

115TH CONGRESS
2D SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill; which was read twice
and referred to the Committee on _____

A BILL

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

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

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

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

7 (b) **TABLE OF CONTENTS.**—The table of contents for
8 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—STRENGTHENING THE NATIONAL HEALTH SECURITY
STRATEGY

2

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 public health emergency preparedness and response systems.

Sec. 204. Public health situational awareness and biosurveillance capabilities.

Sec. 205. Strengthening and supporting the public health emergency **[bridge]** fund.

Sec. 206. Improving preparedness for and response to all-hazards by public health emergency volunteers.

TITLE III—REACHING ALL COMMUNITIES

Sec. 301. Strengthening and assessing the emergency response workforce.

Sec. 302. Health system infrastructure to improve preparedness and response.

Sec. 303. Considerations for at-risk individuals.

Sec. 304. Improving emergency preparedness and response considerations for children.

Sec. 305. Reauthorizing the National Advisory Committee on Children and Disasters.

Sec. 306. Guidance for participation in exercises and drills.

TITLE IV—PRIORITIZING A THREAT-BASED APPROACH

Sec. 401. Assistant Secretary for Preparedness and Response.

Sec. 402. Public Health Emergency Medical Countermeasures Enterprise.

Sec. 403. Strategic National Stockpile.

Sec. 404. Preparing for pandemic influenza, antimicrobial resistance, and other significant threats.

Sec. 405. Reporting on the Federal Select Agent Program.

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

Sec. 501. Medical countermeasure budget plan.

Sec. 502. Material threat and medical countermeasure notifications.

Sec. 503. Availability of regulatory management plans.

Sec. 504. BARDA and the BioShield Special Reserve Fund.

TITLE VI—ADVANCING TECHNOLOGIES FOR MEDICAL COUNTERMEASURES

Sec. 601. Administration of countermeasures.

Sec. 602. Medical countermeasure master files.

Sec. 603. Animal rule report.

TITLE VII—MISCELLANEOUS PROVISIONS

Sec. 701. Reauthorizations and extensions.

Sec. 702. Technical amendments.

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

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

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

7 (1) in subsection (a)—

8 (A) in paragraph (1)—

9 (i) by striking “2014” and inserting
10 “2018”; and

11 (ii) by striking the second sentence
12 and inserting the following: “Such Na-
13 tional Health Security Strategy shall de-
14 scribe potential public health threats and
15 identify the process for achieving the pre-
16 paredness goals described in subsection (b)
17 to be prepared to respond to such threats
18 and shall be consistent with the National
19 Preparedness Goal, the National Incident
20 Management System, and the National Re-
21 sponse Plan developed pursuant to section
22 502(6) of the Homeland Security Act of
23 2002, or any successor plan.”;

24 (B) in paragraph (2), by inserting before
25 the period at the end of the second sentence the

1 following: “, and an analysis of any changes to
2 the evidence-based benchmarks and objective
3 standards under sections 319C–1 and 319C–2”;

4 (C) in paragraph (3)—

5 (i) by striking “2009” and inserting
6 “2018”;

7 (ii) by inserting “(including gaps in
8 the environmental health workforce), de-
9 scribing the status of such workforce”
10 after “gaps in such workforce”;

11 (iii) by striking “and identifying strat-
12 egies” and inserting “ identifying strate-
13 gies”; and

14 (iv) by inserting before the period at
15 the end “, and identifying current capabili-
16 ties to meet the requirements of section
17 2803”;

18 (2) in subsection (b)—

19 (A) in paragraph (2)—

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

24 (ii) in subparagraph (B), by striking
25 “and decontamination” and inserting “de-

1 contamination, health care services and
2 necessary medical supplies, and transpor-
3 tation and disposal of medical waste”; and

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

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

7 (B) in paragraph (3)(F), by inserting “or
8 exposures to agents that could cause a public
9 health emergency” after “workplace exposures”;

10 (C) by amending paragraph (5) by insert-
11 ing “and other applicable compacts” after
12 “Compact”; and

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

14 “(9) ZOONOTIC DISEASE, FOOD, AND AGRI-
15 CULTURE.—Improving coordination among Federal,
16 State, local, and tribal entities to prevent, detect,
17 and respond to outbreaks of plant or animal disease
18 (including zoonotic disease) resulting from a delib-
19 erate attack, the intentional adulteration of food, or
20 other public health threats that could compromise
21 national security, taking into account interactions
22 between animal health, human health, and environ-
23 mental health as directly related to public health
24 emergency preparedness and response capabilities,
25 as applicable.

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

5 **TITLE II—IMPROVING**
6 **PREPAREDNESS AND RESPONSE**

7 **SEC. 201. IMPROVING BENCHMARKS AND STANDARDS FOR**
8 **PREPAREDNESS AND RESPONSE.**

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

14 “(k) EVALUATION.—

15 “(1) IN GENERAL.—Not later than 2 years
16 after the date of enactment of the Pandemic and
17 All-Hazards Preparedness and Advancing Innovation
18 Act of 2018, and every 2 years thereafter, the Sec-
19 retary shall conduct an evaluation of the perform-
20 ance measures and evidence-based benchmarks and
21 objective standards that assess the ability of award-
22 ees to accomplish the activities described in this sec-
23 tion and section 319C–2. Such evaluation shall be
24 submitted to the relevant committees of Congress to-
25 gether with the National Health Security Strategy

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

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

5 “(A) a review of performance measures
6 and associated metrics, targets, and evidence-
7 based benchmarks;

8 “(B) a discussion of changes to any per-
9 formance measures and evidence-based bench-
10 marks and objective standards, and the effect of
11 such changes on the ability to track whether
12 awardees are meeting or making progress to-
13 ward the goals under this section and, to the
14 extent practicable, the applicable goals of the
15 National Health Security Strategy under sec-
16 tion 2802;

17 “(C) a description of allocations with re-
18 spect to amounts received by eligible entities
19 under subsection (b) and section 319C–2(b)
20 and amounts received by sub-recipients and the
21 effect of such allocations on meeting perform-
22 ance measures and evidence-based benchmarks
23 and objective standards; and

24 “(D) recommendations, as applicable and
25 appropriate, to improve performance measures

1 and evidence-based benchmarks and objective
2 standards to more accurately assess the ability
3 of entities receiving awards under this section
4 to better achieve the goals under this section
5 and section 2802.”.

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

12 **SEC. 202. AMENDMENTS TO PREPAREDNESS AND RE-**
13 **SPONSE PROGRAMS.**

14 (a) COOPERATIVE AGREEMENT APPLICATIONS FOR
15 IMPROVING STATE AND LOCAL PUBLIC HEALTH SECU-
16 RITY.—Section 319C–1 of the Public Health Service Act
17 (42 U.S.C. 247d–3a(b)(2)(A)) is amended—

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

21 (2) in subsection (b)(2)(A)—

22 (A) in clause (vi), by inserting “, including
23 public health agencies with specific expertise
24 that may be relevant to public health security,

1 such as environmental health agencies,” after
2 “stakeholders”;

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

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

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

12 (b) PUBLIC HEALTH SECURITY GRANTS AUTHORIZA-
13 TION OF APPROPRIATIONS.—Section 319C–1(h)(1)(A) of
14 the Public Health Service Act (42 U.S.C. 247d–
15 3a(h)(1)(A)) is amended—

16 (1) by striking “\$641,900,000 for fiscal year
17 2014” and inserting “**【\$xx】** for fiscal year 2019”;
18 and

19 (2) by striking “\$641,900,000 for each of fiscal
20 years 2015 through 2018” and inserting “**【\$xx】** for
21 each of fiscal years 2020 through 2023”.

22 (c) PARTNERSHIP FOR STATE AND REGIONAL HOS-
23 PITAL PREPAREDNESS TO IMPROVE SURGE CAPACITY AU-
24 THORIZATION OF APPROPRIATIONS.—Section 319C–
25 2(j)(1) of the Public Health Service Act (42 U.S.C. 247d–

1 3b(j)(1)) is amended by striking “\$374,700,000 for each
2 of fiscal years 2014 through 2018” and inserting “[~~\$xx~~]
3 for each of fiscal years 2019 through 2023”.

4 **SEC. 203. REGIONAL PUBLIC HEALTH EMERGENCY PRE-**
5 **PAREDNESS AND RESPONSE SYSTEMS.**

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

9 **“SEC. 319C–3. GUIDELINES FOR REGIONAL PUBLIC HEALTH**
10 **EMERGENCY PREPAREDNESS AND RESPONSE**
11 **SYSTEMS.**

12 “(a) PURPOSE.—It is the purpose of this section to
13 identify and provide guidelines for regional systems of hos-
14 pitals, health care facilities, and public health facilities
15 with varying levels of capability to treat patients and in-
16 crease medical surge capacity during and in advance of
17 a public health emergency, including threats posed by one
18 or more chemical, biological, radiological, and nuclear
19 agents, including emerging infectious diseases.

20 “(b) GUIDELINES.—The Assistant Secretary for Pre-
21 paredness and Response, in consultation with the Director
22 of the Centers for Disease Control and Prevention, the Ad-
23 ministrator of the Centers for Medicare & Medicaid Serv-
24 ices, the Assistant Secretary of Labor for Occupational
25 Safety and Health, the Secretary of Veterans Affairs, such

1 other Federal agencies as the Secretary determines to be
2 appropriate, and State, local, tribal, and territorial public
3 health officials, shall, not later than 1 year of the date
4 of enactment of this section—

5 “(1) identify and develop a set of guidelines re-
6 lating to practices and protocols for all-hazards pub-
7 lic health emergency preparedness and response for
8 applicable health care facilities and hospitals to pro-
9 vide appropriate patient care during or in advance of
10 a public health emergency, resulting from one or
11 more chemical, biological, radiological, or nuclear
12 agents, including emerging infectious diseases,
13 (which may include, as applicable and appropriate,
14 existing practices such as trauma care and medical
15 surge capacity and capabilities) with respect to—

16 “(A) establishing the capabilities of entities
17 described in clauses (i) and (ii) of section
18 319C–2(b)(1)(A) to identify, evaluate, and pro-
19 vide exposure response and disease containment
20 (within the meaning of section 2802(b)(2)(B));

21 “(B) a regional approach to identifying
22 hospitals and health care facilities based on
23 varying capabilities and capacity to treat pa-
24 tients affected by such emergency, which may
25 include informing and educating appropriate

1 first responders to a public health emergency of
2 the regional emergency preparedness and re-
3 sponse capabilities and medical surge capacity
4 of such hospitals and health care facilities in
5 the community;

6 “(C) physical infrastructure, laboratory ca-
7 pacity, and staffing needs, taking into account
8 resiliency and geographic considerations;

9 “(D) protocols or best practices for health
10 care worker safety and personal protection, in-
11 cluding protective equipment and supplies,
12 waste management processes and decontamina-
13 tion, and training, as applicable;

14 “(E) coordinated medical triage and trans-
15 portation to the appropriate hospitals or health
16 care facilities within the regional system, based
17 on patient medical need (including patients in
18 rural areas) or, as applicable and appropriate,
19 between systems in different States or regions;
20 and

21 “(F) the needs of at-risk individuals;

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

1 “(3) update such guidelines as appropriate, in-
2 cluding to address new and emerging public health
3 threats.

4 “(c) CONSIDERATIONS.—In identifying and devel-
5 oping guidelines under subsection (b), the Assistant Sec-
6 retary for Preparedness and Response shall—

7 “(1) consult and engage with appropriate
8 health care providers and professionals, including
9 physicians, nurses, first responders, health care fa-
10 cilities (including hospitals, primary care clinics,
11 community health centers, mental health facilities,
12 ambulatory care facilities, and dental health facili-
13 ties), pharmacies, emergency medical providers,
14 trauma care providers, State and local public health
15 departments, environmental health agencies, public
16 health laboratories, blood banks, and other health
17 care experts, including experts with relevant exper-
18 tise in chemical, biological, radiological, and nuclear
19 threats, and emerging infectious diseases that the
20 Assistant Secretary determines appropriate, to meet
21 the goals under section 2802(b)(3)(A);

22 “(2) consider feedback related to financial im-
23 plications for health care facilities and hospitals to
24 implement such guidelines, as applicable; and

1 “(3) consider financial requirements and poten-
2 tial incentives for facilities to prepare for and re-
3 spond to public health emergencies.

4 “(d) TECHNICAL ASSISTANCE.—The Assistant Sec-
5 retary for Preparedness and Response, in consultation
6 with the Director of the Centers for Disease Control and
7 Prevention, may provide technical assistance and consulta-
8 tion towards meeting the guidelines described in sub-
9 section (b).

10 “(e) GAO REPORT TO CONGRESS.—

11 “(1) REPORT.—Not later than 2 years after the
12 date of enactment of this section, the Comptroller
13 General shall submit to the Committee on Health,
14 Education, Labor, and Pensions and the Committee
15 on Finance of the Senate, and the Committee on
16 Energy and Commerce and the Committee on Ways
17 and Means of the House of Representatives, a report
18 on the extent to which health care facilities and hos-
19 pitals have implemented the recommended guidelines
20 under subsection (b), including an analysis and eval-
21 uation of any challenges health care facilities or hos-
22 pitals experienced in implementing such guidelines.

23 “(2) IMPLEMENTATION OF GUIDELINES.—The
24 Comptroller General shall include in the report
25 under paragraph (1), data on the preparedness and

1 response capabilities that have been informed by the
2 guidelines under subsection (b) to improve health
3 care facilities and hospital capacity and medical
4 surge capabilities to prepare for, and respond to,
5 public health emergencies.

6 “(3) RECOMMENDATIONS.—Not later than 3
7 years after the date of enactment of this section, the
8 Comptroller General shall submit to the Committees
9 referred to in paragraph (1), recommendations to re-
10 duce gaps in incentives for health care facilities and
11 hospitals to improve capacity and medical surge ca-
12 pabilities to prepare for, and respond to, public
13 health emergencies, consistent with subsection (a).
14 Such recommendations may take into account facili-
15 ties participating in programs under section 319C-
16 2, programs under the jurisdiction of the Centers for
17 Medicare & Medicaid Services (including innovative
18 health care delivery and payment models), and input
19 from private sector financial institutions.

20 “(4) CONSULTATION.—In carrying out para-
21 graphs (1), (2), and (3), the Comptroller General
22 shall consult with appropriate Federal entities, in-
23 cluding—

24 “(A) the Assistant Secretary for Prepared-
25 ness and Response;

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

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

5 “(D) the Assistant Secretary of Labor for
6 Occupational Safety and Health;

7 “(E) the Secretary of Veterans Affairs;
8 and

9 “(F) the heads of such other Federal agen-
10 cies as the Secretary determines to be appro-
11 priate.”.

12 (b) ANNUAL REPORTS.—Section 319C–2(i)(1) of the
13 Public Health Service Act (42 U.S.C. 247d-3b(i)(1)) is
14 amended by inserting after the first sentence the following
15 “The reports submitted under this paragraph shall also
16 include progress towards the implementation of section
17 319C–3.”.

18 (c) NATIONAL HEALTH SECURITY STRATEGY INCOR-
19 PORATION OF REGIONALIZED EMERGENCY PREPARED-
20 NESS AND RESPONSE.—Section 2802(b)(3) of the Public
21 Health Service Act (42 U.S.C. 300hh–1(b)(3)) is amend-
22 ed—

23 (1) in the matter preceding subparagraph (A),
24 by striking “including mental health” and inserting
25 “including pharmacies, mental health,”; and

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

3 “(G) Optimizing a coordinated and flexible
4 approach to the emergency response and med-
5 ical surge capacity of hospitals, other health
6 care facilities, critical care, trauma care (which
7 may include trauma centers), and emergency
8 medical systems, which may include the imple-
9 mentation of guidelines for regional public
10 health emergency preparedness and response
11 systems under section 319C-3.”.

12 (d) IMPROVING STATE AND LOCAL PUBLIC HEALTH
13 SECURITY.—

14 (1) STATE AND LOCAL SECURITY.—Section
15 319C-1(e) of the Public Health Service Act (42
16 U.S.C. 247d-3a(e)) is amended by striking “, and
17 local emergency plans.” and inserting “, local emer-
18 gency plans, and any regional public health emer-
19 gency preparedness and response system established
20 pursuant to the applicable guidelines under section
21 319C-3.”.

22 (2) PARTNERSHIPS.—Section 319C-2(d)(1)(A)
23 of the Public Health Service Act (42 U.S.C. 247d-
24 3b(d)(1)(A)) is amended—

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

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

5 [(C) inserting after clause (i), the fol-
6 lowing:]

7 [“(ii) among one or more facilities in
8 a regional public health emergency system
9 under section 319C-3; and”.]

10 [(e) TRAUMA SYSTEM IMPROVEMENTS.—TBS.]

11 **SEC. 204. PUBLIC HEALTH SITUATIONAL AWARENESS AND**
12 **BIOSURVEILLANCE CAPABILITIES.**

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

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

19 (2) in subsection (a)—

20 (A) in the subsection heading, by striking
21 “FACILITIES; CAPACITIES” and inserting “IN
22 GENERAL”;

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

1 (C) in paragraph (3), by striking “expand,
2 enhance, and improve” and inserting “expand,
3 improve, enhance, and appropriately maintain”;
4 and

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

6 “(4) STUDY OF RESOURCES FOR FACILITIES
7 AND CAPACITIES.—The Comptroller General of the
8 United States shall conduct a study on Federal
9 spending for activities authorized under this sub-
10 section in fiscal years 2013 through 2018. Such
11 study shall include a review and assessment of ex-
12 penses directly related to each activity under para-
13 graphs (2) and (3), including a specific accounting
14 of, and delineation between, expenses incurred for
15 the construction, renovation, equipping, and security
16 upgrades of facilities and associated contracts under
17 this subsection, and the expenses incurred to estab-
18 lish and improve the situational awareness and bio-
19 surveillance network under subsection (b), and iden-
20 tify the agency or agencies incurring such ex-
21 penses.”;

22 (3) in subsection (b)—

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

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

4 (C) in paragraph (2)—

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

7 (ii) by inserting “(in a form readily
8 usable for analytical approaches)” after
9 “another public health emergency”; and

10 (D) by striking paragraph (3) and insert-
11 ing the following:

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 2018, the Secretary,
17 in cooperation with health care providers, State
18 and local public health officials, and relevant
19 Federal agencies (including the Office of the
20 National Coordinator for Health Information
21 Technology and the National Institute of
22 Standards and Technology) shall, as necessary,
23 adopt technical and reporting standards, includ-
24 ing standards for interoperability as defined by
25 section 3000 of this Act, for networks under

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

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

13 (4) in subsection (c)—

14 (A) in paragraph (1)—

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

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

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

1 (iv) by striking “enhanced systems
2 that enable such connectivity” and insert-
3 ing “enhanced systems that enable such
4 interoperability”;

5 (B) by amending paragraph (2) to read as
6 follows:

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

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

22 “(B) consult with the Secretary of Agri-
23 culture, the Secretary of Commerce (including
24 the National Institute of Standards and Tech-
25 nology), the Secretary of Defense, the Secretary

1 of Homeland Security, and the Secretary of
2 Veterans Affairs, and the heads of other Fed-
3 eral agencies, as the Secretary determines ap-
4 propriate.”;

5 (C) in paragraph (3)—

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

10 (ii) in clause (iv), as so redesi-
11 gnated—

12 (I) by inserting “immunization
13 information programs,” after “poison
14 control,”; and

15 (II) by striking “ and clinical
16 laboratories” and inserting “, clinical
17 laboratories, and public environmental
18 health agencies”;

19 (iii) by striking “The network” and
20 inserting the following:

21 “(A) IN GENERAL.—The network”; and

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

24 “(B) REVIEW.—Not later than 2 years
25 after the date of the enactment of the Pan-

1 the Pandemic and All-Hazards Prepared-
2 ness and Advancing Innovation Act of
3 2018, the Secretary shall convene a public
4 meeting for purposes of discussing and
5 providing input on the potential goals,
6 functions, and uses of the network de-
7 scribed in paragraph (1) and incorporating
8 the elements described in paragraph (3).

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

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

3 “(I) data elements, including
4 minimal or essential data elements,
5 which are voluntarily provided for
6 such network, which may include ele-
7 ments from public health and public
8 and private health care entities, to the
9 extent 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) privacy and security pro-
19 tections provided at the Federal,
20 State, local, tribal, and territorial lev-
21 els, and by nongovernmental stake-
22 holders; and

23 “(V) opportunities for the incor-
24 poration of innovative technologies to
25 improve the network.”;

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

3 (I) in clause (i), as so redesign-
4 nated—

5 (aa) by striking “as deter-
6 mined” and inserting “as adopt-
7 ed”; and

8 (bb) by inserting “and the
9 National Institute of Standards
10 and Technology” after “Office of
11 the National Coordinator for
12 Health Information Tech-
13 nology,”;

14 (II) in clause (iii), as so redesign-
15 nated, by striking “; and” and insert-
16 ing a semicolon;

17 (III) in clause (iv), as so redesign-
18 nated, by striking the period and in-
19 serting “; and”; and

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

22 “(v) pilot test standards and imple-
23 mentation specifications, consistent with
24 the process described in section
25 3002(b)(3), which State, local, tribal, and

1 territorial public health entities may uti-
2 lize, on a voluntary basis, as a part of the
3 network.”;

4 (E) by redesignating paragraph (6) as
5 paragraph (7);

6 (F) by inserting after paragraph (5) the
7 following:

8 “(6) STRATEGY AND IMPLEMENTATION
9 PLAN.—

10 “(A) IN GENERAL.—Not later than 2 years
11 after the date of enactment of the Pandemic
12 and All-Hazards Preparedness and Advancing
13 Innovation Act of 2018, the Secretary shall
14 submit to the appropriate committees of Con-
15 gress a coordinated strategy and an accom-
16 panying implementation plan that—

17 “(i) is informed by the public meeting
18 under paragraph (5)(B);

19 “(ii) includes a review and assessment
20 of existing capabilities of the network, in-
21 cluding input provided by the public meet-
22 ing under paragraph (5)(B);

23 “(iii) identifies and demonstrates the
24 measurable steps the Secretary will carry
25 out to—

1 “(I) develop, implement, and
2 evaluate the network described in
3 paragraph (1), utilizing elements de-
4 scribed in paragraph (2)(A);

5 “(II) modernize and enhance bio-
6 surveillance activities, including strat-
7 egies to include innovative tech-
8 nologies and analytical approaches
9 (including prediction and forecasting
10 for pandemics and all-hazards) from
11 public and private entities;

12 “(III) improve information shar-
13 ing, coordination, and communication
14 among disparate biosurveillance sys-
15 tems supported by the Department of
16 Health and Human Services, includ-
17 ing the identification of methods to
18 improve accountability, better utilize
19 resources and workforce capabilities,
20 and incorporate innovative tech-
21 nologies within and across agencies;
22 and

23 “(IV) test and evaluate capabili-
24 ties of the interoperable network of

1 systems to improve situational aware-
2 ness and biosurveillance capabilities;

3 “(iv) includes performance measures
4 and the metrics by which such measures
5 will be assessed with respect to the steps
6 under subclause (iii); and

7 “(v) establishes dates by which each
8 measurable step under clause (iii) will be
9 implemented.”.

10 “(B) ANNUAL BUDGET PLAN.—Not later
11 than 2 years after the date of enactment of the
12 Pandemic and All-Hazards Preparedness and
13 Advancing Innovation Act of 2018 and on an
14 annual basis thereafter, in accordance with the
15 strategy and implementation plan under this
16 section, the Secretary shall, taking into account
17 recommendations provided by the National Bio-
18 defense Science Board, develop a budget plan
19 based on the strategy and implementation plan
20 under this section. Such budget plan shall in-
21 clude—

22 “(i) a summary of resources pre-
23 viously expended to establish, improve, and
24 utilize the nationwide public health situa-

1 tional awareness and biosurveillance net-
2 work under paragraph (1);

3 “(ii) estimates of costs and resources
4 needed to establish and improve the net-
5 work under paragraph (1) according to the
6 strategy and implementation plan under
7 subparagraph (A);

8 “(iii) the identification of gaps and in-
9 efficiencies in nationwide public health sit-
10 uational awareness and biosurveillance ca-
11 pabilities, and resources [and/or authori-
12 ties] needed to address such gaps; and

13 “(iv) a strategy to minimize and ad-
14 dress such gaps and improve inefficien-
15 cies.”;

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

17 (i) in subparagraph (A), by inserting
18 “(taking into account zoonotic disease, in-
19 cluding gaps in scientific understanding of
20 the interactions between human, animal,
21 and environmental health)” after “human
22 health”;

23 (ii) in subparagraph (B)—

1 (I) by inserting “and gaps in sur-
2 veillance programs” after “surveil-
3 lance programs”; and

4 (II) by striking “; and” and in-
5 serting a semicolon;

6 (iii) in subparagraph (C)—

7 (I) by inserting “, animal health
8 organizations related to zoonotic dis-
9 ease,” after “health care entities”;
10 and

11 (II) by striking the period and
12 inserting “; and”; and

13 (iv) by adding at the end the fol-
14 lowing:

15 “(D) provide recommendations to the Sec-
16 retary on policies and procedures to complete
17 the steps outlined in this subsection in a man-
18 ner that is consistent with section 2802.”; and

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

20 “(8) SITUATIONAL AWARENESS AND BIO-
21 SURVEILLANCE AS A NATIONAL SECURITY PRI-
22 ORITY.—The Secretary, on a periodic basis as appli-
23 cable and appropriate, shall meet with [appropriate
24 members of the intelligence community] in order to
25 inform the development and capabilities of the na-

1 tionwide public health situational awareness and bio-
2 surveillance network.”;

3 (5) in subsection (d)—

4 (A) in paragraph (1)—

5 (i) by inserting “environmental health
6 agencies,” after “public health agencies,”;

7 and

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

10 and

11 (B) in paragraph (2)—

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

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

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

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

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

23 “(5) TECHNICAL ASSISTANCE.—The Secretary
24 may provide technical assistance to States or a con-
25 sortium of States receiving an award under this sub-

1 section regarding interoperability and the technical
2 standards set forth by the Secretary.”;

3 (6) by redesignating subsections (f) and (g) as
4 subsections (h) and (i), respectively; and

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

7 “(f) **TIMELINE.**—The Secretary shall accomplish the
8 goals and targets under this section no later than Sep-
9 tember 30, 2023, and shall provide a justification to Con-
10 gress for any missed goals or targets.

11 “(g) **INDEPENDENT EVALUATION.**—Not later than 3
12 years after the date of enactment of the Pandemic and
13 All-Hazards Preparedness and Advancing Innovation Act
14 of 2018, the Comptroller General of the United States
15 shall conduct an independent evaluation, and submit to
16 the Secretary and the appropriate committees of Congress
17 a report concerning the activities conducted under this
18 section, and provide recommendations, as applicable and
19 appropriate, on necessary improvements to the biosurveil-
20 lance and situational awareness network.”.

21 (b) **AUTHORIZATION OF APPROPRIATIONS.**—Sub-
22 section (h) of section 319D of the Public Health Service
23 Act (42 U.S.C. 247d–4), as redesignated by subsection
24 **[(a)(6)]**, is amended by striking “\$138,300,000 for each

1 of fiscal years 2014 through 2018” and inserting “[**\$xx**]
2 for each of fiscal years 2019 through 2023”.

3 **SEC. 205. STRENGTHENING AND SUPPORTING THE PUBLIC**
4 **HEALTH EMERGENCY [BRIDGE] FUND.**

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

7 (1) in subsection (b)—

8 (A) in the first sentence of paragraph (1),
9 by inserting “or if the Secretary determines
10 there is the significant potential for a public
11 health emergency **■**, to allow the Secretary to
12 immediately respond to such public health
13 emergency or potential public health emer-
14 gency**■**” before the period;

15 (B) by redesignating paragraph (2) as
16 paragraph (3);

17 (C) by inserting after paragraph (1) the
18 following:

19 “(2) **USES.**—The Secretary may use amounts
20 in the Fund established under paragraph (a), to—

21 “(A) facilitate coordination between and
22 among Federal, State, local, tribal, and terri-
23 torial entities that the Secretary determines
24 may be affected by a public health emergency,

1 including further supporting programs under
2 section 319C-1 or 319C-2;

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

12 “(C) strengthen biosurveillance capabilities
13 and laboratory capacity to identify, collect, and
14 analyze information on such public health emer-
15 gency or potential public health emergency, in-
16 cluding the systems under section 319D;

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

22 “(E) other activities, as the Secretary de-
23 termines applicable and appropriate.”; and

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

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

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

21 (2) in subsection (c), by striking “section.” and
22 inserting “Act.”.

1 **SEC. 206. IMPROVING PREPAREDNESS FOR AND RESPONSE**
2 **TO ALL-HAZARDS BY PUBLIC HEALTH EMER-**
3 **GENCY VOLUNTEERS.**

4 Section 319I of the Public Health Service Act (42
5 U.S.C. 247d–7b) is amended:

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

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

21 (3) in subsection (k) by striking “\$5,000,000
22 for each of fiscal years 2014 through 2018” and in-
23 sserting “[**\$xx**] for each of fiscal years 2019 through
24 2023”.

1 **TITLE III—REACHING ALL**
2 **COMMUNITIES**

3 **SEC. 301. STRENGTHENING AND ASSESSING THE EMER-**
4 **GENCY RESPONSE WORKFORCE.**

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

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

16 (b) REVIEW OF THE NATIONAL DISASTER MEDICAL
17 SYSTEM.—Section 2812(b)(2) of the Public Health Serv-
18 ice Act (42 U.S.C. 300hh–11(b)(2)) is amended to read
19 as follows:

20 “(2) JOINT REVIEW AND MEDICAL SURGE CA-
21 PACITY STRATEGIC PLAN.—Not later than 180 days
22 after the date of enactment of the Pandemic and
23 All-Hazards Preparedness and Advancing Innovation
24 Act of 2018, the Secretary, in coordination with the
25 Secretary of Homeland Security, the Secretary of

1 Defense, and the Secretary of Veterans Affairs, shall
2 conduct a joint review of the National Disaster Med-
3 ical System. Such review shall include an evaluation
4 of medical surge capacity, as described in section
5 2803(a), an assessment of the available workforce of
6 the intermittent disaster response personnel, as de-
7 scribed in subsection (c), and an assessment of the
8 Medical Reserve Corps, as described in section 2813.
9 Such workforce assessment shall include the capacity
10 of such workforce to meet the needs of an all-haz-
11 ards approach, including capacity to simultaneously
12 respond to multiple public health emergencies and
13 the potential capacity to respond to a nationwide
14 public health emergency, the effectiveness of efforts
15 to recruit, retain, and train the workforce, the gaps
16 that may exist in the workforce, and recommenda-
17 tions for addressing such gaps. As part of the Na-
18 tional Health Security Strategy under section 2802,
19 the Secretary shall update the findings from such re-
20 view and provide recommendations to modify the
21 policies of the National Disaster Medical System and
22 the Medical Reserve Corps as necessary.”.

23 (c) NOTIFICATION OF NDMS SHORTAGE.—Section
24 2812(c) of the Public Health Service Act (42 U.S.C.

1 300hh–11(c)) is amended by adding at the end the fol-
2 lowing:

3 “(3) NOTIFICATION.—Not later than 30 days
4 after the date on which the Secretary determines the
5 number of intermittent disaster response personnel
6 of such System is insufficient to address an on-going
7 or potential public health emergency, the Secretary
8 shall submit to the appropriate committees of Con-
9 gress a notification detailing the impact such short-
10 age could have on meeting public health and emer-
11 gency medical personnel needs during a public
12 health emergency, and any identified measures to
13 address such issue.”.

14 (d) NATIONAL DISASTER MEDICAL SYSTEM AU-
15 THORIZATION OF APPROPRIATIONS.—Section 2812(g) of
16 the Public Health Service Act (42 U.S.C. 300hh–11(g))
17 is amended by striking “\$52,700,000 for each of fiscal
18 years 2014 through 2018” and inserting “**[\$xx]** for each
19 of fiscal years 2019 through 2023”.

20 (e) MEDICAL RESERVE CORPS. AUTHORIZATION OF
21 APPROPRIATIONS.—Section 2813(i) of the Public Health
22 Service Act (42 U.S.C. 300hh–15(i)) is amended by strik-
23 ing “\$11,200,000 for each of fiscal years 2014 through
24 2018” and inserting “**[\$xx]** for each of fiscal years 2019
25 through 2023”.

1 **SEC. 302. HEALTH SYSTEM INFRASTRUCTURE TO IMPROVE**
2 **PREPAREDNESS AND RESPONSE.**

3 (a) COORDINATION OF PREPAREDNESS.—Section
4 2811(b)(5) of the Public Health Service Act (42 U.S.C.
5 300hh–10(b)(5)) is amended by adding at the end the fol-
6 lowing: “Such logistical support shall include working with
7 other relevant Federal, State, local, tribal, and territorial
8 public health officials and private sector partners to iden-
9 tify the critical infrastructure entities capable of assisting
10 with, responding to, or mitigating the effect of a public
11 health emergency under section 319, the Robert T. Staf-
12 ford Disaster Relief and Emergency Assistance Act, or the
13 National Emergencies Act, [including by establishing
14 methods to exchange critical information and deliver
15 goods].”.

16 (b) MANUFACTURING CAPACITY.—Section
17 2811(d)(2)(C) of the Public Health Service Act is amend-
18 ed by inserting “, and necessary medical supplies to assist
19 with the utilization of such products,” after “products”.

20 (c) STRATEGIC NATIONAL STOCKPILE.—Section
21 319F–2(a)(2)(E) of the Public Health Service Act (42
22 U.S.C. 247d–6b(a)(2)(E)) is amended by inserting before
23 the semicolon “, taking into account the manufacturing
24 capacity and other available sources of products and sup-
25 plies in the stockpile”.

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 of the Public Health Service Act (42 U.S.C. 300hh–
5 1(b)(4)(B)) is amended—

6 (1) by striking “this section and sections 319C–
7 1, 319F, and 319L,” and inserting “this Act”; and

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

10 (b) COUNTERMEASURE CONSIDERATIONS.—Section
11 319L(c)(6) is amended—

12 (1) by striking “elderly” and inserting “senior
13 citizens”; and

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

18 **SEC. 304. IMPROVING EMERGENCY PREPAREDNESS AND**
19 **RESPONSE CONSIDERATIONS FOR CHIL-**
20 **DREN.**

21 **[[Section ____]]** of the Public Health Service Act is
22 amended by inserting **[xxx]** the following:**]**

23 **“[(____)] ENHANCING EMERGENCY PREPAREDNESS**
24 **FOR CHILDREN.—**

25 **“(1) IN GENERAL.—**The Secretary, acting
26 through the Director of the Centers for Disease

1 Control and Prevention, shall maintain an internal
2 team of experts to work collaboratively to provide
3 guidance on the considerations for, and the specific
4 needs of, children before, during, and after public
5 health emergencies. The Director may rely upon the
6 expertise of such team as part of emergency pre-
7 paredness and response efforts at the Centers for
8 Disease Control and Prevention.

9 “(2) EXPERTISE.—The team described in para-
10 graph (1) shall be comprised of one or more pedia-
11 tricians, including a developmental-behavior pediatri-
12 cian, and may also include behavioral scientists,
13 child psychologists, epidemiologists, biostatisticians,
14 health communications staff, and individuals with
15 other areas of expertise, as the Secretary determines
16 appropriate.

17 “(3) DUTIES.—The team described in para-
18 graph (1) may—

19 “(A) assist State and local emergency
20 planning and response activities related to chil-
21 dren, which may include developing, identifying,
22 and sharing best practices;

23 “(B) provide technical assistance, training,
24 and consultation to Federal, State, territorial,
25 tribal, and local public health officials to im-

1 prove preparedness and response capabilities
2 with respect to the needs of children, including
3 providing such technical assistance, training,
4 and consultation to eligible entities in order to
5 support the achievement of measurable evi-
6 dence-based benchmarks and objective stand-
7 ards under section 319C-1;

8 “(C) improve the utilization of methods to
9 incorporate the needs of children in planning
10 for and responding to a public health emer-
11 gency, including public awareness of such meth-
12 ods;

13 “(D) coordinate with, and improve, public-
14 private partnerships to address gaps and ineffi-
15 ciencies in emergency preparedness and re-
16 sponse efforts for children;

17 “(E) provide expertise and input during
18 the development of guidance and clinical rec-
19 ommendations to address the needs of children
20 when preparing for, and responding to, public
21 health emergencies; and

22 “(F) carry out other duties related to pre-
23 paredness and response activities for children,
24 as the Secretary determines appropriate.”.

1 **SEC. 305. REAUTHORIZING THE NATIONAL ADVISORY COM-**
2 **MITTEE ON CHILDREN AND DISASTERS.**

3 Section 2811A of the Public Health Service Act (42
4 U.S.C. 300hh–10a) is amended—

5 (1) in subsection (d)—

6 (A) in paragraph (1), by striking “15” and
7 inserting “**[25]**”; and

8 (B) by striking paragraph (2) and insert-
9 ing the following:

10 “(2) **REQUIRED NON-FEDERAL MEMBERS.**—The
11 Secretary, in consultation with such other heads of
12 Federal agencies as may be appropriate, may ap-
13 point to the Advisory Committee under paragraph
14 (1) such individuals as may be appropriate to per-
15 form the duties described in subsections (b) and (c),
16 which may include—

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

20 “(B) at least 2 representatives from State,
21 local, territorial, or tribal agencies with exper-
22 tise in pediatric disaster planning, prepared-
23 ness, response, or recovery;

24 “(C) at least 4 members representing
25 health care professionals, which may include
26 members with expertise in pediatric emergency

1 medicine; pediatric trauma, critical care, or sur-
2 gery; the treatment of pediatric patients af-
3 fected by chemical, biological, radiological, or
4 nuclear agents and emerging infectious dis-
5 eases; pediatric mental or behavioral health re-
6 lated to children who have experienced trau-
7 matic events; or pediatric primary care; and

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

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

12 “(ii) at least one such member shall
13 be an individual with expertise in schools
14 or child care settings;

15 “(iii) at least one such member shall
16 be an individual with expertise in children
17 and youth with special health care needs;
18 and

19 “(iv) at least one such member shall
20 be an individual with expertise in the needs
21 of parents or family caregivers, including
22 the parents or caregivers of children with
23 disabilities.”.

24 “(3) FEDERAL MEMBERS.—The Secretary, in
25 consultation with such other heads of Federal agen-

1 cies as may be appropriate, shall appoint to the Ad-
2 visory Committee under paragraph (1) the following
3 Federal members or their designees—

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

6 “(B) the Director of the Biomedical Ad-
7 vanced Research and Development Authority;

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

10 “(D) the Commissioner of Food and
11 Drugs;

12 “(E) the Director of the National Insti-
13 tutes of Health;

14 “(F) the Assistant Secretary of the Admin-
15 istration for Children and Families;

16 “(G) the Administrator of the Health Re-
17 sources and Services Administration;

18 “(H) the Administrator of the Federal
19 Emergency Management Agency;

20 “(I) the Administrator of the Administra-
21 tion for Community Living; and

22 “(J) representatives from such Federal
23 agencies (such as the Department of Education
24 and the Department of Homeland Security) as
25 the Secretary determines appropriate to fulfill

1 the duties of the Advisory Committee under
2 subsections (b) and (c).”.

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

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

18 (2) in subsection (e), by adding at the end “At
19 least one meeting per year shall be an in-person
20 meeting.”; and

21 (3) in subsection (f) by striking “2018” and in-
22 sserting “2023”.

23 **[SEC. 306. GUIDANCE FOR PARTICIPATION IN EXERCISES**
24 **AND DRILLS.**

25 To be supplied.]

1 **TITLE IV—PRIORITIZING A**
2 **THREAT-BASED APPROACH**

3 **SEC. 401. ASSISTANT SECRETARY FOR PREPAREDNESS AND**
4 **RESPONSE.**

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

7 (1) in the matter preceding paragraph (1) by
8 inserting “utilize experience related to public health
9 emergency preparedness and response, biodefense,
10 medical countermeasures, **【domestic disaster pre-**
11 **paredness,】** and other relevant topics to” after
12 “shall”; and

13 (2) in paragraph (4) by adding at the end the
14 following:

15 “(I) **THREAT AWARENESS.**—Coordinate
16 with the Director of the Centers for Disease
17 Control and Prevention, the Secretary of Home-
18 land Security, the Assistant to the President for
19 National Security Affairs, the Secretary of De-
20 fense, **【members of the intelligence community】**
21 and other relevant Federal officials, to inform
22 preparedness and response capabilities based on
23 the range of the threats that have the potential
24 to result in a public health emergency.”.

1 **SEC. 402. PUBLIC HEALTH EMERGENCY MEDICAL COUN-**
2 **TERMEASURES ENTERPRISE.**

3 (a) IN GENERAL.—Title XXVIII of the Public Health
4 Service Act is amended by inserting after section 2811 (42
5 U.S.C. 300hh–10) the following:

6 **“SEC. 2811-1. PUBLIC HEALTH EMERGENCY MEDICAL**
7 **COUNTERMEASURES ENTERPRISE.**

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

11 “(b) MEMBERS.—The PHEMCE shall consist of
12 each of the following members, or the designee of such
13 members:

14 “(1) The Assistant Secretary for Preparedness
15 and Response.

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

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

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

21 “(5) The Secretary of Defense.

22 “(6) The Secretary of Homeland Security.

23 “(7) The Secretary of Agriculture.

24 “(8) The Secretary of Veterans Affairs.

25 “(9) Representatives of any other Federal agen-
26 cy, which may include the Director of the Bio-

1 medical Advanced Research and Development Au-
2 thority, and the Director of the Strategic National
3 Stockpile, as the Secretary determines appropriate.

4 “(c) FUNCTIONS.—

5 “(1) IN GENERAL.—The PHEMCE shall carry
6 out the following functions:

7 “(A) Establish a process pursuant to sec-
8 tion 2811(d)(2)(B) to make recommendations
9 to the Secretary regarding the prioritization of
10 research, development, and procurement of
11 countermeasures, as defined in section 319F-
12 2(c), based on the health security needs of the
13 United States. Such recommendations shall be
14 informed by the National Health Security
15 Strategy pursuant to section 2802, the Stra-
16 tegic National Stockpile review required under
17 section 319F-2(a)(2), the multi-year budget
18 plan pursuant to section 2811(b)(7), and an as-
19 sessment of current national security threats,
20 including chemical, biological, radiological and
21 nuclear threats, including emerging infectious
22 diseases.

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 provide
3 for alignment of countermeasure procurement
4 with recommendations under subparagraph (A).

5 “(C) Develop strategies related to logistics,
6 deployment, and use of countermeasures that
7 may be applicable to the [activities/responsibil-
8 ities] of the strategic national stockpile under
9 section 319F–2(a).

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

13 “(2) INPUT.—In carrying out paragraph
14 (1)(C), the PHEMCE shall consider input from
15 State and local public health departments, as appro-
16 priate.”.

17 (b) PUBLIC HEALTH EMERGENCY MEDICAL COUN-
18 TERMEASURES ENTERPRISE STRATEGY AND IMPLEMEN-
19 TATION PLAN.—Subsection (d)(1) of section 2811 of the
20 Public Health Service Act (42 U.S.C. 300hh–10) is
21 amended by striking “Director of Biomedical” and all that
22 follows through “Food and Drugs” and inserting “Public
23 Health Emergency Medical Countermeasures Enterprise
24 established under section 2811–1”.

1 **SEC. 403. STRATEGIC NATIONAL STOCKPILE.**

2 (a) Section 319F-2(a) of the Public Health Service
3 Act (42 U.S.C. 247d-6b(a)) is amended—

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

6 (2) in paragraph (1)—

7 (A) by inserting “and optimize” after
8 “provide for”;

9 (B) by inserting “and, in consultation with
10 the Public Health Emergency Medical Counter-
11 measure Enterprise under section 2811-1,
12 make necessary additions or modifications to
13 the contents of such stockpile or stockpiles
14 based on the review conducted under paragraph
15 (2)” before the period of the first sentence; and

16 (C) by striking the second sentence;

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

19 “(2) ANNUAL THREAT-BASED REVIEW.—

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

1 2811–1, review contents within the stockpile
2 and assess whether such contents are consistent
3 with the recommendations made pursuant to
4 section 2811–1(c)(1)(A). Such review shall be
5 submitted annually to the Committee on
6 Health, Education, Labor, and Pensions and
7 the Committee on Appropriations of the Senate
8 and the Committee on Energy and Commerce
9 and the Committee on Appropriations of the
10 House of Representatives, to the extent that
11 disclosure of such information does not com-
12 promise national security.

13 “(B) ADDITIONS, MODIFICATIONS, AND
14 REPLENISHMENTS.—Such annual threat-based
15 review shall, for each new or modified counter-
16 measure procurement or replenishment, provide
17 information regarding—

18 “(i) the quantities of the additional or
19 modified countermeasure procured for, or
20 contracted to be procured for, the stock-
21 pile;

22 “(ii) planning considerations for ap-
23 propriate manufacturing capacity and ca-
24 pability to meet the goals of such additions
25 or modifications;

1 “(iii) the presence or lack of a com-
2 mercial market for the countermeasure at
3 the time of procurement;

4 “(iv) the public health threat or
5 threats such countermeasure procurement
6 is intended to address, including whether
7 such procurement is consistent with meet-
8 ing emergency health security needs associ-
9 ated with such threat or threats;

10 “(v) an assessment of whether the
11 public health threat or threats described in
12 clause (iv) could be addressed in a manner
13 that **【uses fewer of the available re-**
14 **sources】** to meet such needs, without com-
15 promising the level of preparedness;

16 “(vi) whether such countermeasure is
17 replenishing an expired countermeasure, is
18 a different countermeasure with the same
19 indication that is replacing an expired
20 countermeasure, or is a new addition to
21 the stockpile;

22 “(vii) a description of how such addi-
23 tions or modifications align with the coun-
24 termeasure budget plan as required under
25 section 2811(b)(7), including expected life-

1 cycle costs, expenditures related to coun-
2 termeasure procurement to address the
3 threat or threats described in clause (iv),
4 replenishment dates (including the ability
5 to extend the maximum shelf life of a
6 countermeasure), and the manufacturing
7 capacity required to replenish such coun-
8 termeasure;

9 “(viii) appropriate protocols and proc-
10 esses for the deployment, distribution, or
11 dispensing of the countermeasure at the
12 State and local level, including the capa-
13 bility of State and local entities to dis-
14 pense, distribute, and administer the coun-
15 termeasure; and

16 “(ix) an assurance that for each coun-
17 termeasure produced or replenished under
18 this subsection, the Secretary completed a
19 review addressing each item listed under
20 this subsection in advance of such procure-
21 ment or replenishment.”;

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

23 (A) in subparagraph (A), by inserting
24 “and the Public Health Emergency Medical

1 Countermeasures Enterprise under section
2 2811–1” before the semicolon;

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

5 “(E) devise plans for effective and timely
6 supply-chain management of the stockpile, in
7 consultation with the Director of the Centers
8 for Disease Control and Prevention, the Assist-
9 ant Secretary for Preparedness and Response,
10 the Secretary of Transportation, the Secretary
11 of Homeland Security, the Secretary of Vet-
12 erans Affairs, and the heads of other appro-
13 priate Federal agencies, State and local agen-
14 cies, and the public and private health care in-
15 frastructure, as applicable;” and

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

17 “(5) GAO REPORT.—

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

1 stockpile since 2015. Such review shall in-
2 clude—

3 “(i) an assessment of the comprehen-
4 siveness and completeness of each annual
5 threat-based review under paragraph (2),
6 including indicating whether all newly pro-
7 cured or replenished countermeasures with-
8 in the stockpile were described in each an-
9 nual review, and whether, consistent with
10 paragraph (2)(B), the Secretary conducted
11 the necessary internal review in advance of
12 such procurement or replenishment;

13 “(ii) an assessment of whether the
14 Secretary established health security jus-
15 tifications, and a description of such jus-
16 tifications for procurement decisions re-
17 lated to health security needs with respect
18 to the identified threat, for additions or
19 modifications to the stockpile based on the
20 information provided in such reviews under
21 paragraph (2)(B), including whether such
22 review was conducted prior to procure-
23 ment, modification, or replenishment;

24 “(iii) an assessment of the plans de-
25 veloped by the Secretary for the deploy-

1 ment, distribution, and dispensing of coun-
2 termeasures procured, modified, or replen-
3 ished under paragraph (1), including
4 whether such plans were developed prior to
5 procurement, modification, or replenish-
6 ment;

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

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

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

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

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

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

23 (b) AUTHORIZATION OF APPROPRIATIONS, STRA-
24 TEGIC NATIONAL STOCKPILE.—Section 319F–2(f)(1) of
25 the Public Health Service Act (42 U.S.C. 247d–6b(f)(1))

1 is amended by striking “\$533,800,000 for each of fiscal
2 years 2014 through 2018” and inserting “[~~\$xx~~] for each
3 of fiscal years 2019 through 2023”.

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

7 Section 319L(c)(4) of the Public Health Service Act
8 (247d–7e(c)(4)) is amended by adding at the end the fol-
9 lowing:

10 “(F) STRATEGIC INITIATIVES.—The Sec-
11 retary, acting through the Director of BARDA,
12 may implement strategic initiatives, including
13 by building on existing programs, to address
14 priority threats that, as determined by the Sec-
15 retary, pose a significant level of risk to na-
16 tional security based on the characteristics of
17 the chemical, biological, radiological or nuclear
18 threat, or existing capabilities to respond to
19 such threats (including medical response capa-
20 bilities). Such initiatives shall advance innova-
21 tion in, and accelerate and support the ad-
22 vanced research, development, and procurement
23 of, countermeasures and products, as applica-
24 ble, to address areas including—

1 “(i) chemical, biological, radiological
2 or nuclear threats, including emerging in-
3 fectious diseases, for which no approved, li-
4 censed, or authorized countermeasure ex-
5 ists, or for which such threat, or the result
6 of an exposure to such threat, may become
7 resistant to countermeasures or existing
8 countermeasures may be rendered ineffec-
9 tive;

10 “(ii) threats which consistently exist
11 or continually circulate and have signifi-
12 cant potential to become a pandemic,
13 which may include the advanced research
14 and development, manufacturing and ap-
15 propriate stockpiling of qualified pandemic
16 or epidemic products, and products, tech-
17 nologies, or processes to support the devel-
18 opment of such countermeasures (including
19 multiuse platform technologies for
20 diagnostics, [virus seeds, clinical trial
21 lots], novel virus strains, and antigen and
22 adjuvant material); and

23 “(iii) threats that may result from a
24 chemical, biological, radiological, or nuclear
25 agent, and which may present increased

1 complications in treating a countermeasure
2 resistant disease or condition resulting pri-
3 marily or secondarily from such threats or
4 agents, such as through the development of
5 novel countermeasures for drug resistant
6 organisms.”.

7 **SEC. 405. REPORTING ON THE FEDERAL SELECT AGENT**
8 **PROGRAM.**

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

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

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

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

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

19 “(A) IN GENERAL.—Not later than 1 year
20 after the date of the enactment of the Pan-
21 demic and All-Hazards Preparedness and Ad-
22 vancing Innovation Act of 2018, the Secretary
23 shall provide an update to the appropriate com-
24 mittees of Congress on the implementation of
25 recommendations of the Federal Experts Secu-

1 rity Advisory Panel concerning the select agent
2 program.

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

10 **TITLE V—INCREASING COMMU-**
11 **NICATION IN MEDICAL COUN-**
12 **TERMEASURE ADVANCED RE-**
13 **SEARCH AND DEVELOPMENT**

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

15 Section 2811(b)(7) of the Public Health Service Act
16 (42 U.S.C. 300hh–10(b)(7)) is amended—

17 (1) by striking subparagraph (A) and inserting
18 the following:

19 “(A) include consideration of the entire
20 medical countermeasures enterprise, includ-
21 ing—

22 “(i) basic research and advanced re-
23 search and development;

24 “(ii) approval, clearance, licensure,
25 and authorized uses of products;

1 “(iii) procurement, stockpiling, main-
2 tenance, and potential replenishment (in-
3 cluding manufacturing capacity) of all
4 products in the Strategic National Stock-
5 pile;

6 “(iv) current manufacturing capabili-
7 ties and capacity; and

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

15 (2) by redesignating subparagraphs (D) and
16 (E) as subparagraphs (E) and (F), respectively; and

17 (3) by inserting after subparagraph (C), the fol-
18 lowing:

19 “(D) identify medical countermeasure an-
20 ticipated research and development needs, in-
21 cluding the potential need for indications, dos-
22 ing, and administration technologies, and other
23 countermeasure needs as applicable and appro-
24 priate;”.

1 **SEC. 502. MATERIAL THREAT AND MEDICAL COUNTER-**
2 **MEASURE NOTIFICATIONS.**

3 (a) CONGRESSIONAL NOTIFICATION OF MATERIAL
4 THREAT DETERMINATION.—Section 319F–2(c)(2)(C) of
5 the Public Health Service Act (42 U.S.C. 247d–
6 6b(c)(2)(C)) is amended by striking “The Secretary and
7 the Homeland Security Secretary shall promptly notify the
8 appropriate committees of Congress” and inserting “The
9 Secretary and the Secretary of Homeland Security shall
10 send to Congress, on an annual basis, the material threat
11 list and shall promptly notify the Committee on Health,
12 Education, Labor, and Pensions and the Committee on
13 Homeland Security and Government Affairs Committee of
14 the Senate and the Committee on Energy and Commerce
15 and the Committee on Homeland Security of the House
16 of Representatives”.

17 (b) CONTRACTING COMMUNICATIONS.—Section
18 319F–2(c)(7)(ii)(III) of the Public Health Service Act (42
19 U.S.C. 247d–6b(c)(7)(ii)(III)) is amended by adding at
20 the end the following: “Upon a determination by the Sec-
21 retary to renew such contract, the Secretary shall notify
22 the vendor of such determination in as timely a manner
23 as practicable.”.

1 **SEC. 503. AVAILABILITY OF REGULATORY MANAGEMENT**
2 **PLANS.**

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

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

7 (2) by inserting after paragraph (2) the fol-
8 lowing:

9 “(3) PUBLICATION.—The Secretary shall make
10 available on the Internet Website of the Food and
11 Drug Administration information regarding regu-
12 latory management plans, including—

13 “(A) the process by which an applicant
14 may submit a request for a regulatory manage-
15 ment plan;

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

18 “(C) the information required for the sub-
19 mission of such request;

20 “(D) a summary of the milestones and
21 performance targets that may be discussed and
22 achieved, pursuant to paragraph (6); and

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

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

1 (A) by striking “paragraph (4)(A)” and in-
2 serting “paragraph (5)(A)”; and

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

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

8 **SEC. 504. BARDA AND THE BIOSHIELD SPECIAL RESERVE**
9 **FUND.**

10 (a) BIOSHIELD SPECIAL RESERVE FUND.—Section
11 319F–2(g)(1) of the Public Health Service Act (42 U.S.C.
12 247d–6b(g)(1)) is amended—

13 (1) by striking “\$2,800,000,000 for the period
14 of fiscal years 2014 through 2018” and inserting
15 “**[\$xx]** for the period of fiscal years 2019 through
16 2023”; and

17 (2) by striking “2019” and inserting “2024”.

18 (b) BARDA.—Section 319L(d)(2) of the Public
19 Health Service Act (42 U.S.C. 247d–7e(d)(2)) is amended
20 by striking “\$415,000,000 for each of fiscal years 2014
21 through 2018” and inserting “**[\$xx]** for each of fiscal
22 years 2019 through 2023”.

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

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

5 Section 319L(c)(4)(D)(iii) of the Public Health Serv-
6 ice Act (42 U.S.C. 247d-7e(c)(4)(D)(iii)) is amended by
7 inserting “technologies to administer countermeasures,”
8 before “efficacy increasing technologies”.

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

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

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

14 “(a) **PURPOSE.**—The purpose of this section is to
15 support and accelerate the development or manufacture
16 of security countermeasures, qualified countermeasures,
17 and qualified pandemic or epidemic products by facili-
18 tating and encouraging submission of data and informa-
19 tion to support such products to master files, and through
20 clarifying the authority to cross-reference to data and in-
21 formation previously submitted to the Secretary.

22 “(b) **APPLICABILITY OF REFERENCE.**—

23 “(1) **IN GENERAL.**—A person may submit data
24 and information to the Secretary with the intent to
25 reference, or to authorize, in writing, another person

1 to reference, such data or information to support a
2 medical countermeasure submission, as defined in
3 subsection (g) (including a supplement or amend-
4 ment to any such submission), without requiring the
5 master file holder to disclose the data and informa-
6 tion to any such persons authorized to reference the
7 master file.

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

14 “(c) MEDICAL COUNTERMEASURE MASTER FILE
15 CONTENT.—

16 “(1) IN GENERAL.—A master file under this
17 section may include information to support and ac-
18 celerate—

19 “(A) the development of medical counter-
20 measure submissions described in subsection (g)
21 to support the approval, licensure, classifica-
22 tion, clearance, conditional approval, or author-
23 ization of one or more security counter-
24 measures, qualified countermeasures, or quali-

1 fied pandemic or epidemic products; **【and】/**
2 **【or】**

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 described
11 in subsection (g).

12 “(d) SPONSOR REFERENCE.—

13 “(1) IN GENERAL.—Each incorporation of in-
14 formation or data contained in a master file by ref-
15 erence shall describe the incorporated material in a
16 manner in which the Secretary determines appro-
17 priate and that permits the review of such informa-
18 tion without necessitating resubmission of such in-
19 formation or data. Master files shall be submitted in
20 an electronic format in accordance with section
21 745A and as specified in applicable guidance.

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

1 of the intent to reference the medical counter-
2 measure master file as a part of the submission.

3 “(3) REFERENCE BY AN AUTHORIZED PER-
4 SON.—A sponsor of a medical countermeasure sub-
5 mission described in subsection (g) may, where the
6 Secretary determines appropriate, incorporate by
7 reference all or part of the contents of a medical
8 countermeasure master file, if the master file holder
9 authorizes the incorporation in writing.

10 “(e) ACKNOWLEDGEMENT OF MASTER FILE BY THE
11 SECRETARY.—The Secretary shall provide the master file
12 holder with a **【notice/letter】** indicating that the Secretary
13 has reviewed and relied upon **【specified】** information or
14 data within a master file and the purposes for which it
15 was incorporated by reference if the Secretary has re-
16 viewed and relied upon such specified information or data
17 to support the approval, classification, conditional ap-
18 proval, clearance, licensure, or authorization of a security
19 countermeasure, qualified countermeasure, or qualified
20 pandemic or epidemic product. The Secretary may rely
21 upon the data and information within the medical counter-
22 measure master file for which such **【notification/letter】**
23 was provided in additional applications, as applicable and
24 appropriate and upon the request of the master file holder

1 **【so notified/in receipt of the letter】** or by an authorized
2 person of such holder.

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

5 “(1) alter the authority of the Secretary to ap-
6 prove, license, classify, clear, conditionally approve,
7 or authorize drugs, biological products, or devices
8 pursuant to this Act or section 351 of the Public
9 Health Service Act (as authorized prior to the date
10 of enactment of the Pandemic and All-Hazards Pre-
11 paredness and Advancing Innovation Act of 2018),
12 including the standards of evidence, and applicable
13 conditions, for approval under the applicable Act; or

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

1 such submission, and the requirements associated
2 with such reference.

3 “(g) DEFINITIONS.—In this section:

4 “(1) The term ‘medical countermeasure submis-
5 sion’ means an investigational new drug application
6 under section 505(i), a new drug application under
7 section 505(b), or an abbreviated new drug applica-
8 tion under section 505(j) of this Act, a biological
9 product license application under subsection (a) or
10 (k) or section 351 of the Public Health Service Act,
11 a new animal drug application under section
12 512(b)(1) or abbreviated new animal drug applica-
13 tion under section 512(b)(2), an application for con-
14 ditional approval of a new animal drug under 571,
15 an investigational device application under section
16 520(g), an application with respect to a device under
17 section 515(c), a request for classification of a de-
18 vice under section 513(f)(2), a notification with re-
19 spect to a device under section 510(k), or request
20 for an emergency use authorization under section
21 564 to support the approval, licensure, classification,
22 clearance, conditional approval, or authorization of a
23 security countermeasure, qualified countermeasure,
24 or qualified pandemic or epidemic product, or a new
25 indication to an approved security countermeasure,

1 qualified countermeasure, or qualified pandemic or
2 epidemic product.

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

8 (b) STAKEHOLDER INPUT.—Not later than 18
9 months after the date of enactment of this Act, the Sec-
10 retary of Health and Human Services (referred to in this
11 section as the “Secretary”), acting through the Commis-
12 sioner of Food and Drugs, shall solicit input from stake-
13 holders, including stakeholders developing security coun-
14 termeasures, qualified countermeasures, or qualified pan-
15 demic or epidemic products, with respect to how the Food
16 and Drug Administration can help advance the use of tools
17 and technologies, to support and accelerate the develop-
18 ment or manufacture of security countermeasures, quali-
19 fied countermeasures, and qualified pandemic or epidemic
20 products, including through the reliance on cross-ref-
21 erenced data and information contained within master
22 files and submissions previously submitted to the Sec-
23 retary as set forth in section 565B of the Federal Food,
24 Drug, and Cosmetic Act, as added by subsection (a).

1 (c) GUIDANCE.—Not later than 2 years after the
2 after the date of enactment of this Act, the Secretary, act-
3 ing through the Commissioner of Food and Drugs, shall
4 publish draft guidance about how reliance on cross-ref-
5 erenced data and information contained within master
6 files under section 565B or submissions otherwise sub-
7 mitted to the Secretary may be used for specific tools or
8 technologies that have the potential to support and accel-
9 erate the development or manufacture of security counter-
10 measures, qualified countermeasures, qualified pandemic
11 or epidemic products. The Secretary, acting through the
12 Commissioner of Food and Drugs, shall publish the final
13 guidance not later than 3 years after the enactment of
14 this Act.

15 **SEC. 603. ANIMAL RULE REPORT.**

16 (a) STUDY.—The Comptroller General of the United
17 States shall conduct a study on the application of the re-
18 quirements under section 565(d) of the of the Federal
19 Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-4) as
20 a component of medical countermeasure development and
21 review under the Biomedical Advanced Research and De-
22 velopment Authority and the Food and Drug Administra-
23 tion. In conducting such study, the Comptroller General
24 shall examine the following:

1 (1) The extent to which review and development
2 of a medical countermeasure are coordinated be-
3 tween the Biomedical Advanced Research and Devel-
4 opment Authority and the Food and Drug Adminis-
5 tration, including activities to ensure such coordina-
6 tion and resolve discrepancies in the design of clin-
7 ical studies relying on the Animal Rule.

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

11 (3) The flexibilities in the Animal Rule to ad-
12 dress variations in countermeasure development and
13 review processes, including the extent to which quali-
14 fied animal models are adopted and used within the
15 Food and Drug Administration.

16 (4) The extent to which the guidance as re-
17 quired by section 565(c) of the Federal Food Drug
18 and Cosmetic Act (21 U.S.C. 360bbb-4) titled
19 “Product Development Under the Animal Rule
20 Guidance for Industry” (issued in October, 2015)
21 has assisted in achieving the purposes under para-
22 graphs (1), (2), and (3).

23 (b) CONSULTATIONS.—In conducting the study under
24 subsection (a), the Comptroller General of the United
25 States shall consult with—

1 (1) the Federal Government agencies respon-
2 sible for advancing, reviewing, and procuring med-
3 ical countermeasures, including the Department of
4 Health and Human Services, the Office of the As-
5 sistant Secretary for Preparedness and Response,
6 the Biomedical Advanced Research and Development
7 Authority, the Food and Drug Administration, and
8 the Department of Defense;

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

13 (3) other biodefense stakeholders, as applicable.

14 (c) REPORT.—Not later than 3 years after the date
15 of enactment of this Act, the Comptroller General of the
16 United States shall submit to the Committee on Health,
17 Education, Labor, and Pensions of the Senate and the
18 Committee on Energy and Commerce of the House of
19 Representatives a report containing the results of the
20 study conducted under subsection (a) and recommenda-
21 tions to improve the application and consistency of the re-
22 quirements under sections 565(c) and 565(d) of the Fed-
23 eral Food, Drug and Cosmetic Act (21 U.S.C. 360bbb-
24 4(c) and (d)) to support and expedite the research and
25 development of medical countermeasures, as applicable.

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

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
11 “\$155,300,000 for each of fiscal years 2014 through
12 2018” and inserting “**[\$xx]** for each of fiscal years 2019
13 through 2023”.

14 (b) VACCINE TRACKING AND DISTRIBUTION.—Sec-
15 tion 319A(e) of the Public Health Service Act (42 U.S.C.
16 247d–1(e)) is amended by striking “\$30,800,000 for each
17 of fiscal years 2014 through 2018” and inserting “**[\$xx]**
18 for each of fiscal years 2019 through 2023”.

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

22 (d) PUBLIC DISCLOSURE EXEMPTION.—Section
23 319L(e)(1)(C) of the Public Health Service Act (42
24 U.S.C. 47d–7e(e)(1)(C)) is amended by striking “17”.

1 (e) EXTENSION OF LIMITED ANTITRUST EXEMP-
2 TION.—

3 (1) IN GENERAL.—Section 405(b) of the Pan-
4 demic and All-Hazards Preparedness Act (42 U.S.C.
5 247d–6a note) is amended by striking “6-year” and
6 inserting “17-year”.

7 (2) EFFECTIVE DATE.—This subsection shall
8 take effect as if enacted on December 17, 2012.

9 **SEC. 702. TECHNICAL AMENDMENTS.**

10 (a) PUBLIC HEALTH SERVICE ACT.—Title III of the
11 Public Health Service Act (42 U.S.C. 241 et seq.) is
12 amended—

13 (1) in paragraphs (1) and (5) of section 319F–
14 1(a) (42 U.S.C. 247d–6a(a)), by striking “section
15 319F(h)” each place such term appears and insert-
16 ing “section 319F(e)”; and

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

20 (b) PUBLIC HEALTH SECURITY GRANTS.—Section
21 319C–1(b)(2) of the Public Health Service Act (42 U.S.C.
22 247d–3a(b)(2)) is amended—

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

1 (2) in subparagraph (F), by striking “make sat-
2 isfactory annual improvement and describe” and in-
3 serting “makes satisfactory annual improvement and
4 describes”; and

5 (c) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

6 The Federal Food, Drug, and Cosmetic Act is amended—

7 (1) in section 564A(e)(2)(A) (21 U.S.C.
8 360bbb-3a(e)(2)(A)), by striking “subsection
9 (a)(1)(C)(i)” and inserting “subsection (a)(1)(C)”;

10 (2) in section 564B(2)(C) (21 U.S.C. 360bbb-
11 3b(2)(C)), by inserting “or section 564A”; and

12 **[(3) FDA national security concern language**
13 **concern--section 507.]**