

116TH CONGRESS
1ST SESSION

S. 1379

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

IN THE SENATE OF THE UNITED STATES

MAY 8, 2019

Mr. BURR (for himself, Mr. CASEY, Mr. ALEXANDER, and Mrs. MURRAY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

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

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

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Pandemic and All-Hazards Preparedness and Advancing
6 Innovation Act of 2019”.

1 (b) TABLE OF CONTENTS.—The table of contents for
 2 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)—

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

15 (ii) by striking the second sentence
16 and inserting the following: “Such Na-

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

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

21 (C) in paragraph (3)—

22 (i) by striking “2009” and inserting
23 “2022”;

24 (ii) by inserting “(including gaps in
25 the environmental health and animal

1 health workforces, as applicable), describ-
2 ing the status of such workforce” after
3 “gaps in such workforce”;

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

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

11 (2) in subsection (b)—

12 (A) in paragraph (2)—

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

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

22 (iii) by adding at the end the fol-
23 lowing:

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

25 (B) in paragraph (3)—

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

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

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

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

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

1 rectly related to public health emergency prepared-
2 ness and response capabilities, as applicable.

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

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

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

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

15 “(k) EVALUATION.—

16 “(1) IN GENERAL.—Not later than 2 years
17 after the date of enactment of the Pandemic and
18 All-Hazards Preparedness and Advancing Innovation
19 Act of 2019 and every 2 years thereafter, the Sec-
20 retary shall conduct an evaluation of the evidence-
21 based benchmarks and objective standards required
22 under subsection (g). Such evaluation shall be sub-
23 mitted to the congressional committees of jurisdic-
24 tion together with the National Health Security

1 Strategy under section 2802, at such time as such
2 strategy is submitted.

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

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

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

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

22 “(D) recommendations, as applicable and
23 appropriate, to improve evidence-based bench-
24 marks and objective standards to more accu-
25 rately assess the ability of entities receiving

1 awards under this section to better achieve the
2 goals under this section and section 2802.”.

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

8 **SEC. 202. AMENDMENTS TO PREPAREDNESS AND RE-**
9 **SPONSE PROGRAMS.**

10 (a) **COOPERATIVE AGREEMENT APPLICATIONS FOR**
11 **IMPROVING STATE AND LOCAL PUBLIC HEALTH SECUR-**
12 **ITY.**—Section 319C–1 (42 U.S.C. 247d–3a) is amend-
13 ed—

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

17 (2) in subsection (b)(2)(A)—

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

23 (B) by redesignating clauses (vii) through
24 (ix) as clauses (viii) through (x);

1 (C) by inserting after clause (vi) the fol-
2 lowing:

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

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

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

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

17 “(xii) a description of how, as appro-
18 priate and practicable, the entity will in-
19 clude critical infrastructure partners, such
20 as utility companies within the entity’s ju-
21 risdiction, in planning pursuant to this
22 subparagraph to help ensure that critical
23 infrastructure will remain functioning dur-
24 ing, or return to function as soon as prac-
25 ticable after, a public health emergency;”.

1 (b) EXCEPTION RELATING TO APPLICATION OF CER-
2 TAIN REQUIREMENTS.—

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

5 (A) in paragraph (5)—

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

10 (ii) in subparagraph (A)—

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

15 (II) by striking “2008” and in-
16 serting “2018”; and

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

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

24 “(i) For no more than one of each of
25 the first 2 fiscal years immediately fol-

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

7 “(ii) For no more than one of the first
8 2 fiscal years immediately following the
9 third consecutive fiscal year in which an
10 entity experienced such a failure, in lieu of
11 applying clause (i), an amount equal to 15
12 percent of the amount the entity was eligi-
13 ble to receive for the respective fiscal
14 year.”.

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

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

22 (1) in subsection (a)—

23 (A) by inserting “, acting through the As-
24 sistant Secretary for Preparedness and Re-
25 sponse,” after “The Secretary”; and

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

5 (2) in subsection (b)(1)(A)—

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

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

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

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

14 (3) in subsection (d)—

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

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

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

23 (5) in subsection (g)(2)—

24 (A) by striking “Partnerships” and insert-
25 ing “Coalitions”;

1 (B) by striking “partnerships” and insert-
 2 ing “coalitions”; and

3 (C) by inserting “and response” after
 4 “preparedness”; and

5 (6) in subsection (i)(1)—

6 (A) by striking “An entity” and inserting
 7 “A coalition”; and

8 (B) by striking “such partnership” and in-
 9 serting “such coalition”.

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

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

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

25 “(1) IN GENERAL.—

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

7 “(B) RESERVATION OF AMOUNTS FOR RE-
8 GIONAL SYSTEMS.—

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

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

1 for the purpose of carrying out this section
 2 is not less than the amount available for
 3 such purpose for the previous fiscal year.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23 “(2) consult and engage with appropriate
24 health care providers and professionals, including
25 physicians, nurses, first responders, health care fa-

1 facilities (including hospitals, primary care clinics,
2 community health centers, mental health facilities,
3 ambulatory care facilities, and dental health facili-
4 ties), pharmacies, emergency medical providers,
5 trauma care providers, environmental health agen-
6 cies, public health laboratories, poison control cen-
7 ters, blood banks, tissue banks, and other experts
8 that the Assistant Secretary determines appropriate,
9 to meet the goals under section 2802(b)(3);

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

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

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

1 ance and consultation toward meeting the guidelines de-
2 scribed in subsection (b).

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

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

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

18 (b) GAO REPORT TO CONGRESS.—

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

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

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

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

21 (B) recommendations to reduce gaps in in-
22 centives for regional health partners, including
23 hospitals and health care facilities, to improve
24 capacity and medical surge capabilities to pre-
25 pare for, and respond to, public health emer-

1 agencies, consistent with subsection (a), which
2 may include consideration of facilities partici-
3 pating in programs under section 319C-2 of
4 the Public Health Service Act (42 U.S.C.
5 247d-3b) or in programs under the Centers for
6 Medicare & Medicaid Services (including inno-
7 vative health care delivery and payment mod-
8 els), and input from private sector financial in-
9 stitutions.

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

14 (A) the Assistant Secretary for Prepared-
15 ness and Response;

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

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

20 (D) the Assistant Secretary for Mental
21 Health and Substance Use;

22 (E) the Assistant Secretary of Labor for
23 Occupational Safety and Health; and

24 (F) the Secretary of Veterans Affairs.

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

8 (d) NATIONAL HEALTH SECURITY STRATEGY INCOR-
9 PORATION OF REGIONALIZED EMERGENCY PREPARED-
10 NESS AND RESPONSE.—Subparagraph (G) of section
11 2802(b)(3) (42 U.S.C. 300hh–1(b)(3)) is amended to read
12 as follows:

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

19 (e) IMPROVING STATE AND LOCAL PUBLIC HEALTH
20 SECURITY.—

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

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

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

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

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

9 (C) by inserting after clause (i) the fol-
10 lowing:

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

14 **SEC. 204. MILITARY AND CIVILIAN PARTNERSHIP FOR**
15 **TRAUMA READINESS.**

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

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

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

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

24 “(1) IN GENERAL.—The Secretary, acting
25 through the Assistant Secretary for Preparedness

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

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

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

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

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

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

24 “(1) IN GENERAL.—The Secretary, acting
25 through the Assistant Secretary for Preparedness

1 and Response and in consultation with the Secretary
2 of Defense, shall award grants to eligible trauma
3 centers to enable military trauma care providers to
4 provide trauma care and related acute care at such
5 trauma centers.

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

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

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

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

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

20 “(c) GRANT REQUIREMENTS.—

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

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

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

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

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

24 “(e) REPORTING REQUIREMENTS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15 “(B) At least 20 percent of patients treat-
16 ed at such trauma center in the most recent 3-
17 month period for which data are available are
18 treated for a major trauma at such trauma cen-
19 ter.

20 “(C) Such trauma center utilizes a risk-ad-
21 justed benchmarking system and metrics to
22 measure performance, quality, and patient out-
23 comes.

24 “(D) Such trauma center is an academic
25 training center—

1 “(i) affiliated with a medical school;

2 “(ii) that maintains residency pro-
3 grams and fellowships in critical trauma
4 specialties and subspecialties, and provides
5 education and supervision of military trau-
6 ma team members according to those spe-
7 cialties and subspecialties; and

8 “(iii) that undertakes research in the
9 prevention and treatment of traumatic in-
10 jury.

11 “(E) Such trauma center serves as a med-
12 ical and public health preparedness and re-
13 sponse leader for its community, such as by
14 participating in a partnership for State and re-
15 gional hospital preparedness established under
16 section 319C-2 or 319C-3.

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

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

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

5 “(C) Such trauma center demonstrates a
6 need for integrated military trauma care pro-
7 viders to maintain or improve the trauma clin-
8 ical capability of such trauma center.

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

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

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

1 “(g) AUTHORIZATION OF APPROPRIATIONS.—To
2 carry out this section, there is authorized to be appro-
3 priated \$11,500,000 for each of fiscal years 2019 through
4 2023.”.

5 **SEC. 205. PUBLIC HEALTH AND HEALTH CARE SYSTEM SIT-**
6 **UATIONAL AWARENESS AND BIOSURVEIL-**
7 **LANCE CAPABILITIES.**

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

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

14 (2) in subsection (a)—

15 (A) in the subsection heading, by striking
16 “FACILITIES; CAPACITIES” and inserting “IN
17 GENERAL”;

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

21 (C) in paragraph (3), in the matter pre-
22 ceding subparagraph (A), by striking “expand,
23 enhance, and improve” and inserting “expand,
24 improve, enhance, and appropriately maintain”;
25 and

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

2 “(4) STUDY OF RESOURCES FOR FACILITIES
3 AND CAPACITIES.—Not later than June 1, 2022, the
4 Comptroller General of the United States shall con-
5 duct a study on Federal spending in fiscal years
6 2013 through 2018 for activities authorized under
7 this subsection. Such study shall include a review
8 and assessment of obligations and expenditures di-
9 rectly related to each activity under paragraphs (2)
10 and (3), including a specific accounting of, and de-
11 lineation between, obligations and expenditures in-
12 curred for the construction, renovation, equipping,
13 and security upgrades of facilities and associated
14 contracts under this subsection, and the obligations
15 and expenditures incurred to establish and improve
16 the situational awareness and biosurveillance net-
17 work under subsection (b), and shall identify the
18 agency or agencies incurring such obligations and
19 expenditures.”;

20 (3) in subsection (b)—

21 (A) in the subsection heading, by striking
22 “NATIONAL” and inserting “ESTABLISHMENT
23 OF SYSTEMS OF PUBLIC HEALTH”;

1 (B) in paragraph (1)(B), by inserting “im-
2 munization information systems,” after “cen-
3 ters,”;

4 (C) in paragraph (2)—

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

7 (ii) by inserting “and in a form read-
8 ily usable for analytical approaches” after
9 “in a secure manner”; and

10 (D) by amending paragraph (3) to read as
11 follows:

12 “(3) STANDARDS.—

13 “(A) IN GENERAL.—Not later than 1 year
14 after the date of the enactment of the Pan-
15 demic and All-Hazards Preparedness and Ad-
16 vancing Innovation Act of 2019, the Secretary,
17 in cooperation with health care providers, State,
18 local, Tribal, and territorial public health offi-
19 cials, and relevant Federal agencies (including
20 the Office of the National Coordinator for
21 Health Information Technology and the Na-
22 tional Institute of Standards and Technology),
23 shall, as necessary, adopt technical and report-
24 ing standards, including standards for inter-
25 operability as defined by section 3000, for net-

1 works under paragraph (1) and update such
2 standards as necessary. Such standards shall be
3 made available on the internet website of the
4 Department of Health and Human Services, in
5 a manner that does not compromise national se-
6 curity.

7 “(B) DEFERENCE TO STANDARDS DEVEL-
8 OPMENT ORGANIZATIONS.—In adopting and im-
9 plementing standards under this subsection and
10 subsection (c), the Secretary shall give def-
11 erence to standards published by standards de-
12 velopment organizations and voluntary con-
13 sensus-based standards entities.”;

14 (4) in subsection (c)—

15 (A) in paragraph (1)—

16 (i) by striking “Not later than 2 years
17 after the date of enactment of the Pan-
18 demic and All-Hazards Preparedness Re-
19 authorization Act of 2013, the Secretary”
20 and inserting “The Secretary”;

21 (ii) by inserting “, and improve as ap-
22 plicable and appropriate,” after “shall es-
23 tablish”;

24 (iii) by striking “of rapid” and insert-
25 ing “of, rapid”; and

1 (iv) by striking “such connectivity”
2 and inserting “such interoperability”;

3 (B) by amending paragraph (2) to read as
4 follows:

5 “(2) COORDINATION AND CONSULTATION.—In
6 establishing and improving the network under para-
7 graph (1), the Secretary shall—

8 “(A) facilitate coordination among agencies
9 within the Department of Health and Human
10 Services that provide, or have the potential to
11 provide, information and data to, and analyses
12 for, the situational awareness and biosurveil-
13 lance network under paragraph (1), including
14 coordination among relevant agencies related to
15 health care services, the facilitation of health
16 information exchange (including the Office of
17 the National Coordinator for Health Informa-
18 tion Technology), and public health emergency
19 preparedness and response; and

20 “(B) consult with the Secretary of Agri-
21 culture, the Secretary of Commerce (and the
22 Director of the National Institute of Standards
23 and Technology), the Secretary of Defense, the
24 Secretary of Homeland Security, the Secretary
25 of Veterans Affairs, and the heads of other

1 Federal agencies, as the Secretary determines
2 appropriate.”;

3 (C) in paragraph (3)—

4 (i) by redesignating subparagraphs
5 (A) through (E) as clauses (i) through (v),
6 respectively, and adjusting the margins ac-
7 cordingly;

8 (ii) in clause (iv), as so redesign-
9 nated—

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

13 (II) by striking “and clinical lab-
14 oratories” and inserting “, clinical
15 laboratories, and public environmental
16 health agencies”;

17 (iii) by striking “The network” and
18 inserting the following:

19 “(A) IN GENERAL.—The network”; and

20 (iv) by adding at the end the fol-
21 lowing:

22 “(B) REVIEW.—Not later than 2 years
23 after the date of the enactment of the Pan-
24 demic and All-Hazards Preparedness and Ad-
25 vancing Innovation Act of 2019 and every 6

1 years thereafter, the Secretary shall conduct a
2 review of the elements described in subpara-
3 graph (A). Such review shall include a discus-
4 sion of the addition of any elements pursuant to
5 clause (v), including elements added to advanc-
6 ing new technologies, and identify any chal-
7 lenges in the incorporation of elements under
8 subparagraph (A). The Secretary shall provide
9 such review to the congressional committees of
10 jurisdiction.”;

11 (D) in paragraph (5)—

12 (i) by redesignating subparagraphs
13 (A) through (D) as clauses (i) through
14 (iv), respectively, and adjusting the mar-
15 gins accordingly;

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

18 “(A) IN GENERAL.—In establishing”;

19 (iii) by adding at the end the fol-
20 lowing:

21 “(B) PUBLIC MEETING.—

22 “(i) IN GENERAL.—Not later than
23 180 days after the date of enactment of
24 the Pandemic and All-Hazards Prepared-
25 ness and Advancing Innovation Act of

1 2019, the Secretary shall convene a public
2 meeting for purposes of discussing and
3 providing input on the potential goals,
4 functions, and uses of the network de-
5 scribed in paragraph (1) and incorporating
6 the elements described in paragraph
7 (3)(A).

8 “(ii) EXPERTS.—The public meeting
9 shall include representatives of relevant
10 Federal agencies (including representatives
11 from the Office of the National Coordi-
12 nator for Health Information Technology
13 and the National Institute of Standards
14 and Technology); State, local, Tribal, and
15 territorial public health officials; stake-
16 holders with expertise in biosurveillance
17 and situational awareness; stakeholders
18 with expertise in capabilities relevant to
19 biosurveillance and situational awareness,
20 such as experts in informatics and data
21 analytics (including experts in prediction,
22 modeling, or forecasting); and other rep-
23 resentatives as the Secretary determines
24 appropriate.

1 “(iii) TOPICS.—Such public meeting
2 shall include a discussion of—

3 “(I) data elements, including
4 minimal or essential data elements,
5 that are voluntarily provided for such
6 network, which may include elements
7 from public health and public and pri-
8 vate health care entities, to the extent
9 practicable;

10 “(II) standards and implementa-
11 tion specifications that may improve
12 the collection, analysis, and interpre-
13 tation of data during a public health
14 emergency;

15 “(III) strategies to encourage the
16 access, exchange, and use of informa-
17 tion;

18 “(IV) considerations for State,
19 local, Tribal, and territorial capabili-
20 ties and infrastructure related to data
21 exchange and interoperability;

22 “(V) privacy and security protec-
23 tions provided at the Federal, State,
24 local, Tribal, and territorial levels,

1 and by nongovernmental stakeholders;

2 and

3 “(VI) opportunities for the incor-
4 poration of innovative technologies to
5 improve the network.”; and

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

8 (I) in clause (i), as so redesign-
9 nated—

10 (aa) by striking “as deter-
11 mined” and inserting “as adopt-
12 ed”; and

13 (bb) by inserting “and the
14 National Institute of Standards
15 and Technology” after “Office of
16 the National Coordinator for
17 Health Information Technology”;

18 (II) in clause (iii), as so redesign-
19 nated, by striking “; and” and insert-
20 ing a semicolon;

21 (III) in clause (iv), as so redesign-
22 nated, by striking the period and in-
23 serting “; and”; and

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

1 “(v) pilot test standards and imple-
2 mentation specifications, consistent with
3 the process described in section
4 3002(b)(3)(C), which State, local, Tribal,
5 and territorial public health entities may
6 utilize, on a voluntary basis, as a part of
7 the network.”;

8 (E) by redesignating paragraph (6) as
9 paragraph (7);

10 (F) by inserting after paragraph (5) the
11 following:

12 “(6) STRATEGY AND IMPLEMENTATION
13 PLAN.—

14 “(A) IN GENERAL.—Not later than 18
15 months after the date of enactment of the Pan-
16 demic and All-Hazards Preparedness and Ad-
17 vancing Innovation Act of 2019, the Secretary
18 shall submit to the congressional committees of
19 jurisdiction a coordinated strategy and an ac-
20 companying implementation plan that—

21 “(i) is informed by the public meeting
22 under paragraph (5)(B);

23 “(ii) includes a review and assessment
24 of existing capabilities of the network and
25 related infrastructure, including input pro-

1 vided by the public meeting under para-
2 graph (5)(B);

3 “(iii) identifies and demonstrates the
4 measurable steps the Secretary will carry
5 out to—

6 “(I) develop, implement, and
7 evaluate the network described in
8 paragraph (1), utilizing elements de-
9 scribed in paragraph (3)(A);

10 “(II) modernize and enhance bio-
11 surveillance activities, including strat-
12 egies to include innovative tech-
13 nologies and analytical approaches
14 (including prediction and forecasting
15 for pandemics and all-hazards) from
16 public and private entities;

17 “(III) improve information shar-
18 ing, coordination, and communication
19 among disparate biosurveillance sys-
20 tems supported by the Department of
21 Health and Human Services, includ-
22 ing the identification of methods to
23 improve accountability, better utilize
24 resources and workforce capabilities,
25 and incorporate innovative tech-

1 nologies within and across agencies;
2 and

3 “(IV) test and evaluate capabilities
4 ties of the interoperable network of
5 systems to improve situational aware-
6 ness and biosurveillance capabilities;

7 “(iv) includes performance measures
8 and the metrics by which performance
9 measures will be assessed with respect to
10 the measurable steps under clause (iii);
11 and

12 “(v) establishes dates by which each
13 measurable step under clause (iii) will be
14 implemented.

15 “(B) ANNUAL BUDGET PLAN.—Not later
16 than 2 years after the date of enactment of the
17 Pandemic and All-Hazards Preparedness and
18 Advancing Innovation Act of 2019 and on an
19 annual basis thereafter, in accordance with the
20 strategy and implementation plan under this
21 paragraph, the Secretary shall, taking into ac-
22 count recommendations provided by the Na-
23 tional Biodefense Science Board, develop a
24 budget plan based on the strategy and imple-

1 mentation plan under this section. Such budget
2 plan shall include—

3 “(i) a summary of resources pre-
4 viously expended to establish, improve, and
5 utilize the nationwide public health situa-
6 tional awareness and biosurveillance net-
7 work under paragraph (1);

8 “(ii) estimates of costs and resources
9 needed to establish and improve the net-
10 work under paragraph (1) according to the
11 strategy and implementation plan under
12 subparagraph (A);

13 “(iii) the identification of gaps and in-
14 efficiencies in nationwide public health sit-
15 uational awareness and biosurveillance ca-
16 pabilities, resources, and authorities need-
17 ed to address such gaps; and

18 “(iv) a strategy to minimize and ad-
19 dress such gaps and improve inefficien-
20 cies.”;

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

22 (i) in subparagraph (A), by inserting
23 “(taking into account zoonotic disease, in-
24 cluding gaps in scientific understanding of
25 the interactions between human, animal,

1 and environmental health)” after “human
2 health”;

3 (ii) in subparagraph (B)—

4 (I) by inserting “and gaps in sur-
5 veillance programs” after “surveil-
6 lance programs”; and

7 (II) by striking “; and” and in-
8 serting a semicolon;

9 (iii) in subparagraph (C)—

10 (I) by inserting “, animal health
11 organizations related to zoonotic dis-
12 ease,” after “health care entities”;
13 and

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

16 (iv) by adding at the end the fol-
17 lowing:

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

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

23 “(8) SITUATIONAL AWARENESS AND BIO-
24 SURVEILLANCE AS A NATIONAL SECURITY PRI-
25 ORITY.—The Secretary, on a periodic basis as appli-

1 cable and appropriate, shall meet with the Director
2 of National Intelligence to inform the development
3 and capabilities of the nationwide public health situ-
4 ational awareness and biosurveillance network.”;

5 (5) in subsection (d)—

6 (A) in paragraph (1)—

7 (i) by inserting “environmental health
8 agencies,” after “public health agencies,”;
9 and

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

12 (B) in paragraph (2)—

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

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

17 (iii) by adding after subparagraph (C)
18 the following:

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

22 (C) by striking paragraph (5) and insert-
23 ing the following:

24 “(5) TECHNICAL ASSISTANCE.—The Secretary
25 may provide technical assistance to States, localities,

1 Tribes, and territories or a consortium of States, lo-
2 calities, Tribes, and territories receiving an award
3 under this subsection regarding interoperability and
4 the technical standards set forth by the Secretary.”;

5 (6) by redesignating subsections (f) and (g) as
6 subsections (i) and (j), respectively; and

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

9 “(f) PERSONNEL AUTHORITIES.—

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

13 “(A) appoint highly qualified individuals to
14 scientific or professional positions at the Cen-
15 ters for Disease Control and Prevention, not to
16 exceed 30 such employees at any time (specific
17 to positions authorized by this subsection), with
18 expertise in capabilities relevant to biosurveil-
19 lance and situational awareness, such as experts
20 in informatics and data analytics (including ex-
21 perts in prediction, modeling, or forecasting),
22 and other related scientific or technical fields;
23 and

24 “(B) compensate individuals appointed
25 under subparagraph (A) in the same manner

1 and subject to the same terms and conditions in
2 which individuals appointed under 9903 of title
3 5, United States Code, are compensated, with-
4 out regard to the provisions of chapter 51 and
5 subchapter III of chapter 53 of such title relat-
6 ing to classification and General Schedule pay
7 rates.

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

12 “(g) TIMELINE.—The Secretary shall accomplish the
13 purposes under subsections (b) and (c) no later than Sep-
14 tember 30, 2023, and shall provide a justification to the
15 congressional committees of jurisdiction for any missed or
16 delayed implementation of measurable steps identified
17 under subsection (c)(6)(A)(iii).

18 “(h) INDEPENDENT EVALUATION.—Not later than 3
19 years after the date of enactment of the Pandemic and
20 All-Hazards Preparedness and Advancing Innovation Act
21 of 2019, the Comptroller General of the United States
22 shall conduct an independent evaluation and submit to the
23 Secretary and the congressional committees of jurisdiction
24 a report concerning the activities conducted under sub-
25 sections (b) and (c), and provide recommendations, as ap-

1 plicable and appropriate, on necessary improvements to
2 the biosurveillance and situational awareness network.”.

3 (b) AUTHORIZATION OF APPROPRIATIONS.—Sub-
4 section (i) of section 319D (42 U.S.C. 247d–4), as reded-
5 icated by subsection (a)(6), is amended by striking
6 “\$138,300,000 for each of fiscal years 2014 through
7 2018” and inserting “\$161,800,000 for each of fiscal
8 years 2019 through 2023”.

9 (c) BIOLOGICAL THREAT DETECTION REPORT.—The
10 Secretary of Health and Human Services shall, in coordi-
11 nation with the Secretary of Defense and the Secretary
12 of Homeland Security, not later than 180 days after the
13 date of enactment of this Act, report to the Committee
14 on Energy and Commerce, the Committee on Armed Serv-
15 ices, and the Committee on Homeland Security of the
16 House of Representatives and the Committee on Health,
17 Education, Labor, and Pensions, the Committee on Armed
18 Services, and the Committee on Homeland Security and
19 Governmental Affairs of the Senate on the state of Fed-
20 eral biological threat detection efforts, including the fol-
21 lowing:

22 (1) An identification of technological, oper-
23 ational, and programmatic successes and failures of
24 domestic detection programs supported by Federal
25 departments and agencies for intentionally intro-

1 duced or accidentally released biological threat
2 agents and naturally occurring infectious diseases.

3 (2) A description of Federal efforts to facilitate
4 the exchange of information related to the informa-
5 tion described in paragraph (1) among Federal de-
6 partments and agencies that utilize biological threat
7 detection technology.

8 (3) A description of the capabilities of detection
9 systems in use by Federal departments and agencies
10 including the capability to—

11 (A) rapidly detect, identify, characterize,
12 and confirm the presence of biological threat
13 agents;

14 (B) recover live biological agents from col-
15 lection devices;

16 (C) determine the geographical distribution
17 of biological agents;

18 (D) determine the extent of environmental
19 contamination and persistence of biological
20 agents; and

21 (E) provide advanced molecular diagnostics
22 to State, local, Tribal, and territorial public
23 health and other laboratories that support bio-
24 logical threat detection activities.

1 (4) A description of Federal interagency coordi-
2 nation related to biological threat detection.

3 (5) A description of efforts by Federal depart-
4 ments and agencies that utilize biological threat de-
5 tection technology to collaborate with State, local,
6 Tribal, and territorial public health laboratories and
7 other users of biological threat detection systems, in-
8 cluding collaboration regarding the development of—

9 (A) biological threat detection require-
10 ments or standards;

11 (B) a standardized integration strategy;

12 (C) training requirements or guidelines;

13 (D) guidelines for a coordinated public
14 health response, including preparedness capa-
15 bilities, and, as applicable, for coordination with
16 public health surveillance systems; and

17 (E) a coordinated environmental remedi-
18 ation plan, as applicable.

19 (6) Recommendations related to research, ad-
20 vanced research, development, and procurement for
21 Federal departments and agencies to improve and
22 enhance biological threat detection systems, includ-
23 ing recommendations on the transfer of biological
24 threat detection technology among Federal depart-
25 ments and agencies, as necessary and appropriate.

1 **SEC. 206. STRENGTHENING AND SUPPORTING THE PUBLIC**
2 **HEALTH EMERGENCY RAPID RESPONSE**
3 **FUND.**

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

5 (1) in subsection (b)—

6 (A) in paragraph (1)—

7 (i) in the first sentence, by inserting
8 “or if the Secretary determines there is the
9 significant potential for a public health
10 emergency, to allow the Secretary to rap-
11 idly respond to the immediate needs result-
12 ing from such public health emergency or
13 potential public health emergency” before
14 the period; and

15 (ii) by inserting “The Secretary shall
16 plan for the expedited distribution of funds
17 to appropriate agencies and entities.” after
18 the first sentence;

19 (B) by redesignating paragraph (2) as
20 paragraph (3);

21 (C) by inserting after paragraph (1) the
22 following:

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

25 “(A) facilitate coordination between and
26 among Federal, State, local, Tribal, and terri-

1 torial entities and public and private health
2 care entities that the Secretary determines may
3 be affected by a public health emergency or po-
4 tential public health emergency referred to in
5 paragraph (1) (including communication of
6 such entities with relevant international enti-
7 ties, as applicable);

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

14 “(C) facilitate and accelerate, as applica-
15 ble, advanced research and development of secu-
16 rity countermeasures (as defined in section
17 319F-2), qualified countermeasures (as defined
18 in section 319F-1), or qualified pandemic or
19 epidemic products (as defined in section 319F-
20 3), that are applicable to the public health
21 emergency or potential public health emergency
22 under paragraph (1);

23 “(D) strengthen biosurveillance capabilities
24 and laboratory capacity to identify, collect, and
25 analyze information regarding such public

1 health emergency or potential public health
2 emergency, including the systems under section
3 319D;

4 “(E) support initial emergency operations
5 and assets related to preparation and deploy-
6 ment of intermittent disaster response per-
7 sonnel under section 2812 and the Medical Re-
8 serve Corps under section 2813; and

9 “(F) carry out other activities, as the Sec-
10 retary determines applicable and appropriate.”;
11 and

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

14 “(4) REVIEW.—Not later than 2 years after the
15 date of enactment of the Pandemic and All-Hazards
16 Preparedness and Advancing Innovation Act of
17 2019, the Secretary, in coordination with the Assist-
18 ant Secretary for Preparedness and Response, shall
19 conduct a review of the Fund under this section and
20 provide recommendations to the Committee on
21 Health, Education, Labor, and Pensions and the
22 Committee on Appropriations of the Senate and the
23 Committee on Energy and Commerce and the Com-
24 mittee on Appropriations of the House of Represent-

1 atives on policies to improve such Fund for the uses
2 described in paragraph (2).

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

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

11 “(B) submit to the Committee on Health,
12 Education, Labor, and Pensions of the Senate
13 and the Committee on Energy and Commerce
14 of the House of Representatives a report on
15 such review, including recommendations related
16 to such review, as applicable.”; and

17 (2) in subsection (c)—

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

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

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

4 (a) IN GENERAL.—Section 319I (42 U.S.C. 247d–
5 7b) is amended—

6 (1) in the section heading, by striking
7 “**HEALTH PROFESSIONS VOLUNTEERS**” and in-
8 serting “**VOLUNTEER HEALTH PROFESSIONAL**”;

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

14 (3) in subsection (i), by adding at the end the
15 following: “In order to inform the development of
16 such mechanisms by States, the Secretary shall
17 make available information and material provided by
18 States that have developed mechanisms to waive the
19 application of licensing requirements to applicable
20 health professionals seeking to provide medical serv-
21 ices during a public health emergency. Such infor-
22 mation shall be made publicly available in a manner
23 that does not compromise national security.”; and

24 (4) in subsection (k), by striking “2014 through
25 2018” and inserting “2019 through 2023”.

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

5 “(iv) a description of the mechanism the
6 entity will implement to utilize the Emergency
7 Management Assistance Compact, or other mu-
8 tual aid agreement, for medical and public
9 health mutual aid, and, as appropriate, the ac-
10 tivities such entity will implement pursuant to
11 section 319I to improve enrollment and coordi-
12 nation of volunteer health care professionals
13 seeking to provide medical services during a
14 public health emergency, which may include—

15 “(I) providing a public method of
16 communication for purposes of volunteer
17 coordination (such as a phone number);

18 “(II) providing for optional registra-
19 tion to participate in volunteer services
20 during processes related to State medical
21 licensing, registration, or certification or
22 renewal of such licensing, registration, or
23 certification; or

24 “(III) other mechanisms as the State
25 determines appropriate;”.

1 **SEC. 208. CLARIFYING STATE LIABILITY LAW FOR VOLUN-**
2 **TEER HEALTH CARE PROFESSIONALS.**

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

5 **“SEC. 225. HEALTH CARE PROFESSIONALS ASSISTING DUR-**
6 **ING A PUBLIC HEALTH EMERGENCY.**

7 “(a) LIMITATION ON LIABILITY.—Notwithstanding
8 any other provision of law, a health care professional who
9 is a member of the Medical Reserve Corps under section
10 2813 or who is included in the Emergency System for Ad-
11 vance Registration of Volunteer Health Professionals
12 under section 319I and who—

13 “(1) is responding—

14 “(A) to a public health emergency deter-
15 mined under section 319(a), during the initial
16 period of not more than 90 days (as determined
17 by the Secretary) of the public health emer-
18 gency determination (excluding any period cov-
19 ered by a renewal of such determination); or

20 “(B) to a major disaster or an emergency
21 as declared by the President under section 401
22 of the Robert T. Stafford Disaster Relief and
23 Emergency Assistance Act (42 U.S.C. 5170) or
24 under section 201 of the National Emergencies
25 Act (50 U.S.C. 1621) during the initial period
26 of such declaration;

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

3 “(A) during the initial period of a deter-
4 mination or declaration described in paragraph
5 (1) and related to the treatment of individuals
6 in need of health care services due to such pub-
7 lic health emergency, major disaster, or emer-
8 gency;

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

11 “(C) in the health care professional’s ca-
12 pacity as a member of the Medical Reserve
13 Corps or a professional included in the Emer-
14 gency System for Advance Registration of Vol-
15 unteer Health Professionals under section 319I;
16 and

17 “(D) in the course of providing services
18 that are within the scope of the license, reg-
19 istration, or certification of the professional, as
20 defined by the State of licensure, registration,
21 or certification; and

22 “(3) prior to the rendering of such act or omis-
23 sion, was authorized by the State’s authorization of
24 deploying such State’s Emergency System for Ad-
25 vance Registration of Volunteer Health Professionals

1 described in section 319I or the Medical Reserve
2 Corps established under section 2813, to provide
3 health care services,
4 shall be subject only to the State liability laws of the State
5 in which such act or omission occurred, in the same man-
6 ner and to the same extent as a similar health care profes-
7 sional who is a resident of such State would be subject
8 to such State laws, except with respect to the licensure,
9 registration, and certification of such individual.

10 “(b) VOLUNTEER PROTECTION ACT.—Nothing in
11 this section shall be construed to affect an individual’s
12 right to protections under the Volunteer Protection Act
13 of 1997.

14 “(c) PREEMPTION.—This section shall supersede the
15 laws of any State that would subject a health care profes-
16 sional described in subsection (a) to the liability laws of
17 any State other than the State liability laws to which such
18 individual is subject pursuant to such subsection.

19 “(d) DEFINITIONS.—In this section:

20 “(1) The term ‘health care professional’ means
21 an individual licensed, registered, or certified under
22 Federal or State laws or regulations to provide
23 health care services.

24 “(2) The term ‘health care services’ means any
25 services provided by a health care professional, or by

1 any individual working under the supervision of a
2 health care professional, that relate to—

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

5 “(B) the assessment or care of the health
6 of human beings.

7 “(e) EFFECTIVE DATE.—

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

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

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

19 (1) the number of health care providers who
20 register under the Emergency System for Advance
21 Registration of Volunteer Health Professionals
22 under section 319I of the Public Health Service Act
23 (42 U.S.C. 247d–7b) in advance to provide services
24 during a public health emergency;

1 (2) the number of health care providers who are
2 credentialed to provide services during the period of
3 a public health emergency declaration, including
4 those who are credentialed through programs estab-
5 lished in the Emergency System for Advance Reg-
6 istration of Volunteer Health Professionals under
7 such section 319I and those credentialed by authori-
8 ties within the State in which the emergency oc-
9 curred;

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

18 (4) the Emergency System for Advance Reg-
19 istration of Volunteer Health Professionals program
20 in States, including whether physician or medical
21 groups, associations, or other relevant provider orga-
22 nizations utilize such program for purposes of volun-
23 teering during public health emergencies.

1 **SEC. 209. REPORT ON ADEQUATE NATIONAL BLOOD SUP-**
2 **PLY.**

3 Not later than 1 year after the date of the enactment
4 of this Act, the Secretary of Health and Human Services
5 shall submit to Congress a report containing recommenda-
6 tions related to maintaining an adequate national blood
7 supply, including—

8 (1) challenges associated with the continuous
9 recruitment of blood donors (including those newly
10 eligible to donate);

11 (2) ensuring the adequacy of the blood supply
12 in the case of public health emergencies;

13 (3) implementation of the transfusion trans-
14 mission monitoring system; and

15 (4) other measures to promote safety and inno-
16 vation, such as the development, use, or implementa-
17 tion of new technologies, processes, and procedures
18 to improve the safety and reliability of the blood
19 supply.

20 **SEC. 210. REPORT ON THE PUBLIC HEALTH PREPARED-**
21 **NESS AND RESPONSE CAPABILITIES AND CA-**
22 **PACITIES OF HOSPITALS, LONG-TERM CARE**
23 **FACILITIES, AND OTHER HEALTH CARE FA-**
24 **CILITIES.**

25 (a) STUDY.—

1 (1) IN GENERAL.—Not later than one year
2 after the date of enactment of this Act, the Sec-
3 retary of Health and Human Services shall enter
4 into an agreement with an appropriate entity to con-
5 duct a study regarding the public health prepared-
6 ness and response capabilities and medical surge ca-
7 pacities of hospitals, long-term care facilities, and
8 other health care facilities to prepare for, and re-
9 spond to, public health emergencies, including nat-
10 ural disasters.

11 (2) CONSULTATION.—In conducting the study
12 under paragraph (1), the entity shall consult with
13 Federal, State, local, Tribal, and territorial public
14 health officials (as appropriate), and health care
15 providers and facilities with experience in public
16 health preparedness and response activities.

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

19 (A) an evaluation of the current bench-
20 marks and objective standards, as applicable,
21 related to programs that support hospitals,
22 long-term care facilities, and other health care
23 facilities, and their effect on improving public
24 health preparedness and response capabilities
25 and medical surge capacities, including the

1 Hospital Preparedness Program, the Public
2 Health Emergency Preparedness cooperative
3 agreements, and the Regional Health Care
4 Emergency Preparedness and Response Sys-
5 tems under section 319C-3 of the Public
6 Health Service Act (as added by section 203);

7 (B) the identification of gaps in prepared-
8 ness, including with respect to such benchmarks
9 and objective standards, such as those identified
10 during recent public health emergencies, for
11 hospitals, long-term care facilities, and other
12 health care facilities to address future potential
13 public health threats;

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

23 (D) an evaluation of coordination efforts
24 between the recipients of Federal funding for
25 programs described in subparagraph (A) and

1 environmental health agencies with expertise in
2 emergency preparedness and response planning
3 for hospitals, long-term care facilities, and other
4 health care facilities; and

5 (E) an evaluation of current public health
6 preparedness and response capabilities and
7 medical surge capacities related to at-risk indi-
8 viduals during public health emergencies, in-
9 cluding an identification of gaps in such pre-
10 paredness as they relate to such individuals.

11 (b) REPORT.—

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

19 (2) CONTENTS.—The report under paragraph
20 (1) shall—

21 (A) describe the findings and conclusions
22 of the evaluation conducted pursuant to sub-
23 section (a); and

24 (B) provide recommendations for improv-
25 ing public health preparedness and response ca-

1 pability and medical surge capacity for hos-
 2 pitals, long-term care facilities, and other health
 3 care facilities, including—

4 (i) improving the existing benchmarks
 5 and objective standards for the Federal
 6 grant programs described in subsection
 7 (a)(3)(A) or developing new benchmarks
 8 and standards for such programs; and

9 (ii) identifying best practices for im-
 10 proving public health preparedness and re-
 11 sponse programs and medical surge capac-
 12 ity at hospitals, long-term care facilities,
 13 and other health care facilities, including
 14 recommendations for the evaluation under
 15 subparagraphs (C) and (D) of subsection
 16 (a)(3).

17 **TITLE III—REACHING ALL**
 18 **COMMUNITIES**

19 **SEC. 301. STRENGTHENING AND ASSESSING THE EMER-**
 20 **GENCY RESPONSE WORKFORCE.**

21 (a) NATIONAL DISASTER MEDICAL SYSTEM.—

22 (1) STRENGTHENING THE NATIONAL DISASTER
 23 MEDICAL SYSTEM.—Clause (ii) of section
 24 2812(a)(3)(A) (42 U.S.C. 300hh–11(a)(3)(A)) is
 25 amended to read as follows:

1 “(ii) be present at locations, and for
2 limited periods of time, specified by the
3 Secretary on the basis that the Secretary
4 has determined that a location is at risk of
5 a public health emergency during the time
6 specified, or there is a significant potential
7 for a public health emergency.”.

8 (2) REVIEW OF THE NATIONAL DISASTER MED-
9 ICAL SYSTEM.—Section 2812(b)(2) (42 U.S.C.
10 300hh–11(b)(2)) is amended to read as follows:

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

13 “(A) REVIEW.—Not later than 180 days
14 after the date of enactment of the Pandemic
15 and All-Hazards Preparedness and Advancing
16 Innovation Act of 2019, the Secretary, in co-
17 ordination with the Secretary of Homeland Se-
18 curity, the Secretary of Defense, and the Sec-
19 retary of Veterans Affairs, shall conduct a joint
20 review of the National Disaster Medical System.
21 Such review shall include—

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

24 “(ii) an assessment of the available
25 workforce of the intermittent disaster re-

1 sponse personnel described in subsection
2 (c);

3 “(iii) the capacity of the workforce de-
4 scribed in clause (ii) to respond to all haz-
5 ards, including capacity to simultaneously
6 respond to multiple public health emer-
7 gencies and the capacity to respond to a
8 nationwide public health emergency;

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

11 “(v) gaps that may exist in such
12 workforce and recommendations for ad-
13 dressing such gaps.

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

20 (3) NOTIFICATION OF SHORTAGE.—Section
21 2812(c) (42 U.S.C. 300hh–11(c)) is amended by
22 adding at the end the following:

23 “(3) NOTIFICATION.—Not later than 30 days
24 after the date on which the Secretary determines the
25 number of intermittent disaster-response personnel

1 of the National Disaster Medical System is insuffi-
2 cient to address a public health emergency or poten-
3 tial public health emergency, the Secretary shall sub-
4 mit to the congressional committees of jurisdiction a
5 notification detailing—

6 “(A) the impact such shortage could have
7 on meeting public health needs and emergency
8 medical personnel needs during a public health
9 emergency; and

10 “(B) any identified measures to address
11 such shortage.

12 “(4) CERTAIN APPOINTMENTS.—

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

1 “(B) SUNSET.—The authority under this
2 paragraph shall expire on September 30,
3 2021.”.

4 (4) AUTHORIZATION OF APPROPRIATIONS.—
5 Section 2812(g) (42 U.S.C. 300hh–11(g)) is amend-
6 ed by striking “\$52,700,000 for each of fiscal years
7 2014 through 2018” and inserting “\$57,400,000 for
8 each of fiscal years 2019 through 2023”.

9 (b) VOLUNTEER MEDICAL RESERVE CORPS.—

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

16 (2) AUTHORIZATION OF APPROPRIATIONS.—
17 Section 2813(i) (42 U.S.C. 300hh–15(i)) is amended
18 by striking “2014 through 2018” and inserting
19 “2019 through 2023”.

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

23 (1) in subsection (a)—

24 (A) in paragraph (1)—

1 (i) by inserting “or preparedness and
2 response activities, including rapid re-
3 sponse to public health emergencies and
4 significant public health threats” after
5 “conduct prevention activities”; and

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

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

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

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

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

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

1 (d) SERVICE BENEFIT FOR NATIONAL DISASTER
2 MEDICAL SYSTEM VOLUNTEERS.—

3 (1) IN GENERAL.—Section 2812(c) (42 U.S.C.
4 300hh–11(c)), as amended by subsection (a)(3), is
5 further amended by adding at the end the following:

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

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

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

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

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

24 “(E) an individual appointed to the Na-
25 tional Disaster Medical System under section

1 2812 of the Public Health Service Act (42
2 U.S.C. 300hh–11) who is performing official
3 duties of the Department of Health and Human
4 Services, if those official duties are—

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

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

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

17 (e) MISSION READINESS REPORT TO CONGRESS.—

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

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

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

10 (A) the number of health care providers
11 who have volunteered to provide health care
12 services during a public health emergency, in-
13 cluding members of the National Disaster Med-
14 ical System, the Disaster Medical Assistant
15 Teams, the Medical Reserve Corps, and other
16 volunteer health care professionals in the
17 verification network pursuant to section 319I of
18 the Public Health Service Act (42 U.S.C.
19 247d–7b);

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

1 and the capacity to respond to a nationwide
2 public health emergency;

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

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

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

20 **SEC. 302. HEALTH SYSTEM INFRASTRUCTURE TO IMPROVE**
21 **PREPAREDNESS AND RESPONSE.**

22 (a) COORDINATION OF PREPAREDNESS.—Section
23 2811(b)(5) (42 U.S.C. 300hh–10(b)(5)) is amended by
24 adding at the end the following: “Such logistical support
25 shall include working with other relevant Federal, State,

1 local, Tribal, and territorial public health officials and pri-
2 vate sector entities to identify the critical infrastructure
3 assets, systems, and networks needed for the proper func-
4 tioning of the health care and public health sectors that
5 need to be maintained through any emergency or disaster,
6 including entities capable of assisting with, responding to,
7 and mitigating the effect of a public health emergency,
8 including a public health emergency determined by the
9 Secretary pursuant to section 319(a) or an emergency or
10 major disaster declared by the President under the Robert
11 T. Stafford Disaster Relief and Emergency Assistance Act
12 or the National Emergencies Act, including by estab-
13 lishing methods to exchange critical information and de-
14 liver products consumed or used to preserve, protect, or
15 sustain life, health, or safety, and sharing of specialized
16 expertise.”.

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

22 (c) EVALUATION OF BARRIERS TO RAPID DELIVERY
23 OF MEDICAL COUNTERMEASURES.—

24 (1) RAPID DELIVERY STUDY.—The Assistant
25 Secretary for Preparedness and Response may con-

1 duct a study on issues that have the potential to ad-
2 versely affect the handling and rapid delivery of
3 medical countermeasures to individuals during public
4 health emergencies occurring in the United States.

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

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

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

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

5 (1) by striking “this section and sections 319C–
6 1, 319F, and 319L,” and inserting “this Act,”; and

7 (2) by striking “special” and inserting “access
8 or functional”.

9 (b) COUNTERMEASURE CONSIDERATIONS.—Section
10 319L(c)(6) (42 U.S.C. 247d–7e(c)(6)) is amended—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19 **TERS.**

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

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

25 (2) in subsection (d)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17 “(J) The Secretary of Education.

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

1 “(4) TERM OF APPOINTMENT.—Each member
2 of the Advisory Committee appointed under para-
3 graph (2) shall serve for a term of 3 years, except
4 that the Secretary may adjust the terms of the Advi-
5 sory Committee appointees serving on the date of
6 enactment of the Pandemic and All-Hazards Pre-
7 paredness and Advancing Innovation Act of 2019, or
8 appointees who are initially appointed after such
9 date of enactment, in order to provide for a stag-
10 gered term of appointment for all members.

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

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

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

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

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

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

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

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

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

15 “(b) **DUTIES.**—The Advisory Committee shall—

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

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

23 “(3) provide advice and consultation with re-
24 spect to State emergency preparedness and response
25 activities relating to seniors, including related drills

1 and exercises pursuant to the preparedness goals
2 under section 2802(b).

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

9 “(d) MEMBERSHIP.—

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

17 “(2) REQUIRED MEMBERS.—The Advisory
18 Committee shall include Federal members or their
19 designees (who may be nonvoting members, as deter-
20 mined by the Secretary) and non-Federal members,
21 as follows:

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

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

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

3 “(D) The Commissioner of Food and
4 Drugs.

5 “(E) The Director of the National Insti-
6 tutes of Health.

7 “(F) The Administrator of the Centers for
8 Medicare & Medicaid Services.

9 “(G) The Administrator of the Administra-
10 tion for Community Living.

11 “(H) The Administrator of the Federal
12 Emergency Management Agency.

13 “(I) The Under Secretary for Health of
14 the Department of Veterans Affairs.

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

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

23 “(L) Representatives of such other Federal
24 agencies (such as the Department of Energy
25 and the Department of Homeland Security) as

1 the Secretary determines necessary to fulfill the
2 duties of the Advisory Committee.

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

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

9 “(g) SUNSET.—

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

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

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

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

23 “(a) ESTABLISHMENT.—The Secretary, in consulta-
24 tion with the Secretary of Homeland Security, shall estab-
25 lish a national advisory committee to be known as the Na-

1 tional Advisory Committee on Individuals with Disabilities
2 and Disasters (referred to in this section as the ‘Advisory
3 Committee’).

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

5 “(1) provide advice and consultation with re-
6 spect to activities carried out pursuant to section
7 2814, as applicable and appropriate;

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

13 “(3) provide advice and consultation with re-
14 spect to State emergency preparedness and response
15 activities, including related drills and exercises pur-
16 suant to the preparedness goals under section
17 2802(b).

18 “(c) MEMBERSHIP.—

19 “(1) IN GENERAL.—The Secretary, in consulta-
20 tion with such other heads of agencies and depart-
21 ments as appropriate, shall appoint not more than
22 17 members to the Advisory Committee. In appoint-
23 ing such members, the Secretary shall ensure that
24 the total membership of the Advisory Committee is
25 an odd number.

1 “(2) REQUIRED MEMBERS.—The Advisory
2 Committee shall include Federal members or their
3 designees (who may be nonvoting members, as deter-
4 mined by the Secretary) and non-Federal members,
5 as follows:

6 “(A) The Assistant Secretary for Pre-
7 paredness and Response.

8 “(B) The Administrator of the Administra-
9 tion for Community Living.

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

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

14 “(E) The Commissioner of Food and
15 Drugs.

16 “(F) The Director of the National Insti-
17 tutes of Health.

18 “(G) The Administrator of the Federal
19 Emergency Management Agency.

20 “(H) The Chair of the National Council on
21 Disability.

22 “(I) The Chair of the United States Access
23 Board.

24 “(J) The Under Secretary for Health of
25 the Department of Veterans Affairs.

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

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

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

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

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

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

25 “(g) SUNSET.—

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

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

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

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

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

1 meetings under any of sections 2811A(e), 2811B(e), or
2 2811C(d).

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

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

15 **SEC. 306. GUIDANCE FOR PARTICIPATION IN EXERCISES**
16 **AND DRILLS.**

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

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

14 **TITLE IV—PRIORITIZING A** 15 **THREAT-BASED APPROACH**

16 **SEC. 401. ASSISTANT SECRETARY FOR PREPAREDNESS AND** 17 **RESPONSE.**

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

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

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

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

16 **SEC. 402. PUBLIC HEALTH EMERGENCY MEDICAL COUN-**
17 **TERMEASURES ENTERPRISE.**

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

21 **“SEC. 2811-1. PUBLIC HEALTH EMERGENCY MEDICAL**
22 **COUNTERMEASURES ENTERPRISE.**

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

1 The Assistant Secretary for Preparedness and Response
2 shall serve as chair of the PHEMCE.

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

6 “(1) The Assistant Secretary for Preparedness
7 and Response.

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

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

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

13 “(5) The Secretary of Defense.

14 “(6) The Secretary of Homeland Security.

15 “(7) The Secretary of Agriculture.

16 “(8) The Secretary of Veterans Affairs.

17 “(9) The Director of National Intelligence.

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

1 “(c) FUNCTIONS.—

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

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

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

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

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

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

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

20 (b) PUBLIC HEALTH EMERGENCY MEDICAL COUN-
21 TERMEASURES ENTERPRISE STRATEGY AND IMPLEMEN-
22 TATION PLAN.—Section 2811(d) (42 U.S.C. 300hh–
23 10(d)) is amended—

24 (1) in paragraph (1)—

1 (A) by striking “Not later than 180 days
2 after the date of enactment of this subsection,
3 and every year thereafter” and inserting “Not
4 later than March 15, 2020, and biennially
5 thereafter”; and

6 (B) by striking “Director of the Bio-
7 medical” and all that follows through “Food
8 and Drugs” and inserting “Public Health
9 Emergency Medical Countermeasures Enter-
10 prise established under section 2811–1”; and

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

13 **SEC. 403. STRATEGIC NATIONAL STOCKPILE.**

14 (a) IN GENERAL.—Section 319F–2(a) (42 U.S.C.
15 247d–6b(a)) is amended—

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

18 (2) in paragraph (1)—

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

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

24 (C) by inserting “and, as informed by ex-
25 isting recommendations of, or consultations

1 with, the Public Health Emergency Medical
2 Countermeasure Enterprise established under
3 section 2811–1, make necessary additions or
4 modifications to the contents of such stockpile
5 or stockpiles based on the review conducted
6 under paragraph (2)” before the period of the
7 first sentence; and

8 (D) by striking the second sentence;

9 (3) by inserting after paragraph (1) the fol-
10 lowing:

11 “(2) THREAT-BASED REVIEW.—

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

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

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

12 “(i) information regarding—

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

17 “(II) planning considerations for
18 appropriate manufacturing capacity
19 and capability to meet the goals of
20 such additions or modifications (with-
21 out disclosing proprietary informa-
22 tion), including consideration of the
23 effect such additions or modifications
24 may have on the availability of such

1 products and ancillary medical sup-
2 plies in the health care system;

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

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

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

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

1 tion that is replacing an expiring or
2 expired countermeasure, or is a new
3 addition to the stockpile;

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

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

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

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

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

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

20 “(1) IN GENERAL.—In carrying out subsection
21 (b)(3), the Assistant Secretary for Preparedness and
22 Response shall implement strategic initiatives or ac-
23 tivities to address threats, including pandemic influ-
24 enza and which may include a chemical, biological,
25 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(e)(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).

1 “(C) DOCUMENTATION REQUIRED.—The
2 Assistant Secretary for Preparedness and Re-
3 sponse, in accordance with subsection (b)(7),
4 shall document amounts expended for purposes
5 of carrying out this subsection, including
6 amounts appropriated under the heading ‘Pub-
7 lic Health and Social Services Emergency
8 Fund’ under the heading ‘Office of the Sec-
9 retary’ under title II of division H of the Con-
10 solidated Appropriations Act, 2018 (Public Law
11 115–141) and allocated to carrying out section
12 319L(c)(4)(F).”.

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

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

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

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

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

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

24 “(A) IN GENERAL.—Not later than 1 year
25 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

1 procedures shall be used when enter-
2 ing into transactions to carry out
3 projects under this subsection.”; and

4 (ii) in subclause (II)—

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

7 (II) by striking “senior procure-
8 ment executive for the Department
9 (as designated for purpose of section
10 16(c) of the Office of Federal Pro-
11 curement Policy Act (41 U.S.C.
12 414(c))” and inserting “Assistant
13 Secretary for Financial Resources”;
14 and

15 (III) by striking “senior procure-
16 ment executive under” and inserting
17 “Assistant Secretary for Financial Re-
18 sources under”.

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

20 (a) IN GENERAL.—The purpose of this section (in-
21 cluding section 565B of the Federal Food, Drug, and Cos-
22 metic Act, as added by subsection (b)) is to support and
23 advance the development or manufacture of security coun-
24 termeasures, qualified countermeasures, and qualified
25 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(e), 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 termeasures, 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 requirements 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”;

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(e)(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).”.

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