18 (1) by redesignating subsections (d), (e), and
19 (f) as subsections (e), (f), and (g), respectively; and

20 (2) by inserting after subsection (c) the fol-
21 lowing new subsections:

22 “(d) EMERGING INFECTIOUS DISEASE PROGRAM.—

23 “(1) IN GENERAL.—The Secretary, acting
24 through the Director of BARDA, shall establish and
25 implement a program that supports—

1 “(A) advanced research and development
2 activities for qualified pandemic or epidemic
3 products; and

4 “(B) manufacturing infrastructure activi-
5 ties with respect to an emerging infectious dis-
6 ease.

7 “(2) FUNDING.—

8 “(A) IN GENERAL.—To carry out para-
9 graph (1), there is authorized to be appro-
10 priated \$250,000,000 for each of fiscal years
11 2019 through 2023, to remain available until
12 expended.

13 “(B) SUPPLEMENT NOT SUPPLANT.—Any
14 funds provided to the Secretary under this
15 paragraph shall be used to supplement and not
16 supplant any other Federal funds provided to
17 carry out paragraph (1).”.

18 **SEC. 405. REPORTING ON THE FEDERAL SELECT AGENT**
19 **PROGRAM.**

20 Section 351A(k) of the Public Health Service Act (42
21 U.S.C. 262a(k)) is amended—

22 (1) by striking “The Secretary” and inserting
23 the following:

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

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

1 “(2) IMPLEMENTATION OF RECOMMENDATIONS
2 OF THE FEDERAL EXPERTS SECURITY ADVISORY
3 PANEL AND THE FAST TRACK ACTION COMMITTEE
4 ON SELECT AGENT REGULATIONS.—

5 “(A) IN GENERAL.—Not later than 1 year
6 after the date of the enactment of the Pan-
7 demic and All-Hazards Preparedness and Ad-
8 vancing Innovation Act of 2018, the Secretary
9 shall report to the congressional committees of
10 jurisdiction on the implementation of rec-
11 ommendations of the Federal Experts Security
12 Advisory Panel concerning the select agent pro-
13 gram.

14 “(B) CONTINUED UPDATES.—The Sec-
15 retary shall report to the congressional commit-
16 tees of jurisdiction annually following the sub-
17 mission of the report under subparagraph (A)
18 until the recommendations described in such
19 subparagraph are fully implemented, or a jus-
20 tification is provided for the delay in, or lack of,
21 implementation.”.

1 **TITLE V—INCREASING COMMU-**
2 **NICATION IN MEDICAL COUN-**
3 **TERMEASURE ADVANCED RE-**
4 **SEARCH AND DEVELOPMENT**

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

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

8 (1) in the matter preceding subparagraph (A),
9 by striking “March 1” and inserting “March 15”;

10 (2) in subparagraph (A)—

11 (A) in clause (ii), by striking “; and” and
12 inserting “;”; and

13 (B) by striking clause (iii) and inserting
14 the following:

15 “(iii) procurement, stockpiling, main-
16 tenance, and potential replenishment (in-
17 cluding manufacturing capabilities) of all
18 products in the Strategic National Stock-
19 pile;

20 “(iv) the availability of technologies
21 that may assist in the advanced research
22 and development of countermeasures and
23 opportunities to use such technologies to
24 accelerate and navigate challenges unique

1 to countermeasure research and develop-
2 ment; and

3 “(v) potential deployment, distribu-
4 tion, and utilization of medical counter-
5 measures; development of clinical guidance
6 and emergency use instructions for the use
7 of medical countermeasures; and, as appli-
8 cable, potential post-deployment activities
9 related to medical countermeasures;”;

10 (3) by redesignating subparagraphs (D) and
11 (E) as subparagraphs (E) and (F), respectively; and

12 (4) by inserting after subparagraph (C), the fol-
13 lowing:

14 “(D) identify the full range of anticipated
15 medical countermeasure needs related to re-
16 search and development, procurement, and
17 stockpiling, including the potential need for in-
18 dications, dosing, and administration tech-
19 nologies, and other countermeasure needs as
20 applicable and appropriate;”.

21 **SEC. 502. MATERIAL THREAT AND MEDICAL COUNTER-**
22 **MEASURE NOTIFICATIONS.**

23 (a) CONGRESSIONAL NOTIFICATION OF MATERIAL
24 THREAT DETERMINATION.—Section 319F–2(c)(2)(C) of
25 the Public Health Service Act (42 U.S.C. 247d–

1 6b(c)(2)(C)) is amended by striking “The Secretary and
2 the Homeland Security Secretary shall promptly notify the
3 appropriate committees of Congress” and inserting “The
4 Secretary and the Secretary of Homeland Security shall
5 send to Congress, on an annual basis, all current material
6 threat determinations and shall promptly notify the Com-
7 mittee on Health, Education, Labor, and Pensions and the
8 Committee on Homeland Security and Governmental Af-
9 fairs of the Senate and the Committee on Energy and
10 Commerce and the Committee on Homeland Security of
11 the House of Representatives”.

12 (b) CONTRACTING COMMUNICATION.—Section 319F–
13 2(c)(7)(B)(ii)(III) of the Public Health Service Act (42
14 U.S.C. 247d–6b(c)(7)(B)(ii)(III)) is amended by adding
15 at the end the following: “The Secretary shall notify the
16 vendor within 90 days of a determination by the Secretary
17 to renew, extend, or terminate such contract.”.

18 **SEC. 503. AVAILABILITY OF REGULATORY MANAGEMENT**
19 **PLANS.**

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

- 22 (1) by redesignating paragraphs (3) through
23 (6) as paragraphs (4) through (7), respectively;
24 (2) by inserting after paragraph (2) the fol-
25 lowing:

1 “(3) PUBLICATION.—The Secretary shall make
2 available on the internet website of the Food and
3 Drug Administration information regarding regu-
4 latory management plans, including—

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

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

10 “(C) the information required for the sub-
11 mission of such request;

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

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

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

20 (A) by striking “paragraph (4)(A)” and in-
21 serting “paragraph (5)(A)”; and

22 (B) by striking “paragraph (4)(B)” and
23 inserting “paragraph (5)(B)”; and

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

4 **SEC. 504. THE BIOMEDICAL ADVANCED RESEARCH AND DE-**
5 **VELOPMENT AUTHORITY AND THE BIO-**
6 **SHIELD SPECIAL RESERVE FUND.**

7 (a) BIOSHIELD SPECIAL RESERVE FUND.—Section
8 319F–2(g)(1) of the Public Health Service Act (42 U.S.C.
9 247d–6b(g)(1)) is amended—

10 (1) by striking “\$2,800,000,000 for the period
11 of fiscal years 2014 through 2018” and inserting
12 “\$7,100,000,000 for the period of fiscal years 2019
13 through 2028, to remain available until expended”;
14 and

15 (2) by striking the second sentence.

16 (b) THE BIOMEDICAL ADVANCED RESEARCH AND
17 DEVELOPMENT AUTHORITY.—Subsection (f)(2) of section
18 319L of the Public Health Service Act (42 U.S.C. 247d–
19 7e), as redesignated by section 404, is amended by strik-
20 ing “\$415,000,000 for each of fiscal years 2014 through
21 2018” and inserting “\$611,700,000 for each of fiscal
22 years 2019 through 2023”.

1 **SEC. 505. ADDITIONAL STRATEGIES FOR COMBATING ANTI-**
2 **BIOTIC RESISTANCE.**

3 Part B of title III of the Public Health Service Act
4 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
5 tion 319E the following:

6 **“SEC. 319E–1. ADVISORY COUNCIL ON COMBATING ANTI-**
7 **BIOTIC-RESISTANT BACTERIA.**

8 “(a) DEFINITIONS.—In this section:

9 “(1) ACTION PLAN.—The term ‘Action Plan’
10 means the Action Plan described in section
11 319E(a)(1).

12 “(2) ADVISORY COUNCIL.—The term ‘Advisory
13 Council’ means the Presidential Advisory Council on
14 Combating Antibiotic-Resistant Bacteria established
15 by Executive Order 13676 of September 18, 2014
16 (79 Fed. Reg. 56931; relating to combating anti-
17 biotic-resistant bacteria).

18 “(3) NATIONAL STRATEGY.—The term ‘Na-
19 tional Strategy’ means the National Strategy for
20 Combating Antibiotic-Resistant Bacteria issued by
21 the White House in September 2014, and any subse-
22 quent update to such strategy or a successor strat-
23 egy.

24 “(b) ADVISORY COUNCIL.—The Advisory Council
25 shall provide advice, information, and recommendations to
26 the Secretary regarding programs and policies intended to

1 support and evaluate the implementation of Executive
2 Order 13676 of September 18, 2014 (79 Fed. Reg. 56931;
3 relating to combating antibiotic-resistant bacteria), includ-
4 ing the National Strategy, and the Action Plan.

5 “(c) MEETINGS AND DUTIES.—

6 “(1) MEETINGS.—The Advisory Council shall
7 meet as the Chair determines appropriate but not
8 less than twice per year, and, to the extent prac-
9 ticable, in conjunction with meetings of the task
10 force described in section 319E.

11 “(2) RECOMMENDATIONS.—The Advisory Coun-
12 cil shall make recommendations to the Secretary, in
13 consultation with the Secretary of Agriculture and
14 the Secretary of Defense, regarding programs and
15 policies intended to—

16 “(A) preserve the effectiveness of anti-
17 biotics by optimizing their use;

18 “(B) advance research to develop improved
19 methods for combating antibiotic resistance and
20 conducting antimicrobial stewardship, as de-
21 fined in section 319E(h)(3);

22 “(C) strengthen surveillance of antibiotic-
23 resistant bacterial infections;

24 “(D) prevent the transmission of anti-
25 biotic-resistant bacterial infections;

1 “(E) advance the development of rapid
2 point-of-care and agricultural diagnostics;

3 “(F) further research on new treatments
4 for bacterial infections;

5 “(G) develop alternatives to antibiotics for
6 animal health purposes;

7 “(H) maximize the dissemination of up-to-
8 date information on the appropriate and proper
9 use of antibiotics to the general public and
10 human and animal health care providers; and

11 “(I) improve international coordination of
12 efforts to combat antibiotic resistance.

13 “(3) COORDINATION.—The Advisory Council
14 shall, to the greatest extent practicable, coordinate
15 activities carried out by the Council with the Anti-
16 microbial Resistance Task Force established under
17 section 319E(a) (commonly referred to as the ‘Com-
18 battling Antibiotic-Resistant Bacteria Task Force’).”.

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

22 **SEC. 601. ADMINISTRATION OF COUNTERMEASURES.**

23 Section 319L(c)(4)(D)(iii) of the Public Health Serv-
24 ice Act (42 U.S.C. 247d–7e(c)(4)(D)(iii)) is amended by
25 striking “and platform technologies” and inserting “plat-

1 form technologies, technologies to administer counter-
2 measures, and technologies to improve storage and trans-
3 portation of countermeasures”.

4 **SEC. 602. UPDATING DEFINITIONS OF OTHER TRANS-**
5 **ACTIONS.**

6 Section 319L of the Public Health Service Act (42
7 U.S.C. 247d–7e) is amended—

8 (1) in subsection (a)(3), by striking “, such as”
9 and all that follows through “Code”;

10 (2) in subsection (c)(5)(A)—

11 (A) in clause (i), by striking “under this
12 subsection” and all that follows through “Code”
13 and inserting “(as defined in subsection (a)(3))
14 under this subsection”; and

15 (B) in clause (ii)—

16 (i) by amending subclause (I) to read
17 as follows:

18 “(I) IN GENERAL.—To the max-
19 imum extent practicable, competitive
20 procedures shall be used when enter-
21 ing into transactions to carry out
22 projects under this subsection.”; and

23 (ii) in subclause (II)—

24 (I) by striking “\$20,000,000”
25 and inserting “\$100,000,000”;

1 (II) by striking “senior procure-
2 ment executive for the Department
3 (as designated for the purpose of sec-
4 tion 16(c) of the Office of Federal
5 Procurement Policy Act (41 U.S.C.
6 414(c)))” and inserting “Assistant
7 Secretary for Financial Resources”;
8 and

9 (III) by striking “senior procure-
10 ment executive under” and inserting
11 “Assistant Secretary for Financial Re-
12 sources under”.

13 **SEC. 603. MEDICAL COUNTERMEASURE MASTER FILES.**

14 (a) IN GENERAL.—The purpose of this section (in-
15 cluding section 565B of the Federal Food, Drug, and Cos-
16 metic Act, as added by subsection (b)) is to support and
17 advance the development or manufacture of security coun-
18 termeasures, qualified countermeasures, and qualified
19 pandemic or epidemic products by facilitating and encour-
20 aging submission of data and information to support such
21 products to medical countermeasure master files, and
22 through clarifying the authority to cross-reference to data
23 and information previously submitted to the Secretary of
24 Health and Human Services (referred to in this section
25 as the “Secretary”).

1 (b) MEDICAL COUNTERMEASURE MASTER FILES.—
2 Chapter V of the Federal Food, Drug, and Cosmetic Act
3 (21 U.S.C. 351 et seq.) is amended by inserting after sec-
4 tion 565A the following:

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

6 “(a) APPLICABILITY OF REFERENCE.—

7 “(1) IN GENERAL.—A person may submit data
8 and information in a medical countermeasure master
9 file to the Secretary with the intent to reference, or
10 to authorize, in writing, another person to reference,
11 such data or information within a medical counter-
12 measure master file to support a medical counter-
13 measure submission (including a supplement or
14 amendment to any such submission), without requir-
15 ing the master file holder to disclose the data and
16 information to any such persons authorized to ref-
17 erence the master file. Such data and information
18 shall be available for reference by the master file
19 holder or by a person authorized by the master file
20 holder, in accordance with applicable privacy and
21 confidentiality protocols and regulations.

22 “(2) REFERENCE OF CERTAIN MASTER
23 FILES.—In the case that data or information within
24 a medical countermeasure master file is used only to
25 support the conditional approval of an application

1 filed under section 571, such master file may be re-
2 lied upon to help support the effectiveness of a prod-
3 uct that is the subject of a subsequent medical coun-
4 termeasure submission only if such application is
5 supplemented by additional data or information to
6 support review and approval in a manner consistent
7 with the standards applicable to such review and ap-
8 proval for such countermeasure, qualified counter-
9 measure, or qualified pandemic or epidemic product.

10 “(b) MEDICAL COUNTERMEASURE MASTER FILE
11 CONTENT.—

12 “(1) IN GENERAL.—A master file under this
13 section may include data or information to sup-
14 port—

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

22 “(B) the manufacture of security counter-
23 measures, qualified countermeasures, or quali-
24 fied pandemic or epidemic products.

1 “(2) REQUIRED UPDATES.—The Secretary may
2 require, as appropriate, that the master file holder
3 ensure that the contents of such master file are up-
4 dated during the time such master file is referenced
5 for a medical countermeasure submission.

6 “(c) SPONSOR REFERENCE.—

7 “(1) IN GENERAL.—Each incorporation of data
8 or information within a medical countermeasure
9 master file shall describe the incorporated material
10 in a manner in which the Secretary determines ap-
11 propriate and that permits the review of such infor-
12 mation within such master file without necessitating
13 re-submission of such data or information. Master
14 files shall be submitted in an electronic format in ac-
15 cordance with sections 512(b)(4), 571(a)(4), and
16 745A, as applicable, and as specified in applicable
17 guidance.

18 “(2) REFERENCE BY A MASTER FILE HOLD-
19 ER.—A master file holder that is the sponsor of a
20 medical countermeasure submission shall notify the
21 Secretary in writing of the intent to reference the
22 medical countermeasure master file as a part of the
23 submission.

24 “(3) REFERENCE BY AN AUTHORIZED PER-
25 SON.—A person submitting an application for review

1 may, where the Secretary determines appropriate,
2 incorporate by reference all or part of the contents
3 of a medical countermeasure master file, if the mas-
4 ter file holder authorizes the incorporation in writ-
5 ing.

6 “(d) ACKNOWLEDGEMENT OF THE RELIANCE UPON
7 A MASTER FILE BY THE SECRETARY.—

8 “(1) IN GENERAL.—The Secretary shall provide
9 the master file holder with a written notification in-
10 dicating that the Secretary has reviewed and relied
11 upon specified data or information within a master
12 file and the purposes for which such data or infor-
13 mation was incorporated by reference if the Sec-
14 retary has reviewed and relied upon such specified
15 data or information to support the approval, classi-
16 fication, conditional approval, clearance, licensure, or
17 authorization of a security countermeasure, qualified
18 countermeasure, or qualified pandemic or epidemic
19 product. The Secretary may rely upon the data and
20 information within the medical countermeasure mas-
21 ter file for which such written notification was pro-
22 vided in additional applications, as applicable and
23 appropriate and upon the request of the master file
24 holder so notified in writing or by an authorized per-
25 son of such holder.

1 “(2) CERTAIN APPLICATIONS.—If the Secretary
2 has reviewed and relied upon specified data or infor-
3 mation within a medical countermeasure master file
4 to support the conditional approval of an application
5 under section 571 to subsequently support the ap-
6 proval, clearance, licensure, or authorization of a se-
7 curity countermeasure, qualified countermeasure, or
8 qualified pandemic or epidemic product, the Sec-
9 retary shall provide a brief written description to the
10 master file holder regarding the elements of the ap-
11 plication fulfilled by the data or information within
12 the master file and how such data or information
13 contained in such application meets the standards of
14 evidence under subsection (c) or (d) of section 505,
15 subsection (d) of section 512, or section 351 of the
16 Public Health Service Act (as applicable) unless
17 such disclosure includes any trade secret or con-
18 fidential commercial information.

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

21 “(1) limit the authority of the Secretary to ap-
22 prove, license, clear, conditionally approve, or au-
23 thorize drugs, biological products, or devices pursu-
24 ant to, as applicable, this Act or section 351 of the
25 Public Health Service Act (as such applicable Act is

1 in effect on the day before the date of enactment of
2 the Pandemic and All-Hazards Preparedness and
3 Advancing Innovation Act of 2018), including the
4 standards of evidence, and applicable conditions, for
5 approval under the applicable Act;

6 “(2) alter the standards of evidence with re-
7 spect to approval, licensure, or clearance, as applica-
8 ble, of drugs, biological products, or devices under
9 this Act or section 351 of the Public Health Service
10 Act, including, as applicable, the substantial evi-
11 dence standards under sections 505(d) and 512(d)
12 or this Act and section 351(a) of the Public Health
13 Service Act; or

14 “(3) alter the authority of the Secretary under
15 this Act or the Public Health Service Act to deter-
16 mine the types of data or information previously
17 submitted by a sponsor or any other person that
18 may be incorporated by reference in an application,
19 request, or notification for a drug, biological prod-
20 uct, or device submitted under sections 505(i),
21 505(b), 505(j), 512(b)(1), 512(b)(2), 512(j), 564,
22 571, 520(g), 515(c), 513(f)(2), or 510(k) of this
23 Act, or subsection (a) or (k) of section 351 of the
24 Public Health Service Act, including a supplement

1 or amendment to any such submission, and the re-
2 quirements associated with such reference.

3 “(f) DEFINITIONS.—In this section:

4 “(1) The term ‘master file holder’ means a per-
5 son who submits data and information to the Sec-
6 retary with the intent to reference or authorize an-
7 other person to reference such data or information
8 to support a medical countermeasure submission, as
9 described in subsection (a).

10 “(2) The term ‘medical countermeasure submis-
11 sion’ means an investigational new drug application
12 under section 505(i), a new drug application under
13 section 505(b), or an abbreviated new drug applica-
14 tion under section 505(j) of this Act, a biological
15 product license application under section 351(a) of
16 the Public Health Service Act or a biosimilar biologi-
17 cal product license application under section 351(k)
18 of the Public Health Service Act, a new animal drug
19 application under section 512(b)(1) or abbreviated
20 new animal drug application under section
21 512(b)(2), an application for conditional approval of
22 a new animal drug under section 571, an investiga-
23 tional device application under section 520(g), an
24 application with respect to a device under section
25 515(c), a request for classification of a device under

1 section 513(f)(2), a notification with respect to a de-
2 vice under section 510(k), or a request for an emer-
3 gency use authorization under section 564 to sup-
4 port—

5 “(A) the approval, licensure, classification,
6 clearance, conditional approval, or authorization
7 of a security countermeasure, qualified counter-
8 measure, or qualified pandemic or epidemic
9 product; or

10 “(B) a new indication to an approved secu-
11 rity countermeasure, qualified countermeasure,
12 or qualified pandemic or epidemic product.

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

18 (c) STAKEHOLDER INPUT.—Not later than 18
19 months after the date of enactment of this Act, the Sec-
20 retary, acting through the Commissioner of Food and
21 Drugs and in consultation with the Assistant Secretary
22 for Preparedness and Response, shall solicit input from
23 stakeholders, including stakeholders developing security
24 countermeasures, qualified countermeasures, or qualified
25 pandemic or epidemic products, and stakeholders devel-

1 oping technologies to assist in the development of such
2 countermeasures with respect to how the Food and Drug
3 Administration can advance the use of tools and tech-
4 nologies to support and advance the development or manu-
5 facture of security countermeasures, qualified counter-
6 measures, and qualified pandemic or epidemic products,
7 including through reliance on cross-referenced data and
8 information contained within master files and submissions
9 previously submitted to the Secretary as set forth in sec-
10 tion 565B of the Federal Food, Drug, and Cosmetic Act,
11 as added by subsection (b).

12 (d) GUIDANCE.—Not later than 2 years after the
13 date of enactment of this Act, the Secretary, acting
14 through the Commissioner of Food and Drugs, shall pub-
15 lish draft guidance about how reliance on cross-referenced
16 data and information contained within master files under
17 section 565B of the Federal Food, Drug, and Cosmetic
18 Act, as added by subsection (b) or submissions otherwise
19 submitted to the Secretary may be used for specific tools
20 or technologies (including platform technologies) that have
21 the potential to support and advance the development or
22 manufacture of security countermeasures, qualified coun-
23 termasures, and qualified pandemic or epidemic products.
24 The Secretary, acting through the Commissioner of Food

1 and Drugs, shall publish the final guidance not later than
2 3 years after the enactment of this Act.

3 **SEC. 604. ANIMAL RULE REPORT.**

4 (a) STUDY.—The Comptroller General of the United
5 States shall conduct a study on the application of the re-
6 quirements under subsections (c) and (d) of section 565
7 of the of the Federal Food, Drug, and Cosmetic Act (21
8 U.S.C. 360bbb–4) (referred to in this section as the “ani-
9 mal rule”) as a component of medical countermeasure ad-
10 vanced development under the Biomedical Advanced Re-
11 search and Development Authority and regulatory review
12 by the Food and Drug Administration. In conducting such
13 study, the Comptroller General shall examine the fol-
14 lowing:

15 (1) The extent to which advanced development
16 and review of a medical countermeasure are coordi-
17 nated between the Biomedical Advanced Research
18 and Development Authority and the Food and Drug
19 Administration, including activities that facilitate
20 appropriate and efficient design of studies to sup-
21 port approval, licensure, and authorization under the
22 animal rule, consistent with the recommendations in
23 the animal rule guidance, issued pursuant to section
24 565(c) of the Federal Food Drug and Cosmetic Act
25 (21 U.S.C. 360bbb–4(c)) and entitled “Product De-

1 velopment Under the Animal Rule: Guidance for In-
2 dustry” (issued in October 2015), to resolve discrep-
3 ancies in the design of adequate and well-controlled
4 efficacy studies conducted in animal models related
5 to the provision of substantial evidence of effective-
6 ness for the product approved, licensed, or author-
7 ized under the animal rule.

8 (2) The consistency of the application of the
9 animal rule among and between review divisions
10 within the Food and Drug Administration.

11 (3) The flexibility pursuant to the animal rule
12 to address variations in countermeasure development
13 and review processes, including the extent to which
14 qualified animal models are adopted and used within
15 the Food and Drug Administration in regulatory de-
16 cisionmaking with respect to medical counter-
17 measures.

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

1 (b) CONSULTATIONS.—In conducting the study under
2 subsection (a), the Comptroller General of the United
3 States shall consult with—

4 (1) the Federal agencies responsible for advancing,
5 reviewing, and procuring medical counter-
6 measures, including the Office of the Assistant Secretary
7 for Preparedness and Response, the Biomedical Advanced Research and Development Authority,
8 the Food and Drug Administration, and the
9 Department of Defense;
10

11 (2) manufacturers involved in the research and
12 development of medical countermeasures to address
13 biological, chemical, radiological, or nuclear threats;
14 and

15 (3) other biodefense stakeholders, as applicable.

16 (c) REPORT.—Not later than 3 years after the date
17 of enactment of this Act, the Comptroller General of the
18 United States shall submit to the Committee on Health,
19 Education, Labor, and Pensions of the Senate and the
20 Committee on Energy and Commerce of the House of
21 Representatives a report containing the results of the
22 study conducted under subsection (a) and recommendations
23 to improve the application and consistency of the requirements
24 under subsections (c) and (d) of section 565
25 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

1 360bbb-4) to support and expedite the research and devel-
2 opment of medical countermeasures, as applicable.

3 (d) PROTECTION OF NATIONAL SECURITY.—The
4 Comptroller General of the United States shall conduct
5 the study and issue the assessment and report under this
6 section in a manner that does not compromise national
7 security.

8 **SEC. 605. REVIEW OF THE BENEFITS OF GENOMIC ENGI-**
9 **NEERING TECHNOLOGIES AND THEIR POTEN-**
10 **TIAL ROLE IN NATIONAL SECURITY.**

11 (a) MEETING.—

12 (1) IN GENERAL.—Not later than 1 year after
13 the date of enactment of this Act, the Secretary of
14 Health and Human Services (referred to in this sec-
15 tion as the “Secretary”) shall convene a meeting to
16 discuss the potential role advancements in genomic
17 engineering technologies (including genome editing
18 technologies) may have in advancing national health
19 security. Such meeting shall be held in a manner
20 that does not compromise national security.

21 (2) ATTENDEES.—The attendees of the meeting
22 under paragraph (1)—

23 (A) shall include—

24 (i) representatives from the Office of
25 the Assistant Secretary for Preparedness

1 and Response, the National Institutes of
2 Health, the Centers for Disease Control
3 and Prevention, and the Food and Drug
4 Administration; and

5 (ii) representatives from academic,
6 private, and nonprofit entities with exper-
7 tise in genome engineering technologies,
8 biopharmaceuticals, medicine, or bio-
9 defense, and other relevant stakeholders;
10 and

11 (B) may include—

12 (i) other representatives from the De-
13 partment of Health and Human Services,
14 as the Secretary determines appropriate;
15 and

16 (ii) representatives from the Depart-
17 ment of Homeland Security, the Depart-
18 ment of Defense, the Department of Agri-
19 culture, and other departments, as the Sec-
20 retary may request for the meeting.

21 (3) TOPICS.—The meeting under paragraph (1)
22 shall include a discussion of—

23 (A) the current state of the science of
24 genomic engineering technologies related to na-
25 tional health security, including—

1 (i) medical countermeasure develop-
2 ment, including potential efficiencies in the
3 development pathway and detection tech-
4 nologies; and

5 (ii) the international and domestic
6 regulation of products utilizing genome ed-
7 iting technologies; and

8 (B) national security implications, includ-
9 ing—

10 (i) capabilities of the United States to
11 leverage genomic engineering technologies
12 as a part of the medical countermeasure
13 enterprise, including current applicable re-
14 search, development, and application ef-
15 forts underway within the Department of
16 Defense;

17 (ii) the potential for state and non-
18 state actors to utilize genomic engineering
19 technologies as a national health security
20 threat; and

21 (iii) security measures to monitor and
22 assess the potential threat that may result
23 from utilization of genomic engineering
24 technologies and related technologies for

1 the purpose of compromising national
2 health security.

3 (b) REPORT.—Not later than 270 days after the
4 meeting described in subsection (a) is held, the Assistant
5 Secretary for Preparedness and Response shall issue a re-
6 port to the congressional committees of jurisdiction on the
7 topics discussed at such meeting, and provide rec-
8 ommendations, as applicable, to utilize innovations in
9 genomic engineering (including genome editing) and re-
10 lated technologies as a part of preparedness and response
11 activities to advance national health security. Such report
12 shall be issued in a manner that does not compromise na-
13 tional security.

14 **SEC. 606. REPORT ON VACCINES DEVELOPMENT.**

15 Not later than one year after the date of the enact-
16 ment of this Act, the Secretary of Health and Human
17 Services shall submit to the Committee on Health, Edu-
18 cation, Labor, and Pensions of the Senate and the Com-
19 mittee on Energy and Commerce of the House of Rep-
20 resentatives a report describing efforts and activities to
21 coordinate with other countries and international partners
22 during recent public health emergencies with respect to
23 the research and advanced research on, and development
24 of, qualified pandemic or epidemic products (as defined
25 in section 319F–3 of the Public Health Service Act (42

1 U.S.C. 247d–6d)). Such report may include information
2 regarding relevant work carried out under section
3 319L(c)(5)(E) of the Public Health Service Act (42
4 U.S.C. 247d–7e(c)(5)(E)), through public-private partner-
5 ships, and through collaborations with other countries to
6 assist with or expedite the research and development of
7 qualified pandemic or epidemic products. Such report shall
8 not include information that may compromise national se-
9 curity.

10 **SEC. 607. STRENGTHENING MOSQUITO ABATEMENT FOR**
11 **SAFETY AND HEALTH.**

12 (a) REAUTHORIZATION OF MOSQUITO ABATEMENT
13 FOR SAFETY AND HEALTH PROGRAM.—Section 317S of
14 the Public Health Service Act (42 U.S.C. 247b–21) is
15 amended—

16 (1) in subsection (a)(1)(B)—

17 (A) by inserting “including programs to
18 address emerging infectious mosquito-borne dis-
19 eases,” after “subdivisions for control pro-
20 grams,”; and

21 (B) by inserting “or improving existing
22 control programs” before the period at the end;

23 (2) in subsection (b)—

24 (A) in paragraph (1), by inserting “, in-
25 cluding improvement,” after “operation”;

1 (B) in paragraph (2)—

2 (i) in subparagraph (A)—

3 (I) in clause (ii), by striking “or”

4 at the end;

5 (II) in clause (iii), by striking the

6 semicolon at the end and inserting “,

7 including an emerging infectious mos-

8 quito-borne disease that presents a se-

9 rious public health threat; or”; and

10 (III) by adding at the end the

11 following:

12 “(iv) a public health emergency due to

13 the incidence or prevalence of a mosquito-

14 borne disease that presents a serious pub-

15 lic health threat;”; and

16 (ii) by amending subparagraph (D) to

17 read as follows:

18 “(D)(i) is located in a State that has re-

19 ceived a grant under subsection (a); or

20 “(ii) that demonstrates to the Secretary

21 that the control program is consistent with ex-

22 isting State mosquito control plans or policies,

23 or other applicable State preparedness plans.”;

24 (C) in paragraph (4)(C), by striking “that

25 extraordinary” and all that follows through the

1 period at the end and inserting the following:

2 “that—

3 “(i) extraordinary economic conditions
4 in the political subdivision or consortium of
5 political subdivisions involved justify the
6 waiver; or

7 “(ii) the geographical area covered by
8 a political subdivision or consortium for a
9 grant under paragraph (1) has an extreme
10 mosquito control need due to—

11 “(I) the size or density of the po-
12 tentially impacted human population;

13 “(II) the size or density of a
14 mosquito population that requires
15 heightened control; or

16 “(III) the severity of the mos-
17 quito-borne disease, such that ex-
18 pected serious adverse health out-
19 comes for the human population jus-
20 tify the waiver.”; and

21 (D) by amending paragraph (6) to read as
22 follows:

23 “(6) NUMBER OF GRANTS.—A political subdivi-
24 sion or a consortium of political subdivisions may

1 not receive more than one grant under paragraph
2 (1).”; and

3 (3) in subsection (f)—

4 (A) in paragraph (1) by striking “for fiscal
5 year 2003, and such sums as may be necessary
6 for each of fiscal years 2004 through 2007”
7 and inserting “for each of fiscal years 2019
8 through 2023”;

9 (B) in paragraph (2), by striking “the
10 Public Health Security and Bioterrorism Pre-
11 paredness and Response Act of 2002” and in-
12 serting “this Act and other medical and public
13 health preparedness and response laws”; and

14 (C) in paragraph (3)—

15 (i) in the heading, by striking “2004”
16 and inserting “2019”; and

17 (ii) by striking “2004” and inserting
18 “2019”.

19 (b) EPIDEMIOLOGY-LABORATORY CAPACITY
20 GRANTS.—Section 2821 of the Public Health Service Act
21 (42 U.S.C. 300hh–31) is amended—

22 (1) in subsection (a)(1), by inserting “, includ-
23 ing mosquito and other vector-borne diseases,” after
24 “infectious diseases”; and

1 (2) in subsection (b), by striking “2010 through
2 2013” and inserting “2019 through 2023”.

3 **TITLE VII—MISCELLANEOUS**
4 **PROVISIONS**

5 **SEC. 701. REAUTHORIZATIONS AND EXTENSIONS.**

6 (a) VACCINE TRACKING AND DISTRIBUTION.—Sec-
7 tion 319A(e) of the Public Health Service Act (42 U.S.C.
8 247d–1(e)) is amended by striking “2014 through 2018”
9 and inserting “2019 through 2023”.

10 (b) TEMPORARY REASSIGNMENT.—Section 319(e)(8)
11 of the Public Health Service Act (42 U.S.C. 247d(e)(8))
12 is amended by striking “2018” and inserting “2023”.

13 (c) STRATEGIC INNOVATION PARTNER.—Section
14 319L(c)(4)(E)(ix) of the Public Health Service Act (42
15 U.S.C. 247d–7e(c)(4)(E)(ix)) is amended by striking
16 “2022” and inserting “2023”.

17 (d) LIMITED ANTITRUST EXEMPTION.—

18 (1) IN GENERAL.—Section 405 of the Pandemic
19 and All-Hazards Preparedness Act (42 U.S.C.
20 247d–6a note) is amended—

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

23 (B) by transferring such section to the
24 Public Health Service Act (42 U.S.C. 201 et

1 seq.), to appear after section 319L of such Act
2 (42 U.S.C. 247d–7e);

3 (C) in subsection (a)(1)(A)—

4 (i) by striking “Secretary of Health
5 and Human Services (referred to in this
6 subsection as the ‘Secretary’)” and insert-
7 ing “Secretary”;

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

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

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

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

18 (2) CONFORMING AMENDMENT.—The table of
19 contents in section 1(b) of the Pandemic and All-
20 Hazards Preparedness Act (Public Law 109–417) is
21 amended by striking the item related to section 405.

22 (e) INAPPLICABILITY OF CERTAIN PROVISIONS.—
23 Subsection (g)(1) of section 319L of the Public Health
24 Service Act (42 U.S.C. 247d–7e), as redesignated by sec-
25 tion 404, is amended—

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

3 “(A) NON-DISCLOSURE OF INFORMA-
4 TION.—

5 “(i) IN GENERAL.—Information de-
6 scribed in clause (ii) shall be deemed to be
7 information described in section 552(b)(3)
8 of title 5, United States Code.

9 “(ii) INFORMATION DESCRIBED.—The
10 information described in this clause is in-
11 formation relevant to programs of the De-
12 partment of Health and Human Services
13 that could compromise national security
14 and reveal significant and not otherwise
15 publicly known vulnerabilities of existing
16 medical or public health defenses against
17 chemical, biological, radiological, or nuclear
18 threats, and is comprised of—

19 “(I) specific technical data or sci-
20 entific information that is created or
21 obtained during the countermeasure
22 and product advanced research and
23 development carried out under sub-
24 section (c);

1 “(II) information pertaining to
2 the location security, personnel, and
3 research materials and methods of
4 high-containment laboratories con-
5 ducting research with select agents,
6 toxins, or other agents with a material
7 threat determination under section
8 319F–2(c)(2); or

9 “(III) security and vulnerability
10 assessments.”;

11 (2) by redesignating subparagraph (C) as sub-
12 paragraph (D);

13 (3) by inserting after subparagraph (B) the fol-
14 lowing:

15 “(C) REPORTING.—One year after the
16 date of enactment of the Pandemic and All-
17 Hazards Preparedness and Advancing Innova-
18 tion Act of 2018, and annually thereafter, the
19 Secretary shall report to the Committee on
20 Health, Education, Labor, and Pensions of the
21 Senate and the Committee on Energy and Com-
22 merce of the House of Representatives on the
23 number of instances in which the Secretary has
24 used the authority under this subsection to
25 withhold information from disclosure, as well as

1 the nature of any request under section 552 of
2 title 5, United States Code that was denied
3 using such authority.”; and

4 (4) in subparagraph (D), as so redesignated, by
5 striking “12” and inserting “17”.

6 **SEC. 702. LOCATION OF MATERIALS IN THE STOCKPILE.**

7 Subsection (d) of section 319F–2 of the Public
8 Health Service Act (42 U.S.C. 247d–6b) is amended to
9 read as follows:

10 “(d) DISCLOSURES.—No Federal agency may dis-
11 close under section 552 of title 5, United States Code any
12 information identifying the location at which materials in
13 the stockpile described in subsection (a) are stored, or
14 other information regarding the contents or deployment
15 capability of the stockpile that could compromise national
16 security.”.

17 **SEC. 703. CYBERSECURITY.**

18 (a) STRATEGY FOR PUBLIC HEALTH PREPAREDNESS
19 AND RESPONSE TO CYBERSECURITY THREATS.—

20 (1) STRATEGY.—Not later than 18 months
21 after the date of enactment of this Act, the Sec-
22 retary of Health and Human Services (referred to in
23 this section as the “Secretary”) shall prepare and
24 submit to the relevant committees of Congress a
25 strategy for public health preparedness and response

1 to address cybersecurity threats (as defined in sec-
2 tion 102 of Cybersecurity Information Sharing Act
3 of 2015 (6 U.S.C. 1501)) that present a threat to
4 national health security. Such strategy shall in-
5 clude—

6 (A) identifying the duties, functions, and
7 preparedness goals for which the Secretary is
8 responsible in order to prepare for and respond
9 to such cybersecurity threats, including metrics
10 by which to measure success in meeting pre-
11 paredness goals;

12 (B) identifying gaps in public health capa-
13 bilities to achieve such preparedness goals; and

14 (C) strategies to address identified gaps
15 and strengthen public health emergency pre-
16 paredness and response capabilities to address
17 such cybersecurity threats.

18 (2) PROTECTION OF NATIONAL SECURITY.—

19 The Secretary shall make such strategy available to
20 the Committee on Health, Education, Labor, and
21 Pensions of the Senate, the Committee on Energy
22 and Commerce of the House of Representatives, and
23 other congressional committees of jurisdiction, in a
24 manner that does not compromise national security.

1 (b) COORDINATION OF PREPAREDNESS FOR AND RE-
2 SPONSE TO ALL-HAZARDS PUBLIC HEALTH EMER-
3 GENCIES.—Subparagraph (D) of section 2811(b)(4) of the
4 Public Health Service Act (42 U.S.C. 300hh–10(b)(4)) is
5 amended to read as follows:

6 “(D) POLICY COORDINATION AND STRA-
7 TEGIC DIRECTION.—Provide integrated policy
8 coordination and strategic direction, before,
9 during, and following public health emergencies,
10 with respect to all matters related to Federal
11 public health and medical preparedness and
12 execution and deployment of the Federal re-
13 sponse for public health emergencies and inci-
14 dents covered by the National Response Plan
15 described in section 504(a)(6) of the Homeland
16 Security Act of 2002 (6 U.S.C. 314(a)(6)), or
17 any successor plan; and such Federal responses
18 covered by the National Cybersecurity Incident
19 Response Plan developed under section 228(c)
20 of the Homeland Security Act of 2002 (6
21 U.S.C. 149(c)), including public health emer-
22 gencies or incidents related to cybersecurity
23 threats that present a threat to national health
24 security.”.

1 **SEC. 704. TECHNICAL AMENDMENTS.**

2 (a) PUBLIC HEALTH SERVICE ACT.—Title III of the
3 Public Health Service Act (42 U.S.C. 241 et seq.) is
4 amended—

5 (1) in paragraphs (1) and (5) of section 319F–
6 1(a) (42 U.S.C. 247d–6a(a)), by striking “section
7 319F(h)” each place such term appears and insert-
8 ing “section 319F(e)”; and

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

12 (b) PUBLIC HEALTH SECURITY GRANTS.—Section
13 319C–1(b)(2) of the Public Health Service Act (42 U.S.C.
14 247d–3a(b)(2)) is amended—

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

17 (2) in subparagraph (F), by striking “make sat-
18 isfactory annual improvement and describe” and in-
19 serting “makes satisfactory annual improvement and
20 describes”.

21 (c) EMERGENCY USE INSTRUCTIONS.—Subpara-
22 graph (A) of section 564A(e)(2) of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 360bbb–3a(e)(2)) is
24 amended by striking “subsection (a)(1)(C)(i)” and insert-
25 ing “subsection (a)(1)(C)”.

1 (d) PRODUCTS HELD FOR EMERGENCY USE.—Sec-
2 tion 564B(2) of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 360bbb–3b) is amended—

4 (1) in subparagraph (B), by inserting a comma
5 after “505”; and

6 (2) in subparagraph (C), by inserting “or sec-
7 tion 564A” before the period at the end.

8 (e) TRANSPARENCY.—Section 507(c)(3) of the Fed-
9 eral Food, Drug, and Cosmetic Act (21 U.S.C. 357(c)(3))
10 is amended—

11 (1) by striking “Nothing in” and inserting the
12 following:

13 “(A) IN GENERAL.—Nothing in”;

14 (2) by striking “disclose any” and inserting
15 “disclose or direct—

16 “(i) any”;

17 (3) by striking the period and inserting “; or”;

18 and

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

20 “(ii) in the case of a drug develop-
21 ment tool that may be used to support the
22 development of a qualified countermeasure,
23 security countermeasure, or qualified pan-
24 demic or epidemic product, as defined in
25 sections 319F–1, 319F–2, and 319F–3,

1 respectively, of the Public Health Service
2 Act, any information that the Secretary
3 determines has a significant potential to
4 affect national security.

5 “(B) PUBLIC ACKNOWLEDGMENT.—In the
6 case that the Secretary, pursuant to subpara-
7 graph (A), does not make information publicly
8 available, the Secretary shall provide on the
9 internet website of the Food and Drug Admin-
10 istration an acknowledgement of the informa-
11 tion that has not been disclosed, pursuant to
12 subparagraph (A).”.

13 **SEC. 705. FORMAL STRATEGY RELATING TO CHILDREN**
14 **SEPARATED FROM PARENTS AND GUARD-**
15 **IANAS AS A RESULT OF ZERO TOLERANCE POL-**
16 **ICY.**

17 Not later than 14 days after the date of enactment
18 of this Act, the Assistant Secretary for Preparedness and
19 Response and the Assistant Secretary for the Administra-
20 tion on Children and Families shall submit to the Com-
21 mittee on Energy and Commerce of the House of Rep-
22 resentatives a formal strategy to reunify with their parent
23 or guardian, if the parent or guardian chooses such reuni-
24 fication, each child who—

1 (1) as a result of the initiative announced on
2 April 7, 2018, and due to prosecution under section
3 1325(a) of title 8, United States Code;

4 (2) was separated from their parent or guard-
5 ian and placed into a facility funded by the Depart-
6 ment of Health and Human Services; and

7 (3) can be safely reunited with such parent or
8 guardian.

9 **SEC. 706. REPORTING RELATING TO CHILDREN SEPARATED**
10 **FROM PARENTS AND GUARDIANS AS A RE-**
11 **SULT OF ZERO TOLERANCE POLICY.**

12 Beginning on the date of enactment of this Act, the
13 Assistant Secretary for Preparedness and Response shall
14 submit to the Committee on Energy and Commerce of the
15 House of Representatives weekly reports on the status and
16 welfare of the children who, as a result of the “zero toler-
17 ance” policy, were separated from their parent or guard-
18 ian and are awaiting reunification with their parent or
19 guardian, as well as the number of such children in facili-
20 ties funded by the Department of Health and Human
21 Services.

22 **SEC. 707. TECHNICAL CORRECTION.**

23 Section 801(e)(4)(E)(iii) of the Federal Food, Drug,
24 and Cosmetic Act (21 U.S.C. 381(e)(4)(E)(iii)) is amend-
25 ed by striking “subparagraph” both places it appears in

1 subclause (I) and subclause (II) and inserting “para-
2 graph”.

3 **SEC. 708. SAVINGS CLAUSE.**

4 Nothing in this Act shall be construed as reducing
5 or limiting the authorities vested in any other Federal
6 agency by any other Federal law.

Amend the title so as to read: “A bill to reauthorize
certain programs under the Pandemic and All-Hazards
Preparedness Reauthorization Act.”.