

116TH CONGRESS
1ST SESSION

S. 1379

AN ACT

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 2019”.

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

Sec. 1. Short title; table of contents.

Sec. 2. References in Act.

**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. Strategy and report.
- Sec. 705. Technical amendments.

1 SEC. 2. REFERENCES IN ACT.

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

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

9 SEC. 101. NATIONAL HEALTH SECURITY STRATEGY.

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

11 (1) in subsection (a)—

12 (A) in paragraph (1)—

1 (i) by striking “2014” and inserting
2 “2018”; and

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

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

25 (C) in paragraph (3)—

1 (i) by striking “2009” and inserting
2 “2022”;

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

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

11 (iv) by inserting before the period at
12 the end “, and identifying current capabili-
13 ties to meet the requirements of section
14 2803”; and

15 (2) in subsection (b)—

16 (A) in paragraph (2)—

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

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

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

3 “(E) Response to environmental hazards.”;
 4 (B) in paragraph (3)—

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

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

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

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

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

public health threats, taking into account interactions between animal health, human health, and animals' and humans' shared environment as directly related to public health emergency preparedness and response capabilities, as applicable.

“(10) GLOBAL HEALTH SECURITY.—Assessing current or potential health security threats from abroad to inform domestic public health preparedness and response capabilities.”.

TITLE II—IMPROVING PREPAREDNESS AND RESPONSE

SEC. 201. IMPROVING BENCHMARKS AND STANDARDS FOR PREPAREDNESS AND RESPONSE.

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

“(k) EVALUATION.—

“(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 and every 2 years thereafter, the Secretary shall conduct an evaluation of the evidence-based benchmarks and objective standards required under subsection (g). Such evaluation shall be sub-

mitted to the congressional committees of jurisdiction together with the National Health Security Strategy under section 2802, at such time as such strategy is submitted.

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

“(A) a review of evidence-based benchmarks and objective standards, and associated metrics and targets;

“(B) a discussion of changes to any evidence-based benchmarks and objective standards, and the effect of such changes on the ability to track whether entities are meeting or making progress toward the goals under this section and, to the extent practicable, the applicable goals of the National Health Security Strategy under section 2802;

“(C) a description of amounts received by eligible entities described in subsection (b) and section 319C–2(b), and amounts received by subrecipients and the effect of such funding on meeting evidence-based benchmarks and objective standards; and

“(D) recommendations, as applicable and appropriate, to improve evidence-based bench-

marks and objective standards to more accurately assess the ability of entities receiving awards under this section to better achieve the goals under this section and section 2802.”.

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

SEC. 202. AMENDMENTS TO PREPAREDNESS AND RESPONSE PROGRAMS.

(a) COOPERATIVE AGREEMENT APPLICATIONS FOR IMPROVING STATE AND LOCAL PUBLIC HEALTH SECURITY.—Section 319C–1 (42 U.S.C. 247d–3a) is amended—

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

(2) in subsection (b)(2)(A)—

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

12 (E) by adding at the end the following:

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

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

1 ing, or return to function as soon as prac-
 2 ticable after, a public health emergency;”.

3 (b) EXCEPTION RELATING TO APPLICATION OF CER-
 4 TAIN REQUIREMENTS.—

5 (1) IN GENERAL.—Section 319C–1(g) (42
 6 U.S.C. 247d–3a(g)) is amended—

7 (A) in paragraph (5)—

8 (i) in the matter preceding subpara-
 9 graph (A), by striking “Beginning with fis-
 10 cal year 2009” and inserting “Beginning
 11 with fiscal year 2019”; and

12 (ii) in subparagraph (A)—

13 (I) by striking “for the imme-
 14 diately preceding fiscal year” and in-
 15 serting “for either of the 2 imme-
 16 diately preceding fiscal years”; and

17 (II) by striking “2008” and in-
 18 serting “2018”; and

19 (B) in paragraph (6), by amending sub-
 20 paragraph (A) to read as follows:

21 “(A) IN GENERAL.—The amounts de-
 22 scribed in this paragraph are the following
 23 amounts that are payable to an entity for ac-
 24 tivities described in this section or section
 25 319C–2:

1 “(i) For no more than one of each of
2 the first 2 fiscal years immediately fol-
3 lowing a fiscal year in which an entity ex-
4 perienceed a failure described in subpara-
5 graph (A) or (B) of paragraph (5), an
6 amount equal to 10 percent of the amount
7 the entity was eligible to receive for the re-
8 spective fiscal year.

9 “(ii) For no more than one of the first
10 2 fiscal years immediately following the
11 third consecutive fiscal year in which an
12 entity experienced such a failure, in lieu of
13 applying clause (i), an amount equal to 15
14 percent of the amount the entity was eligi-
15 ble to receive for the respective fiscal
16 year.”.

17 (2) EFFECTIVE DATE.—The amendments made
18 by paragraph (1) shall apply with respect to cooper-
19 ative agreements awarded on or after the date of en-
20 actment of this Act.

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

24 (1) in subsection (a)—

1 (A) by inserting “, acting through the As-
2 sistant Secretary for Preparedness and Re-
3 sponse,” after “The Secretary”; and

4 (B) by striking “preparedness for public
5 health emergencies” and inserting “prepared-
6 ness for, and response to, public health emer-
7 gencies in accordance with subsection (c)”;

8 (2) in subsection (b)(1)(A)—

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

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

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

14 “(iv) one or more emergency medical serv-
15 ice organizations or emergency management or-
16 ganizations; and”;

17 (3) in subsection (d)—

18 (A) in paragraph (1)(B), by striking “part-
19 nership” each place it appears and inserting
20 “coalition”; and

21 (B) in paragraph (2)(C), by striking “med-
22 ical preparedness” and inserting “preparedness
23 and response”;

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

1 (5) in subsection (g)(2)—

2 (A) by striking “Partnerships” and insert-
3 ing “Coalitions”;

4 (B) by striking “partnerships” and insert-
5 ing “coalitions”; and

6 (C) by inserting “and response” after
7 “preparedness”; and

8 (6) in subsection (i)(1)—

9 (A) by striking “An entity” and inserting
10 “A coalition”; and

11 (B) by striking “such partnership” and in-
12 serting “such coalition”.

13 (d) PUBLIC HEALTH SECURITY GRANTS AUTHORIZA-
14 TION OF APPROPRIATIONS.—Section 319C–1(h)(1)(A)
15 (42 U.S.C. 247d–3a(h)(1)(A)) is amended by striking
16 “\$641,900,000 for fiscal year 2014” and all that follows
17 through the period at the end and inserting
18 “\$685,000,000 for each of fiscal years 2019 through 2023
19 for awards pursuant to paragraph (3) (subject to the au-
20 thority of the Secretary to make awards pursuant to para-
21 graphs (4) and (5)).”.

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

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

3 “(1) IN GENERAL.—

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

10 “(B) RESERVATION OF AMOUNTS FOR RE-
 11 GIONAL SYSTEMS.—

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

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

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

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

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

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

18 **SEC. 203. REGIONAL HEALTH CARE EMERGENCY PRE-**
 19 **PAREDNESS AND RESPONSE SYSTEMS.**

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

1 **“SEC. 319C–3. GUIDELINES FOR REGIONAL HEALTH CARE**
2 **EMERGENCY PREPAREDNESS AND RESPONSE**
3 **SYSTEMS.**

4 “(a) PURPOSE.—It is the purpose of this section to
5 identify and provide guidelines for regional systems of hos-
6 pitals, health care facilities, and other public and private
7 sector entities, with varying levels of capability to treat
8 patients and increase medical surge capacity during, in ad-
9 vance of, and immediately following a public health emer-
10 gency, including threats posed by one or more chemical,
11 biological, radiological, or nuclear agents, including emerg-
12 ing infectious diseases.

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

“(1) identify and develop a set of guidelines relating to practices and protocols for all-hazards public health emergency preparedness and response for hospitals and health care facilities to provide appropriate patient care during, in advance of, or immediately following, a public health emergency, resulting from one or more chemical, biological, radiological, or nuclear agents, including emerging infectious diseases (which may include existing practices, such as trauma care and medical surge capacity and capabilities), with respect to—

“(A) a regional approach to identifying hospitals and health care facilities based on varying capabilities and capacity to treat patients affected by such emergency, including—

“(i) the manner in which the system will coordinate with and integrate the partnerships and health care coalitions established under section 319C–2(b); and

“(ii) informing and educating appropriate first responders and health care supply chain partners of the regional emergency preparedness and response capabilities and medical surge capacity of such

1 hospitals and health care facilities in the
2 community;

3 “(B) physical and technological infrastruc-
4 ture, laboratory capacity, staffing, blood supply,
5 and other supply chain needs, taking into ac-
6 count resiliency, geographic considerations, and
7 rural considerations;

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

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

1 “(E) the needs of children and other at-
2 risk individuals;

3 “(2) make such guidelines available on the
4 internet website of the Department of Health and
5 Human Services in a manner that does not com-
6 promise national security; and

7 “(3) update such guidelines as appropriate, in-
8 cluding based on input received pursuant to sub-
9 sections (c) and (e) and information resulting from
10 applicable reports required under the Pandemic and
11 All-Hazards Preparedness and Advancing Innovation
12 Act of 2019 (including any amendments made by
13 such Act), to address new and emerging public
14 health threats.

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

18 “(1) include input from hospitals and health
19 care facilities (including health care coalitions under
20 section 319C–2), State, local, Tribal, and territorial
21 public health departments, and health care or sub-
22 ject matter experts (including experts with relevant
23 expertise in chemical, biological, radiological, or nu-
24 clear threats, including emerging infectious dis-

1 eases), as the Assistant Secretary determines appro-
2 priate, to meet the goals under section 2802(b)(3);

3 “(2) consult and engage with appropriate
4 health care providers and professionals, including
5 physicians, nurses, first responders, health care fa-
6 cilities (including hospitals, primary care clinics,
7 community health centers, mental health facilities,
8 ambulatory care facilities, and dental health facili-
9 ties), pharmacies, emergency medical providers,
10 trauma care providers, environmental health agen-
11 cies, public health laboratories, poison control cen-
12 ters, blood banks, tissue banks, and other experts
13 that the Assistant Secretary determines appropriate,
14 to meet the goals under section 2802(b)(3);

15 “(3) consider feedback related to financial im-
16 plications for hospitals, health care facilities, public
17 health agencies, laboratories, blood banks, tissue
18 banks, and other entities engaged in regional pre-
19 paredness planning to implement and follow such
20 guidelines, as applicable; and

21 “(4) consider financial requirements and poten-
22 tial incentives for entities to prepare for, and re-
23 spond to, public health emergencies as part of the
24 regional health care emergency preparedness and re-
25 sponse system.

1 “(d) TECHNICAL ASSISTANCE.—The Assistant Sec-
2 retary for Preparedness and Response, in consultation
3 with the Director of the Centers for Disease Control and
4 Prevention and the Assistant Secretary of Labor for Occu-
5 pational Safety and Health, may provide technical assist-
6 ance and consultation toward meeting the guidelines de-
7 scribed in subsection (b).

8 “(e) DEMONSTRATION PROJECT FOR REGIONAL
9 HEALTH CARE PREPAREDNESS AND RESPONSE SYS-
10 TEMS.—

11 “(1) IN GENERAL.—The Assistant Secretary for
12 Preparedness and Response may establish a dem-
13 onstration project pursuant to the development and
14 implementation of guidelines under subsection (b) to
15 award grants to improve medical surge capacity for
16 all hazards, build and integrate regional medical re-
17 sponse capabilities, improve specialty care expertise
18 for all-hazards response, and coordinate medical pre-
19 paredness and response across State, local, Tribal,
20 territorial, and regional jurisdictions.

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

23 (b) GAO REPORT TO CONGRESS.—

24 (1) REPORT.—Not later than 3 years after the
25 date of enactment of this Act, the Comptroller Gen-

1 eral of the United States (referred to in this sub-
2 section as the “Comptroller General”) shall submit
3 to the Committee on Health, Education, Labor, and
4 Pensions and the Committee on Finance of the Sen-
5 ate and the Committee on Energy and Commerce
6 and the Committee on Ways and Means of the
7 House of Representatives, a report on the extent to
8 which hospitals and health care facilities have imple-
9 mented the recommended guidelines under section
10 319C–3(b) of the Public Health Service Act (as
11 added by subsection (a)), including an analysis and
12 evaluation of any challenges hospitals or health care
13 facilities experienced in implementing such guide-
14 lines.

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

17 (A) data on the preparedness and response
18 capabilities that have been informed by the
19 guidelines under section 319C–3(b) of the Pub-
20 lic Health Service Act to improve regional emer-
21 gency health care preparedness and response
22 capability, including hospital and health care
23 facility capacity and medical surge capabilities
24 to prepare for, and respond to, public health
25 emergencies; and

(B) recommendations to reduce gaps in incentives for regional health partners, including hospitals and health care facilities, to improve capacity and medical surge capabilities to prepare for, and respond to, public health emergencies, consistent with subsection (a), which may include consideration of facilities participating in programs under section 319C–2 of the Public Health Service Act (42 U.S.C. 247d–3b) or in programs under the Centers for Medicare & Medicaid Services (including innovative health care delivery and payment models), and input from private sector financial institutions.

(3) CONSULTATION.—In carrying out paragraphs (1) and (2), the Comptroller General shall consult with the heads of appropriate Federal agencies, including—

(A) the Assistant Secretary for Preparedness and Response;

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

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

1 (D) the Assistant Secretary for Mental
2 Health and Substance Use;

3 (E) the Assistant Secretary of Labor for
4 Occupational Safety and Health; and

5 (F) the Secretary of Veterans Affairs.

6 (c) ANNUAL REPORTS.—Section 319C–2(i)(1) (42
7 U.S.C. 247d–3b(i)(1)) is amended by inserting after the
8 first sentence the following: “In submitting reports under
9 this paragraph, a coalition shall include information on the
10 progress that the coalition has made toward the implemen-
11 tation of section 319C–3 (or barriers to progress, if
12 any).”.

13 (d) NATIONAL HEALTH SECURITY STRATEGY INCOR-
14 PORATION OF REGIONALIZED EMERGENCY PREPARED-
15 NESS AND RESPONSE.—Subparagraph (G) of section
16 2802(b)(3) (42 U.S.C. 300hh–1(b)(3)) is amended to read
17 as follows:

18 “(G) Optimizing a coordinated and flexible
19 approach to the emergency response and med-
20 ical surge capacity of hospitals, other health
21 care facilities, critical care, trauma care (which
22 may include trauma centers), and emergency
23 medical systems.”.

24 (e) IMPROVING STATE AND LOCAL PUBLIC HEALTH
25 SECURITY.—

(1) STATE AND LOCAL SECURITY.—Section 319C–1(e) (42 U.S.C. 247d–3a(e)) is amended by striking “, and local emergency plans.” and inserting “, local emergency plans, and any regional health care emergency preparedness and response system established pursuant to the applicable guidelines under section 319C–3.”.

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

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

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

(C) by inserting after clause (i) the following:

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

SEC. 204. MILITARY AND CIVILIAN PARTNERSHIP FOR TRAUMA READINESS.

Title XII (42 U.S.C. 300d et seq.) is amended by adding at the end the following new part:

1 **“PART I—MILITARY AND CIVILIAN PARTNERSHIP**
2 **FOR TRAUMA READINESS GRANT PROGRAM**

3 **“SEC. 1291. MILITARY AND CIVILIAN PARTNERSHIP FOR**
4 **TRAUMA READINESS GRANT PROGRAM.**

5 “(a) MILITARY TRAUMA TEAM PLACEMENT PRO-
6 GRAM.—

7 “(1) IN GENERAL.—The Secretary, acting
8 through the Assistant Secretary for Preparedness
9 and Response and in consultation with the Secretary
10 of Defense, shall award grants to not more than 20
11 eligible high-acuity trauma centers to enable military
12 trauma teams to provide, on a full-time basis, trau-
13 ma care and related acute care at such trauma cen-
14 ters.

15 “(2) LIMITATIONS.—In the case of a grant
16 awarded under paragraph (1) to an eligible high-
17 acuity trauma center, such grant—

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

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

23 “(3) AVAILABILITY OF FUNDS.—Notwith-
24 standing section 1552 of title 31, United States
25 Code, or any other provision of law, funds available
26 to the Secretary for obligation for a grant under this

1 subsection shall remain available for expenditure for
2 100 days after the last day of the performance pe-
3 riod of such grant.

4 “(b) MILITARY TRAUMA CARE PROVIDER PLACE-
5 MENT PROGRAM.—

6 “(1) IN GENERAL.—The Secretary, acting
7 through the Assistant Secretary for Preparedness
8 and Response and in consultation with the Secretary
9 of Defense, shall award grants to eligible trauma
10 centers to enable military trauma care providers to
11 provide trauma care and related acute care at such
12 trauma centers.

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

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

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

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

1 “(ii) \$50,000 for each other military
2 trauma care provider at such eligible trauma
3 center.

4 “(c) GRANT REQUIREMENTS.—

5 “(1) DEPLOYMENT AND PUBLIC HEALTH EMER-
6 GENCIES.—As a condition of receipt of a grant
7 under this section, a grant recipient shall agree to
8 allow military trauma care providers providing care
9 pursuant to such grant to—

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

13 “(B) be deployed by the Secretary of De-
14 fense, in consultation with the Secretary of
15 Health and Human Services, for response to a
16 public health emergency pursuant to section
17 319.

18 “(2) USE OF FUNDS.—Grants awarded under
19 this section to an eligible trauma center may be used
20 to train and incorporate military trauma care pro-
21 viders into such trauma center, including incorpora-
22 tion into operational exercises and training drills re-
23 lated to public health emergencies, expenditures for
24 malpractice insurance, office space, information
25 technology, specialty education and supervision,

1 trauma programs, research, and applicable license
2 fees for such military trauma care providers.

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

8 “(e) REPORTING REQUIREMENTS.—

9 “(1) REPORT TO THE SECRETARY AND THE
10 SECRETARY OF DEFENSE.—Each eligible trauma
11 center or eligible high-acuity trauma center awarded
12 a grant under subsection (a) or (b) for a year shall
13 submit to the Secretary and the Secretary of De-
14 fense a report for such year that includes informa-
15 tion on—

16 “(A) the number and types of trauma
17 cases managed by military trauma teams or
18 military trauma care providers pursuant to such
19 grant during such year;

20 “(B) the ability to maintain the integration
21 of the military trauma providers or teams of
22 providers as part of the trauma center, includ-
23 ing the financial effect of such grant on the
24 trauma center;

1 “(C) the educational effect on resident
2 trainees in centers where military trauma teams
3 are assigned;

4 “(D) any research conducted during such
5 year supported by such grant; and

6 “(E) any other information required by the
7 Secretaries for the purpose of evaluating the ef-
8 fect of such grant.

9 “(2) REPORT TO CONGRESS.—Not less than
10 once every 2 years, the Secretary, in consultation
11 with the Secretary of Defense, shall submit a report
12 to the congressional committees of jurisdiction that
13 includes information on the effect of placing military
14 trauma care providers in trauma centers awarded
15 grants under this section on—

16 “(A) maintaining military trauma care
17 providers’ readiness and ability to respond to
18 and treat battlefield injuries;

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

21 “(C) the capability of trauma centers and
22 military trauma care providers to increase med-
23 ical surge capacity, including as a result of a
24 large-scale event;

1 “(D) the ability of grant recipients to
2 maintain the integration of the military trauma
3 providers or teams of providers as part of the
4 trauma center;

5 “(E) efforts to incorporate military trauma
6 care providers into operational exercises and
7 training and drills for public health emer-
8 gencies; and

9 “(F) the capability of military trauma care
10 providers to participate as part of a medical re-
11 sponse during or in advance of a public health
12 emergency, as determined by the Secretary, or
13 a mass casualty incident.

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

15 “(1) ELIGIBLE HIGH-ACUITY TRAUMA CEN-
16 TER.—The term ‘eligible high-acuity trauma center’
17 means a Level I trauma center that satisfies each of
18 the following:

19 “(A) Such trauma center has an agree-
20 ment with the Secretary of Defense to enable
21 military trauma teams to provide trauma care
22 and related acute care at such trauma center.

23 “(B) At least 20 percent of patients treat-
24 ed at such trauma center in the most recent 3-
25 month period for which data are available are

1 treated for a major trauma at such trauma cen-
2 ter.

3 “(C) Such trauma center utilizes a risk-ad-
4 justed benchmarking system and metrics to
5 measure performance, quality, and patient out-
6 comes.

7 “(D) Such trauma center is an academic
8 training center—

9 “(i) affiliated with a medical school;

10 “(ii) that maintains residency pro-
11 grams and fellowships in critical trauma
12 specialties and subspecialties, and provides
13 education and supervision of military trau-
14 ma team members according to those spe-
15 cialties and subspecialties; and

16 “(iii) that undertakes research in the
17 prevention and treatment of traumatic in-
18 jury.

19 “(E) Such trauma center serves as a med-
20 ical and public health preparedness and re-
21 sponse leader for its community, such as by
22 participating in a partnership for State and re-
23 gional hospital preparedness established under
24 section 319C-2 or 319C-3.

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

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

9 “(B) Such trauma center utilizes a risk-ad-
10 justed benchmarking system and metrics to
11 measure performance, quality, and patient out-
12 comes.

13 “(C) Such trauma center demonstrates a
14 need for integrated military trauma care pro-
15 viders to maintain or improve the trauma clin-
16 ical capability of such trauma center.

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

20 “(4) MILITARY TRAUMA TEAM.—The term
21 ‘military trauma team’ means a complete military
22 trauma team consisting of military trauma care pro-
23 viders.

24 “(5) MILITARY TRAUMA CARE PROVIDER.—The
25 term ‘military trauma care provider’ means a mem-

1 ber of the Armed Forces who furnishes emergency,
 2 critical care, and other trauma acute care services
 3 (including a physician, surgeon, physician assistant,
 4 nurse, nurse practitioner, respiratory therapist,
 5 flight paramedic, combat medic, or enlisted medical
 6 technician) or other military trauma care provider as
 7 the Secretary determines appropriate.

8 “(g) AUTHORIZATION OF APPROPRIATIONS.—To
 9 carry out this section, there is authorized to be appro-
 10 priated \$11,500,000 for each of fiscal years 2019 through
 11 2023.”.

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

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

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

21 (2) in subsection (a)—

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

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 2019, 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

the Office of the National Coordinator for Health Information Technology and the National Institute of Standards and Technology), shall, as necessary, adopt technical and reporting standards, including standards for interoperability as defined by section 3000, for networks under paragraph (1) and update such standards as necessary. Such standards shall be made available on the internet website of the Department of Health and Human Services, in a manner that does not compromise national security.

“(B) DEFERENCE TO STANDARDS DEVELOPMENT ORGANIZATIONS.—In adopting and implementing standards under this subsection and subsection (c), the Secretary shall give deference to standards published by standards development organizations and voluntary consensus-based standards entities.”;

(4) in subsection (c)—

(A) in paragraph (1)—

(i) by striking “Not later than 2 years after the date of enactment of the Pandemic 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-

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

“(B) consult with the Secretary of Agriculture, the Secretary of Commerce (and the Director of the National Institute of Standards and Technology), the Secretary of Defense, the Secretary of Homeland Security, the Secretary of Veterans Affairs, and the heads of other Federal agencies, as the Secretary determines appropriate.”;

(C) in paragraph (3)—

(i) by redesignating subparagraphs (A) through (E) as clauses (i) through (v), respectively, and adjusting the margins accordingly;

(ii) in clause (iv), as so redesignated—

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

(II) by striking “and clinical laboratories” and inserting “, clinical laboratories, and public environmental 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 2019 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;

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

“(A) IN GENERAL.—In establishing”;

(iii) by adding at the end the following:

“(B) PUBLIC MEETING.—

“(i) IN GENERAL.—Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, the Secretary shall convene a public meeting for purposes of discussing and providing input on the potential goals, functions, and uses of the network described in paragraph (1) and incorporating the elements described in paragraph (3)(A).

“(ii) EXPERTS.—The public meeting shall include representatives of relevant Federal agencies (including representatives from the Office of the National Coordinator for Health Information Technology and the National Institute of Standards and Technology); State, local, Tribal, and 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 capabili-
6 ties and infrastructure related to data
7 exchange and interoperability;

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

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

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

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

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

23 (bb) by inserting “and the
24 National Institute of Standards
25 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 2019, 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.

“(B) ANNUAL BUDGET PLAN.—Not later than 2 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 and on an annual basis thereafter, in accordance with the strategy and implementation plan under this paragraph, the Secretary shall, taking into account recommendations provided by the National Biodefense Science Board, develop a budget plan based on the strategy and implementation plan under this section. Such budget plan shall include—

“(i) a summary of resources previously expended to establish, improve, and utilize the nationwide public health situational awareness and biosurveillance network under paragraph (1);

“(ii) estimates of costs and resources needed to establish and improve the network under paragraph (1) according to the strategy and implementation plan under subparagraph (A);

“(iii) the identification of gaps and inefficiencies in nationwide public health situational awareness and biosurveillance ca-

pabilities, resources, and authorities needed to address such gaps; and

“(iv) a strategy to minimize and address such gaps and improve inefficiencies.”;

(G) in paragraph (7), as so redesignated—

(i) in subparagraph (A), by inserting “(taking into account zoonotic disease, including gaps in scientific understanding of the interactions between human, animal, and environmental health)” after “human health”;

(ii) in subparagraph (B)—

(I) by inserting “and gaps in surveillance programs” after “surveillance programs”; and

(II) by striking “; and” and inserting a semicolon;

(iii) in subparagraph (C)—

(I) by inserting “, animal health organizations related to zoonotic disease,” after “health care entities”; and

(II) by striking the period and 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 (B) in paragraph (2)—

23 (i) in subparagraph (B), by striking
 24 “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-

ters for Disease Control and Prevention, not to exceed 30 such employees at any time (specific to positions authorized by this subsection), with expertise in capabilities relevant to biosurveillance and situational awareness, such as experts in informatics and data analytics (including experts in prediction, modeling, or forecasting), and other related scientific or technical fields; and

“(B) compensate individuals appointed under subparagraph (A) in the same manner and subject to the same terms and conditions in which individuals appointed under 9903 of title 5, United States Code, are compensated, without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

“(2) LIMITATIONS.—The Secretary shall exercise the authority under paragraph (1) in a manner that is consistent with the limitations described in section 319F–1(e)(2).

“(g) TIMELINE.—The Secretary shall accomplish the purposes under subsections (b) and (c) no later than September 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 2019, the Comptroller General of the United States
8 shall conduct an independent evaluation and submit to the
9 Secretary and the congressional committees of jurisdiction
10 a report concerning the activities conducted under sub-
11 sections (b) and (c), and provide recommendations, as ap-
12 plicable 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 (42 U.S.C. 247d–4), as redes-
16 igned by subsection (a)(6), is amended by striking
17 “\$138,300,000 for each of fiscal years 2014 through
18 2018” and inserting “\$161,800,000 for each of fiscal
19 years 2019 through 2023”.

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

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

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

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

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

22 (A) rapidly detect, identify, characterize,
23 and confirm the presence of biological threat
24 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-

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

(E) a coordinated environmental remediation plan, as applicable.

(6) Recommendations related to research, advanced research, development, and procurement for Federal departments and agencies to improve and enhance biological threat detection systems, including recommendations on the transfer of biological threat detection technology among Federal departments and agencies, as necessary and appropriate.

SEC. 206. STRENGTHENING AND SUPPORTING THE PUBLIC HEALTH EMERGENCY RAPID RESPONSE FUND.

Section 319 (42 U.S.C. 247d) is amended—

(1) in subsection (b)—

(A) in paragraph (1)—

(i) in the first sentence, by inserting “or if the Secretary determines there is the significant potential for a public health emergency, to allow the Secretary to rapidly respond to the immediate needs resulting from such public health emergency or potential public health emergency” before the period; and

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

5 (B) by redesignating paragraph (2) as
6 paragraph (3);

7 (C) by inserting after paragraph (1) the
8 following:

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

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

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

“(C) facilitate and accelerate, as applicable, advanced research and development of security countermeasures (as defined in section 319F–2), qualified countermeasures (as defined in section 319F–1), or qualified pandemic or epidemic products (as defined in section 319F–3), that are applicable to the public health emergency or potential public health emergency under paragraph (1);

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

“(E) support initial emergency operations and assets related to preparation and deployment of intermittent disaster response personnel under section 2812 and the Medical Reserve Corps under section 2813; and

“(F) carry out other activities, as the Secretary determines applicable and appropriate.”; and

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

1 “(4) REVIEW.—Not later than 2 years after the
2 date of enactment of the Pandemic and All-Hazards
3 Preparedness and Advancing Innovation Act of
4 2019, the Secretary, in coordination with the Assist-
5 ant Secretary for Preparedness and Response, shall
6 conduct a review of the Fund under this section and
7 provide recommendations to the Committee on
8 Health, Education, Labor, and Pensions and the
9 Committee on Appropriations of the Senate and the
10 Committee on Energy and Commerce and the Com-
11 mittee on Appropriations of the House of Represent-
12 atives on policies to improve such Fund for the uses
13 described in paragraph (2).

14 “(5) GAO REPORT.—Not later than 4 years
15 after the date of enactment of the Pandemic and
16 All-Hazards Preparedness and Advancing Innovation
17 Act of 2019, the Comptroller General of the United
18 States shall—

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

22 “(B) submit to the Committee on Health,
23 Education, Labor, and Pensions of the Senate
24 and the Committee on Energy and Commerce
25 of the House of Representatives a report on

such review, including recommendations related to such review, as applicable.”; and

(2) in subsection (c)—

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

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

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

(a) IN GENERAL.—Section 319I (42 U.S.C. 247d–7b) is amended—

(1) in the section heading, by striking “**HEALTH PROFESSIONS VOLUNTEERS**” and inserting “**VOLUNTEER HEALTH PROFESSIONAL**”;

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

(3) in subsection (i), by adding at the end the following: “In order to inform the development of such mechanisms by States, the Secretary shall

1 make available information and material provided by
 2 States that have developed mechanisms to waive the
 3 application of licensing requirements to applicable
 4 health professionals seeking to provide medical serv-
 5 ices during a public health emergency. Such infor-
 6 mation shall be made publicly available in a manner
 7 that does not compromise national security.”; and

8 (4) in subsection (k), by striking “2014 through
 9 2018” and inserting “2019 through 2023”.

10 (b) ALL-HAZARDS PUBLIC HEALTH EMERGENCY
 11 PREPAREDNESS AND RESPONSE PLAN.—Section 319C–
 12 1(b)(2)(A)(iv) (42 U.S.C. 247d–3a(b)(2)(A)(iv)) is
 13 amended to read as follows:

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

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

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

10 “(III) other mechanisms as the State
 11 determines appropriate;”.

12 **SEC. 208. CLARIFYING STATE LIABILITY LAW FOR VOLUN-**
 13 **TEER HEALTH CARE PROFESSIONALS.**

14 (a) IN GENERAL.—Title II (42 U.S.C. 202 et seq.)
 15 is amended by inserting after section 224 the following:

16 **“SEC. 225. HEALTH CARE PROFESSIONALS ASSISTING DUR-**
 17 **ING A PUBLIC HEALTH EMERGENCY.**

18 “(a) LIMITATION ON LIABILITY.—Notwithstanding
 19 any other provision of law, a health care professional who
 20 is a member of the Medical Reserve Corps under section
 21 2813 or who is included in the Emergency System for Ad-
 22 vance Registration of Volunteer Health Professionals
 23 under section 319I and who—

24 “(1) is responding—

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

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

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

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

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

24 “(C) in the health care professional’s ca-
25 pacity as a member of the Medical Reserve

1 Corps or a professional included in the Emer-
2 gency System for Advance Registration of Vol-
3 unteer Health Professionals under section 319I;
4 and

5 “(D) in the course of providing services
6 that are within the scope of the license, reg-
7 istration, or certification of the professional, as
8 defined by the State of licensure, registration,
9 or certification; and

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

17 shall be subject only to the State liability laws of the State
18 in which such act or omission occurred, in the same man-
19 ner and to the same extent as a similar health care profes-
20 sional who is a resident of such State would be subject
21 to such State laws, except with respect to the licensure,
22 registration, and certification of such individual.

23 “(b) VOLUNTEER PROTECTION ACT.—Nothing in
24 this section shall be construed to affect an individual’s

1 right to protections under the Volunteer Protection Act
2 of 1997.

3 “(c) PREEMPTION.—This section shall supersede the
4 laws of any State that would subject a health care profes-
5 sional described in subsection (a) to the liability laws of
6 any State other than the State liability laws to which such
7 individual is subject pursuant to such subsection.

8 “(d) DEFINITIONS.—In this section:

9 “(1) The term ‘health care professional’ means
10 an individual licensed, registered, or certified under
11 Federal or State laws or regulations to provide
12 health care services.

13 “(2) The term ‘health care services’ means any
14 services provided by a health care professional, or by
15 any individual working under the supervision of a
16 health care professional, that relate to—

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

19 “(B) the assessment or care of the health
20 of human beings.

21 “(e) EFFECTIVE DATE.—

22 “(1) IN GENERAL.—This section shall take ef-
23 fect 90 days after the date of the enactment of the
24 Pandemic and All-Hazards Preparedness and Ad-
25 vancing Innovation Act of 2019.

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

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

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

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

23 (3) the average time to verify the credentials of
24 a health care provider during the period of a public
25 health emergency declaration, including the average

1 time pursuant to the Emergency System for Ad-
2 vance Registration of Volunteer Health Professionals
3 under such section 319I and for an individual's cre-
4 dentials to be verified by an authority within the
5 State; and

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

12 **SEC. 209. REPORT ON ADEQUATE NATIONAL BLOOD SUP-**
13 **PLY.**

14 Not later than 1 year after the date of the enactment
15 of this Act, the Secretary of Health and Human Services
16 shall submit to Congress a report containing recommenda-
17 tions related to maintaining an adequate national blood
18 supply, including—

19 (1) challenges associated with the continuous
20 recruitment of blood donors (including those newly
21 eligible to donate);

22 (2) ensuring the adequacy of the blood supply
23 in the case of public health emergencies;

24 (3) implementation of the transfusion trans-
25 mission monitoring system; and

(4) other measures to promote safety and innovation, such as the development, use, or implementation of new technologies, processes, and procedures to improve the safety and reliability of the 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.

(a) STUDY.—

(1) IN GENERAL.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services shall enter into an agreement with an appropriate entity to conduct a study regarding the public health preparedness and response capabilities and medical surge capacities of hospitals, long-term care facilities, and other health care facilities to prepare for, and respond to, public health emergencies, including natural disasters.

(2) CONSULTATION.—In conducting the study under paragraph (1), the entity shall consult with Federal, State, local, Tribal, and territorial public health officials (as appropriate), and health care

1 providers and facilities with experience in public
2 health preparedness and response activities.

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

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

18 (B) the identification of gaps in prepared-
19 ness, including with respect to such benchmarks
20 and objective standards, such as those identified
21 during recent public health emergencies, for
22 hospitals, long-term care facilities, and other
23 health care facilities to address future potential
24 public health threats;

1 (C) an evaluation of coordination efforts
2 between the recipients of Federal funding for
3 programs described in subparagraph (A) and
4 entities with expertise in emergency power sys-
5 tems and other critical infrastructure partners
6 during a public health emergency, to ensure a
7 functioning critical infrastructure, to the great-
8 est extent practicable, during a public health
9 emergency;

10 (D) an evaluation of coordination efforts
11 between the recipients of Federal funding for
12 programs described in subparagraph (A) and
13 environmental health agencies with expertise in
14 emergency preparedness and response planning
15 for hospitals, long-term care facilities, and other
16 health care facilities; and

17 (E) an evaluation of current public health
18 preparedness and response capabilities and
19 medical surge capacities related to at-risk indi-
20 viduals during public health emergencies, in-
21 cluding an identification of gaps in such pre-
22 paredness as they relate to such individuals.

23 (b) REPORT.—

24 (1) IN GENERAL.—The agreement under sub-
25 section (a) shall require the entity to submit to the

1 Secretary of Health and Human Services and the
2 congressional committees of jurisdiction, not later
3 than 3 years after the date of enactment of this Act,
4 a report on the results of the study conducted pur-
5 suant to this section.

6 (2) CONTENTS.—The report under paragraph
7 (1) shall—

8 (A) describe the findings and conclusions
9 of the evaluation conducted pursuant to sub-
10 section (a); and

11 (B) provide recommendations for improv-
12 ing public health preparedness and response ca-
13 pability and medical surge capacity for hos-
14 pitals, long-term care facilities, and other health
15 care facilities, including—

16 (i) improving the existing benchmarks
17 and objective standards for the Federal
18 grant programs described in subsection
19 (a)(3)(A) or developing new benchmarks
20 and standards for such programs; and

21 (ii) identifying best practices for im-
22 proving public health preparedness and re-
23 sponse programs and medical surge capac-
24 ity at hospitals, long-term care facilities,
25 and other health care facilities, including

1 recommendations for the evaluation under
 2 subparagraphs (C) and (D) of subsection
 3 (a)(3).

4 **TITLE III—REACHING ALL** 5 **COMMUNITIES**

6 **SEC. 301. STRENGTHENING AND ASSESSING THE EMER-** 7 **GENCY RESPONSE WORKFORCE.**

8 (a) NATIONAL DISASTER MEDICAL SYSTEM.—

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

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

20 (2) REVIEW OF THE NATIONAL DISASTER MED-
 21 ICAL SYSTEM.—Section 2812(b)(2) (42 U.S.C.
 22 300hh–11(b)(2)) is amended to read as follows:

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

1 “(A) REVIEW.—Not later than 180 days
2 after the date of enactment of the Pandemic
3 and All-Hazards Preparedness and Advancing
4 Innovation Act of 2019, the Secretary, in co-
5 ordination with the Secretary of Homeland Se-
6 curity, the Secretary of Defense, and the Sec-
7 retary of Veterans Affairs, shall conduct a joint
8 review of the National Disaster Medical System.
9 Such review shall include—

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

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

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

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

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

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

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

13 “(3) NOTIFICATION.—Not later than 30 days
14 after the date on which the Secretary determines the
15 number of intermittent disaster-response personnel
16 of the National Disaster Medical System is insuffi-
17 cient to address a public health emergency or poten-
18 tial public health emergency, the Secretary shall sub-
19 mit to the congressional committees of jurisdiction a
20 notification detailing—

21 “(A) the impact such shortage could have
22 on meeting public health needs and emergency
23 medical personnel needs during a public health
24 emergency; and

1 “(B) any identified measures to address
2 such shortage.

3 “(4) CERTAIN APPOINTMENTS.—

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

17 “(B) SUNSET.—The authority under this
18 paragraph shall expire on September 30,
19 2021.”.

20 (4) AUTHORIZATION OF APPROPRIATIONS.—

21 Section 2812(g) (42 U.S.C. 300hh–11(g)) is amend-
22 ed by striking “\$52,700,000 for each of fiscal years
23 2014 through 2018” and inserting “\$57,400,000 for
24 each of fiscal years 2019 through 2023”.

25 (b) VOLUNTEER MEDICAL RESERVE CORPS.—

1 (1) IN GENERAL.—Section 2813(a) (42 U.S.C.
 2 42 U.S.C. 300hh–15(a)) is amended by striking the
 3 second sentence and inserting “The Secretary may
 4 appoint a Director to head the Corps and oversee
 5 the activities of the Corps chapters that exist at the
 6 State, local, Tribal, and territorial levels.”.

7 (2) AUTHORIZATION OF APPROPRIATIONS.—
 8 Section 2813(i) (42 U.S.C. 300hh–15(i)) is amended
 9 by striking “2014 through 2018” and inserting
 10 “2019 through 2023”.

11 (c) STRENGTHENING THE EPIDEMIC INTELLIGENCE
 12 SERVICE.—Section 317F (42 U.S.C. Sec. 247b–7) is
 13 amended—

14 (1) in subsection (a)—

15 (A) in paragraph (1)—

16 (i) by inserting “or preparedness and
 17 response activities, including rapid re-
 18 sponse to public health emergencies and
 19 significant public health threats” after
 20 “conduct prevention activities”; and

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

23 (B) in paragraph (2)(B), by striking “3
 24 years” and inserting “2 years”; and

25 (2) in subsection (c)—

1 (A) by striking “For the purpose of car-
 2 rying out this section” and inserting the fol-
 3 lowing:

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

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

8 “(2) EPIDEMIC INTELLIGENCE SERVICE PRO-
 9 GRAM.—For purposes of carrying out this section
 10 with respect to qualified health professionals serving
 11 in the Epidemic Intelligence Service, as authorized
 12 under section 317G, there is authorized to be appro-
 13 priated \$1,000,000 for each of fiscal years 2019
 14 through 2023.”.

15 (d) SERVICE BENEFIT FOR NATIONAL DISASTER
 16 MEDICAL SYSTEM VOLUNTEERS.—

17 (1) IN GENERAL.—Section 2812(c) (42 U.S.C.
 18 300hh–11(c)), as amended by subsection (a)(3), is
 19 further amended by adding at the end the following:

20 “(5) SERVICE BENEFIT.—Individuals appointed
 21 to serve under this subsection shall be considered eli-
 22 gible for benefits under part L of title I of the Om-
 23 nibus Crime Control and Safe Streets Act of 1968.
 24 The Secretary shall provide notification to any eligi-
 25 ble individual of any effect such designation may

1 have on other benefits for which such individual is
2 eligible, including benefits from private entities.”.

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

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

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

11 (C) by inserting after subparagraph (D)
12 the following:

13 “(E) an individual appointed to the Na-
14 tional Disaster Medical System under section
15 2812 of the Public Health Service Act (42
16 U.S.C. 300hh–11) who is performing official
17 duties of the Department of Health and Human
18 Services, if those official duties are—

19 “(i) related to responding to a public
20 health emergency or potential public health
21 emergency, or other activities for which the
22 Secretary of Health and Human Services
23 has activated such National Disaster Med-
24 ical System; and

1 “(ii) determined by the Secretary of
2 Health and Human Services to be haz-
3 ardous.”.

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

7 (e) MISSION READINESS REPORT TO CONGRESS.—

8 (1) REPORT.—Not later than one year after the
9 date of enactment of this section, the Comptroller
10 General of the United States (referred to in this
11 subsection as the “Comptroller General”) shall sub-
12 mit to the Committee on Health, Education, Labor,
13 and Pensions of the Senate and the Committee on
14 Energy and Commerce of the House of Representa-
15 tives, a report on the medical surge capacity of the
16 United States in the event of a public health emer-
17 gency, including the capacity and capability of the
18 current health care workforce to prepare for, and re-
19 spond to, the full range of public health emergencies
20 or potential public health emergencies, and rec-
21 ommendations to address any gaps identified in such
22 workforce.

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

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

11 (B) the capacity of the workforce described
12 in subparagraph (A) to respond to a public
13 health emergency or potential public health
14 emergency, including the capacity to respond to
15 multiple concurrent public health emergencies
16 and the capacity to respond to a nationwide
17 public health emergency;

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

1 (D) an assessment of the effectiveness of
2 efforts to recruit, retain, and train such work-
3 force; and

4 (E) identification of gaps that may exist in
5 such workforce and recommendations for ad-
6 dressing such gaps, the extent to which the As-
7 sistant Secretary for Preparedness and Re-
8 sponse plans to address such gaps, and any rec-
9 ommendations from the Comptroller General to
10 address such gaps.

11 **SEC. 302. HEALTH SYSTEM INFRASTRUCTURE TO IMPROVE**
12 **PREPAREDNESS AND RESPONSE.**

13 (a) COORDINATION OF PREPAREDNESS.—Section
14 2811(b)(5) (42 U.S.C. 300hh–10(b)(5)) is amended by
15 adding at the end the following: “Such logistical support
16 shall include working with other relevant Federal, State,
17 local, Tribal, and territorial public health officials and pri-
18 vate sector entities to identify the critical infrastructure
19 assets, systems, and networks needed for the proper func-
20 tioning of the health care and public health sectors that
21 need to be maintained through any emergency or disaster,
22 including entities capable of assisting with, responding to,
23 and mitigating the effect of a public health emergency,
24 including a public health emergency determined by the
25 Secretary pursuant to section 319(a) or an emergency or

1 major disaster declared by the President under the Robert
 2 T. Stafford Disaster Relief and Emergency Assistance Act
 3 or the National Emergencies Act, including by estab-
 4 lishing methods to exchange critical information and de-
 5 liver products consumed or used to preserve, protect, or
 6 sustain life, health, or safety, and sharing of specialized
 7 expertise.”.

8 (b) MANUFACTURING CAPACITY.—Section
 9 2811(d)(2)(C) (42 U.S.C. 300hh–10(d)(2)(C)) is amended
 10 by inserting “, and ancillary medical supplies to assist
 11 with the utilization of such countermeasures or products,”
 12 after “products”.

13 (c) EVALUATION OF BARRIERS TO RAPID DELIVERY
 14 OF MEDICAL COUNTERMEASURES.—

15 (1) RAPID DELIVERY STUDY.—The Assistant
 16 Secretary for Preparedness and Response may con-
 17 duct a study on issues that have the potential to ad-
 18 versely affect the handling and rapid delivery of
 19 medical countermeasures to individuals during public
 20 health emergencies occurring in the United States.

21 (2) NOTICE TO CONGRESS.—Not later than 9
 22 months after the date of the enactment of this Act,
 23 the Assistant Secretary for Preparedness and Re-
 24 sponse shall notify the Committee on Energy and
 25 Commerce of the House of Representatives and the

1 Committee on Health, Education, Labor, and Pen-
 2 sions of the Senate if the Assistant Secretary for
 3 Preparedness and Response does not plan to conduct
 4 the study under paragraph (1) and shall provide
 5 such committees a summary explanation for such de-
 6 cision.

7 (3) REPORT TO CONGRESS.—Not later than 1
 8 year after the Assistant Secretary for Preparedness
 9 and Response conducts the study under paragraph
 10 (1), such Assistant Secretary shall submit a report
 11 to the Committee on Energy and Commerce of the
 12 House of Representatives and the Committee on
 13 Health, Education, Labor, and Pensions of the Sen-
 14 ate containing the findings of such study.

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

16 (a) AT-RISK INDIVIDUALS IN THE NATIONAL
 17 HEALTH SECURITY STRATEGY.—Section 2802(b)(4)(B)
 18 (42 U.S.C. 300hh–1(b)(4)(B)) is amended—

19 (1) by striking “this section and sections 319C–
 20 1, 319F, and 319L,” and inserting “this Act,”; and

21 (2) by striking “special” and inserting “access
 22 or functional”.

23 (b) COUNTERMEASURE CONSIDERATIONS.—Section
 24 319L(c)(6) (42 U.S.C. 247d–7e(c)(6)) is amended—

1 (1) by striking “elderly” and inserting “older
2 adults”; and

3 (2) by inserting “with relevant characteristics
4 that warrant consideration during the process of re-
5 searching and developing such countermeasures and
6 products” before the period.

7 (c) BIOSURVEILLANCE OF EMERGING PUBLIC
8 HEALTH THREATS.—Section 2814 is amended—

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

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

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

14 “(9) facilitate coordination to ensure that, in
15 implementing the situational awareness and bio-
16 surveillance network under section 319D, the Sec-
17 retary considers incorporating data and information
18 from Federal, State, local, Tribal, and territorial
19 public health officials and entities relevant to detect-
20 ing emerging public health threats that may affect
21 at-risk individuals, such as pregnant and postpartum
22 women and infants, including adverse health out-
23 comes of such populations related to such emerging
24 public health threats.”.

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

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

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

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

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

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

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

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

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

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

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

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

9 **SEC. 305. NATIONAL ADVISORY COMMITTEES ON DISAS-**
 10 **TERS.**

11 (a) REAUTHORIZING THE NATIONAL ADVISORY COM-
 12 MITTEE ON CHILDREN AND DISASTERS.—Section 2811A
 13 (42 U.S.C. 300hh–10a) is amended—

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

16 (2) in subsection (d)—

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

19 (B) by striking paragraph (2) and insert-
 20 ing the following:

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

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

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

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

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

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

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

1 “(iii) at least one such member shall
2 be an individual with expertise in children
3 and youth with special health care needs;
4 and

5 “(iv) at least one such member shall
6 be an individual with expertise in the needs
7 of parents or family caregivers, including
8 the parents or caregivers of children with
9 disabilities.

10 “(3) FEDERAL MEMBERS.—The Advisory Com-
11 mittee under paragraph (1) shall include the fol-
12 lowing Federal members or their designees (who
13 may be nonvoting members, as determined by the
14 Secretary):

15 “(A) The Assistant Secretary for Pre-
16 paredness and Response.

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

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

21 “(D) The Commissioner of Food and
22 Drugs.

23 “(E) The Director of the National Insti-
24 tutes of Health.

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

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

5 “(H) The Administrator of the Federal
6 Emergency Management Agency.

7 “(I) The Administrator of the Administra-
8 tion for Community Living.

9 “(J) The Secretary of Education.

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

17 “(4) TERM OF APPOINTMENT.—Each member
18 of the Advisory Committee appointed under para-
19 graph (2) shall serve for a term of 3 years, except
20 that the Secretary may adjust the terms of the Advi-
21 sory Committee appointees serving on the date of
22 enactment of the Pandemic and All-Hazards Pre-
23 paredness and Advancing Innovation Act of 2019, or
24 appointees who are initially appointed after such

1 date of enactment, in order to provide for a stag-
 2 gered term of appointment for all members.

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

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

11 (4) by redesignating subsection (f) as sub-
 12 section (g);

13 (5) by inserting after subsection (e) the fol-
 14 lowing:

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

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

20 (b) AUTHORIZING THE NATIONAL ADVISORY COM-
 21 MITTEE ON SENIORS AND DISASTERS.—Subtitle B of title
 22 XXVIII (42 U.S.C. 300hh et seq.) is amended by inserting
 23 after section 2811A the following:

1 **“SEC. 2811B. NATIONAL ADVISORY COMMITTEE ON SEN-**
2 **IORES AND DISASTERS.**

3 “(a) ESTABLISHMENT.—The Secretary, in consulta-
4 tion with the Secretary of Homeland Security and the Sec-
5 retary of Veterans Affairs, shall establish an advisory com-
6 mittee to be known as the National Advisory Committee
7 on Seniors and Disasters (referred to in this section as
8 the ‘Advisory Committee’).

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

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

13 “(2) evaluate and provide input with respect to
14 the medical and public health needs of seniors re-
15 lated to preparation for, response to, and recovery
16 from all-hazards emergencies; and

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

22 “(c) ADDITIONAL DUTIES.—The Advisory Committee
23 may provide advice and recommendations to the Secretary
24 with respect to seniors and the medical and public health
25 grants and cooperative agreements as applicable to pre-

1 paredness and response activities under this title and title
 2 III.

3 “(d) MEMBERSHIP.—

4 “(1) IN GENERAL.—The Secretary, in consulta-
 5 tion with such other heads of agencies as appro-
 6 priate, shall appoint not more than 17 members to
 7 the Advisory Committee. In appointing such mem-
 8 bers, the Secretary shall ensure that the total mem-
 9 bership of the Advisory Committee is an odd num-
 10 ber.

11 “(2) REQUIRED MEMBERS.—The Advisory
 12 Committee shall include Federal members or their
 13 designees (who may be nonvoting members, as deter-
 14 mined by the Secretary) and non-Federal members,
 15 as follows:

16 “(A) The Assistant Secretary for Pre-
 17 paredness and Response.

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

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

22 “(D) The Commissioner of Food and
 23 Drugs.

24 “(E) The Director of the National Insti-
 25 tutes of Health.

1 “(F) The Administrator of the Centers for
2 Medicare & Medicaid Services.

3 “(G) The Administrator of the Administra-
4 tion for Community Living.

5 “(H) The Administrator of the Federal
6 Emergency Management Agency.

7 “(I) The Under Secretary for Health of
8 the Department of Veterans Affairs.

9 “(J) At least 2 non-Federal health care
10 professionals with expertise in geriatric medical
11 disaster planning, preparedness, response, or
12 recovery.

13 “(K) At least 2 representatives of State,
14 local, Tribal, or territorial agencies with exper-
15 tise in geriatric disaster planning, preparedness,
16 response, or recovery.

17 “(L) Representatives of such other Federal
18 agencies (such as the Department of Energy
19 and the Department of Homeland Security) as
20 the Secretary determines necessary to fulfill the
21 duties of the Advisory Committee.

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

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) EXTENSION OF COMMITTEE.—Not later
 8 than October 1, 2022, the Secretary shall submit to
 9 Congress a recommendation on whether the Advisory
 10 Committee should be extended.”.

11 (c) NATIONAL ADVISORY COMMITTEE ON INDIVID-
 12 UALS WITH DISABILITIES AND DISASTERS.—Subtitle B
 13 of title XXVIII (42 U.S.C. 300hh et seq.), as amended
 14 by subsection (b), is further amended by inserting after
 15 section 2811B the following:

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

18 “(a) ESTABLISHMENT.—The Secretary, in consulta-
 19 tion with the Secretary of Homeland Security, shall estab-
 20 lish a national advisory committee to be known as the Na-
 21 tional Advisory Committee on Individuals with Disabilities
 22 and Disasters (referred to in this section as the ‘Advisory
 23 Committee’).

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

1 “(1) provide advice and consultation with re-
2 spect to activities carried out pursuant to section
3 2814, as applicable and appropriate;

4 “(2) evaluate and provide input with respect to
5 the medical, public health, and accessibility needs of
6 individuals with disabilities related to preparation
7 for, response to, and recovery from all-hazards emer-
8 gencies; and

9 “(3) provide advice and consultation with re-
10 spect to State emergency preparedness and response
11 activities, including related drills and exercises pur-
12 suant to the preparedness goals under section
13 2802(b).

14 “(c) MEMBERSHIP.—

15 “(1) IN GENERAL.—The Secretary, in consulta-
16 tion with such other heads of agencies and depart-
17 ments as appropriate, shall appoint not more than
18 17 members to the Advisory Committee. In appoint-
19 ing such members, the Secretary shall ensure that
20 the total membership of the Advisory Committee is
21 an odd number.

22 “(2) REQUIRED MEMBERS.—The Advisory
23 Committee shall include Federal members or their
24 designees (who may be nonvoting members, as deter-

1 mined by the Secretary) and non-Federal members,
2 as follows:

3 “(A) The Assistant Secretary for Pre-
4 paredness and Response.

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

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

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

11 “(E) The Commissioner of Food and
12 Drugs.

13 “(F) The Director of the National Insti-
14 tutes of Health.

15 “(G) The Administrator of the Federal
16 Emergency Management Agency.

17 “(H) The Chair of the National Council on
18 Disability.

19 “(I) The Chair of the United States Access
20 Board.

21 “(J) The Under Secretary for Health of
22 the Department of Veterans Affairs.

23 “(K) At least 2 non-Federal health care
24 professionals with expertise in disability accessi-
25 bility before, during, and after disasters, med-

1 ical and mass care disaster planning, prepared-
2 ness, response, or recovery.

3 “(L) At least 2 representatives from State,
4 local, Tribal, or territorial agencies with exper-
5 tise in disaster planning, preparedness, re-
6 sponse, or recovery for individuals with disabil-
7 ities.

8 “(M) At least 2 individuals with a dis-
9 ability with expertise in disaster planning, pre-
10 paredness, response, or recovery for individuals
11 with disabilities.

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

15 “(e) DISABILITY DEFINED.—For purposes of this
16 section, the term ‘disability’ has the meaning given such
17 term in section 3 of the Americans with Disabilities Act
18 of 1990.

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

22 “(g) SUNSET.—

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

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

5 (d) ADVISORY COMMITTEE COORDINATION.—Sub-
6 title B of title XXVIII (42 U.S.C. 300hh et seq.), as
7 amended by subsection (c), is further amended by insert-
8 ing after section 2811C the following:

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

10 “(a) IN GENERAL.—The Secretary shall coordinate
11 duties and activities authorized under sections 2811A,
12 2811B, and 2811C, and make efforts to reduce unneces-
13 sary or duplicative reporting, or unnecessary duplicative
14 meetings and recommendations under such sections, as
15 practicable. Members of the advisory committees author-
16 ized under such sections, or their designees, shall annually
17 meet to coordinate any recommendations, as appropriate,
18 that may be similar, duplicative, or overlapping with re-
19 spect to addressing the needs of children, seniors, and in-
20 dividuals with disabilities during public health emer-
21 gencies. If such coordination occurs through an in-person
22 meeting, it shall not be considered the required in-person
23 meetings under any of sections 2811A(e), 2811B(e), or
24 2811C(d).

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

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

13 **SEC. 306. GUIDANCE FOR PARTICIPATION IN EXERCISES**
14 **AND DRILLS.**

15 Not later than 2 years after the date of enactment
16 of this Act, the Secretary of Health and Human Services
17 shall issue final guidance regarding the ability of per-
18 sonnel funded by programs authorized under this Act (in-
19 cluding the amendments made by this Act) to participate
20 in drills and operational exercises related to all-hazards
21 medical and public health preparedness and response.
22 Such drills and operational exercises may include activities
23 that incorporate medical surge capacity planning, medical
24 countermeasure distribution and administration, and pre-
25 paring for and responding to identified threats for that

1 region. Such personnel may include State, local, Tribal,
 2 and territorial public health department or agency per-
 3 sonnel funded under this Act (including the amendments
 4 made by this Act). The Secretary shall consult with the
 5 Department of Homeland Security, the Department of
 6 Defense, the Department of Veterans Affairs, and other
 7 applicable Federal departments and agencies as necessary
 8 and appropriate in the development of such guidance. The
 9 Secretary shall make the guidance available on the inter-
 10 net website of the Department of Health and Human
 11 Services.

12 **TITLE IV—PRIORITIZING A** 13 **THREAT-BASED APPROACH**

14 **SEC. 401. ASSISTANT SECRETARY FOR PREPAREDNESS AND** 15 **RESPONSE.**

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

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

23 (2) in paragraph (4), by adding at the end the
 24 following:

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

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

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

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

21 “(a) IN GENERAL.—The Secretary shall establish the
 22 Public Health Emergency Medical Countermeasures En-
 23 terprise (referred to in this section as the ‘PHEMCE’).
 24 The Assistant Secretary for Preparedness and Response
 25 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-

cluding any regulatory challenges), and support alignment of countermeasure procurement with recommendations to address such needs under subparagraph (A).

“(C) Assist the Secretary in developing strategies related to logistics, deployment, distribution, dispensing, and use of countermeasures that may be applicable to the activities of the strategic national stockpile under section 319F–2(a).

“(D) Provide consultation for the development of the strategy and implementation plan under section 2811(d).

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

(b) PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE STRATEGY AND IMPLEMENTATION PLAN.—Section 2811(d) (42 U.S.C. 300hh–10(d)) is amended—

(1) in paragraph (1)—

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

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

(B) by striking “Director of the Biomedical” and all that follows through “Food and Drugs” and inserting “Public Health Emergency Medical Countermeasures Enterprise established under section 2811–1”; and

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

SEC. 403. STRATEGIC NATIONAL STOCKPILE.

(a) IN GENERAL.—Section 319F–2(a) (42 U.S.C. 247d–6b(a)) is amended—

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

(2) in paragraph (1)—

(A) by inserting “the Assistant Secretary for Preparedness and Response and” after “collaboration with”;

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

(C) by inserting “and, as informed by existing recommendations of, or consultations with, the Public Health Emergency Medical 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 on June 15, 2019, and on
22 March 15 of each year thereafter, to the Com-
23 mittee on Health, Education, Labor, and Pen-
24 sions and the Committee on Appropriations of
25 the Senate and the Committee on Energy and

1 Commerce and the Committee on Appropria-
2 tions of the House of Representatives, in a
3 manner that does not compromise national se-
4 curity.

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

10 “(i) information regarding—

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

15 “(II) planning considerations for
16 appropriate manufacturing capacity
17 and capability to meet the goals of
18 such additions or modifications (with-
19 out disclosing proprietary informa-
20 tion), including consideration of the
21 effect such additions or modifications
22 may have on the availability of such
23 products and ancillary medical sup-
24 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,
4 and territorial agencies; and the public and pri-
5 vate health care infrastructure, as applicable,
6 taking into account the manufacturing capacity
7 and other available sources of products and ap-
8 propriate alternatives to supplies in the stock-
9 pile;”;

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

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

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

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

24 “(J) provide assistance, including technical
25 assistance, to maintain and improve State and

1 local public health preparedness capabilities to
2 distribute and dispense medical counter-
3 measures and products from the stockpile, as
4 appropriate.”; and

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

6 “(5) GAO REPORT.—

7 “(A) IN GENERAL.—Not later than 3 years
8 after the date of enactment of the Pandemic
9 and All-Hazards Preparedness and Advancing
10 Innovation Act of 2019, and every 5 years
11 thereafter, the Comptroller General of the
12 United States shall conduct a review of any
13 changes to the contents or management of the
14 stockpile since January 1, 2015. Such review
15 shall include—

16 “(i) an assessment of the comprehen-
17 siveness and completeness of each annual
18 threat-based review under paragraph (2),
19 including whether all newly procured or re-
20 plenished countermeasures within the
21 stockpile were described in each annual re-
22 view, and whether, consistent with para-
23 graph (2)(B), the Secretary conducted the
24 necessary internal review in advance of
25 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 2019 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 the Strategic National Stockpile and the
11 Director of the Biomedical Advanced Research and Devel-
12 opment 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 or products receive or had
19 received funding under section 319L of the Public Health
20 Service Act (42 U.S.C. 247d–7e), and whether such coun-
21 termeasures and products are the most appropriate to
22 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) (42

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

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 a 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

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

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

(b) PROTECTION OF NATIONAL SECURITY FROM
 THREATS.—Section 2811 (42 U.S.C. 300hh–10) is
 amended by adding at the end the following:

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

“(1) IN GENERAL.—In carrying out subsection
 (b)(3), the Assistant Secretary for Preparedness and
 Response shall implement strategic initiatives or ac-
 tivities to address threats, including pandemic influ-
 enza and which may include a chemical, biological,
 radiological, or nuclear agent (including any such

1 agent with a significant potential to become a pan-
2 demic), that pose a significant level of risk to public
3 health and national security based on the character-
4 istics of such threat. Such initiatives shall include
5 activities to—

6 “(A) accelerate and support the advanced
7 research, development, manufacturing capacity,
8 procurement, and stockpiling of counter-
9 measures, including initiatives under section
10 319L(c)(4)(F);

11 “(B) support the development and manu-
12 facturing of virus seeds, clinical trial lots, and
13 stockpiles of novel virus strains; and

14 “(C) maintain or improve preparedness ac-
15 tivities, including for pandemic influenza.

16 “(2) AUTHORIZATION OF APPROPRIATIONS.—

17 “(A) IN GENERAL.—To carry out this sub-
18 section, there is authorized to be appropriated
19 \$250,000,000 for each of fiscal years 2019
20 through 2023.

21 “(B) SUPPLEMENT, NOT SUPPLANT.—
22 Amounts appropriated under this paragraph
23 shall be used to supplement and not supplant
24 funds provided under sections 319L(d) and
25 319F–2(g).

“(C) DOCUMENTATION REQUIRED.—The Assistant Secretary for Preparedness and Response, in accordance with subsection (b)(7), shall document amounts expended for purposes of carrying out this subsection, including amounts appropriated under the heading ‘Public Health and Social Services Emergency Fund’ under the heading ‘Office of the Secretary’ under title II of division H of the Consolidated Appropriations Act, 2018 (Public Law 115–141) and allocated to carrying out section 319L(c)(4)(F).”.

SEC. 405. REPORTING ON THE FEDERAL SELECT AGENT PROGRAM.

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

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

“(1) IN GENERAL.—The Secretary”; and

(2) by adding at the end the following:

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

“(A) IN GENERAL.—Not later than 1 year after the date of the enactment of the Pan-

1 demic and All-Hazards Preparedness and Ad-
 2 vancing Innovation Act of 2019, the Secretary
 3 shall report to the congressional committees of
 4 jurisdiction on the implementation of rec-
 5 ommendations of the Federal Experts Security
 6 Advisory Panel concerning the select agent pro-
 7 gram.

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

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

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

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

- 23 (1) in the matter preceding subparagraph (A),
 24 by striking “March 1” and inserting “March 15”;
 25 (2) in subparagraph (A)—

1 (A) in clause (ii), by striking “; and” and
2 inserting “;”; and

3 (B) by striking clause (iii) and inserting
4 the following:

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

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

17 “(v) potential deployment, distribu-
18 tion, and utilization of medical counter-
19 measures; development of clinical guidance
20 and emergency use instructions for the use
21 of medical countermeasures; and, as appli-
22 cable, potential postdeployment activities
23 related to medical countermeasures;”;

24 (3) by redesignating subparagraphs (D) and
25 (E) as subparagraphs (E) and (F), respectively; and

1 (4) by inserting after subparagraph (C), the fol-
2 lowing:

3 “(D) identify the full range of anticipated
4 medical countermeasure needs related to re-
5 search and development, procurement, and
6 stockpiling, including the potential need for in-
7 dications, dosing, and administration tech-
8 nologies, and other countermeasure needs as
9 applicable and appropriate;”.

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

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

1 (b) CONTRACTING COMMUNICATION.—Section 319F–
 2 2(c)(7)(B)(ii)(III) (42 U.S.C. 247d–6b(c)(7)(B)(ii)(III))
 3 is amended by adding at the end the following: “The Sec-
 4 retary shall notify the vendor within 90 days of a deter-
 5 mination by the Secretary to renew, extend, or terminate
 6 such contract.”.

7 **SEC. 503. AVAILABILITY OF REGULATORY MANAGEMENT**
 8 **PLANS.**

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

11 (1) by redesignating paragraphs (3) through
 12 (6) as paragraphs (4) through (7), respectively;

13 (2) by inserting after paragraph (2) the fol-
 14 lowing:

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

19 “(A) the process by which an applicant
 20 may submit a request for a regulatory manage-
 21 ment plan;

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

24 “(C) the information required for the sub-
 25 mission of such request;

1 “(D) a description of the types of develop-
 2 ment milestones and performance targets that
 3 could be discussed and included in such plans;
 4 and

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

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

9 (A) by striking “paragraph (4)(A)” and in-
 10 serting “paragraph (5)(A)”; and

11 (B) by striking “paragraph (4)(B)” and
 12 inserting “paragraph (5)(B)”; and

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

16 **SEC. 504. THE BIOMEDICAL ADVANCED RESEARCH AND DE-**
 17 **VELOPMENT AUTHORITY AND THE BIO-**
 18 **SHIELD SPECIAL RESERVE FUND.**

19 (a) BIOSHIELD SPECIAL RESERVE FUND.—Section
 20 319F–2(g)(1) (42 U.S.C. 247d–6b(g)(1)) is amended—

21 (1) by striking “\$2,800,000,000 for the period
 22 of fiscal years 2014 through 2018” and inserting
 23 “\$7,100,000,000 for the period of fiscal years 2019
 24 through 2028, to remain available until expended”;
 25 and

1 (2) by striking the second sentence.

2 (b) THE BIOMEDICAL ADVANCED RESEARCH AND
3 DEVELOPMENT AUTHORITY.—Section 319L(d)(2) (42
4 U.S.C. 247d–7e(d)(2)) is amended by striking
5 “\$415,000,000 for each of fiscal years 2014 through
6 2018” and inserting “\$611,700,000 for each of fiscal
7 years 2019 through 2023”.

8 **SEC. 505. ADDITIONAL STRATEGIES FOR COMBATING ANTI-**
9 **BIOTIC RESISTANCE.**

10 (a) ADVISORY COUNCIL.—The Secretary of Health
11 and Human Services (referred to in this section as the
12 “Secretary”) may continue the Presidential Advisory
13 Council on Combating Antibiotic-Resistant Bacteria, re-
14 ferred to in this section as the “Advisory Council”.

15 (b) DUTIES.—The Advisory Council shall advise and
16 provide information and recommendations to the Sec-
17 retary regarding programs and policies intended to reduce
18 or combat antibiotic-resistant bacteria that may present
19 a public health threat and improve capabilities to prevent,
20 diagnose, mitigate, or treat such resistance. Such advice,
21 information, and recommendations may be related to im-
22 proving—

- 23 (1) the effectiveness of antibiotics;
- 24 (2) research and advanced research on, and the
- 25 development of, improved and innovative methods

1 for combating or reducing antibiotic resistance, in-
2 cluding new treatments, rapid point-of-care
3 diagnostics, alternatives to antibiotics, including al-
4 ternatives to animal antibiotics, and antimicrobial
5 stewardship activities;

6 (3) surveillance of antibiotic-resistant bacterial
7 infections, including publicly available and up-to-
8 date information on resistance to antibiotics;

9 (4) education for health care providers and the
10 public with respect to up-to-date information on an-
11 tibiotic resistance and ways to reduce or combat
12 such resistance to antibiotics related to humans and
13 animals;

14 (5) methods to prevent or reduce the trans-
15 mission of antibiotic-resistant bacterial infections,
16 including stewardship programs; and

17 (6) coordination with respect to international
18 efforts in order to inform and advance United States
19 capabilities to combat antibiotic resistance.

20 (c) MEETINGS AND COORDINATION.—

21 (1) MEETINGS.—The Advisory Council shall
22 meet not less than biannually and, to the extent
23 practicable, in coordination with meetings of the
24 Antimicrobial Resistance Task Force established in
25 section 319E(a) of the Public Health Service Act.

1 (2) COORDINATION.—The Advisory Council
2 shall, to the greatest extent practicable, coordinate
3 activities carried out by the Council with the Anti-
4 microbial Resistance Task Force established under
5 section 319E(a) of the Public Health Service Act
6 (42 U.S.C. 247d–5(a)).

7 (d) FACA.—The Federal Advisory Committee Act (5
8 U.S.C. App.) shall apply to the activities and duties of
9 the Advisory Council.

10 (e) EXTENSION OF ADVISORY COUNCIL.—Not later
11 than October 1, 2022, the Secretary shall submit to the
12 Committee on Health, Education, Labor, and Pensions of
13 the Senate and the Committee on Energy and Commerce
14 of the House of Representatives a recommendation on
15 whether the Advisory Council should be extended, and in
16 addition, identify whether there are other committees,
17 councils, or task forces that have overlapping or similar
18 duties to that of the Advisory Council, and whether such
19 committees, councils, or task forces should be combined,
20 including with respect to section 319E(a) of the Public
21 Health Service Act (42 U.S.C. 247d–5(a)).

1 **TITLE VI—ADVANCING TECH-**
 2 **NOLOGIES FOR MEDICAL**
 3 **COUNTERMEASURES**

4 **SEC. 601. ADMINISTRATION OF COUNTERMEASURES.**

5 Section 319L(c)(4)(D)(iii) (42 U.S.C. 247d–
 6 7e(c)(4)(D)(iii)) is amended by striking “and platform
 7 technologies” and inserting “platform technologies, tech-
 8 nologies to administer countermeasures, and technologies
 9 to improve storage and transportation of counter-
 10 measures”.

11 **SEC. 602. UPDATING DEFINITIONS OF OTHER TRANS-**
 12 **ACTIONS.**

13 Section 319L (42 U.S.C. 247d–7e) is amended—

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

16 (2) in subsection (c)(5)(A)—

17 (A) in clause (i), by striking “under this
 18 subsection” and all that follows through “Code”
 19 and inserting “(as defined in subsection (a)(3))
 20 under this subsection”; and

21 (B) in clause (ii)—

22 (i) by amending subclause (I) to read
 23 as follows:

24 “(I) IN GENERAL.—To the max-
 25 imum extent practicable, competitive

procedures shall be used when entering into transactions to carry out projects under this subsection.”; and
(ii) in subclause (II)—

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

(II) by striking “senior procurement executive for the Department (as designated for purpose of section 16(c) of the Office of Federal Procurement Policy Act (41 U.S.C. 414(c)))” and inserting “Assistant Secretary for Financial Resources”; and

(III) by striking “senior procurement executive under” and inserting “Assistant Secretary for Financial Resources under”.

SEC. 603. MEDICAL COUNTERMEASURE MASTER FILES.

(a) IN GENERAL.—The purpose of this section (including section 565B of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b)) is to support and advance the development or manufacture of security countermeasures, qualified countermeasures, and qualified pandemic or epidemic products by facilitating and encour-

1 aging submission of data and information to support the
2 development of such products, and through clarifying the
3 authority to cross-reference to data and information pre-
4 viously submitted to the Secretary of Health and Human
5 Services (referred to in this section as the “Secretary”),
6 including data and information submitted to medical coun-
7 termeasure master files or other master files.

8 (b) MEDICAL COUNTERMEASURE MASTER FILES.—
9 Chapter V of the Federal Food, Drug, and Cosmetic Act
10 (21 U.S.C. 351 et seq.) is amended by inserting after sec-
11 tion 565A the following:

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

13 “(a) APPLICABILITY OF REFERENCE.—

14 “(1) IN GENERAL.—A person may submit data
15 and information in a master file to the Secretary
16 with the intent to reference, or to authorize, in writ-
17 ing, another person to reference, such data or infor-
18 mation to support a medical countermeasure submis-
19 sion (including a supplement or amendment to any
20 such submission), without requiring the master file
21 holder to disclose the data and information to any
22 such persons authorized to reference the master file.
23 Such data and information shall be available for ref-
24 erence by the master file holder or by a person au-
25 thorized by the master file holder, in accordance

1 with applicable privacy and confidentiality protocols
2 and regulations.

3 “(2) REFERENCE OF CERTAIN MASTER
4 FILES.—In the case that data or information within
5 a medical countermeasure master file is used only to
6 support the conditional approval of an application
7 filed under section 571, such master file may be re-
8 lied upon to support the effectiveness of a product
9 that is the subject of a subsequent medical counter-
10 measure submission only if such application is sup-
11 plemented by additional data or information to sup-
12 port review and approval in a manner consistent
13 with the standards applicable to such review and ap-
14 proval for such countermeasure, qualified counter-
15 measure, or qualified pandemic or epidemic product.

16 “(b) MEDICAL COUNTERMEASURE MASTER FILE
17 CONTENT.—

18 “(1) IN GENERAL.—A master file under this
19 section may include data or information to sup-
20 port—

21 “(A) the development of medical counter-
22 measure submissions to support the approval,
23 licensure, classification, clearance, conditional
24 approval, or authorization of one or more secu-
25 rity countermeasures, qualified counter-

1 measures, or qualified pandemic or epidemic
2 products; and

3 “(B) the manufacture of security counter-
4 measures, qualified countermeasures, or quali-
5 fied pandemic or epidemic products.

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

11 “(c) SPONSOR REFERENCE.—

12 “(1) IN GENERAL.—Each incorporation of data
13 or information within a medical countermeasure
14 master file shall describe the incorporated material
15 in a manner in which the Secretary determines ap-
16 propriate and that permits the review of such infor-
17 mation within such master file without necessitating
18 resubmission of such data or information. Master
19 files shall be submitted in an electronic format in ac-
20 cordance with sections 512(b)(4), 571(a)(4), and
21 745A, as applicable, and as specified in applicable
22 guidance.

23 “(2) REFERENCE BY A MASTER FILE HOLD-
24 ER.—A master file holder that is the sponsor of a
25 medical countermeasure submission shall notify the

1 Secretary in writing of the intent to reference the
2 medical countermeasure master file as a part of the
3 submission.

4 “(3) REFERENCE BY AN AUTHORIZED PER-
5 SON.—A person submitting an application for review
6 may, where the Secretary determines appropriate,
7 incorporate by reference all or part of the contents
8 of a medical countermeasure master file, if the mas-
9 ter file holder authorizes the incorporation in writ-
10 ing.

11 “(d) ACKNOWLEDGMENT OF AND RELIANCE UPON A
12 MASTER FILE BY THE SECRETARY.—

13 “(1) IN GENERAL.—The Secretary shall provide
14 the master file holder with a written notification in-
15 dicating that the Secretary has reviewed and relied
16 upon specified data or information within a master
17 file and the purposes for which such data or infor-
18 mation was incorporated by reference if the Sec-
19 retary has reviewed and relied upon such specified
20 data or information to support the approval, classi-
21 fication, conditional approval, clearance, licensure, or
22 authorization of a security countermeasure, qualified
23 countermeasure, or qualified pandemic or epidemic
24 product. The Secretary may rely upon the data and
25 information within the medical countermeasure mas-

1 ter file for which such written notification was pro-
2 vided in additional applications, as applicable and
3 appropriate and upon the request of the master file
4 holder so notified in writing or by an authorized per-
5 son of such holder.

6 “(2) CERTAIN APPLICATIONS.—If the Secretary
7 has reviewed and relied upon specified data or infor-
8 mation within a medical countermeasure master file
9 to support the conditional approval of an application
10 under section 571 to subsequently support the ap-
11 proval, clearance, licensure, or authorization of a se-
12 curity countermeasure, qualified countermeasure, or
13 qualified pandemic or epidemic product, the Sec-
14 retary shall provide a brief written description to the
15 master file holder regarding the elements of the ap-
16 plication fulfilled by the data or information within
17 the master file and how such data or information
18 contained in such application meets the standards of
19 evidence under subsection (c) or (d) of section 505,
20 subsection (d) of section 512, or section 351 of the
21 Public Health Service Act (as applicable), which
22 shall not include any trade secret or confidential
23 commercial information.

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

1 “(1) limit the authority of the Secretary to ap-
2 prove, license, clear, conditionally approve, or au-
3 thorize drugs, biological products, or devices pursu-
4 ant to, as applicable, this Act or section 351 of the
5 Public Health Service Act (as such applicable Act is
6 in effect on the day before the date of enactment of
7 the Pandemic and All-Hazards Preparedness and
8 Advancing Innovation Act of 2019), including the
9 standards of evidence, and applicable conditions, for
10 approval under the applicable Act;

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

19 “(3) alter the authority of the Secretary under
20 this Act or the Public Health Service Act to deter-
21 mine the types of data or information previously
22 submitted by a sponsor or any other person that
23 may be incorporated by reference in an application,
24 request, or notification for a drug, biological prod-
25 uct, or device submitted under sections 505(i),

1 505(b), 505(j), 512(b)(1), 512(b)(2), 512(j), 564,
2 571, 520(g), 515(c), 513(f)(2), or 510(k) of this
3 Act, or subsection (a) or (k) of section 351 of the
4 Public Health Service Act, including a supplement
5 or amendment to any such submission, and the re-
6 quirements associated with such reference.

7 “(f) DEFINITIONS.—In this section:

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

14 “(2) The term ‘medical countermeasure submis-
15 sion’ means an investigational new drug application
16 under section 505(i), a new drug application under
17 section 505(b), or an abbreviated new drug applica-
18 tion under section 505(j) of this Act, a biological
19 product license application under section 351(a) of
20 the Public Health Service Act or a biosimilar biologi-
21 cal product license application under section 351(k)
22 of the Public Health Service Act, a new animal drug
23 application under section 512(b)(1) or abbreviated
24 new animal drug application under section
25 512(b)(2), an application for conditional approval of

1 a new animal drug under section 571, an investiga-
2 tional device application under section 520(g), an
3 application with respect to a device under section
4 515(c), a request for classification of a device under
5 section 513(f)(2), a notification with respect to a de-
6 vice under section 510(k), or a request for an emer-
7 gency use authorization under section 564 to sup-
8 port—

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

14 “(B) a new indication to an approved secu-
15 rity countermeasure, qualified countermeasure,
16 or qualified pandemic or epidemic product.

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

22 (c) STAKEHOLDER INPUT.—Not later than 18
23 months after the date of enactment of this Act, the Sec-
24 retary, acting through the Commissioner of Food and
25 Drugs and in consultation with the Assistant Secretary

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

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

1 manufacture of security countermeasures, qualified coun-
2 termesures, and qualified pandemic or epidemic products.
3 The Secretary, acting through the Commissioner of Food
4 and Drugs, shall publish the final guidance not later than
5 3 years after the enactment of this Act.

6 **SEC. 604. ANIMAL RULE REPORT.**

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

18 (1) The extent to which advanced development
19 and review of a medical countermeasure are coordi-
20 nated between the Biomedical Advanced Research
21 and Development Authority and the Food and Drug
22 Administration, including activities that facilitate
23 appropriate and efficient design of studies to sup-
24 port approval, licensure, and authorization under the
25 animal rule, consistent with the recommendations in

1 the animal rule guidance, issued pursuant to section
2 565(c) of the Federal Food, Drug, and Cosmetic Act
3 (21 U.S.C. 360bbb–4(c)) and entitled “Product De-
4 velopment Under the Animal Rule: Guidance for In-
5 dustry” (issued in October 2015), to resolve discrep-
6 ancies in the design of adequate and well-controlled
7 efficacy studies conducted in animal models related
8 to the provision of substantial evidence of effective-
9 ness for the product approved, licensed, or author-
10 ized under the animal rule.

11 (2) The consistency of the application of the
12 animal rule among and between review divisions
13 within the Food and Drug Administration.

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

21 (4) The extent to which the guidance issued
22 under section 565(c) of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 360bbb–4(c)), entitled,
24 “Product Development Under the Animal Rule:
25 Guidance for Industry” (issued in October 2015),

1 has assisted in achieving the purposes described in
2 paragraphs (1), (2), and (3).

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

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

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

17 (3) other biodefense stakeholders, as applicable.

18 (c) REPORT.—Not later than 3 years after the date
19 of enactment of this Act, the Comptroller General of the
20 United States shall submit to the Committee on Health,
21 Education, Labor, and Pensions of the Senate and the
22 Committee on Energy and Commerce of the House of
23 Representatives a report containing the results of the
24 study conducted under subsection (a) and recommenda-
25 tions to improve the application and consistency of the re-

1 quirements under subsections (c) and (d) of section 565
 2 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 3 360bbb-4) to support and expedite the research and devel-
 4 opment of medical countermeasures, as applicable.

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

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

13 (a) MEETING.—

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

23 (2) ATTENDEES.—The attendees of the meeting
 24 under paragraph (1)—

25 (A) shall include—

1 (i) representatives from the Office of
2 the Assistant Secretary for Preparedness
3 and Response, the National Institutes of
4 Health, the Centers for Disease Control
5 and Prevention, and the Food and Drug
6 Administration; and

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

13 (B) may include—

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

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

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

1 (A) the current state of the science of
2 genomic engineering technologies related to na-
3 tional health security, including—

4 (i) medical countermeasure develop-
5 ment, including potential efficiencies in the
6 development pathway and detection tech-
7 nologies; and

8 (ii) the international and domestic
9 regulation of products utilizing genome ed-
10 iting technologies; and

11 (B) national security implications, includ-
12 ing—

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

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

24 (iii) security measures to monitor and
25 assess the potential threat that may result

1 from utilization of genomic engineering
2 technologies and related technologies for
3 the purpose of compromising national
4 health security.

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

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

17 Not later than one year after the date of the enact-
18 ment of this Act, the Secretary of Health and Human
19 Services shall submit to the Committee on Health, Edu-
20 cation, Labor, and Pensions of the Senate and the Com-
21 mittee on Energy and Commerce of the House of Rep-
22 resentatives a report describing efforts and activities to
23 coordinate with other countries and international partners
24 during recent public health emergencies with respect to
25 the research and advanced research on, and development

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

12 **SEC. 607. STRENGTHENING MOSQUITO ABATEMENT FOR**
 13 **SAFETY AND HEALTH.**

14 (a) REAUTHORIZATION OF MOSQUITO ABATEMENT
 15 FOR SAFETY AND HEALTH PROGRAM.—Section 317S (42
 16 U.S.C. 247b–21) is amended—

17 (1) in subsection (a)(1)(B)—

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

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

24 (2) in subsection (b)—

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

3 (B) in paragraph (2)—

4 (i) in subparagraph (A)—

5 (I) in clause (ii), by striking “or”
6 at the end;

7 (II) in clause (iii), by striking the
8 semicolon at the end and inserting “,
9 including an emerging infectious mos-
10 quito-borne disease that presents a se-
11 rious public health threat; or”; and

12 (III) by adding at the end the
13 following:

14 “(iv) a public health emergency due to
15 the incidence or prevalence of a mosquito-
16 borne disease that presents a serious pub-
17 lic health threat;”; and

18 (ii) by amending subparagraph (D) to
19 read as follows:

20 “(D)(i) is located in a State that has re-
21 ceived a grant under subsection (a); or

22 “(ii) that demonstrates to the Secretary
23 that the control program is consistent with ex-
24 isting State mosquito control plans or policies,
25 or other applicable State preparedness plans.”;

1 (C) in paragraph (4)(C), by striking “that
2 extraordinary” and all that follows through the
3 period at the end and inserting the following:
4 “that—

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

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

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

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

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

23 (D) by amending paragraph (6) to read as
24 follows:

1 “(6) NUMBER OF GRANTS.—A political subdivi-
 2 sion or a consortium of political subdivisions may
 3 not receive more than one grant under paragraph
 4 (1).”; and

5 (3) in subsection (f)—

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

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

16 (C) in paragraph (3)—

17 (i) in the paragraph heading, by strik-
 18 ing “2004” and inserting “2019”; and

19 (ii) by striking “2004,” and inserting
 20 “2019,”.

21 (b) EPIDEMIOLOGY-LABORATORY CAPACITY
 22 GRANTS.—Section 2821 (42 U.S.C. 300hh–31) is amend-
 23 ed—

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

4 (2) in subsection (b), by striking “2010 through
 5 2013” and inserting “2019 through 2023”.

6 **TITLE VII—MISCELLANEOUS** 7 **PROVISIONS**

8 **SEC. 701. REAUTHORIZATIONS AND EXTENSIONS.**

9 (a) VETERANS AFFAIRS.—Section 8117(g) of title
 10 38, United States Code, is amended by striking “2014
 11 through 2018” and inserting “2019 through 2023”.

12 (b) VACCINE TRACKING AND DISTRIBUTION.—Sec-
 13 tion 319A(e) (42 U.S.C. 247d–1(e)) is amended by strik-
 14 ing “2014 through 2018” and inserting “2019 through
 15 2023”.

16 (c) TEMPORARY REASSIGNMENT.—Section 319(e)(8)
 17 (42 U.S.C. 247d(e)(8)) is amended by striking “2018”
 18 and inserting “2023”.

19 (d) STRATEGIC INNOVATION PARTNER.—Section
 20 319L(c)(4)(E)(ix) (42 U.S.C. 247d–7e(c)(4)(E)(ix)) is
 21 amended by striking “2022” and inserting “2023”.

22 (e) LIMITED ANTITRUST EXEMPTION.—

23 (1) IN GENERAL.—Section 405 of the Pandemic
 24 and All-Hazards Preparedness Act (Public Law
 25 109–417; 42 U.S.C. 247d–6a note) is amended—

1 (A) in subsection (a)(1)(A)—

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

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

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

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

14 (B) in subsection (b), by striking “12-
15 year” and inserting “17-year”;

16 (C) by redesignating such section 405 as
17 section 319L–1; and

18 (D) by transferring such section 319L–1,
19 as redesignated, to the Public Health Service
20 Act (42 U.S.C. 201 et seq.), to appear after
21 section 319L of such Act (42 U.S.C. 247d–7e).

22 (2) CONFORMING AMENDMENTS.—

23 (A) TABLE OF CONTENTS.—The table of
24 contents in section 1(b) of the Pandemic and
25 All-Hazards Preparedness Act (Public Law

1 109–417) is amended by striking the item re-
2 lated to section 405.

3 (B) REFERENCE.—Section
4 319L(c)(4)(A)(iii) (42 U.S.C. 247d–7e) is
5 amended by striking “section 405 of the Pan-
6 demic and All-Hazards Preparedness Act” and
7 inserting “section 319L–1”.

8 (f) INAPPLICABILITY OF CERTAIN PROVISIONS.—
9 Subsection (e)(1) of section 319L (42 U.S.C. 247d–
10 7e(e)(1)) is amended—

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

13 “(A) NONDISCLOSURE OF INFORMA-
14 TION.—

15 “(i) IN GENERAL.—Information de-
16 scribed in clause (ii) shall be deemed to be
17 information described in section 552(b)(3)
18 of title 5, United States Code.

19 “(ii) INFORMATION DESCRIBED.—The
20 information described in this clause is in-
21 formation relevant to programs of the De-
22 partment of Health and Human Services
23 that could compromise national security
24 and reveal significant and not otherwise
25 publicly known vulnerabilities of existing

1 medical or public health defenses against
2 chemical, biological, radiological, or nuclear
3 threats, and is comprised of—

4 “(I) specific technical data or sci-
5 entific information that is created or
6 obtained during the countermeasure
7 and product advanced research and
8 development carried out under sub-
9 section (c);

10 “(II) information pertaining to
11 the location security, personnel, and
12 research materials and methods of
13 high-containment laboratories con-
14 ducting research with select agents,
15 toxins, or other agents with a material
16 threat determination under section
17 319F–2(c)(2); or

18 “(III) security and vulnerability
19 assessments.”;

20 (2) by redesignating subparagraph (C) as sub-
21 paragraph (D);

22 (3) by inserting after subparagraph (B) the fol-
23 lowing:

24 “(C) REPORTING.—One year after the
25 date of enactment of the Pandemic and All-

1 Hazards Preparedness and Advancing Innova-
2 tion Act of 2019, and annually thereafter, the
3 Secretary shall report to the Committee on
4 Health, Education, Labor, and Pensions of the
5 Senate and the Committee on Energy and Com-
6 merce of the House of Representatives on the
7 number of instances in which the Secretary has
8 used the authority under this subsection to
9 withhold information from disclosure, as well as
10 the nature of any request under section 552 of
11 title 5, United States Code that was denied
12 using such authority.”; and
13 (4) in subparagraph (D), as so redesignated, by
14 striking “12” and inserting “17”.

15 **SEC. 702. LOCATION OF MATERIALS IN THE STOCKPILE.**

16 Subsection (d) of section 319F–2 (42 U.S.C. 247d–
17 6b) is amended to read as follows:

18 “(d) DISCLOSURES.—No Federal agency may dis-
19 close under section 552 of title 5, United States Code any
20 information identifying the location at which materials in
21 the stockpile described in subsection (a) are stored, or
22 other information regarding the contents or deployment
23 capability of the stockpile that could compromise national
24 security.”.

1 **SEC. 703. CYBERSECURITY.**

2 (a) STRATEGY FOR PUBLIC HEALTH PREPAREDNESS
3 AND RESPONSE TO CYBERSECURITY THREATS.—

4 (1) STRATEGY.—Not later than 18 months
5 after the date of enactment of this Act, the Sec-
6 retary of Health and Human Services (referred to in
7 this section as the “Secretary”) shall prepare and
8 submit to the relevant committees of Congress a
9 strategy for public health preparedness and response
10 to address cybersecurity threats (as defined in sec-
11 tion 102 of Cybersecurity Information Sharing Act
12 of 2015 (6 U.S.C. 1501)) that present a threat to
13 national health security. Such strategy shall in-
14 clude—

15 (A) identifying the duties, functions, and
16 preparedness goals for which the Secretary is
17 responsible in order to prepare for and respond
18 to such cybersecurity threats, including metrics
19 by which to measure success in meeting pre-
20 paredness goals;

21 (B) identifying gaps in public health capa-
22 bilities to achieve such preparedness goals; and

23 (C) strategies to address identified gaps
24 and strengthen public health emergency pre-
25 paredness and response capabilities to address
26 such cybersecurity threats.

1 (2) PROTECTION OF NATIONAL SECURITY.—

2 The Secretary shall make such strategy available to
3 the Committee on Health, Education, Labor, and
4 Pensions of the Senate, the Committee on Energy
5 and Commerce of the House of Representatives, and
6 other congressional committees of jurisdiction, in a
7 manner that does not compromise national security.

8 (b) COORDINATION OF PREPAREDNESS FOR AND RE-
9 SPONSE TO ALL-HAZARDS PUBLIC HEALTH EMER-
10 GENCIES.—Subparagraph (D) of section 2811(b)(4) (42
11 U.S.C. 300hh–10(b)(4)) is amended to read as follows:

12 “(D) POLICY COORDINATION AND STRA-
13 TEGIC DIRECTION.—Provide integrated policy
14 coordination and strategic direction, before,
15 during, and following public health emergencies,
16 with respect to all matters related to Federal
17 public health and medical preparedness and
18 execution and deployment of the Federal re-
19 sponse for public health emergencies and inci-
20 dents covered by the National Response Plan
21 described in section 504(a)(6) of the Homeland
22 Security Act of 2002 (6 U.S.C. 314(a)(6)), or
23 any successor plan; and such Federal responses
24 covered by the National Cybersecurity Incident
25 Response Plan developed under section 228(c)

1 of the Homeland Security Act of 2002 (6
2 U.S.C. 149(c)), including public health emer-
3 gencies or incidents related to cybersecurity
4 threats that present a threat to national health
5 security.”.

6 **SEC. 704. STRATEGY AND REPORT.**

7 Not later than 14 days after the date of the enact-
8 ment of this Act, the Secretary of Health and Human
9 Services, in coordination with the Assistant Secretary for
10 Preparedness and Response and the Assistant Secretary
11 for the Administration on Children and Families or other
12 appropriate office, and in collaboration with other depart-
13 ments, as appropriate, shall submit to the Committee on
14 Energy and Commerce of the House of Representatives,
15 the Committee on Health, Education, Labor, and Pen-
16 sions of the Senate, and other relevant congressional com-
17 mittees—

18 (1) a formal strategy, including interdepart-
19 mental actions and efforts to reunify children with
20 their parents or guardians, in all cases in which such
21 children have been separated from their parents or
22 guardians as a result of the initiative announced on
23 April 6, 2018, and due to prosecution under section
24 275(a) of the Immigration and Nationality Act (8

1 U.S.C. 1325(a)), if the parent or guardian chooses
2 such reunification and the child—

3 (A) was separated from a parent or guard-
4 ian and placed into a facility funded by the De-
5 partment of Health and Human Services;

6 (B) as of the date of the enactment of this
7 Act, remains in the care of the Department of
8 Health and Human Services; and

9 (C) can be safely reunited with such parent
10 or guardian; and

11 (2) a report on challenges and deficiencies re-
12 lated to the oversight of, and care for, unaccom-
13 panied alien children and appropriately reuniting
14 such children with their parents or guardians, and
15 the actions taken to address any challenges and defi-
16 ciencies related to unaccompanied alien children in
17 the custody of the Department of Health and
18 Human Services, including deficiencies identified
19 and publicly reported by Congress, the Government
20 Accountability Office, or the inspectors general of
21 the Department of Health and Human Services or
22 other Federal departments.

23 **SEC. 705. TECHNICAL AMENDMENTS.**

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

1 (1) in paragraphs (1) and (5) of section 319F–
 2 1(a) (42 U.S.C. 247d–6a(a)), by striking “section
 3 319F(h)” each place such term appears and insert-
 4 ing “section 319F(e)”; and

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

8 (b) PUBLIC HEALTH SECURITY GRANTS.—Section
 9 319C–1(b)(2) (42 U.S.C. 247d–3a(b)(2)) is amended—

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

12 (2) in subparagraph (F), by striking “make sat-
 13 isfactory annual improvement and describe” and in-
 14 serting “makes satisfactory annual improvement and
 15 describes”.

16 (c) EMERGENCY USE INSTRUCTIONS.—Subpara-
 17 graph (A) of section 564A(e)(2) of the Federal Food,
 18 Drug, and Cosmetic Act (21 U.S.C. 360bbb–3a(e)(2)) is
 19 amended by striking “subsection (a)(1)(C)(i)” and insert-
 20 ing “subsection (a)(1)(C)”.

21 (d) PRODUCTS HELD FOR EMERGENCY USE.—Sec-
 22 tion 564B(2) of the Federal Food, Drug, and Cosmetic
 23 Act (21 U.S.C. 360bbb–3b) is amended—

24 (1) in subparagraph (B), by inserting a comma
 25 after “505”; and

1 (2) in subparagraph (C), by inserting “or sec-
2 tion 564A” before the period at the end.

3 (e) TRANSPARENCY.—Section 507(c)(3) of the Fed-
4 eral Food, Drug, and Cosmetic Act (21 U.S.C. 357(c)(3))
5 is amended—

6 (1) by striking “Nothing in” and inserting the
7 following:

8 “(A) IN GENERAL.—Nothing in”;

9 (2) by inserting “or directing” after “author-
10 izing”;

11 (3) by striking “disclose any” and inserting
12 “disclose—

13 “(i) any”;

14 (4) by striking the period and inserting “; or”;
15 and

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

17 “(ii) in the case of a drug develop-
18 ment tool that may be used to support the
19 development of a qualified countermeasure,
20 security countermeasure, or qualified pan-
21 demic or epidemic product, as defined in
22 sections 319F–1, 319F–2, and 319F–3,
23 respectively, of the Public Health Service
24 Act, any information that the Secretary

1 determines has a significant potential to
2 affect national security.

3 “(B) PUBLIC ACKNOWLEDGMENT.—In the
4 case that the Secretary, pursuant to subpara-
5 graph (A)(ii), does not make information pub-
6 licly available, the Secretary shall provide on
7 the internet website of the Food and Drug Ad-
8 ministration an acknowledgment of the informa-
9 tion that has not been disclosed, pursuant to
10 subparagraph (A)(ii).”.

Passed the Senate May 16, 2019.

Attest:

Secretary.

116TH CONGRESS
1ST SESSION

S. 1379

AN ACT

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.