



AMENDMENT NO. \_\_\_\_\_ Calendar No. \_\_\_\_\_

Purpose: In the nature of a substitute.

**IN THE SENATE OF THE UNITED STATES—115th Cong., 2d Sess.**

**S. 2852**

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

Referred to the Committee on \_\_\_\_\_ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by \_\_\_\_\_

Viz:

1 Strike all after the enacting clause and insert the fol-  
2 lowing:

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

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

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

- Sec. 1. Short title; table of contents.
- Sec. 2. References in Act.

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 preparedness for and response to all-hazards by public health emergency volunteers.
- Sec. 208. Clarifying State liability law for volunteer health care professionals.

#### 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. Authorizing the National Advisory Committee on Seniors and Disasters.
- Sec. 307. Guidance for participation in exercises and drills.

#### TITLE IV—PRIORITIZING A THREAT-BASED APPROACH

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

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

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

#### TITLE VI—ADVANCING TECHNOLOGIES FOR MEDICAL COUNTERMEASURES

- Sec. 601. Administration of countermeasures.
- Sec. 602. Medical countermeasure master files.
- Sec. 603. Priority zoonotic animal drugs.
- Sec. 604. Animal rule report.
- Sec. 605. Review of the benefits of genomic engineering technologies and their potential role in national security.

#### TITLE VII—MISCELLANEOUS PROVISIONS

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

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

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

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

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

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

11 (1) in subsection (a)—

12 (A) in paragraph (1)—

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

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

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

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

11 (C) in paragraph (3)—

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

14 (ii) by inserting “(including gaps in  
15 the environmental health and animal  
16 health workforces, as applicable), describ-  
17 ing the status of such workforce” after  
18 “gaps in such workforce”;

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

22 (iv) by inserting before the period at  
23 the end “, and identifying current capabili-  
24 ties to meet the requirements of section  
25 2803”; and

1 (2) in subsection (b)—

2 (A) in paragraph (2)—

3 (i) in subparagraph (A), by striking  
4 “and investigation” and inserting “inves-  
5 tigation, and related information tech-  
6 nology activities”;

7 (ii) in subparagraph (B), by striking  
8 “and decontamination” and inserting “de-  
9 contamination, relevant health care serv-  
10 ices and supplies, and transportation and  
11 disposal of medical waste”; and

12 (iii) by adding at the end the fol-  
13 lowing:

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

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

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

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

22 “(9) ZOONOTIC DISEASE, FOOD, AND AGRI-  
23 CULTURE.—Improving coordination among Federal,  
24 State, local, tribal, and territorial entities (including  
25 through consultation with the Secretary of Agri-

1 culture) to prevent, detect, and respond to outbreaks  
2 of plant or animal disease (including zoonotic dis-  
3 ease) that could compromise national security result-  
4 ing from a deliberate attack, a naturally occurring  
5 threat, the intentional adulteration of food, or other  
6 public health threats, taking into account inter-  
7 actions between animal health, human health, and  
8 animals' and humans' shared environment as di-  
9 rectly related to public health emergency prepared-  
10 ness and response capabilities, as applicable.

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

15 **TITLE II—IMPROVING**  
16 **PREPAREDNESS AND RESPONSE**

17 **SEC. 201. IMPROVING BENCHMARKS AND STANDARDS FOR**  
18 **PREPAREDNESS AND RESPONSE.**

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

23 “(k) EVALUATION.—

24 “(1) IN GENERAL.—Not later than 2 years  
25 after the date of enactment of the Pandemic and

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

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

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

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

23 “(C) a description of amounts received by  
24 eligible entities, as described in subsection (b)  
25 and section 319C–2(b), and amounts received

1 by sub-recipients and the effect of such funding  
2 on meeting evidence-based benchmarks and ob-  
3 jective standards; and

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

10 (b) EVALUATING THE PARTNERSHIP FOR STATE AND  
11 REGIONAL HOSPITAL PREPAREDNESS.—Section 319C-  
12 2(i)(1) (42 U.S.C. 247-3b(i)(1)) is amended by striking  
13 “section 319C-1(g), (i), and (j)” and inserting “section  
14 319C-1(g), (i), (j), and (k)”.

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

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

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

24 (2) in subsection (b)(2)(A)—

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

6 (B) by redesignating clauses (vii) through  
7 (ix) as clauses (viii) through (x); and

8 (C) by inserting after clause (vi) the fol-  
9 lowing:

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

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

18 (1) in subsection (a)—

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

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

1 (2) in subsection (b)(1)(A)—

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

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

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

11 “(i) consisting of—”; and

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

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

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

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

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

7 “(1) IN GENERAL.—

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

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

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

21 “(ii) RESERVATIONS CONTINGENT ON  
22 CONTINUED APPROPRIATIONS FOR THIS  
23 SECTION.—If for fiscal year 2019 or a sub-  
24 sequent fiscal year, the amount appro-  
25 priated under subparagraph (A) is such

1           that, after application of clause (i), the  
2           amount remaining for the purpose of car-  
3           rying out this section would be less than  
4           the amount available for such purpose for  
5           the previous fiscal year, the amount that  
6           may be reserved under clause (i) shall be  
7           reduced such that the amount remaining  
8           for the purpose of carrying out this section  
9           is not less than the amount available for  
10          such purpose for the previous fiscal year.

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

14           (2) in paragraph (2), by striking “paragraph  
15           (1) for a fiscal year” and inserting “paragraph  
16           (1)(A) for a fiscal year and not reserved for the pur-  
17           pose described in paragraph (1)(B)(i)”;

18           (3) in paragraph (3)(A), by striking “paragraph  
19           (1) and not reserved under paragraph (2)” and in-  
20           serting “paragraph (1)(A) and not reserved under  
21           paragraph (1)(B)(i) or (2)”.

1 **SEC. 203. REGIONAL HEALTH CARE EMERGENCY PRE-**  
2 **PAREDNESS AND RESPONSE SYSTEMS.**

3 (a) IN GENERAL.—Part B of title III (42 U.S.C. 243  
4 et seq.) is amended by inserting after section 319C-2 the  
5 following:

6 **“SEC. 319C-3. GUIDELINES FOR REGIONAL HEALTH CARE**  
7 **EMERGENCY PREPAREDNESS AND RESPONSE**  
8 **SYSTEMS.**

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

18 “(b) GUIDELINES.—The Assistant Secretary for Pre-  
19 paredness and Response, in consultation with the Director  
20 of the Centers for Disease Control and Prevention, the Ad-  
21 ministrator of the Centers for Medicare & Medicaid Serv-  
22 ices, the Administrator of the Health Resources and Serv-  
23 ices Administration, the Commissioner of Food and  
24 Drugs, the Assistant Secretary for Mental Health and  
25 Substance Use, the Assistant Secretary of Labor for Occu-  
26 pational Safety and Health, the Secretary of Veterans Af-

1   fairs, the heads of such other Federal agencies as the Sec-  
2   retary determines to be appropriate, and State, local, trib-  
3   al, and territorial public health officials, shall, not later  
4   than 2 years after the date 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           hospitals and health care facilities to provide appro-  
9           priate patient care during, in advance of, or imme-  
10          diately following, a public health emergency, result-  
11          ing from one or more chemical, biological, radio-  
12          logical, or nuclear agents, including emerging infec-  
13          tious diseases (which may include existing practices,  
14          such as trauma care and medical surge capacity and  
15          capabilities), with respect to—

16                  “(A) a regional approach to identifying  
17                  hospitals and health care facilities based on  
18                  varying capabilities and capacity to treat pa-  
19                  tients affected by such emergency, including—

20                          “(i) the manner in which the system  
21                          will coordinate with and integrate the part-  
22                          nerships and health care coalitions estab-  
23                          lished under section 319C-2(b); and

24                          “(ii) informing and educating appro-  
25                          priate first responders and health care sup-

1           ply chain partners of the regional emer-  
2           gency preparedness and response capabili-  
3           ties and medical surge capacity of such  
4           hospitals and health care facilities in the  
5           community;

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

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

20          “(D) in a manner that allows for disease  
21          containment (within the meaning of section  
22          2802(b)(2)(B)), coordinated medical triage,  
23          treatment, and transportation of patients, based  
24          on patient medical need (including patients in  
25          rural areas), to the appropriate hospitals or

1 health care facilities within the regional system  
2 or, as applicable and appropriate, between sys-  
3 tems in different States or regions; and

4 “(E) the needs of children and other at-  
5 risk individuals;

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

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

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

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

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

13           “(3) consider feedback related to financial im-  
14 plications for hospitals, health care facilities, public  
15 health agencies, laboratories, and other entities en-  
16 gaged in regional preparedness planning to imple-  
17 ment and follow such guidelines, as applicable; and

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

23           “(d) TECHNICAL ASSISTANCE.—The Assistant Sec-  
24 retary for Preparedness and Response, in consultation  
25 with the Director of the Centers for Disease Control and

1 Prevention and the Assistant Secretary of Labor for Occu-  
2 pational Safety and Health, may provide technical assist-  
3 ance and consultation towards meeting the guidelines de-  
4 scribed in subsection (b).

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

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

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

20 “(f) GAO REPORT TO CONGRESS.—

21 “(1) REPORT.—Not later than 3 years after the  
22 date of enactment of this section, the Comptroller  
23 General of the United States (referred to in this  
24 subsection as the ‘Comptroller General’) shall submit  
25 to the Committee on Health, Education, Labor, and

1 Pensions and the Committee on Finance of the Sen-  
2 ate and the Committee on Energy and Commerce  
3 and the Committee on Ways and Means of the  
4 House of Representatives, a report on the extent to  
5 which hospitals and health care facilities have imple-  
6 mented the recommended guidelines under sub-  
7 section (b), including an analysis and evaluation of  
8 any challenges hospitals or health care facilities ex-  
9 perience in implementing such guidelines.

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

12 “(A) data on the preparedness and re-  
13 sponse capabilities that have been informed by  
14 the guidelines under subsection (b) to improve  
15 regional emergency health care preparedness  
16 and response capability, including hospital and  
17 health care facility capacity and medical surge  
18 capabilities to prepare for, and respond to, pub-  
19 lic health emergencies; and

20 “(B) recommendations to reduce gaps in  
21 incentives for regional health partners, includ-  
22 ing hospitals and health care facilities to im-  
23 prove capacity and medical surge capabilities to  
24 prepare for, and respond to, public health emer-  
25 gencies, consistent with subsection (a), which

1           may include consideration of facilities partici-  
2           pating in programs under section 319C-2, pro-  
3           grams under the Centers for Medicare & Med-  
4           icaid Services (including innovative health care  
5           delivery and payment models), and input from  
6           private sector financial institutions.

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

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

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

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

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

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

21                   “(F) the Secretary of Veterans Affairs;  
22                   and

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

1 (b) 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 “The reports submitted under  
4 this paragraph shall also include progress towards the im-  
5 plementation of section 319C–3.”.

6 (c) NATIONAL HEALTH SECURITY STRATEGY INCOR-  
7 PORATION OF REGIONALIZED EMERGENCY PREPARED-  
8 NESS AND RESPONSE.—Section 2802(b)(3) (42 U.S.C.  
9 300hh–1(b)(3)) is amended—

10 (1) in the matter preceding subparagraph (A),  
11 by striking “including mental health” and inserting  
12 “including pharmacies, mental health facilities,”;  
13 and

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

16 “(G) Optimizing a coordinated and flexible  
17 approach to the emergency response and med-  
18 ical surge capacity of hospitals, other health  
19 care facilities, critical care, trauma care (which  
20 may include trauma centers), and emergency  
21 medical systems, which may include the imple-  
22 mentation of guidelines for regional health care  
23 emergency preparedness and response systems  
24 under section 319C–3.”.

1 (d) IMPROVING STATE AND LOCAL PUBLIC HEALTH  
2 SECURITY.—

3 (1) STATE AND LOCAL SECURITY.—Section  
4 319C–1(e) (42 U.S.C. 247d–3a(e)) is amended by  
5 striking “, and local emergency plans.” and inserting  
6 “, local emergency plans, and any regional health  
7 care emergency preparedness and response system  
8 established pursuant to the applicable guidelines  
9 under section 319C–3.”.

10 (2) PARTNERSHIPS.—Section 319C–2(d)(1)(A)  
11 (42 U.S.C. 247d-3b(d)(1)(A)) is amended—

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

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

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

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

20 **SEC. 204. MILITARY AND CIVILIAN PARTNERSHIP FOR**  
21 **TRAUMA READINESS.**

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

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

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

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

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

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

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

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

24 **“(b) MILITARY TRAUMA CARE PROVIDER PLACE-**  
25 **MENT PROGRAM.—**

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

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

11           “(A) shall be for a period of at least 1 fis-  
12 cal year and not more than 3 fiscal years (and  
13 may be renewed at the end of such period); and

14           “(B) shall be in an amount that does not  
15 exceed, in a fiscal year—

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

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

22           “(c) GRANT REQUIREMENTS.—

23           “(1) DEPLOYMENT AND PUBLIC HEALTH EMER-  
24 GENCIES.—As a condition of receipt of a grant  
25 under this section, a grant recipient shall agree to

1 allow military trauma care providers providing care  
2 pursuant to such grant to—

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

6 “(B) be deployed by the Secretary of  
7 Health and Human Services for response to a  
8 public health emergency pursuant to section  
9 319.

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

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

25 “(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 fiscal year  
5           shall submit to the Secretary and the Secretary of  
6           Defense a report for such fiscal year that includes  
7           information 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 fiscal 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                  fiscal 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 fiscal years, the Secretary, in consulta-  
3           tion with the Secretary of Defense, shall submit a  
4           report to the congressional committees of jurisdic-  
5           tion that includes information on the effect of plac-  
6           ing military trauma care providers in trauma centers  
7           awarded 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 declared pub-  
4           lic health emergency.

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

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

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

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

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

22          “(2) ELIGIBLE HIGH ACUITY TRAUMA CEN-  
23          TER.—The term ‘eligible high acuity trauma center’  
24          means a Level I trauma center that satisfies each of  
25          the following:

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

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

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

14           “(D) Such trauma center is an academic  
15           training center—

16                   “(i) affiliated with a medical school;

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

23                   “(iii) that undertakes research in the  
24                   prevention and treatment of traumatic in-  
25                   jury.

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

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

10           “(4) MILITARY TRAUMA TEAM.—The term  
11           ‘military trauma team’ means a complete military  
12           trauma team consisting of military trauma care pro-  
13           viders specializing in providing trauma care.

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

24           “(g) AUTHORIZATION OF APPROPRIATIONS.—To  
25           carry out this section, there are authorized to be appro-

1 priated \$6,800,000 for each of fiscal years 2019 through  
2 2023.”.

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

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

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

12 (2) in subsection (a)—

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

16 (B) in paragraph (1), by striking “and im-

17 proved” and inserting “, improved, and appro-

18 priately maintained”;

19 (C) in paragraph (3), in the matter pre-

20 ceding subparagraph (A), by striking “expand,

21 enhance, and improve” and inserting “expand,

22 improve, enhance, and appropriately maintain”;

23 and

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

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

19               (3) in subsection (b)—

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

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

1 (C) in paragraph (2)—

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

4 (ii) by inserting “and in a form read-  
5 ily usable for analytical approaches” after  
6 “in a secure manner”; and

7 (D) by amending paragraph (3) to read as  
8 follows:

9 “(3) STANDARDS.—

10 “(A) IN GENERAL.—Not later than 1 year  
11 after the date of the enactment of the Pan-  
12 demic and All-Hazards Preparedness and Ad-  
13 vancing Innovation Act of 2018, the Secretary,  
14 in cooperation with health care providers, State,  
15 local, tribal, and territorial public health offi-  
16 cials, and relevant Federal agencies (including  
17 the Office of the National Coordinator for  
18 Health Information Technology and the Na-  
19 tional Institute of Standards and Technology),  
20 shall, as necessary, adopt technical and report-  
21 ing standards, including standards for inter-  
22 operability as defined by section 3000, for net-  
23 works under paragraph (1) and update such  
24 standards as necessary. Such standards shall be  
25 made available on the internet website of the

1 Department of Health and Human Services, in  
2 a manner that does not compromise national se-  
3 curity.

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

11 (4) in subsection (c)—

12 (A) in paragraph (1)—

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

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

21 (iii) by striking “of rapid” and insert-  
22 ing “of, rapid”; and

23 (iv) by striking “such connectivity”  
24 and inserting “such interoperability”;

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

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

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

18 “(B) consult with the Secretary of Agri-  
19 culture, the Secretary of Commerce (and the  
20 Director of the National Institute of Standards  
21 and Technology), the Secretary of Defense, the  
22 Secretary of Homeland Security, and the Sec-  
23 retary of Veterans Affairs, and the heads of  
24 other Federal agencies, as the Secretary deter-  
25 mines appropriate.”;

1 (C) in paragraph (3)—

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

6 (ii) in clause (iv), as so redesign-  
7 nated—

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

11 (II) by striking “ and clinical  
12 laboratories” and inserting “, clinical  
13 laboratories, and public environmental  
14 health agencies”;

15 (iii) by striking “The network” and  
16 inserting the following:

17 “(A) IN GENERAL.—The network”; and

18 (iv) by adding at the end the fol-  
19 lowing:

20 “(B) REVIEW.—Not later than 2 years  
21 after the date of the enactment of the Pan-  
22 demic and All-Hazards Preparedness and Ad-  
23 vancing Innovation Act of 2018 and every 6  
24 years thereafter, the Secretary shall conduct a  
25 review of the elements described in subpara-

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

9 (D) in paragraph (5)—

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

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

16 “(A) IN GENERAL.—In establishing”;

17 (iii) by adding at the end the fol-  
18 lowing:

19 “(B) PUBLIC MEETING.—

20 “(i) IN GENERAL.—Not later than  
21 180 days after the date of enactment of  
22 the Pandemic and All-Hazards Prepared-  
23 ness and Advancing Innovation Act of  
24 2018, the Secretary shall convene a public  
25 meeting for purposes of discussing and

1 providing input on the potential goals,  
2 functions, and uses of the network de-  
3 scribed in paragraph (1) and incorporating  
4 the elements described in paragraph  
5 (3)(A).

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

23 “(iii) TOPICS.—Such public meeting  
24 shall include a discussion of—

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

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

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

16                  “(IV) considerations for State,  
17                  local, tribal, and territorial capabilities  
18                  and infrastructure related to data ex-  
19                  change and interoperability;

20                  “(V) privacy and security protec-  
21                  tions provided at the Federal, State,  
22                  local, tribal, and territorial levels, and  
23                  by nongovernmental stakeholders; and

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

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

6 (I) in clause (i), as so redesign-  
7 nated—

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

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

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

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

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

24 “(v) pilot test standards and imple-  
25 mentation specifications, consistent with

1           the process described in section  
2           3002(b)(3)(C), which State, local, tribal,  
3           and territorial public health entities may  
4           utilize, on a voluntary basis, as a part of  
5           the network.”;

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

8           (F) by inserting after paragraph (5) the  
9           following:

10          “(6) STRATEGY AND IMPLEMENTATION  
11          PLAN.—

12                 “(A) IN GENERAL.—Not later than 18  
13                 months after the date of enactment of the Pan-  
14                 demic and All-Hazards Preparedness and Ad-  
15                 vancing Innovation Act of 2018, the Secretary  
16                 shall submit to the congressional committees of  
17                 jurisdiction a coordinated strategy and an ac-  
18                 companying implementation plan that—

19                         “(i) is informed by the public meeting  
20                         under paragraph (5)(B);

21                         “(ii) includes a review and assessment  
22                         of existing capabilities of the network and  
23                         related infrastructure, including input pro-  
24                         vided by the public meeting under para-  
25                         graph (5)(B);

1                   “(iii) identifies and demonstrates the  
2                   measurable steps the Secretary will carry  
3                   out to—  
4                   “(I) develop, implement, and  
5                   evaluate the network described in  
6                   paragraph (1), utilizing elements de-  
7                   scribed in paragraph (3)(A);  
8                   “(II) modernize and enhance bio-  
9                   surveillance activities, including strat-  
10                  egies to include innovative tech-  
11                  nologies and analytical approaches  
12                  (including prediction and forecasting  
13                  for pandemics and all-hazards) from  
14                  public and private entities;  
15                  “(III) improve information shar-  
16                  ing, coordination, and communication  
17                  among disparate biosurveillance sys-  
18                  tems supported by the Department of  
19                  Health and Human Services, includ-  
20                  ing the identification of methods to  
21                  improve accountability, better utilize  
22                  resources and workforce capabilities,  
23                  and incorporate innovative tech-  
24                  nologies within and across agencies;  
25                  and

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

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

10                   “(v) establishes dates by which each  
11                   measurable step under clause (iii) will be  
12                   implemented.”.

13                   “(B) ANNUAL BUDGET PLAN.—Not later  
14                   than 2 years after the date of enactment of the  
15                   Pandemic and All-Hazards Preparedness and  
16                   Advancing Innovation Act of 2018 and on an  
17                   annual basis thereafter, in accordance with the  
18                   strategy and implementation plan under this  
19                   paragraph, the Secretary shall, taking into ac-  
20                   count recommendations provided by the Na-  
21                   tional Biodefense Science Board, develop a  
22                   budget plan based on the strategy and imple-  
23                   mentation plan under this section. Such budget  
24                   plan shall include—

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

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

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

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

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

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

1 (ii) in subparagraph (B)—

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

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

7 (iii) in subparagraph (C)—

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

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

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

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

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

21 “(8) SITUATIONAL AWARENESS AND BIO-  
22 SURVEILLANCE AS A NATIONAL SECURITY PRI-  
23 ORITY.—The Secretary, on a periodic basis as appli-  
24 cable and appropriate, shall meet with the Director  
25 of National Intelligence to inform the development

1 and capabilities of the nationwide public health situ-  
2 ational awareness and biosurveillance 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 purposes  
20 described in 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, localities,  
25 tribes, and territories or a consortium of States, lo-

1 calities, tribes, and territories receiving an award  
2 under this subsection regarding interoperability and  
3 the technical standards set forth by the Secretary.”;

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

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

8 “(f) PERSONNEL AUTHORITIES.—

9 “(1) SPECIALLY QUALIFIED PERSONNEL.—In  
10 addition to any other personnel authorities, to carry  
11 out subsection (b) and subsection (c), the Secretary  
12 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, modelling, 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 that 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 2018, the Comptroller General of the United States  
22          shall conduct an independent evaluation, and submit to  
23          the Secretary and the congressional committees of juris-  
24          diction a report concerning the activities conducted under  
25          subsections (b) and (c), and provide recommendations, as

1 applicable 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 igned 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 **SEC. 206. STRENGTHENING AND SUPPORTING THE PUBLIC**  
10 **HEALTH EMERGENCY RAPID RESPONSE**  
11 **FUND.**

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

13 (1) in subsection (b)—

14 (A) in paragraph (1)—

15 (i) in the first sentence, by inserting

16 “or if the Secretary determines there is the  
17 significant potential for a public health  
18 emergency, to allow the Secretary to rap-  
19 idly respond to the immediate needs result-  
20 ing from such public health emergency or  
21 potential public health emergency” before  
22 the period; and

23 (ii) by inserting “The Secretary shall  
24 plan for the expedited distribution of funds

1 to appropriate agencies and entities.” after  
2 the first sentence;

3 (B) by redesignating paragraph (2) as  
4 paragraph (3);

5 (C) by inserting after paragraph (1) the  
6 following:

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

9 “(A) facilitate coordination between and  
10 among Federal, State, local, tribal, and terri-  
11 torial entities and public and private health  
12 care entities that the Secretary determines may  
13 be affected by a public health emergency or po-  
14 tential public health emergency (including com-  
15 munication of such entities with relevant inter-  
16 national entities, as applicable);

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

23 “(C) facilitate and accelerate, as applica-  
24 ble, advanced research and development of secu-  
25 rity countermeasures (as defined in section

1           319F–2), qualified countermeasures (as defined  
2           in section 319F–1), or qualified pandemic or  
3           epidemic products (as defined in section 319F–  
4           3), that are applicable to the public health  
5           emergency or potential public health emergency  
6           under paragraph (1);

7           “(D) strengthen biosurveillance capabilities  
8           and laboratory capacity to identify, collect, and  
9           analyze information regarding such public  
10          health emergency or potential public health  
11          emergency, including the systems under section  
12          319D;

13          “(E) support initial emergency operations  
14          and assets related to preparation and deploy-  
15          ment of intermittent disaster response per-  
16          sonnel expenses under section 2812, and the  
17          Medical Reserve Corps under section 2813; and

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

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

22          “(4) REVIEW.—Not later than 2 years after the  
23          date of enactment of the Pandemic and All-Hazards  
24          Preparedness and Advancing Innovation Act of  
25          2018, the Secretary, in coordination with the Assist-

1 ant Secretary for Preparedness and Response, shall  
2 conduct a review of the Fund under this section, and  
3 provide recommendations to the Committee on  
4 Health, Education, Labor, and Pensions and the  
5 Committee on Appropriations of the Senate and the  
6 Committee on Energy and Commerce and the Com-  
7 mittee on Appropriations of the House of Represent-  
8 atives on policies to improve such Fund for the uses  
9 described in paragraph (2).

10 “(5) GAO REPORT.—Not later than 4 years  
11 after the date of enactment of the Pandemic and  
12 All-Hazards Preparedness and Advancing Innovation  
13 Act of 2018, the Comptroller General of the United  
14 States shall conduct a review of the Fund under this  
15 section, including the uses and the resources avail-  
16 able in the Fund.”; 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 PREPAREDNESS FOR AND RESPONSE**  
2 **TO ALL-HAZARDS BY PUBLIC HEALTH EMER-**  
3 **GENCY VOLUNTEERS.**

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

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

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

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

22 **SEC. 208. CLARIFYING STATE LIABILITY LAW FOR VOLUN-**  
23 **TEER HEALTH CARE PROFESSIONALS.**

24 (a) IN GENERAL.—Part B of title III (42 U.S.C. 243  
25 et seq.) is amended by inserting after section 319I the fol-  
26 lowing:

1 **“SEC. 319I-1. HEALTH CARE PROFESSIONALS ASSISTING**  
2 **DURING A PUBLIC HEALTH EMERGENCY.**

3 “(a) LIMITATION ON LIABILITY.—Notwithstanding  
4 any other provision of law, a health care professional who  
5 is a member of the Medical Reserve Corps under section  
6 2813 or who is included in the verification network under  
7 section 319I and who—

8 “(1) is responding to a public health emergency  
9 declared under section 319(a) during the initial 90-  
10 day period of the public health emergency deter-  
11 mination (excluding any period covered by a renewal  
12 of such determination);

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

15 “(A) during the 90-day period of the pub-  
16 lic health emergency described in paragraph (1)  
17 and related to the treatment of individuals in  
18 need of health care services due to such public  
19 health emergency;

20 “(B) in the State or States in which the  
21 public health emergency is declared;

22 “(C) in the health care professional’s ca-  
23 pacity as a member of the Medical Reserve  
24 Corps or a professional included in the  
25 verification network under section 319I; and

1           “(D) in the course of providing services  
2           that are within the scope of the license, reg-  
3           istration, or certification of the professional, as  
4           defined by the State of licensure, registration,  
5           or certification; and

6           “(3) prior to the rendering of such act or omis-  
7           sion, was authorized by the State’s authorization of  
8           a deploying State’s Emergency System for Advance  
9           Registration of Volunteer Health Professionals de-  
10          scribed in section 319I or the Medical Reserve Corps  
11          established under section 2813, to provide health  
12          care services,

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

19          “(b) VOLUNTEER PROTECTION ACT.—Nothing in  
20 this section shall be construed to affect an individual’s  
21 right to protections under the Volunteer Protection Act  
22 of 1997.

23          “(c) PREEMPTION.—This section shall supercede the  
24 laws of any State that would subject a health care profes-  
25 sional described in subsection (a) to the liability laws of

1 any State other than the State liability laws to which such  
2 individual is subject pursuant to such subsection.

3 “(d) DEFINITIONS.—In this section:

4 “(1) The term ‘health care professional’ means  
5 an individual licensed, registered, or certified under  
6 Federal or State laws or regulations to provide  
7 health care services.

8 “(2) The term ‘health care services’ means any  
9 services provided by a health care professional, or by  
10 any individual working under the supervision of a  
11 health care professional, that relate to—

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

14 “(B) the assessment or care of the health  
15 of human beings.”.

16 (b) EFFECTIVE DATE.—

17 (1) IN GENERAL.—Section 319I–1 of the Public  
18 Health Service Act, as added by subsection (a), shall  
19 take effect 90 days after the date of the enactment  
20 of this Act.

21 (2) APPLICATION.—Section 319I–1 of the Pub-  
22 lic Health Service Act, as added by subsection (a),  
23 applies to a claim for harm only if the act or omis-  
24 sion that caused such harm occurred on or after the  
25 effective date described in paragraph (1).

1 (c) GAO STUDY.—Not later than one year after the  
2 date of enactment of this Act, the Comptroller General  
3 of the United States shall conduct a review of—

4 (1) the number of health care providers who  
5 register under the verification network pursuant to  
6 section 319I of the Public Health Service Act (42  
7 U.S.C. 247d–7b) in advance to provide services dur-  
8 ing a public health emergency;

9 (2) the number of health care providers who are  
10 credentialed to provide services during the period of  
11 a public health emergency declaration, including  
12 those who are credentialed through programs estab-  
13 lished in the verification network pursuant to such  
14 section 319I and those credentialed by authorities  
15 within the State in which the emergency occurred;

16 (3) the average time to verify the credentials of  
17 a health care provider during the period of a public  
18 health emergency declaration, including the average  
19 time pursuant to the verification network under such  
20 section 319I and for an individual’s credentials to be  
21 verified by an authority within the State; and

22 (4) the States’ Emergency System for Advance  
23 Registration of Volunteer Health Professionals vol-  
24 unteer program, including whether physician or  
25 medical groups, associations, or other relevant pro-

1 vider organizations utilize such program for pur-  
2 poses of volunteering during public health emer-  
3 gencies.

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

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

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

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

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

1           (c) REVIEW OF THE NATIONAL DISASTER MEDICAL  
2 SYSTEM.—Section 2812(b)(2) (42 U.S.C. 300hh-  
3 11(b)(2)) is amended to read as follows:

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

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

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

17           “(ii) an assessment of the available  
18 workforce of the intermittent disaster re-  
19 sponse personnel described in subsection  
20 (c);

21           “(iii) the capacity of the workforce de-  
22 scribed in clause (ii) to respond to all haz-  
23 ards, including capacity to simultaneously  
24 respond to multiple public health emer-

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

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

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

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

14 (d) NOTIFICATION OF NDMS SHORTAGE.—Section  
15 2812(c) (42 U.S.C. 300hh–11(c)) is amended by adding  
16 at the end the following:

17 “(3) SERVICE BENEFIT.—Individuals appointed  
18 to serve under this subsection shall be considered  
19 public safety officers under part L of title I of the  
20 Omnibus Crime Control and Safe Streets Act of  
21 1968. The Secretary shall provide notification to eli-  
22 gible individuals of any effect such designation may  
23 have on other benefits for which such individuals are  
24 eligible, including benefits from private entities.

1           “(4) NOTIFICATION.—Not later than 30 days  
2 after the date on which the Secretary determines the  
3 number of intermittent disaster response personnel  
4 of such System is insufficient to address a public  
5 health emergency or potential public health emer-  
6 gency, the Secretary shall submit to the congres-  
7 sional committees of jurisdiction a notification de-  
8 tailing the impact such shortage could have on meet-  
9 ing public health needs and emergency medical per-  
10 sonnel needs during a public health emergency, and  
11 any identified measures to address such shortage.

12           “(5) 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           (e) PUBLIC SAFETY OFFICER BENEFITS.—Section  
5 1204(9) of title I of the Omnibus Crime Control and Safe  
6 Streets Act of 1968 (34 U.S.C. 10284(9)) is amended—

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

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

11          (3) by inserting after subparagraph (D) the fol-  
12          lowing:

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

24           (f) NATIONAL DISASTER MEDICAL SYSTEM AUTHOR-  
25          IZATION OF APPROPRIATIONS.—Section 2812(g) (42

1 U.S.C. 300hh–11(g)) is amended by striking  
2 “\$52,700,000 for each of fiscal years 2014 through 2018”  
3 and inserting “\$57,400,000 for each of fiscal years 2019  
4 through 2023”.

5 (g) MEDICAL RESERVE CORPS. AUTHORIZATION OF  
6 APPROPRIATIONS.—Section 2813(i) (42 U.S.C. 300hh–  
7 15(i)) is amended by striking “2014 through 2018” and  
8 inserting “2019 through 2023”.

9 **SEC. 302. HEALTH SYSTEM INFRASTRUCTURE TO IMPROVE**  
10 **PREPAREDNESS AND RESPONSE.**

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

1 change critical information and deliver products consumed  
2 or used to preserve, protect, or sustain life, health, or safe-  
3 ty, and sharing of specialized expertise.”.

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

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

9 (a) AT-RISK INDIVIDUALS IN THE NATIONAL  
10 HEALTH SECURITY STRATEGY.—Section 2802(b)(4)(B)  
11 (42 U.S.C. 300hh–1(b)(4)(B)) is amended—

12 (1) by striking “this section and sections 319C–  
13 1, 319F, and 319L,” and inserting “this Act”; and

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

16 (b) COUNTERMEASURE CONSIDERATIONS.—Section  
17 319L(e)(6) (42 U.S.C. 247d–7e(e)(6)) is amended—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14           (2) in subsection (d)—

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

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

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

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

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

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

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

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

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



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

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

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

7                   “(J) The Secretary of Education.

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

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



1   retary of Veterans Affairs, shall establish an advisory com-  
2   mittee to be known as the National Advisory Committee  
3   on Seniors and Disasters (referred to in this section as  
4   the ‘Advisory Committee’).

5       “(b) DUTIES.—

6           “(1) IN GENERAL.—The Advisory Committee  
7       shall—

8                   “(A) provide advice and consultation with  
9       respect to the activities carried out pursuant to  
10      section 2814, as applicable and appropriate;

11                   “(B) evaluate and provide input with re-  
12      spect to the medical and public health needs of  
13      seniors related to the preparation for, response  
14      to, and recovery from all-hazards emergencies;  
15      and

16                   “(C) provide advice and consultation with  
17      respect to State emergency preparedness and  
18      response activities and seniors, including related  
19      drills and exercises pursuant to the prepared-  
20      ness goals under section 2802(b).

21           “(2) ADDITIONAL DUTIES.—The Advisory Com-  
22      mittee may provide advice and recommendations to  
23      the Secretary with respect to seniors and the med-  
24      ical and public health grants and cooperative agree-

1       ments as applicable to preparedness and response  
2       activities under this title and title III.

3           “(3) MEMBERSHIP.—

4               “(A) IN GENERAL.—The Secretary, in con-  
5       sultation with such other heads of agencies as  
6       appropriate, shall appoint not more than 15  
7       members to the Advisory Committee. In ap-  
8       pointing such members, the Secretary shall en-  
9       sure that the total membership of the Advisory  
10      Committee is an odd number.

11           “(B) REQUIRED MEMBERS.—The members  
12      appointed under paragraph (1) shall include—

13               “(i) the Assistant Secretary for Pre-  
14      paredness and Response;

15               “(ii) the Director of the Biomedical  
16      Advanced Research and Development Au-  
17      thority;

18               “(iii) the Director of the Centers for  
19      Disease Control and Prevention;

20               “(iv) the Commissioner of Food and  
21      Drugs;

22               “(v) the Director of the National In-  
23      stitutes of Health;

24               “(vi) the Administrator of the Centers  
25      for Medicare & Medicaid Services;

1                   “(vii) the Administrator of the Ad-  
2                   ministration for Community Living;

3                   “(viii) the Administrator of the Fed-  
4                   eral Emergency Management Agency;

5                   “(ix) the Under Secretary for Health  
6                   of the Department of Veterans Affairs;

7                   “(x) at least 2 non-Federal health  
8                   care professionals with expertise in medical  
9                   disaster planning, preparedness, response,  
10                  or recovery;

11                  “(xi) at least 2 representatives of  
12                  State, local, territorial, or tribal agencies  
13                  with expertise in disaster planning, pre-  
14                  paredness, response, or recovery; and

15                  “(xii) representatives of such other  
16                  Federal agencies (such as the Department  
17                  of Energy and the Department of Home-  
18                  land Security) as the Secretary determines  
19                  necessary to fulfill the duties of the Advi-  
20                  sory Committee.

21                  “(c) MEETINGS.—The Advisory Committee shall  
22                  meet not less frequently than biannually.

23                  “(d) ADVISORY COMMITTEE COORDINATION.—

24                  “(1) IN GENERAL.—The Secretary shall coordi-  
25                  nate activities authorized under this section and sec-

1       tion 2811A, and make efforts to reduce unnecessary  
2       or duplication of meetings, recommendations, and  
3       reporting under such sections. Members of the advi-  
4       sory committees under this section and section  
5       2811A, or their designees, shall meet periodically,  
6       and not less than annually, to—

7               “(A) review the recommendations devel-  
8               oped by such committees to coordinate, as ap-  
9               propriate, the implementation of recommenda-  
10              tions, in order to reduce gaps, overlap, and du-  
11              plication of effort in Federal programs or by  
12              Federal grantees; and

13              “(B) align preparedness and response pro-  
14              grams or activities to address the dual or over-  
15              lapping needs of children and seniors and any  
16              challenges in preparing for and responding to  
17              such needs.

18              “(2) NOTIFICATION.—The Secretary shall no-  
19              tify the congressional committees of jurisdiction  
20              upon the convening of each meeting under para-  
21              graph (1), and provide minutes from such meeting  
22              not later than 90 days after the meeting.

23              “(e) SUNSET.—The Advisory Committee shall termi-  
24              nate on September 30, 2023.”.

1 **SEC. 307. GUIDANCE FOR PARTICIPATION IN EXERCISES**  
2 **AND DRILLS.**

3 Not later than 2 years after the date of enactment  
4 of this Act, the Secretary of Health and Human Services  
5 shall issue final guidance regarding the participation of  
6 State, local, tribal, and territorial public health depart-  
7 ment or agency personnel funded in whole or in part  
8 through programs authorized under this Act in drills and  
9 operational exercises in order to identify, inform, and ad-  
10 dress the gaps in and policies related to all-hazards med-  
11 ical and public health preparedness and response, which  
12 may include drills and operational exercises that incor-  
13 porate medical surge capacity planning, medical counter-  
14 measure distribution and administration, and preparing  
15 for and responding to identified threats for that region.  
16 The Secretary shall consult with the Department of  
17 Homeland Security, the Department of Defense, the De-  
18 partment of Veterans Affairs, and other applicable Fed-  
19 eral departments and agencies as necessary and appro-  
20 priate in the development of such guidance. The Secretary  
21 shall make the guidance available on the internet website  
22 of the Department of Health and Human Services.

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

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

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

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, and other relevant topics  
11 to” after “shall”; and

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

14           “(I) THREAT AWARENESS.—Coordinate  
15 with the Director of the Centers for Disease  
16 Control and Prevention, the Director of Na-  
17 tional Intelligence, the Secretary of Homeland  
18 Security, the Assistant to the President for Na-  
19 tional Security Affairs, the Secretary of De-  
20 fense, and other relevant Federal officials, such  
21 as the Secretary of Agriculture, to maintain a  
22 current assessment of national security threats  
23 and inform preparedness and response capabili-  
24 ties based on the range of the threats that have

1           the potential to result in a public health emer-  
2           gency.”.

3 **SEC. 402. PUBLIC HEALTH EMERGENCY MEDICAL COUN-**  
4                                   **TERMEASURES ENTERPRISE.**

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

8 **“SEC. 2811-1. PUBLIC HEALTH EMERGENCY MEDICAL**  
9                                   **COUNTERMEASURES ENTERPRISE.**

10           “(a) IN GENERAL.—The Secretary shall establish the  
11           Public Health Emergency Medical Countermeasures En-  
12           terprise (referred to in this section as the ‘PHEMCE’).  
13           The Assistant Secretary for Preparedness and Response  
14           shall serve as chair of the PHEMCE.

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

18                   “(1) The Assistant Secretary for Preparedness  
19                   and Response.

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

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

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

25                   “(5) The Secretary of Defense.

1 “(6) The Secretary of Homeland Security.

2 “(7) The Secretary of Agriculture.

3 “(8) The Secretary of Veterans Affairs.

4 “(9) Representatives of any other Federal agency,  
5 which may include the Director of the Bio-  
6 medical Advanced Research and Development Au-  
7 thority, the Director of the Strategic National Stock-  
8 pile, the Director of the National Institute of Allergy  
9 and Infectious Diseases, and the Director of the Of-  
10 fice of Public Health Preparedness and Response, as  
11 the Secretary determines appropriate.

12 “(c) FUNCTIONS.—

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

15 “(A) Establish a process pursuant to sec-  
16 tion 2811(d)(2)(B) to make recommendations  
17 to the Secretary regarding the prioritization of  
18 research, development, and procurement of  
19 countermeasures, as defined in section 319F-  
20 2(e), based on the health security needs of the  
21 United States. Such recommendations shall be  
22 informed by the National Health Security  
23 Strategy pursuant to section 2802, the Stra-  
24 tegic National Stockpile review required under  
25 section 319F-2(a)(2), the countermeasures

1 budget plan pursuant to section 2811(b)(7),  
2 and an assessment of current national security  
3 threats, including chemical, biological, radio-  
4 logical and nuclear threats, including emerging  
5 infectious diseases. In the event that members  
6 of the PHEMCE do not agree upon a rec-  
7 ommendation, the Secretary shall provide a de-  
8 termination regarding such recommendation.

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

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

21 “(D) Provide consultation for the develop-  
22 ment of the strategy and implementation plan  
23 under section 2811(d).

24 “(2) INPUT.—In carrying out subparagraphs  
25 (B) and (C) of paragraph (1), the PHEMCE shall

1 solicit and consider input from State, local, tribal,  
2 and territorial public health departments, as appro-  
3 priate.”.

4 (b) PUBLIC HEALTH EMERGENCY MEDICAL COUN-  
5 TERMEASURES ENTERPRISE STRATEGY AND IMPLEMEN-  
6 TATION PLAN.—Section 2811(d) (42 U.S.C. 300hh-  
7 10(d)) is amended—

8 (1) in paragraph (1)—

9 (A) by striking “Not later than 180 days  
10 after the date of enactment of this subsection,  
11 and every year thereafter” and inserting “Not  
12 later than March 15, 2020, and biennially  
13 thereafter”; and

14 (B) by striking “Director of Biomedical”  
15 and all that follows through “Food and Drugs”  
16 and inserting “Public Health Emergency Med-  
17 ical Countermeasures Enterprise established  
18 under section 2811-1”; and

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

21 **SEC. 403. STRATEGIC NATIONAL STOCKPILE.**

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

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

1 (2) in paragraph (1)—

2 (A) by inserting “and optimize” after  
3 “provide for”;

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

13 (C) by striking the second sentence;

14 (3) by inserting after paragraph (1) the fol-  
15 lowing:

16 “(2) THREAT-BASED REVIEW.—

17 “(A) IN GENERAL.—The Secretary shall  
18 conduct an annual threat-based review (taking  
19 into account at-risk individuals) of the contents  
20 of the stockpile under paragraph (1), including  
21 non-pharmaceutical supplies, and, in consulta-  
22 tion with the Public Health Emergency Medical  
23 Countermeasures Enterprise established under  
24 section 2811–1, review contents within the  
25 stockpile and assess whether such contents are

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

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

16 “(i) information regarding—

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

21 “(II) planning considerations for  
22 appropriate manufacturing capacity  
23 and capability to meet the goals of  
24 such additions or modifications (with-  
25 out disclosing proprietary informa-

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

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

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

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

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

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

21                  “(VIII) appropriate protocols and  
22                  processes for the deployment, distribu-  
23                  tion, or dispensing of the counter-  
24                  measure at the State and local level,  
25                  including plans for relevant capabili-

1                   ties of State and local entities to dis-  
2                   pense, distribute, and administer the  
3                   countermeasure; and

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

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

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

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

20                   (C) by amending subparagraph (E) to read  
21                   as follows:

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

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

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

13 “(5) GAO REPORT.—

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

23 “(i) an assessment of the comprehen-  
24 siveness and completeness of each annual  
25 threat-based review under paragraph (2),

1 including whether all newly procured or re-  
2 plenished countermeasures within the  
3 stockpile were described in each annual re-  
4 view, and whether, consistent with para-  
5 graph (2)(B), the Secretary conducted the  
6 necessary internal review in advance of  
7 such procurement or replenishment;

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

20 “(iii) an assessment of the plans de-  
21 veloped by the Secretary for the deploy-  
22 ment, distribution, and dispensing of coun-  
23 termeasures procured, modified, or replen-  
24 ished under paragraph (1), including  
25 whether such plans were developed prior to

1 procurement, modification, or replenish-  
2 ment;

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

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

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

22 “(vii) an assessment of the extent to  
23 which additions, modifications, and replen-  
24 ishments reviewed under paragraph (2)  
25 align with previous relevant reports or re-

1 views by the Secretary or the Comptroller  
2 General; and

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

13 “(B) SUBMISSION.—Not later than 6  
14 months after completing a classified version of  
15 the review under subparagraph (A), the Comp-  
16 troller General shall submit an unclassified  
17 version of the review to the congressional com-  
18 mittees of jurisdiction.”.

19 (b) AUTHORIZATION OF APPROPRIATIONS, STRA-  
20 TEGIC NATIONAL STOCKPILE.—Section 319F–2(f)(1) (42  
21 U.S.C. 247d–6b(f)(1)) is amended by striking  
22 “\$533,800,000 for each of fiscal years 2014 through  
23 2018” and inserting “\$610,000,000 for each of fiscal  
24 years 2019 through 2023”.

1 **SEC. 404. PREPARING FOR PANDEMIC INFLUENZA, ANTI-**  
2 **MICROBIAL RESISTANCE, AND OTHER SIG-**  
3 **NIFICANT THREATS.**

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

6 “(F) STRATEGIC INITIATIVES.—The Sec-  
7 retary, acting through the Director of BARDA,  
8 may implement strategic initiatives, including  
9 by building on existing programs and by award-  
10 ing grants supporting innovative candidate  
11 products in preclinical and clinical development,  
12 to address priority, naturally occurring and  
13 man-made threats that, as determined by the  
14 Secretary, pose a significant level of risk to na-  
15 tional security based on the characteristics of a  
16 chemical, biological, radiological or nuclear  
17 threat, or existing capabilities to respond to  
18 such a threat (including medical response and  
19 treatment capabilities and manufacturing infra-  
20 structure). Such initiatives shall accelerate and  
21 support the advanced research, development,  
22 and procurement of, countermeasures and prod-  
23 ucts, as applicable, to address areas including—  
24 “(i) chemical, biological, radiological,  
25 or nuclear threats, including emerging in-  
26 fectious diseases, for which insufficient ap-

1           proved, licensed, or authorized counter-  
2           measures exist, or for which such threat,  
3           or the result of an exposure to such threat,  
4           may become resistant to countermeasures  
5           or existing countermeasures may be ren-  
6           dered ineffective;

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

22          “(iii) threats that may result pri-  
23          marily or secondarily from a chemical, bio-  
24          logical, radiological, or nuclear agent, or  
25          emerging infectious disease, and which

1           may present increased treatment complica-  
2           tions such as the occurrence of resistance  
3           to available countermeasures or potential  
4           countermeasures, including antimicrobial  
5           resistant pathogens.”.

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

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

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

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

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

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

17           “(A) IN GENERAL.—Not later than 1 year  
18          after the date of the enactment of the Pan-  
19          demic and All-Hazards Preparedness and Ad-  
20          vancing Innovation Act of 2018, the Secretary  
21          shall report to the congressional committees of  
22          jurisdiction on the implementation of rec-  
23          ommendations of the Federal Experts Security  
24          Advisory Panel concerning the select agent pro-  
25          gram.

1           “(B) CONTINUED UPDATES.—The Sec-  
2           retary shall report to the congressional commit-  
3           tees of jurisdiction annually following the sub-  
4           mission of the report under subparagraph (A)  
5           until the recommendations described in such  
6           subparagraph are fully implemented, or a jus-  
7           tification is provided for the delay in, or lack of,  
8           implementation.”.

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

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

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

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

18           (2) by striking subparagraph (A) and inserting  
19   the following:

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

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

1                   “(ii) approval, clearance, licensure,  
2                   and authorized uses of products;

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

8                   “(iv) 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                  (3) by redesignating subparagraphs (D) and  
16                  (E) as subparagraphs (E) and (F), respectively; and

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

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

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) (42  
5 U.S.C. 247d–6b(c)(2)(C)) is amended by striking “The  
6 Secretary and the Homeland Security Secretary shall  
7 promptly notify the appropriate committees of Congress”  
8 and inserting “The Secretary and the Secretary of Home-  
9 land Security shall send to Congress, on an annual basis,  
10 all current material threat determinations and shall  
11 promptly notify the Committee on Health, Education,  
12 Labor, and Pensions and the Committee on Homeland Se-  
13 curity and Government Affairs of the Senate and the Com-  
14 mittee on Energy and Commerce and the Committee on  
15 Homeland Security of the House of Representatives”.

16 (b) CONTRACTING COMMUNICATIONS.—

17 (1) CONTRACT DURATION.—Section 319F–  
18 2(c)(7)(B)(ii)(III) (42 U.S.C. 247d–  
19 6b(c)(7)(B)(ii)(III)) is amended by adding at the  
20 end the following: “The Secretary shall notify the  
21 vendor within 90 days of a determination by the  
22 Secretary to renew such contract.”.

23 (2) EXPEDITED AUTHORITIES.—Section  
24 319L(c)(5)(B)(i) (42 U.S.C. 247d–7e(c)(5)(B)(i)) is  
25 amended by adding at the end the following: “Upon  
26 award, extension, or termination of any such con-



1 could be discussed and included in such plans;

2 and

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

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

7 (A) by striking “paragraph (4)(A)” and in-  
8 serting “paragraph (5)(A)”; and

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

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

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

17 (a) BIOSHIELD SPECIAL RESERVE FUND.—Section  
18 319F–2(g)(1) (42 U.S.C. 247d–6b(g)(1)) is amended—

19 (1) by striking “\$2,800,000,000 for the period  
20 of fiscal years 2014 through 2018” and inserting  
21 “\$3,500,000,000 for the period of fiscal years 2019  
22 through 2023, to remain available until expended”;  
23 and

24 (2) by striking the second sentence.

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

7 **TITLE VI—ADVANCING TECH-**  
8 **NOLOGIES FOR MEDICAL**  
9 **COUNTERMEASURES**

10 **SEC. 601. ADMINISTRATION OF COUNTERMEASURES.**

11 Section 319L(c)(4)(D)(iii) (42 U.S.C. 247d–  
12 7e(c)(4)(D)(iii)) is amended by striking “and platform  
13 technologies” inserting “platform technologies, tech-  
14 nologies to administer countermeasures, and technologies  
15 to improve storage and transportation of counter-  
16 measures”.

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

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

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

22 “(a) PURPOSE.—The purpose of this section is to  
23 support and accelerate the development or manufacture  
24 of security countermeasures, qualified countermeasures,  
25 and qualified pandemic or epidemic products by facili-

1 tating and encouraging submission of data and informa-  
2 tion to support such products to master files, and through  
3 clarifying the authority to cross-reference to data and in-  
4 formation previously submitted to the Secretary.

5 “(b) APPLICABILITY OF REFERENCE.—

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

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

1           “(c) MEDICAL COUNTERMEASURE MASTER FILE  
2 CONTENT.—

3           “(1) IN GENERAL.—A master file under this  
4 section may include information to support and ac-  
5 celerate—

6           “(A) the development of medical counter-  
7 measure submissions to support the approval,  
8 licensure, classification, clearance, conditional  
9 approval, or authorization of one or more secu-  
10 rity countermeasures, qualified counter-  
11 measures, or qualified pandemic or epidemic  
12 products; and

13           “(B) the manufacture of security counter-  
14 measures, qualified countermeasures, or quali-  
15 fied pandemic or epidemic products.

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

21           “(d) SPONSOR REFERENCE.—

22           “(1) IN GENERAL.—Each incorporation of in-  
23 formation or data contained in a master file by ref-  
24 erence shall describe the incorporated material in a  
25 manner in which the Secretary determines appro-

1        appropriate and that permits the review of such informa-  
2        tion without necessitating resubmission of such in-  
3        formation or data. Master files shall be submitted in  
4        an electronic format in accordance with section  
5        745A and as specified in applicable guidance.

6            “(2) REFERENCE BY A MASTER FILE HOLD-  
7        ER.—A master file holder that is the sponsor of a  
8        medical countermeasure submission shall notify the  
9        Secretary in writing of the intent to reference the  
10       medical countermeasure master file as a part of the  
11       submission.

12           “(3) REFERENCE BY AN AUTHORIZED PER-  
13        SON.—A sponsor of a medical countermeasure sub-  
14        mission may, where the Secretary determines appro-  
15        priate, incorporate by reference all or part of the  
16        contents of a medical countermeasure master file, if  
17        the master file holder authorizes the incorporation in  
18        writing.

19           “(e) ACKNOWLEDGEMENT OF MASTER FILE BY THE  
20        SECRETARY.—The Secretary shall provide the master file  
21        holder with a written notification indicating that the Sec-  
22        retary has reviewed and relied upon specified information  
23        or data within a master file and the purposes for which  
24        such information or data was incorporated by reference  
25        if the Secretary has reviewed and relied upon such speci-

1 fied information or data to support the approval, classi-  
2 fication, conditional approval, clearance, licensure, or au-  
3 thorization of a security countermeasure, qualified coun-  
4 termeasure, or qualified pandemic or epidemic product.  
5 The Secretary may rely upon the data and information  
6 within the medical countermeasure master file for which  
7 such written notification was provided in additional appli-  
8 cations, as applicable and appropriate and upon the re-  
9 quest of the master file holder so notified in writing or  
10 by an authorized person of such holder.

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

13 “(1) alter the authority of the Secretary to ap-  
14 prove, license, classify, clear, conditionally approve,  
15 or authorize drugs, biological products, or devices  
16 pursuant to this Act or section 351 of the Public  
17 Health Service Act (as authorized prior to the date  
18 of enactment of the Pandemic and All-Hazards Pre-  
19 paredness and Advancing Innovation Act of 2018),  
20 including the standards of evidence, and applicable  
21 conditions, for approval under the applicable Act; or

22 “(2) alter the authority of the Secretary under  
23 this Act or the Public Health Service Act to deter-  
24 mine the types of information or data previously  
25 submitted by a sponsor or any other person that

1        may be incorporated by reference in an application,  
2        request, or notification for a drug, biological prod-  
3        uct, or device submitted under sections 505(i),  
4        505(b), 505(j), 512(b)(1), 512(b)(2), 564, 571,  
5        520(g), 515(c), 513(f)(2), or 510(k) of this Act, or  
6        subsection (a) or (k) of section 351 of the Public  
7        Health Service Act, including a supplement or  
8        amendment to any such submission, and the require-  
9        ments associated with such reference.

10       “(g) DEFINITIONS.—In this section:

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

1       quest for classification of a device under section  
2       513(f)(2), a notification with respect to a device  
3       under section 510(k), or request for an emergency  
4       use authorization under section 564 to support—

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

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

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

18       (b) **STAKEHOLDER INPUT.**—Not later than 18  
19 months after the date of enactment of this Act, the Sec-  
20 retary of Health and Human Services (referred to in this  
21 section as the “Secretary”), acting through the Commis-  
22 sioner of Food and Drugs and in consultation with the  
23 Assistant Secretary for Preparedness and Response, shall  
24 solicit input from stakeholders, including stakeholders de-  
25 veloping security countermeasures, qualified counter-

1 measures, or qualified pandemic or epidemic products, and  
2 stakeholders developing technologies to assist in the devel-  
3 opment of such countermeasures with respect to how the  
4 Food and Drug Administration can advance the use of  
5 tools and technologies to support and accelerate the devel-  
6 opment or manufacture of security countermeasures,  
7 qualified countermeasures, and qualified pandemic or epi-  
8 demic products, including through the reliance on cross-  
9 referenced data and information contained within master  
10 files and submissions previously submitted to the Sec-  
11 retary as set forth in section 565B of the Federal Food,  
12 Drug, and Cosmetic Act, as added by subsection (a).

13 (c) GUIDANCE.—Not later than 2 years after the  
14 after the date of enactment of this Act, the Secretary, act-  
15 ing through the Commissioner of Food and Drugs, shall  
16 publish draft guidance about how reliance on cross-ref-  
17 erenced data and information contained within master  
18 files under section 565B of the Federal Food, Drug, and  
19 Cosmetic Act, as added by subsection (a) or submissions  
20 otherwise submitted to the Secretary may be used for spe-  
21 cific tools or technologies (including platform technologies)  
22 that have the potential to support and accelerate the devel-  
23 opment or manufacture of security countermeasures,  
24 qualified countermeasures, qualified pandemic or epidemic  
25 products. The Secretary, acting through the Commissioner

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

3 **SEC. 603. PRIORITY ZOO NOTIC ANIMAL DRUGS.**

4 Chapter V of the Federal Food, Drug, and Cosmetic  
5 Act (21 U.S.C. 351 et seq.) is amended by inserting after  
6 section 512 the following:

7 **“SEC. 512A. PRIORITY ZOO NOTIC ANIMAL DRUGS.**

8 “(a) DESIGNATION OF A NEW ANIMAL DRUG AS A  
9 PRIORITY ZOO NOTIC ANIMAL DRUG.—

10 “(1) IN GENERAL.—The Secretary shall, at the  
11 request of the sponsor of an application for approval  
12 of a new animal drug under section 512(b)(1) or an  
13 application for conditional approval of a new animal  
14 drug under section 571, expedite the development  
15 and review of such new animal drug if preliminary  
16 clinical evidence indicates that the new animal drug,  
17 alone or in combination with 1 or more other animal  
18 drugs, has the potential to prevent or treat a  
19 zoonotic disease in animals, including a vector  
20 borne-disease, that has the potential to cause serious  
21 adverse health consequences for, or serious or life-  
22 threatening diseases in, humans.

23 “(2) REQUEST FOR DESIGNATION.—The spon-  
24 sor of a new animal drug may request the Secretary  
25 to designate a new animal drug described in para-

1 graph (1) as a priority zoonotic animal drug. A re-  
2 quest for the designation may be made concurrently  
3 with, or at any time after, the opening of an inves-  
4 tigational new animal drug file under section 512(j)  
5 or the filing of an application under section  
6 512(b)(1) or 571.

7 “(3) DESIGNATION.—

8 “(A) IN GENERAL.—Not later than 60 cal-  
9 endar days after the receipt of a request under  
10 paragraph (2), the Secretary shall determine  
11 whether the new animal drug that is the subject  
12 of the request meets the criteria described in  
13 paragraph (1). If the Secretary determines that  
14 the new animal drug meets the criteria, the  
15 Secretary shall designate the new animal drug  
16 as a priority zoonotic animal drug and shall  
17 take such actions as are appropriate to expedite  
18 the development and review of the application  
19 for approval or conditional approval of such  
20 new animal drug.

21 “(B) ACTIONS.—The actions to expedite  
22 the development and review of an application  
23 under subparagraph (A) may include, as appro-  
24 priate—

1                   “(i) taking steps to ensure that the  
2                   design of clinical trials is as efficient as  
3                   practicable, when scientifically appropriate,  
4                   such as by utilizing novel trial designs or  
5                   drug development tools (including biomark-  
6                   ers) that may reduce the number of ani-  
7                   mals needed for studies;

8                   “(ii) providing timely advice to, and  
9                   interactive communication with, the spon-  
10                  sor (which may include meetings with the  
11                  sponsor and review team) regarding the  
12                  development of the new animal drug to en-  
13                  sure that the development program to  
14                  gather the nonclinical and clinical data  
15                  necessary for approval is as efficient as  
16                  practicable;

17                  “(iii) involving senior managers and  
18                  review staff with experience in zoonotic or  
19                  vector-borne disease to facilitate collabo-  
20                  rative, cross-disciplinary review, including,  
21                  as appropriate, across agency centers; and

22                  “(iv) implementing additional admin-  
23                  istrative or process enhancements, as nec-  
24                  essary, to facilitate an efficient review and  
25                  development program.”.

1 **SEC. 604. ANIMAL RULE REPORT.**

2 (a) STUDY.—The Comptroller General of the United  
3 States shall conduct a study on the application of the re-  
4 quirements under section 565(d) of the of the Federal  
5 Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4(d))  
6 (referred to in this section as the “animal rule”) as a com-  
7 ponent of medical countermeasure advanced development  
8 under the Biomedical Advanced Research and Develop-  
9 ment Authority and regulatory review by the Food and  
10 Drug Administration. In conducting such study, the  
11 Comptroller General shall examine the following:

12 (1) The extent to which advanced development  
13 and review of a medical countermeasure are coordi-  
14 nated between the Biomedical Advanced Research  
15 and Development Authority and the Food and Drug  
16 Administration, including activities facilitate appro-  
17 priate and efficient design of studies to support ap-  
18 proval, licensure, and authorization under the ani-  
19 mal rule, consistent with the recommendations in the  
20 animal rule guidance, issued pursuant to section  
21 565(c) of the Federal Food Drug and Cosmetic Act  
22 (21 U.S.C. 360bbb–4(c)) and entitled “Product De-  
23 velopment Under the Animal Rule Guidance for In-  
24 dustry” (issued in October 2015), to resolve discrep-  
25 ancies in the design of adequate and well-controlled  
26 efficacy studies conducted in animal models related

1 to the provision of substantial evidence of effective-  
2 ness for the product approved, licensed, or author-  
3 ized under the animal rule.

4 (2) The consistency of the application of the  
5 animal rule among and between review divisions  
6 within the Food and Drug Administration.

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

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

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

24 (1) the Federal agencies responsible for advanc-  
25 ing, reviewing, and procuring medical counter-

1 measures, including the Office of the Assistant Sec-  
2 retary for Preparedness and Response, the Bio-  
3 medical Advanced Research and Development Au-  
4 thority, the Food and Drug Administration, and the  
5 Department of Defense;

6 (2) manufacturers involved in the research and  
7 development of medical countermeasures to address  
8 biological, chemical, radiological, and nuclear  
9 threats; and

10 (3) other biodefense stakeholders, as applicable.

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

23 (d) PROTECTION OF NATIONAL SECURITY.—The  
24 Comptroller General of the United States shall conduct  
25 the study and issue the assessment and report under this

1 section in a manner that does not compromise national  
2 security.

3 **SEC. 605. REVIEW OF THE BENEFITS OF GENOMIC ENGI-**  
4 **NEERING TECHNOLOGIES AND THEIR POTEN-**  
5 **TIAL ROLE IN NATIONAL SECURITY.**

6 (a) MEETING.—

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

16 (2) ATTENDEES.—The attendees of the meeting  
17 under paragraph (1)—

18 (A) shall include—

19 (i) representatives from the Office of  
20 the Assistant Secretary for Preparedness  
21 and Response, the National Institutes of  
22 Health, the Centers for Disease Control  
23 and Prevention, and the Food and Drug  
24 Administration; and

1 (ii) representatives from academic,  
2 private, and non-profit entities with exper-  
3 tise in genome engineering technologies,  
4 biopharmaceuticals, medicine, or bio-  
5 defense, and other relevant stakeholders;  
6 and

7 (B) may include—

8 (i) other representatives from the De-  
9 partment of Health and Human Services,  
10 as the Secretary determines appropriate;  
11 and

12 (ii) representatives from the Depart-  
13 ment of Homeland Security, the Depart-  
14 ment of Defense, the Department of Agri-  
15 culture, and other departments, as the Sec-  
16 retary may request for the meeting.

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

19 (A) the current state of the science of  
20 genomic engineering technologies related to na-  
21 tional health security, including—

22 (i) medical countermeasure develop-  
23 ment, including potential efficiencies in the  
24 development pathway and detection tech-  
25 nologies; and

1 (ii) the international and domestic  
2 regulation of products utilizing genome ed-  
3 iting technologies; and

4 (B) national security implications, includ-  
5 ing—

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

13 (ii) the potential for state and non-  
14 state actors to utilize genomic engineering  
15 technologies as a national health security  
16 threat; and

17 (iii) security measures to monitor and  
18 assess the potential threat of genomic engi-  
19 neering technologies and related tech-  
20 nologies.

21 (b) REPORT.—Not later than 180 days after the  
22 meeting described in subsection (a) is held, the Assistant  
23 Secretary for Preparedness and Response shall issue a re-  
24 port to the congressional committees of jurisdiction on the  
25 topics discussed at such meeting, and provide rec-

1 ommendations, as applicable, to utilize innovations in  
2 genomic engineering (including genome editing) and re-  
3 lated technologies as a part of preparedness and response  
4 activities to advance national health security. Such report  
5 shall be issued in a manner that does not compromise na-  
6 tional security.

7 **TITLE VII—MISCELLANEOUS**  
8 **PROVISIONS**

9 **SEC. 701. REAUTHORIZATIONS AND EXTENSIONS.**

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

13 (b) **VACCINE TRACKING AND DISTRIBUTION.**—Sec-  
14 tion 319A(e) (42 U.S.C. 247d–1(e)) is amended by strik-  
15 ing “2014 through 2018” and inserting “2019 through  
16 2023”.

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

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

23 (e) **PUBLIC DISCLOSURE EXEMPTION.**—Section  
24 319L(e)(1)(C) (42 U.S.C. 247d–7e(e)(1)(C)) is amended  
25 by striking “12” and inserting “17”.

1 (f) LIMITED ANTITRUST EXEMPTION.—

2 (1) IN GENERAL.—Section 405 of the Pandemic  
3 and All-Hazards Preparedness Act (42 U.S.C.  
4 247d–6a note) is amended—

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

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

11 (C) in subsection (a)(1)—

12 (i) by striking “Secretary of Health  
13 and Human Services (referred to in this  
14 subsection as the ‘Secretary’)” and insert-  
15 ing “Secretary”;

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

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

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

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

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

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

8 **SEC. 702. TECHNICAL AMENDMENTS.**

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

11           (1) in paragraphs (1) and (5) of section 319F–  
12 1(a) (42 U.S.C. 247d–6a(a)), by striking “section  
13 319F(h)” each place such term appears and insert-  
14 ing “section 319F(e)”; and

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

18           (b) **PUBLIC HEALTH SECURITY GRANTS.**—Section  
19 319C–1(b)(2) (42 U.S.C. 247d–3a(b)(2)) is amended—

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

22           (2) in subparagraph (F), by striking “make sat-  
23 isfactory annual improvement and describe” and in-  
24 serting “makes satisfactory annual improvement and  
25 describes”.

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

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

3 (1) in section 564A(e)(2)(A) (21 U.S.C.

4 360bbb-3a(e)(2)(A)), by striking “subsection

5 (a)(1)(C)(i)” and inserting “subsection (a)(1)(C)”;

6 and

7 (2) in section 564B(2)(C) (21 U.S.C. 360bbb-

8 3b(2)(C)), by inserting “or section 564A”.