

115<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 6378

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## AN ACT

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

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

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

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

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

Sec. 1. Short title; table of contents.

TITLE I—STRENGTHENING THE NATIONAL HEALTH SECURITY  
 STRATEGY

Sec. 101. National Health Security Strategy.

TITLE II—IMPROVING PREPAREDNESS AND RESPONSE

- Sec. 201. Improving benchmarks and standards for preparedness and response.
- Sec. 202. Amendments to preparedness and response programs.
- Sec. 203. Regional health care emergency preparedness and response systems.
- Sec. 204. Military and civilian partnership for trauma readiness.
- Sec. 205. Public health and health care system situational awareness and bio-surveillance capabilities.
- Sec. 206. Strengthening and supporting the public health emergency rapid response fund.
- Sec. 207. Improving all-hazards preparedness and response by public health emergency volunteers.
- Sec. 208. Clarifying State liability law for volunteer health care professionals.
- Sec. 209. Report on adequate national blood supply.
- Sec. 210. Report on the public health preparedness and response capabilities and capacities of hospitals, long-term care facilities, and other health care facilities.

TITLE III—REACHING ALL COMMUNITIES

- Sec. 301. Strengthening and assessing the emergency response workforce.
- Sec. 302. Health system infrastructure to improve preparedness and response.
- Sec. 303. Considerations for at-risk individuals.
- Sec. 304. Improving emergency preparedness and response considerations for children.
- Sec. 305. National advisory committees on disasters.
- Sec. 306. Guidance for participation in exercises and drills.

TITLE IV—PRIORITIZING A THREAT-BASED APPROACH

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

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

- Sec. 501. Medical countermeasure budget plan.  
 Sec. 502. Material threat and medical countermeasure notifications.  
 Sec. 503. Availability of regulatory management plans.  
 Sec. 504. The Biomedical Advanced Research and Development Authority and  
                   the BioShield Special Reserve Fund.  
 Sec. 505. Additional strategies for combating antibiotic resistance.

TITLE VI—ADVANCING TECHNOLOGIES FOR MEDICAL  
COUNTERMEASURES

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

TITLE VII—MISCELLANEOUS PROVISIONS

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

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

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

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

7 (1) in subsection (a)—

8 (A) in paragraph (1)—

9 (i) by striking “2014” and inserting

10 “2018”; and

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

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

23          (C) in paragraph (3)—

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

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

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

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

13 (2) in subsection (b)—

14 (A) in paragraph (2)—

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

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

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

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

2 (B) in paragraph (3)—

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

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

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

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

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

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

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

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

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

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

17 “(k) EVALUATION.—

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

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

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

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

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

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

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



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

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

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

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

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

19           (2) in subsection (b)(2)(A)—

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

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

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

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

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

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

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

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

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

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

5           (b) EXCEPTION RELATING TO APPLICATION OF CER-  
6 TAIN REQUIREMENTS.—

7           (1) IN GENERAL.—Section 319C–1(g) of the  
8           Public Health Service Act (42 U.S.C. 247d–3a(g)) is  
9           amended—

10           (A) in paragraph (5)—

11           (i) by striking “Beginning with fiscal  
12           year 2009” and inserting “Beginning with  
13           fiscal year 2019”;

14           (ii) by striking “for the immediately  
15           preceding fiscal year” and inserting “for  
16           either of the two immediately preceding  
17           fiscal years”; and

18           (iii) by striking “2008” and inserting  
19           “2018”; and

20           (B) by amending subparagraph (A) of  
21           paragraph (6) to read as follows:

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

1           “(i) For one (but not both) of the  
2           first two fiscal years immediately following  
3           a fiscal year in which an entity experienced  
4           a failure described in subparagraph (A) or  
5           (B) of paragraph (5) by the entity, an  
6           amount equal to 10 percent of the amount  
7           the entity was eligible to receive for the re-  
8           spective fiscal year.

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

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

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

25           (1) in subsection (a)—

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

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

8 (2) in subsection (b)(1)(A)—

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

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

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

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

17 (3) in subsection (d)—

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

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

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

1 (5) in subsection (g)(2)—

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

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

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

8 (6) in subsection (i)(1)—

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

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

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

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

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

3           “(1) IN GENERAL.—

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

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

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

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

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

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

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

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

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

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



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

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

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

1           “(1) identify and develop a set of guidelines re-  
2 relating to practices and protocols for all-hazards pub-  
3 lic health emergency preparedness and response for  
4 hospitals and health care facilities to provide appro-  
5 priate patient care during, in advance of, or imme-  
6 diately following, a public health emergency, result-  
7 ing from one or more chemical, biological, radio-  
8 logical, or nuclear agents, including emerging infec-  
9 tious diseases (which may include existing practices,  
10 such as trauma care and medical surge capacity and  
11 capabilities), with respect to—

12           “(A) a regional approach to identifying  
13 hospitals and health care facilities based on  
14 varying capabilities and capacity to treat pa-  
15 tients affected by such emergency, including—

16           “(i) the manner in which the system  
17 will coordinate with and integrate the part-  
18 nerships and health care coalitions estab-  
19 lished under section 319C–2(b); and

20           “(ii) informing and educating appro-  
21 priate first responders and health care sup-  
22 ply chain partners of the regional emer-  
23 gency preparedness and response capabili-  
24 ties and medical surge capacity of such

1 hospitals and health care facilities in the  
2 community;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23           (b) GAO REPORT TO CONGRESS.—

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

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

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

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

1           (B) recommendations to reduce gaps in in-  
2           centives for regional health partners, including  
3           hospitals and health care facilities, to improve  
4           capacity and medical surge capabilities to pre-  
5           pare for, and respond to, public health emer-  
6           gencies, consistent with subsection (a), which  
7           may include consideration of facilities partici-  
8           pating in programs under section 319C–2 of  
9           the Public Health Service Act (42 U.S.C.  
10          247d–3b) or in programs under the Centers for  
11          Medicare & Medicaid Services (including inno-  
12          vative health care delivery and payment mod-  
13          els), and input from private sector financial in-  
14          stitutions.

15          (3) CONSULTATION.—In carrying out para-  
16          graphs (1) and (2), the Comptroller General shall  
17          consult with the heads of appropriate Federal agen-  
18          cies, including—

19                 (A) the Assistant Secretary for Prepared-  
20                 ness and Response;

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

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



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

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

5 (F) the Secretary of Veterans Affairs.

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

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

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

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

1           (1) STATE AND LOCAL SECURITY.—Section  
2           319C–1(e) of the Public Health Service Act (42  
3           U.S.C. 247d–3a(e)) is amended by striking “, and  
4           local emergency plans.” and inserting “, local emer-  
5           gency plans, and any regional health care emergency  
6           preparedness and response system established pursu-  
7           ant to the applicable guidelines under section 319C–  
8           3.”.

9           (2) PARTNERSHIPS.—Section 319C–2(d)(1)(A)  
10          of the Public Health Service Act (42 U.S.C. 247d-  
11          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 of the Public Health Service Act (42 U.S.C.  
23   300d et seq.) is amended by adding at the end the fol-  
24   lowing 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 at least 3  
19 years and not more than 5 years (and may be  
20 renewed at the end of such period); and

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

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

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

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

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

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

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

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

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

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

4                   “(c) GRANT REQUIREMENTS.—

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

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

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

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

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

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

8 “(e) REPORTING REQUIREMENTS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23           “(B) Such trauma center utilizes a risk-ad-  
24 justed benchmarking system and metrics to



1 measure performance, quality, and patient out-  
2 comes.

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

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

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

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

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

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

1 “(i) affiliated with a medical school;

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

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

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

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

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

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

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

8 “(g) AUTHORIZATION OF APPROPRIATIONS.—To  
9 carry out this section, there are authorized to be appro-  
10 priated \$15,000,000 for each of fiscal years 2019 through  
11 2023, of which—

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

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

18 **SEC. 205. PUBLIC HEALTH AND HEALTH CARE SYSTEM SIT-**  
19 **UATIONAL AWARENESS AND BIOSURVEIL-**  
20 **LANCE CAPABILITIES.**

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

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

4 (2) in subsection (a)—

5 (A) in the subsection heading, by striking  
6 “FACILITIES; CAPACITIES” and inserting “IN  
7 GENERAL”;

8 (B) in paragraph (1), by striking “and im-  
9 proved” and inserting “, improved, and appro-  
10 priately maintained”;

11 (C) in paragraph (3), in the matter pre-  
12 ceding subparagraph (A), by striking “expand,  
13 enhance, and improve” and inserting “expand,  
14 improve, enhance, and appropriately maintain”;  
15 and

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

17 “(4) STUDY OF RESOURCES FOR FACILITIES  
18 AND CAPACITIES.—Not later than June 1, 2022, the  
19 Comptroller General of the United States shall con-  
20 duct a study on Federal spending in fiscal years  
21 2013 through 2018 for activities authorized under  
22 this subsection. Such study shall include a review  
23 and assessment of obligations and expenditures di-  
24 rectly related to each activity under paragraphs (2)  
25 and (3), including a specific accounting of, and de-

1 lineation between, obligations and expenditures in-  
2 curred for the construction, renovation, equipping,  
3 and security upgrades of facilities and associated  
4 contracts under this subsection, and the obligations  
5 and expenditures incurred to establish and improve  
6 the situational awareness and biosurveillance net-  
7 work under subsection (b), and shall identify the  
8 agency or agencies incurring such obligations and  
9 expenditures.”;

10 (3) in subsection (b)—

11 (A) in the subsection heading, by striking  
12 “NATIONAL” and inserting “ESTABLISHMENT  
13 OF SYSTEMS OF PUBLIC HEALTH”;

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

17 (C) in paragraph (2)—

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

20 (ii) by inserting “and in a form read-  
21 ily usable for analytical approaches” after  
22 “in a secure manner”; and

23 (D) by amending paragraph (3) to read as  
24 follows:

25 “(3) STANDARDS.—

1           “(A) IN GENERAL.—Not later than 1 year  
2 after the date of the enactment of the Pan-  
3 demic and All-Hazards Preparedness and Ad-  
4 vancing Innovation Act of 2018, the Secretary,  
5 in cooperation with health care providers, State,  
6 local, tribal, and territorial public health offi-  
7 cials, and relevant Federal agencies (including  
8 the Office of the National Coordinator for  
9 Health Information Technology and the Na-  
10 tional Institute of Standards and Technology),  
11 shall, as necessary, adopt technical and report-  
12 ing standards, including standards for inter-  
13 operability as defined by section 3000, for net-  
14 works under paragraph (1) and update such  
15 standards as necessary. Such standards shall be  
16 made available on the internet website of the  
17 Department of Health and Human Services, in  
18 a manner that does not compromise national se-  
19 curity.

20           “(B) DEFERENCE TO STANDARDS DEVEL-  
21 OPMENT ORGANIZATIONS.—In adopting and im-  
22 plementing standards under this subsection and  
23 subsection (c), the Secretary shall give def-  
24 erence to standards published by standards de-

1           velopment organizations and voluntary con-  
2           sensus-based standards entities.”;

3           (4) in subsection (c)—

4                 (A) in paragraph (1)—

5                     (i) by striking “Not later than 2 years  
6                     after the date of enactment of the Pan-  
7                     demic and All-Hazards Preparedness Re-  
8                     authorization Act of 2013, the Secretary”  
9                     and inserting “The Secretary”;

10                    (ii) by inserting “, and improve as ap-  
11                    plicable and appropriate,” after “shall es-  
12                    tablish”;

13                    (iii) by striking “of rapid” and insert-  
14                    ing “of, rapid”; and

15                    (iv) by striking “such connectivity”  
16                    and inserting “such interoperability”;

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

19                    “(2) COORDINATION AND CONSULTATION.—In  
20                    establishing and improving the network under para-  
21                    graph (1) the Secretary shall—

22                         “(A) facilitate coordination among agencies  
23                         within the Department of Health and Human  
24                         Services that provide, or have the potential to  
25                         provide, information and data to, and analyses

1 for, the situational awareness and biosurveil-  
2 lance network under paragraph (1), including  
3 coordination among relevant agencies related to  
4 health care services, the facilitation of health  
5 information exchange (including the Office of  
6 the National Coordinator for Health Informa-  
7 tion Technology), and public health emergency  
8 preparedness and response; and

9 “(B) consult with the Secretary of Agri-  
10 culture, the Secretary of Commerce (and the  
11 Director of the National Institute of Standards  
12 and Technology), the Secretary of Defense, the  
13 Secretary of Homeland Security, the Secretary  
14 of Veterans Affairs, and the heads of other  
15 Federal agencies, as the Secretary determines  
16 appropriate.”;

17 (C) in paragraph (3)—

18 (i) by redesignating subparagraphs  
19 (A) through (E) as clauses (i) through (v),  
20 respectively, and adjusting the margins ac-  
21 cordingly;

22 (ii) in clause (iv), as so redesign-  
23 nated—



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

4 (II) by striking “and clinical lab-  
5 oratories” and inserting “, clinical  
6 laboratories, and public environmental  
7 health agencies”;

8 (iii) by striking “The network” and  
9 inserting the following:

10 “(A) IN GENERAL.—The network”; and

11 (iv) by adding at the end the fol-  
12 lowing:

13 “(B) REVIEW.—Not later than 2 years  
14 after the date of the enactment of the Pan-  
15 demic and All-Hazards Preparedness and Ad-  
16 vancing Innovation Act of 2018 and every 6  
17 years thereafter, the Secretary shall conduct a  
18 review of the elements described in subpara-  
19 graph (A). Such review shall include a discus-  
20 sion of the addition of any elements pursuant to  
21 clause (v), including elements added to advanc-  
22 ing new technologies, and identify any chal-  
23 lenges in the incorporation of elements under  
24 subparagraph (A). The Secretary shall provide

1 such review to the congressional committees of  
2 jurisdiction.”;

3 (D) in paragraph (5)—

4 (i) by redesignating subparagraphs  
5 (A) through (D) as clauses (i) through  
6 (iv), respectively, and adjusting the mar-  
7 gins accordingly;

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

10 “(A) IN GENERAL.—In establishing”;

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

13 “(B) PUBLIC MEETING.—

14 “(i) IN GENERAL.—Not later than  
15 180 days after the date of enactment of  
16 the Pandemic and All-Hazards Prepared-  
17 ness and Advancing Innovation Act of  
18 2018, the Secretary shall convene a public  
19 meeting for purposes of discussing and  
20 providing input on the potential goals,  
21 functions, and uses of the network de-  
22 scribed in paragraph (1) and incorporating  
23 the elements described in paragraph  
24 (3)(A).

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

18          “(iii) TOPICS.—Such public meeting  
19          shall include a discussion of—

20                 “(I) data elements, including  
21                 minimal or essential data elements,  
22                 that are voluntarily provided for such  
23                 network, which may include elements  
24                 from public health and public and pri-

1 vate health care entities, to the extent  
2 practicable;

3 “(II) standards and implementa-  
4 tion specifications that may improve  
5 the collection, analysis, and interpre-  
6 tation of data during a public health  
7 emergency;

8 “(III) strategies to encourage the  
9 access, exchange, and use of informa-  
10 tion;

11 “(IV) considerations for State,  
12 local, tribal, and territorial capabilities  
13 and infrastructure related to data ex-  
14 change and interoperability;

15 “(V) privacy and security protec-  
16 tions provided at the Federal, State,  
17 local, tribal, and territorial levels, and  
18 by nongovernmental stakeholders; and

19 “(VI) opportunities for the incor-  
20 poration of innovative technologies to  
21 improve the network.”; and

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

24 (I) in clause (i), as so redesign-  
25 nated—

1 (aa) by striking “as deter-  
2 mined” and inserting “as adopt-  
3 ed”; and

4 (bb) by inserting “and the  
5 National Institute of Standards  
6 and Technology” after “Office of  
7 the National Coordinator for  
8 Health Information Technology”;

9 (II) in clause (iii), as so redesign-  
10 nated, by striking “; and” and insert-  
11 ing a semicolon;

12 (III) in clause (iv), as so redesign-  
13 nated, by striking the period and in-  
14 serting “; and”; and

15 (IV) by adding at the end the fol-  
16 lowing:

17 “(v) pilot test standards and imple-  
18 mentation specifications, consistent with  
19 the process described in section  
20 3002(b)(3)(C), which State, local, tribal,  
21 and territorial public health entities may  
22 utilize, on a voluntary basis, as a part of  
23 the network.”;

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

1 (F) by inserting after paragraph (5) the  
2 following:

3 “(6) STRATEGY AND IMPLEMENTATION  
4 PLAN.—

5 “(A) IN GENERAL.—Not later than 18  
6 months after the date of enactment of the Pan-  
7 demic and All-Hazards Preparedness and Ad-  
8 vancing Innovation Act of 2018, the Secretary  
9 shall submit to the congressional committees of  
10 jurisdiction a coordinated strategy and an ac-  
11 companying implementation plan that—

12 “(i) is informed by the public meeting  
13 under paragraph (5)(B);

14 “(ii) includes a review and assessment  
15 of existing capabilities of the network and  
16 related infrastructure, including input pro-  
17 vided by the public meeting under para-  
18 graph (5)(B);

19 “(iii) identifies and demonstrates the  
20 measurable steps the Secretary will carry  
21 out to—

22 “(I) develop, implement, and  
23 evaluate the network described in  
24 paragraph (1), utilizing elements de-  
25 scribed in paragraph (3)(A);

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

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

19                  “(IV) test and evaluate capabili-  
20                  ties of the interoperable network of  
21                  systems to improve situational aware-  
22                  ness and biosurveillance capabilities;

23                  “(iv) includes performance measures  
24                  and the metrics by which performance  
25                  measures will be assessed with respect to

1 the measurable steps under clause (iii);  
2 and

3 “(v) establishes dates by which each  
4 measurable step under clause (iii) will be  
5 implemented.

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

18 “(i) a summary of resources pre-  
19 viously expended to establish, improve, and  
20 utilize the nationwide public health situa-  
21 tional awareness and biosurveillance net-  
22 work under paragraph (1);

23 “(ii) estimates of costs and resources  
24 needed to establish and improve the net-  
25 work under paragraph (1) according to the



1 strategy and implementation plan under  
2 subparagraph (A);

3 “(iii) the identification of gaps and in-  
4 efficiencies in nationwide public health sit-  
5 uational awareness and biosurveillance ca-  
6 pabilities, resources, and authorities need-  
7 ed to address such gaps; and

8 “(iv) a strategy to minimize and ad-  
9 dress such gaps and improve inefficien-  
10 cies.”;

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

12 (i) in subparagraph (A), by inserting  
13 “(taking into account zoonotic disease, in-  
14 cluding gaps in scientific understanding of  
15 the interactions between human, animal,  
16 and environmental health)” after “human  
17 health”;

18 (ii) in subparagraph (B)—

19 (I) by inserting “and gaps in sur-  
20 veillance programs” after “surveil-  
21 lance programs”; and

22 (II) by striking “; and” and in-  
23 serting a semicolon;

24 (iii) in subparagraph (C)—

1 (I) by inserting “, animal health  
2 organizations related to zoonotic dis-  
3 ease,” after “health care entities”;  
4 and

5 (II) by striking the period and  
6 inserting “; and”; and

7 (iv) by adding at the end the fol-  
8 lowing:

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

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

14 “(8) SITUATIONAL AWARENESS AND BIO-  
15 SURVEILLANCE AS A NATIONAL SECURITY PRI-  
16 ORITY.—The Secretary, on a periodic basis as appli-  
17 cable and appropriate, shall meet with the Director  
18 of National Intelligence to inform the development  
19 and capabilities of the nationwide public health situ-  
20 ational awareness and biosurveillance network.”;

21 (5) in subsection (d)—

22 (A) in paragraph (1)—

23 (i) by inserting “environmental health  
24 agencies,” after “public health agencies,”;  
25 and

- 1                   (ii) by inserting “immunization pro-  
2                   grams,” after “poison control centers,”;  
3                   and  
4                   (B) in paragraph (2)—  
5                   (i) in subparagraph (B), by striking  
6                   “and” at the end;  
7                   (ii) in subparagraph (C), by striking  
8                   the period and inserting “; and”; and  
9                   (iii) by adding after subparagraph (C)  
10                  the following:  
11                  “(D) an implementation plan that may in-  
12                  clude measurable steps to achieve the purposes  
13                  described in paragraph (1).”; and  
14                  (C) by striking paragraph (5) and insert-  
15                  ing the following:  
16                  “(5) TECHNICAL ASSISTANCE.—The Secretary  
17                  may provide technical assistance to States, localities,  
18                  tribes, and territories or a consortium of States, lo-  
19                  calities, tribes, and territories receiving an award  
20                  under this subsection regarding interoperability and  
21                  the technical standards set forth by the Secretary.”;  
22                  (6) by redesignating subsections (f) and (g) as  
23                  subsections (i) and (j), respectively; and  
24                  (7) by inserting after subsection (e) the fol-  
25                  lowing:

1 “(f) PERSONNEL AUTHORITIES.—

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

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

16 “(B) compensate individuals appointed  
17 under subparagraph (A) in the same manner  
18 and subject to the same terms and conditions in  
19 which individuals appointed under 9903 of title  
20 5, United States Code, are compensated, with-  
21 out regard to the provisions of chapter 51 and  
22 subchapter III of chapter 53 of such title relat-  
23 ing to classification and General Schedule pay  
24 rates.

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

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

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

21          (b) AUTHORIZATION OF APPROPRIATIONS.—Sub-  
22          section (i) of section 319D of the Public Health Service  
23          Act (42 U.S.C. 247d–4), as redesignated by subsection  
24          (a)(6), is amended by striking “\$138,300,000 for each of  
25          fiscal years 2014 through 2018” and inserting

1 “\$161,800,000 for each of fiscal years 2019 through  
2 2023”.

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

16 (1) an identification of technological, oper-  
17 ational, and programmatic successes and failures of  
18 domestic detection programs supported by Federal  
19 departments and agencies for intentionally-intro-  
20 duced or accidentally-released biological threat  
21 agents and naturally occurring infectious diseases;

22 (2) a description of Federal efforts to facilitate  
23 the exchange of information related to the informa-  
24 tion described in paragraph (1) among Federal de-

1       partments and agencies that utilize biological threat  
2       detection technology;

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

6                       (A) rapidly detect, identify, characterize,  
7                       and confirm the presence of biological threat  
8                       agents;

9                       (B) recover live biological agents from col-  
10                      lection devices;

11                      (C) determine the geographical distribution  
12                      of biological agents;

13                      (D) determine the extent of environmental  
14                      contamination and persistence of biological  
15                      agents; and

16                      (E) provide advanced molecular diagnostics  
17                      to State, local, tribal, and territorial public  
18                      health and other laboratories that support bio-  
19                      logical threat detection activities;

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

22               (5) a description of efforts by Federal depart-  
23       ments and agencies that utilize biological threat de-  
24       tection technology to collaborate with State, local,  
25       tribal, and territorial public health laboratories and

1 other users of biological threat detection systems, in-  
2 cluding collaboration regarding the development of—

3 (A) biological threat detection require-  
4 ments or standards;

5 (B) a standardized integration strategy;

6 (C) training requirements or guidelines;

7 (D) guidelines for a coordinated public  
8 health response, including preparedness capa-  
9 bilities, and, as applicable, for coordination with  
10 public health surveillance systems; and

11 (E) a coordinated environmental remedi-  
12 ation plan, as applicable; and

13 (6) recommendations related to research, ad-  
14 vanced research, development, and procurement for  
15 Federal departments and agencies to improve and  
16 enhance biological threat detection systems, includ-  
17 ing recommendations on the transfer of biological  
18 threat detection technology among Federal depart-  
19 ments and agencies, as necessary and appropriate.

20 **SEC. 206. STRENGTHENING AND SUPPORTING THE PUBLIC**  
21 **HEALTH EMERGENCY RAPID RESPONSE**  
22 **FUND.**

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

25 (1) in subsection (b)—



1 (A) in paragraph (1)—

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

10 (ii) by inserting “The Secretary shall  
11 plan for the expedited distribution of funds  
12 to appropriate agencies and entities.” after  
13 the first sentence;

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

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

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

20 “(A) facilitate coordination between and  
21 among Federal, State, local, tribal, and terri-  
22 torial entities and public and private health  
23 care entities that the Secretary determines may  
24 be affected by a public health emergency or po-  
25 tential public health emergency referred to in

1 paragraph (1) (including communication of  
2 such entities with relevant international enti-  
3 ties, as applicable);

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

10 “(C) facilitate and accelerate, as applica-  
11 ble, advanced research and development of secu-  
12 rity countermeasures (as defined in section  
13 319F–2), qualified countermeasures (as defined  
14 in section 319F–1), or qualified pandemic or  
15 epidemic products (as defined in section 319F–  
16 3), that are applicable to the public health  
17 emergency or potential public health emergency  
18 under paragraph (1);

19 “(D) strengthen biosurveillance capabilities  
20 and laboratory capacity to identify, collect, and  
21 analyze information regarding such public  
22 health emergency or potential public health  
23 emergency, including the systems under section  
24 319D;

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

6           “(F) carry out other activities, as the Sec-  
7           retary determines applicable and appropriate.”;  
8           and

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

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

24          “(5) GAO REPORT.—Not later than 4 years  
25          after the date of enactment of the Pandemic and

1 All-Hazards Preparedness and Advancing Innovation  
2 Act of 2018, the Comptroller General of the United  
3 States shall—

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

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

13 (2) in subsection (c)—

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

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

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

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

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

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

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

19 (4) in subsection (k) by striking “2014 through  
20 2018” and inserting “2019 through 2023”.

21 (b) **ALL-HAZARDS PUBLIC HEALTH EMERGENCY**  
22 **PREPAREDNESS AND RESPONSE PLAN.**—Section 319C-  
23 1(b)(2)(A)(iv) of the Public Health Service Act (42 U.S.C.  
24 247d-3a(b)(2)(A)(iv)) is amended to read as follows:

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

11                   “(I) providing a public method of  
12                   communication for purposes of volunteer  
13                   coordination (such as a phone number);

14                   “(II) providing for optional registra-  
15                   tion to participate in volunteer services  
16                   during processes related to State medical  
17                   licensing, registration, or certification or  
18                   renewal of such licensing, registration or  
19                   certification; or

20                   “(III) other mechanisms as the State  
21                   determines appropriate;”.

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

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

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

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

14 “(1) is responding—

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

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

1 Act (50 U.S.C.1621) during the initial period of  
2 such declaration; and

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

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

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

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

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

24 “(3) prior to the rendering of such act or omis-  
25 sion, was authorized by the State’s authorization of



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

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

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

21       “(d) DEFINITIONS.—In this section:

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

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

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

7                   “(B) the assessment or care of the health  
8 of human beings.

9           “(e) EFFECTIVE DATE.—

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

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

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

21                   (1) the number of health care providers who  
22 register under the Emergency System for Advance  
23 Registration of Volunteer Health Professionals  
24 under section 319I of the Public Health Service Act

1 (42 U.S.C. 247d–7b) in advance to provide services  
2 during a public health emergency;

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

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

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

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

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

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

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

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

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

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

25 (a) STUDY.—

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

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

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

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

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

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

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

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

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

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

11 (b) REPORT.—

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

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

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

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

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

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

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

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

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

21 (a) NATIONAL DISASTER MEDICAL SYSTEM.—

22 (1) STRENGTHENING THE NATIONAL DISASTER  
23 MEDICAL SYSTEM.—Clause (ii) of section  
24 2812(a)(3)(A) of the Public Health Service Act (42



1 U.S.C. 300hh–11(a)(3)(A) is amended to read as  
2 follows:

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

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

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

16 “(A) REVIEW.—Not later than 180 days  
17 after the date of enactment of the Pandemic  
18 and All-Hazards Preparedness and Advancing  
19 Innovation Act of 2018, the Secretary, in co-  
20 ordination with the Secretary of Homeland Se-  
21 curity, the Secretary of Defense, and the Sec-  
22 retary of Veterans Affairs, shall conduct a joint  
23 review of the National Disaster Medical System.  
24 Such review shall include—

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

3           “(ii) an assessment of the available  
4           workforce of the intermittent disaster re-  
5           sponse personnel described in subsection  
6           (c);

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

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

15          “(v) gaps that may exist in such  
16          workforce and recommendations for ad-  
17          dressing such gaps.

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

24          (3) NOTIFICATION OF SHORTAGE.—Section  
25          2812(e) of the Public Health Service Act (42 U.S.C.

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

3 “(3) NOTIFICATION.—Not later than 30 days  
4 after the date on which the Secretary determines the  
5 number of intermittent disaster-response personnel  
6 of the National Disaster Medical System is insuffi-  
7 cient to address a public health emergency or poten-  
8 tial public health emergency, the Secretary shall sub-  
9 mit to the congressional committees of jurisdiction a  
10 notification detailing—

11 “(A) the impact such shortage could have  
12 on meeting public health needs and emergency  
13 medical personnel needs during a public health  
14 emergency; and

15 “(B) any identified measures to address  
16 such shortage.

17 “(4) CERTAIN APPOINTMENTS.—

18 “(A) IN GENERAL.—If the Secretary deter-  
19 mines that the number of intermittent disaster  
20 response personnel within the National Disaster  
21 Medical System under this section is insuffi-  
22 cient to address a public health emergency or  
23 potential public health emergency, the Secretary  
24 may appoint candidates directly to personnel  
25 positions for intermittent disaster response

1           within such system. The Secretary shall provide  
2           updates on the number of vacant or unfilled po-  
3           sitions within such system to the congressional  
4           committees of jurisdiction each quarter for  
5           which this authority is in effect.

6           “(B) SUNSET.—The authority under this  
7           paragraph shall expire on September 30,  
8           2021.”.

9           (4) AUTHORIZATION OF APPROPRIATIONS.—  
10          Section 2812(g) of the Public Health Service Act  
11          (42 U.S.C. 300hh–11(g)) is amended by striking  
12          “\$52,700,000 for each of fiscal years 2014 through  
13          2018” and inserting “\$57,400,000 for each of fiscal  
14          years 2019 through 2023”.

15          (b) VOLUNTEER MEDICAL RESERVE CORPS.—

16               (1) IN GENERAL.—Section 2813(a) of the Pub-  
17          lic Health Service Act (42 U.S.C. 42 U.S.C. 300hh–  
18          15(a)) is amended by striking the second sentence  
19          and inserting “The Secretary may appoint a Direc-  
20          tor to head the Corps and oversee the activities of  
21          the Corps chapters that exist at the State, local,  
22          tribal, and territorial levels.”.

23               (2) AUTHORIZATION OF APPROPRIATIONS.—  
24          Section 2813(i) of the Public Health Service Act (42

1 U.S.C. 300hh–15(i)) is amended by striking “2014  
2 through 2018” and inserting “2019 through 2023”.

3 (c) STRENGTHENING THE EPIDEMIC INTELLIGENCE  
4 SERVICE.—Section 317F of the Public Health Service Act  
5 (42 U.S.C. Sec. 247b–7) is amended—

6 (1) in subsection (a)—

7 (A) in paragraph (1)—

8 (i) by inserting “or preparedness and  
9 response activities, including rapid re-  
10 sponse to public health emergencies and  
11 significant public health threats” after  
12 “conduct prevention activities”; and

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

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

17 (2) in subsection (c)—

18 (A) by striking “For the purpose of car-  
19 rying out this section” and inserting the fol-  
20 lowing:

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

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

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

8           (d) SERVICE BENEFIT FOR NATIONAL DISASTER  
9           MEDICAL SYSTEM VOLUNTEERS.—

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

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

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

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

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

5 (C) by inserting after subparagraph (D)  
6 the following:

7 “(E) an individual appointed to the Na-  
8 tional Disaster Medical System under section  
9 2812 of the Public Health Service Act (42  
10 U.S.C. 300hh–11) who is performing official  
11 duties of the Department of Health and Human  
12 Services, if those official duties are—

13 “(i) related to responding to a public  
14 health emergency or potential public health  
15 emergency, or other activities for which the  
16 Secretary of Health and Human Services  
17 has activated such National Disaster Med-  
18 ical System; and

19 “(ii) determined by the Secretary of  
20 Health and Human Services to be haz-  
21 ardous.”.

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

25 (e) MISSION READINESS REPORT TO CONGRESS.—

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

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

18                (A) the number of health care providers  
19                who have volunteered to provide health care  
20                services during a public health emergency, in-  
21                cluding members of the National Disaster Med-  
22                ical System, the Disaster Medical Assistant  
23                Teams, the Medical Reserve Corps, and other  
24                volunteer health care professionals in the  
25                verification network pursuant to section 319I of



1 the Public Health Service Act (42 U.S.C.  
2 247d–7b);

3 (B) the capacity of the workforce described  
4 in subparagraph (A) to respond to a public  
5 health emergency or potential public health  
6 emergency, including the capacity to respond to  
7 multiple concurrent public health emergencies  
8 and the capacity to respond to a nationwide  
9 public health emergency;

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

17 (D) an assessment of the effectiveness of  
18 efforts to recruit, retain, and train such work-  
19 force; and

20 (E) identification of gaps that may exist in  
21 such workforce and recommendations for ad-  
22 dressing such gaps, the extent to which the As-  
23 sistant Secretary for Preparedness and Re-  
24 sponse plans to address such gaps, and any rec-

1           ommendations from the Comptroller General to  
2           address such gaps.

3 **SEC. 302. HEALTH SYSTEM INFRASTRUCTURE TO IMPROVE**  
4                                   **PREPAREDNESS AND RESPONSE.**

5           (a) COORDINATION OF PREPAREDNESS.—Section  
6 2811(b)(5) of the Public Health Service Act (42 U.S.C.  
7 300hh–10(b)(5)) is amended by adding at the end the fol-  
8 lowing: “Such logistical support shall include working with  
9 other relevant Federal, State, local, tribal, and territorial  
10 public health officials and private sector entities to identify  
11 the critical infrastructure assets, systems, and networks  
12 needed for the proper functioning of the health care and  
13 public health sectors that need to be maintained through  
14 any emergency or disaster, including entities capable of  
15 assisting with, responding to, and mitigating the effect of  
16 a public health emergency, including a public health emer-  
17 gency determined by the Secretary pursuant to section  
18 319(a), an emergency or major disaster declared by the  
19 President under the Robert T. Stafford Disaster Relief  
20 and Emergency Assistance Act, or the National Emer-  
21 gencies Act, including by establishing methods to exchange  
22 critical information and deliver products consumed or used  
23 to preserve, protect, or sustain life, health, or safety, and  
24 sharing of specialized expertise.”.

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

6           (c) EVALUATION OF BARRIERS TO RAPID DELIVERY  
7 OF MEDICAL COUNTERMEASURES.—

8                   (1) RAPID DELIVERY STUDY.—The Assistant  
9 Secretary for Preparedness and Response may con-  
10 duct a study on issues that have the potential to ad-  
11 versely affect the handling and rapid delivery of  
12 medical countermeasures to individuals during public  
13 health emergencies occurring in the United States.

14                   (2) NOTICE TO CONGRESS.—Not later than 9  
15 months after the date of the enactment of this Act,  
16 the Assistant Secretary for Preparedness and Re-  
17 sponse shall notify the Committee on Energy and  
18 Commerce of the House of Representatives and the  
19 Committee on Health, Education, Labor, and Pen-  
20 sions of the Senate if the Assistant Secretary for  
21 Preparedness and Response does not plan to conduct  
22 the study under paragraph (1) and shall provide  
23 such committees a summary explanation for such de-  
24 cision.

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

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

10          (a) AT-RISK INDIVIDUALS IN THE NATIONAL  
11          HEALTH SECURITY STRATEGY.—Section 2802(b)(4)(B)  
12          of the Public Health Service Act (42 U.S.C. 300hh-  
13          1(b)(4)(B)) is amended—

14                 (1) by striking “this section and sections 319C-  
15                 1, 319F, and 319L,” and inserting “this Act,”; and

16                 (2) by striking “special” and inserting “access  
17                 or functional”.

18          (b) COUNTERMEASURE CONSIDERATIONS.—Section  
19          319L(c)(6) of the Public Health Service Act (42 U.S.C.  
20          247d-7e(c)(6)) is amended—

21                 (1) by striking “elderly” and inserting “senior  
22                 citizens”; and

23                 (2) by inserting “with relevant characteristics  
24                 that warrant consideration during the process of re-

1 searching and developing such countermeasures and  
2 products” before the period.

3 (c) BIOSURVEILLANCE OF EMERGING PUBLIC  
4 HEALTH THREATS.—Section 2814 is amended—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17                   (2) in subsection (d)—

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

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

22                   “(2) REQUIRED NON-FEDERAL MEMBERS.—The  
23                   Secretary, in consultation with such other heads of  
24                   Federal agencies as may be appropriate, shall ap-



1 point to the Advisory Committee under paragraph  
2 (1) at least 13 individuals, including—

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

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

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

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

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

1           “(ii) at least one such member shall  
2           be an individual with expertise in schools  
3           or child care settings;

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

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

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

18           “(A) The Assistant Secretary for Pre-  
19          paredness and Response.

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

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

24           “(D) The Commissioner of Food and  
25          Drugs.

1           “(E) The Director of the National Insti-  
2           tutes of Health.

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

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

7           “(H) The Administrator of the Federal  
8           Emergency Management Agency.

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

11          “(J) The Secretary of Education.

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

19          “(4) TERM OF APPOINTMENT.—Each member  
20          of the Advisory Committee appointed under para-  
21          graph (2) shall serve for a term of 3 years, except  
22          that the Secretary may adjust the terms of the Advi-  
23          sory Committee appointees serving on the date of  
24          enactment of the Pandemic and All-Hazards Pre-  
25          paredness and Advancing Innovation Act of 2018, or

1 appointees who are initially appointed after such  
2 date of enactment, in order to provide for a stag-  
3 gered term of appointment for all members.

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

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

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

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

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

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

21 (b) AUTHORIZING THE NATIONAL ADVISORY COM-  
22 MITTEE ON SENIORS AND DISASTERS.—Subtitle B of title  
23 XXVIII of the Public Health Service Act (42 U.S.C.  
24 300hh et seq.) is amended by inserting after section  
25 2811A the following:

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

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

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

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

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

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

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

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

3 “(d) MEMBERSHIP.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 “(g) SUNSET.—

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

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

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

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

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

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



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

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

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

14          “(c) MEMBERSHIP.—

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

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

1       terminated by the Secretary) and non-Federal mem-  
2       bers, as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22          “(g) SUNSET.—

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

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

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

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

11           “(a) IN GENERAL.—The Secretary shall coordinate  
12           duties and activities authorized under sections 2811A,  
13           2811B, and 2811C, and make efforts to reduce unneces-  
14           sary or duplicative reporting, or unnecessary duplicative  
15           meetings and recommendations under such sections, as  
16           practicable. Members of the advisory committees author-  
17           ized under such sections, or their designees, shall annually  
18           meet to coordinate any recommendations, as appropriate,  
19           that may be similar, duplicative, or overlapping with re-  
20           spect to addressing the needs of children, seniors, and in-  
21           dividuals with disabilities during public health emer-  
22           gencies. If such coordination occurs through an in-person  
23           meeting, it shall not be considered the required in-person  
24           meetings under any of sections 2811A(e), 2811B(e), or  
25           2811C(d).

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

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

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

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

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

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

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

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

18 (1) in subsection (b)—

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

24 (B) in paragraph (4) by adding at the end  
25 the following:

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

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

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

17               “(1) IN GENERAL.—In carrying out the duties  
18               under subsection (b)(3), the Assistant Secretary for  
19               Preparedness and Response shall implement stra-  
20               tegic initiatives or activities to address threats, in-  
21               cluding pandemic influenza, that pose a significant  
22               level of risk to public health and national security  
23               based on the characteristics of such threat, which  
24               may also include a chemical, biological, radiological,  
25               or nuclear agent, including threats with a significant

1 potential to become a pandemic. Such initiatives  
2 shall include activities to accelerate and support the  
3 advanced research, development, manufacturing ca-  
4 pacity, procurement, and stockpiling of counter-  
5 measures, including initiatives under section  
6 319L(e)(4)(F). Such activities may also include  
7 those related to readiness to respond to pandemic in-  
8 fluenza threats by supporting the development and  
9 manufacturing of influenza virus seeds, clinical trial  
10 lots, and stockpiles of novel influenza strains.

11 “(2) AUTHORIZATION OF APPROPRIATIONS.—

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

16 “(B) SUPPLEMENT, NOT SUPPLANT.—  
17 Funds appropriated under this subsection shall  
18 be used to supplement and not supplant funds  
19 provided under section 319L(e) and section  
20 319F–2(g).

21 “(C) DOCUMENTATION REQUIRED.—The  
22 Assistant Secretary for Preparedness and Re-  
23 sponse shall, as required under subsection  
24 (b)(7), document amounts expended for pur-  
25 poses of carrying out this subsection, including



1 amounts appropriated to the Public Health and  
2 Social Services Emergency Fund under title II  
3 of Division H of the Consolidated Appropria-  
4 tions Act, 2018 (Public Law 115–141), as ap-  
5 plicable to section 319L(c)(4)(F).”.

6 **SEC. 402. PUBLIC HEALTH EMERGENCY MEDICAL COUN-**  
7 **TERMEASURES ENTERPRISE.**

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

11 **“SEC. 2811–1. PUBLIC HEALTH EMERGENCY MEDICAL**  
12 **COUNTERMEASURES ENTERPRISE.**

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

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

21 “(1) The Assistant Secretary for Preparedness  
22 and Response.

23 “(2) The Director of the Centers for Disease  
24 Control and Prevention.

1           “(3) The Director of the National Institutes of  
2 Health.

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

4           “(5) The Secretary of Defense.

5           “(6) The Secretary of Homeland Security.

6           “(7) The Secretary of Agriculture.

7           “(8) The Secretary of Veterans Affairs.

8           “(9) The Director of National Intelligence.

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

17       “(c) FUNCTIONS.—

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

20           “(A) Utilize a process to make rec-  
21 ommendations to the Secretary regarding re-  
22 search, advanced research, development, pro-  
23 curement, stockpiling, deployment, distribution,  
24 and utilization with respect to countermeasures,  
25 as defined in section 319F–2(c), including

1 prioritization based on the health security needs  
2 of the United States. Such recommendations  
3 shall be informed by, when available and prac-  
4 ticable, the National Health Security Strategy  
5 pursuant to section 2802, the Strategic Na-  
6 tional Stockpile needs pursuant to section  
7 319F-2, and assessments of current national  
8 security threats, including chemical, biological,  
9 radiological and nuclear threats, including  
10 emerging infectious diseases. In the event that  
11 members of the PHEMCE do not agree upon a  
12 recommendation, the Secretary shall provide a  
13 determination regarding such recommendation.

14 “(B) Identify national health security  
15 needs, including gaps in public health prepared-  
16 ness and response related to countermeasures  
17 and challenges to addressing such needs (in-  
18 cluding any regulatory challenges), and support  
19 alignment of countermeasure procurement with  
20 recommendations to address such needs under  
21 subparagraph (A).

22 “(C) Assist the Secretary in developing  
23 strategies related to logistics, deployment, dis-  
24 tribution, dispensing, and use of counter-  
25 measures that may be applicable to the activi-

1 ties of the strategic national stockpile under  
2 section 319F–2(a).

3 “(D) Provide consultation for the develop-  
4 ment of the strategy and implementation plan  
5 under section 2811(d).

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

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

15 (1) in paragraph (1)—

16 (A) by striking “Not later than 180 days  
17 after the date of enactment of this subsection,  
18 and every year thereafter” and inserting “Not  
19 later than March 15, 2020, and biennially  
20 thereafter”; and

21 (B) by striking “Director of Biomedical”  
22 and all that follows through “Food and Drugs”  
23 and inserting “Public Health Emergency Med-  
24 ical Countermeasures Enterprise established  
25 under section 2811–1”; and

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

3 **SEC. 403. STRATEGIC NATIONAL STOCKPILE.**

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

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

8           (2) in paragraph (1)—

9                   (A) by inserting “the Assistant Secretary  
10                   for Preparedness and Response and” after “col-  
11                   laboration with”;

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

14                   (C) by inserting “and, as informed by ex-  
15                   isting recommendations of, or consultations  
16                   with, the Public Health Emergency Medical  
17                   Countermeasure Enterprise established under  
18                   section 2811–1, make necessary additions or  
19                   modifications to the contents of such stockpile  
20                   or stockpiles based on the review conducted  
21                   under paragraph (2)” before the period of the  
22                   first sentence; and

23                   (D) by striking the second sentence;

24           (3) by inserting after paragraph (1) the fol-  
25           lowing:

1 “(2) THREAT-BASED REVIEW.—

2 “(A) IN GENERAL.—The Secretary shall  
3 conduct an annual threat-based review (taking  
4 into account at-risk individuals) of the contents  
5 of the stockpile under paragraph (1), including  
6 non-pharmaceutical supplies, and, in consulta-  
7 tion with the Public Health Emergency Medical  
8 Countermeasures Enterprise established under  
9 section 2811–1, review contents within the  
10 stockpile and assess whether such contents are  
11 consistent with the recommendations made pur-  
12 suant to section 2811–1(c)(1)(A). Such review  
13 shall be submitted annually, beginning on  
14 March 15, 2019, to the Committee on Health,  
15 Education, Labor, and Pensions and the Com-  
16 mittee on Appropriations of the Senate and the  
17 Committee on Energy and Commerce and the  
18 Committee on Appropriations of the House of  
19 Representatives, in a manner that does not  
20 compromise national security.

21 “(B) ADDITIONS, MODIFICATIONS, AND  
22 REPLENISHMENTS.—Each annual threat-based  
23 review under subparagraph (A) shall, for each  
24 new or modified countermeasure procurement  
25 or replenishment, provide—

1 “(i) information regarding—

2 “(I) the quantities of the addi-  
3 tional or modified countermeasure  
4 procured for, or contracted to be pro-  
5 cured for, the stockpile;

6 “(II) planning considerations for  
7 appropriate manufacturing capacity  
8 and capability to meet the goals of  
9 such additions or modifications (with-  
10 out disclosing proprietary informa-  
11 tion), including consideration of the  
12 effect such additions or modifications  
13 may have on the availability of such  
14 products and ancillary medical sup-  
15 plies in the health care system;

16 “(III) the presence or lack of a  
17 commercial market for the counter-  
18 measure at the time of procurement;

19 “(IV) the emergency health secu-  
20 rity threat or threats such counter-  
21 measure procurement is intended to  
22 address, including whether such pro-  
23 curement is consistent with meeting  
24 emergency health security needs asso-  
25 ciated with such threat or threats;

1           “(V) an assessment of whether  
2           the emergency health security threat  
3           or threats described in subclause (IV)  
4           could be addressed in a manner that  
5           better utilizes the resources of the  
6           stockpile and permits the greatest  
7           possible increase in the level of emer-  
8           gency preparedness to address such  
9           threats;

10           “(VI) whether such counter-  
11           measure is replenishing an expiring or  
12           expired countermeasure, is a different  
13           countermeasure with the same indica-  
14           tion that is replacing an expiring or  
15           expired countermeasure, or is a new  
16           addition to the stockpile;

17           “(VII) a description of how such  
18           additions or modifications align with  
19           projected investments under previous  
20           countermeasures budget plans under  
21           section 2811(b)(7), including expected  
22           life-cycle costs, expenditures related to  
23           countermeasure procurement to ad-  
24           dress the threat or threats described  
25           in subclause (IV), replenishment dates



1 (including the ability to extend the  
2 maximum shelf life of a counter-  
3 measure), and the manufacturing ca-  
4 pacity required to replenish such  
5 countermeasure; and

6 “(VIII) appropriate protocols and  
7 processes for the deployment, distribu-  
8 tion, or dispensing of the counter-  
9 measure at the State and local level,  
10 including plans for relevant capabili-  
11 ties of State and local entities to dis-  
12 pense, distribute, and administer the  
13 countermeasure; and

14 “(ii) an assurance, which need not be  
15 provided in advance of procurement, that  
16 for each countermeasure procured or re-  
17 plenished under this subsection, the Sec-  
18 retary completed a review addressing each  
19 item listed under this subsection in ad-  
20 vance of such procurement or replenish-  
21 ment.”;

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

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

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

3 (B) in subparagraph (C), by inserting “,  
4 and the availability, deployment, dispensing,  
5 and administration of countermeasures” before  
6 the semicolon;

7 (C) by amending subparagraph (E) to read  
8 as follows:

9 “(E) devise plans for effective and timely  
10 supply-chain management of the stockpile, in  
11 consultation with the Director of the Centers  
12 for Disease Control and Prevention, the Assist-  
13 ant Secretary for Preparedness and Response,  
14 the Secretary of Transportation, the Secretary  
15 of Homeland Security, the Secretary of Vet-  
16 erans Affairs, and the heads of other appro-  
17 priate Federal agencies; State, local, tribal, and  
18 territorial agencies; and the public and private  
19 health care infrastructure, as applicable, taking  
20 into account the manufacturing capacity and  
21 other available sources of products and appro-  
22 priate alternatives to supplies in the stockpile;”;

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

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

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

4 “(I) ensure that each countermeasure or  
5 product under consideration for procurement  
6 pursuant to this subsection receives the same  
7 consideration regardless of whether such coun-  
8 termeasure or product receives or had received  
9 funding under section 319L, including with re-  
10 spect to whether the countermeasure or product  
11 is most appropriate to meet the emergency  
12 health security needs of the United States; and

13 “(J) provide assistance, including technical  
14 assistance, to maintain and improve State and  
15 local public health preparedness capabilities to  
16 distribute and dispense medical counter-  
17 measures and products from the stockpile, as  
18 appropriate.”; and

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

20 “(5) GAO REPORT.—

21 “(A) IN GENERAL.—Not later than 3 years  
22 after the date of enactment of the Pandemic  
23 and All-Hazards Preparedness and Advancing  
24 Innovation Act of 2018, and every 5 years  
25 thereafter, the Comptroller General of the

1 United States shall conduct a review of any  
2 changes to the contents or management of the  
3 stockpile since January 1, 2015. Such review  
4 shall include—

5 “(i) an assessment of the comprehen-  
6 siveness and completeness of each annual  
7 threat-based review under paragraph (2),  
8 including whether all newly procured or re-  
9 plenished countermeasures within the  
10 stockpile were described in each annual re-  
11 view, and whether, consistent with para-  
12 graph (2)(B), the Secretary conducted the  
13 necessary internal review in advance of  
14 such procurement or replenishment;

15 “(ii) an assessment of whether the  
16 Secretary established health security and  
17 science-based justifications, and a descrip-  
18 tion of such justifications for procurement  
19 decisions related to health security needs  
20 with respect to the identified threat, for  
21 additions or modifications to the stockpile  
22 based on the information provided in such  
23 reviews under paragraph (2)(B), including  
24 whether such review was conducted prior

1 to procurement, modification, or replenish-  
2 ment;

3 “(iii) an assessment of the plans de-  
4 veloped by the Secretary for the deploy-  
5 ment, distribution, and dispensing of coun-  
6 termeasures procured, modified, or replen-  
7 ished under paragraph (1), including  
8 whether such plans were developed prior to  
9 procurement, modification, or replenish-  
10 ment;

11 “(iv) an accounting of counter-  
12 measures procured, modified, or replen-  
13 ished under paragraph (1) that received  
14 advanced research and development fund-  
15 ing from the Biomedical Advanced Re-  
16 search and Development Authority;

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

23 “(vi) a description of the resources ex-  
24 pended related to the procurement of coun-  
25 termeasures (including additions, modifica-

1 tions, and replenishments) in the stockpile,  
2 and how such expenditures relate to the  
3 ability of the stockpile to meet emergency  
4 health security needs;

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

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

21 “(ix) an assessment of whether the  
22 processes and procedures described by the  
23 Secretary pursuant to section 403(b) of  
24 the Pandemic and All-Hazards Prepared-  
25 ness and Advancing Innovation Act of

1           2018 are sufficient to ensure counter-  
2           measures and products under consideration  
3           for procurement pursuant to subsection (a)  
4           receive the same consideration regardless  
5           of whether such countermeasures and  
6           products receive or had received funding  
7           under section 319L, including with respect  
8           to whether such countermeasures and  
9           products are most appropriate to meet the  
10          emergency health security needs of the  
11          United States.

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

18          (b) ADDITIONAL REPORTING.—In the first threat-  
19          based review submitted after the date of enactment of this  
20          Act pursuant to paragraph (2) of section 319F–2(a) of  
21          the Public Health Service Act (42 U.S.C. 247d–6b(a)), as  
22          amended by subsection (a), the Secretary shall include a  
23          description of the processes and procedures through which  
24          the Director of Strategic National Stockpile and the Di-  
25          rector of the Biomedical Advanced Research and Develop-

1 ment Authority coordinate with respect to counter-  
2 measures and products procured under such section  
3 319F–2(a), including such processes and procedures in  
4 place to ensure countermeasures and products under con-  
5 sideration for procurement pursuant to such section  
6 319F–2(a) receive the same consideration regardless of  
7 whether such countermeasures and products receive or  
8 had received funding under section 319L of the Public  
9 Health Service Act (42 U.S.C. 247d–7e), and whether  
10 such countermeasures and products are the most appro-  
11 priate to meet the emergency health security needs of the  
12 United States.

13 (c) AUTHORIZATION OF APPROPRIATIONS, STRA-  
14 TEGIC NATIONAL STOCKPILE.—Section 319F–2(f)(1) of  
15 the Public Health Service Act (42 U.S.C. 247d–6b(f)(1))  
16 is amended by striking “\$533,800,000 for each of fiscal  
17 years 2014 through 2018” and inserting “\$610,000,000  
18 for each of fiscal years 2019 through 2023, to remain  
19 available until expended”.

20 **SEC. 404. PREPARING FOR PANDEMIC INFLUENZA, ANTI-**  
21 **MICROBIAL RESISTANCE, AND OTHER SIG-**  
22 **NIFICANT THREATS.**

23 (a) STRATEGIC INITIATIVES.—Section 319L(c)(4)  
24 (247d–7e(c)(4)) is amended by adding at the end the fol-  
25 lowing:



1           “(F) STRATEGIC INITIATIVES.—The Sec-  
2           retary, acting through the Director of BARDA,  
3           may implement strategic initiatives, including  
4           by building on existing programs and by award-  
5           ing contracts, grants, and cooperative agree-  
6           ments, or entering into other transactions, to  
7           support innovative candidate products in pre-  
8           clinical and clinical development that address  
9           priority, naturally occurring and man-made  
10          threats that, as determined by the Secretary,  
11          pose a significant level of risk to national secu-  
12          rity based on the characteristics of a chemical,  
13          biological, radiological or nuclear threat, or ex-  
14          isting capabilities to respond to such a threat  
15          (including medical response and treatment ca-  
16          pabilities and manufacturing infrastructure).  
17          Such initiatives shall accelerate and support the  
18          advanced research, development, and procure-  
19          ment of, countermeasures and products, as ap-  
20          plicable, to address areas including—

21                 “(i) chemical, biological, radiological,  
22                 or nuclear threats, including emerging in-  
23                 fectious diseases, for which insufficient ap-  
24                 proved, licensed, or authorized counter-  
25                 measures exist, or for which such threat,

1 or the result of an exposure to such threat,  
2 may become resistant to countermeasures  
3 or existing countermeasures may be ren-  
4 dered ineffective;

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

20 “(iii) threats that may result pri-  
21 marily or secondarily from a chemical, bio-  
22 logical, radiological, or nuclear agent, or  
23 emerging infectious diseases, and which  
24 may present increased treatment complica-  
25 tions such as the occurrence of resistance

1 to available countermeasures or potential  
2 countermeasures, including antimicrobial  
3 resistant pathogens.”.

4 (b) EMERGING INFECTIOUS DISEASE PROGRAM.—  
5 Section 319L of the Public Health Service Act (42 U.S.C.  
6 247d–7e) is amended—

7 (1) by redesignating subsections (d), (e), and  
8 (f) as subsections (e), (f), and (g), respectively; and

9 (2) by inserting after subsection (c) the fol-  
10 lowing new subsections:

11 “(d) EMERGING INFECTIOUS DISEASE PROGRAM.—

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

15 “(A) advanced research and development  
16 activities for qualified pandemic or epidemic  
17 products; and

18 “(B) manufacturing infrastructure activi-  
19 ties with respect to an emerging infectious dis-  
20 ease.

21 “(2) FUNDING.—

22 “(A) IN GENERAL.—To carry out para-  
23 graph (1), there is authorized to be appro-  
24 priated \$250,000,000 for each of fiscal years

1           2019 through 2023, to remain available until  
2           expended.

3           “(B) SUPPLEMENT NOT SUPPLANT.—Any  
4           funds provided to the Secretary under this  
5           paragraph shall be used to supplement and not  
6           supplant any other Federal funds provided to  
7           carry out paragraph (1).”.

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

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

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

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

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

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

20           “(A) IN GENERAL.—Not later than 1 year  
21   after the date of the enactment of the Pan-  
22   demic and All-Hazards Preparedness and Ad-  
23   vancing Innovation Act of 2018, the Secretary  
24   shall report to the congressional committees of  
25   jurisdiction on the implementation of rec-

1           ommendations of the Federal Experts Security  
2           Advisory Panel concerning the select agent pro-  
3           gram.

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

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

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

17           Section 2811(b)(7) of the Public Health Service Act  
18 (42 U.S.C. 300hh–10(b)(7)) is amended—

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

21           (2) in subparagraph (A)—

22           (A) in clause (ii), by striking “; and” and  
23           inserting “;”; and

24           (B) by striking clause (iii) and inserting  
25           the following:

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

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

13          “(v) potential deployment, distribu-  
14          tion, and utilization of medical counter-  
15          measures; development of clinical guidance  
16          and emergency use instructions for the use  
17          of medical countermeasures; and, as appli-  
18          cable, potential post-deployment activities  
19          related to medical countermeasures;”;

20          (3) by redesignating subparagraphs (D) and  
21          (E) as subparagraphs (E) and (F), respectively; and

22          (4) by inserting after subparagraph (C), the fol-  
23          lowing:

24                  “(D) identify the full range of anticipated  
25                  medical countermeasure needs related to re-

1 search and development, procurement, and  
2 stockpiling, including the potential need for in-  
3 dications, dosing, and administration tech-  
4 nologies, and other countermeasure needs as  
5 applicable and appropriate;”.

6 **SEC. 502. MATERIAL THREAT AND MEDICAL COUNTER-**  
7 **MEASURE NOTIFICATIONS.**

8 (a) CONGRESSIONAL NOTIFICATION OF MATERIAL  
9 THREAT DETERMINATION.—Section 319F–2(c)(2)(C) of  
10 the Public Health Service Act (42 U.S.C. 247d–  
11 6b(c)(2)(C)) is amended by striking “The Secretary and  
12 the Homeland Security Secretary shall promptly notify the  
13 appropriate committees of Congress” and inserting “The  
14 Secretary and the Secretary of Homeland Security shall  
15 send to Congress, on an annual basis, all current material  
16 threat determinations and shall promptly notify the Com-  
17 mittee on Health, Education, Labor, and Pensions and the  
18 Committee on Homeland Security and Governmental Af-  
19 fairs of the Senate and the Committee on Energy and  
20 Commerce and the Committee on Homeland Security of  
21 the House of Representatives”.

22 (b) CONTRACTING COMMUNICATION.—Section 319F–  
23 2(c)(7)(B)(ii)(III) of the Public Health Service Act (42  
24 U.S.C. 247d–6b(c)(7)(B)(ii)(III)) is amended by adding  
25 at the end the following: “The Secretary shall notify the

1 vendor within 90 days of a determination by the Secretary  
2 to renew, extend, or terminate such contract.”.

3 **SEC. 503. AVAILABILITY OF REGULATORY MANAGEMENT**  
4 **PLANS.**

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

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

9 (2) by inserting after paragraph (2) the fol-  
10 lowing:

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

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

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

20 “(C) the information required for the sub-  
21 mission of such request;

22 “(D) a description of the types of develop-  
23 ment milestones and performance targets that  
24 could be discussed and included in such plans;  
25 and



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

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

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

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

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

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

15 (a) BIOSHIELD SPECIAL RESERVE FUND.—Section  
16 319F–2(g)(1) of the Public Health Service Act (42 U.S.C.  
17 247d–6b(g)(1)) is amended—

18 (1) by striking “\$2,800,000,000 for the period  
19 of fiscal years 2014 through 2018” and inserting  
20 “\$7,100,000,000 for the period of fiscal years 2019  
21 through 2028, to remain available until expended”;  
22 and

23 (2) by striking the second sentence.

24 (b) THE BIOMEDICAL ADVANCED RESEARCH AND  
25 DEVELOPMENT AUTHORITY.—Subsection (e)(2) of section

1 319L of the Public Health Service Act (42 U.S.C. 247d–  
2 7e), as redesignated by section 404(b), is amended by  
3 striking “\$415,000,000 for each of fiscal years 2014  
4 through 2018” and inserting “\$611,700,000 for each of  
5 fiscal years 2019 through 2023”.

6 **SEC. 505. ADDITIONAL STRATEGIES FOR COMBATING ANTI-**  
7 **BIOTIC RESISTANCE.**

8 Part B of title III of the Public Health Service Act  
9 (42 U.S.C. 243 et seq.) is amended by inserting after sec-  
10 tion 319E the following:

11 **“SEC. 319E-1. ADVISORY COUNCIL ON COMBATING ANTI-**  
12 **BIOTIC-RESISTANT BACTERIA.**

13 “(a) DEFINITIONS.—In this section:

14 “(1) ACTION PLAN.—The term ‘Action Plan’  
15 means the Action Plan described in section  
16 319E(a)(1).

17 “(2) ADVISORY COUNCIL.—The term ‘Advisory  
18 Council’ means the Presidential Advisory Council on  
19 Combating Antibiotic-Resistant Bacteria established  
20 by Executive Order 13676 of September 18, 2014  
21 (79 Fed. Reg. 56931; relating to combating anti-  
22 biotic-resistant bacteria).

23 “(3) NATIONAL STRATEGY.—The term ‘Na-  
24 tional Strategy’ means the National Strategy for  
25 Combating Antibiotic-Resistant Bacteria issued by

1 the White House in September 2014, and any subse-  
2 quent update to such strategy or a successor strat-  
3 egy.

4 “(b) ADVISORY COUNCIL.—The Advisory Council  
5 shall provide advice, information, and recommendations to  
6 the Secretary regarding programs and policies intended to  
7 support and evaluate the implementation of Executive  
8 Order 13676 of September 18, 2014 (79 Fed. Reg. 56931;  
9 relating to combating antibiotic-resistant bacteria), includ-  
10 ing the National Strategy, and the Action Plan.

11 “(c) MEETINGS AND DUTIES.—

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

17 “(2) RECOMMENDATIONS.—The Advisory Coun-  
18 cil shall make recommendations to the Secretary, in  
19 consultation with the Secretary of Agriculture and  
20 the Secretary of Defense, regarding programs and  
21 policies intended to—

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

24 “(B) advance research to develop improved  
25 methods for combating antibiotic resistance and

1           conducting antimicrobial stewardship, as de-  
2           fined in section 319E(h)(3);

3           “(C) strengthen surveillance of antibiotic-  
4           resistant bacterial infections;

5           “(D) prevent the transmission of anti-  
6           biotic-resistant bacterial infections;

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

9           “(F) further research on new treatments  
10          for bacterial infections;

11          “(G) develop alternatives to antibiotics for  
12          animal health purposes;

13          “(H) maximize the dissemination of up-to-  
14          date information on the appropriate and proper  
15          use of antibiotics to the general public and  
16          human and animal health care providers; and

17          “(I) improve international coordination of  
18          efforts to combat antibiotic resistance.

19          “(3) COORDINATION.—The Advisory Council  
20          shall, to the greatest extent practicable, coordinate  
21          activities carried out by the Council with the Anti-  
22          microbial Resistance Task Force established under  
23          section 319E(a) (commonly referred to as the ‘Com-  
24          bating Antibiotic-Resistant Bacteria Task Force’).”.

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

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

5 Section 319L(e)(4)(D)(iii) of the Public Health Serv-  
6 ice Act (42 U.S.C. 247d–7e(e)(4)(D)(iii)) is amended by  
7 striking “and platform technologies” and inserting “plat-  
8 form technologies, technologies to administer counter-  
9 measures, and technologies to improve storage and trans-  
10 portation of countermeasures”.

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

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

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

17 (2) in subsection (c)(5)(A)—

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

22 (B) in clause (ii)—

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

1           “(I) IN GENERAL.—To the max-  
2           imum extent practicable, competitive  
3           procedures shall be used when enter-  
4           ing into transactions to carry out  
5           projects under this subsection.”; and

6           (ii) in subclause (II)—

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

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

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

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

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

1 termeasures, qualified countermeasures, and qualified  
2 pandemic or epidemic products by facilitating and encour-  
3 aging submission of data and information to support such  
4 products to medical countermeasure master files, and  
5 through clarifying the authority to cross-reference to data  
6 and information previously submitted to the Secretary of  
7 Health and Human Services (referred to in this section  
8 as the “Secretary”).

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

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

14 “(a) **APPLICABILITY OF REFERENCE.**—

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

1       thorized by the master file holder, in accordance  
2       with applicable privacy and confidentiality protocols  
3       and regulations.

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

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

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

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



1           rity countermeasures, qualified counter-  
2           measures, or qualified pandemic or epidemic  
3           products; and

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

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

12          “(c) SPONSOR REFERENCE.—

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

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

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

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

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

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

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

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

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

3           “(1) limit the authority of the Secretary to ap-  
4 prove, license, clear, conditionally approve, or au-  
5 thorize drugs, biological products, or devices pursu-  
6 ant to, as applicable, this Act or section 351 of the  
7 Public Health Service Act (as such applicable Act is  
8 in effect on the day before the date of enactment of  
9 the Pandemic and All-Hazards Preparedness and  
10 Advancing Innovation Act of 2018), including the  
11 standards of evidence, and applicable conditions, for  
12 approval under the applicable Act;

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

21           “(3) alter the authority of the Secretary under  
22 this Act or the Public Health Service Act to deter-  
23 mine the types of data or information previously  
24 submitted by a sponsor or any other person that  
25 may be incorporated by reference in an application,

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

9 “(f) DEFINITIONS.—In this section:

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

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

1 new animal drug application under section  
2 512(b)(2), an application for conditional approval of  
3 a new animal drug under section 571, an investiga-  
4 tional device application under section 520(g), an  
5 application with respect to a device under section  
6 515(c), a request for classification of a device under  
7 section 513(f)(2), a notification with respect to a de-  
8 vice under section 510(k), or a request for an emer-  
9 gency use authorization under section 564 to sup-  
10 port—

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

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

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

24 (c) STAKEHOLDER INPUT.—Not later than 18  
25 months after the date of enactment of this Act, the Sec-

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

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

1 or technologies (including platform technologies) that have  
2 the potential to support and advance the development or  
3 manufacture of security countermeasures, qualified coun-  
4 termeasures, and qualified pandemic or epidemic products.  
5 The Secretary, acting through the Commissioner of Food  
6 and Drugs, shall publish the final guidance not later than  
7 3 years after the enactment of this Act.

8 **SEC. 604. ANIMAL RULE REPORT.**

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

20 (1) The extent to which advanced development  
21 and review of a medical countermeasure are coordi-  
22 nated between the Biomedical Advanced Research  
23 and Development Authority and the Food and Drug  
24 Administration, including activities that facilitate  
25 appropriate and efficient design of studies to sup-



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

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

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

23 (4) The extent to which the guidance issued  
24 under section 565(c) of the Federal Food Drug and  
25 Cosmetic Act (21 U.S.C. 360bbb–4(c)), entitled,

1 “Product Development Under the Animal Rule:  
2 Guidance for Industry” (issued in October 2015),  
3 has assisted in achieving the purposes described in  
4 paragraphs (1), (2), and (3).

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

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

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

19 (3) other biodefense stakeholders, as applicable.

20 (c) REPORT.—Not later than 3 years after the date  
21 of enactment of this Act, the Comptroller General of the  
22 United States shall submit to the Committee on Health,  
23 Education, Labor, and Pensions of the Senate and the  
24 Committee on Energy and Commerce of the House of  
25 Representatives a report containing the results of the

1 study conducted under subsection (a) and recommenda-  
2 tions to improve the application and consistency of the re-  
3 quirements under subsections (c) and (d) of section 565  
4 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
5 360bbb-4) to support and expedite the research and devel-  
6 opment of medical countermeasures, as applicable.

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

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

15 (a) MEETING.—

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

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

3           (A) shall include—

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

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

16          (B) may include—

17          (i) other representatives from the De-  
18 partment of Health and Human Services,  
19 as the Secretary determines appropriate;  
20 and

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

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

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

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

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

13           (B) national security implications, includ-  
14 ing—

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

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

1 (iii) security measures to monitor and  
2 assess the potential threat that may result  
3 from utilization of genomic engineering  
4 technologies and related technologies for  
5 the purpose of compromising national  
6 health security.

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

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

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

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

14 **SEC. 607. STRENGTHENING MOSQUITO ABATEMENT FOR**  
15 **SAFETY AND HEALTH.**

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

20 (1) in subsection (a)(1)(B)—

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

1 (B) by inserting “or improving existing  
2 control programs” before the period at the end;  
3 (2) in subsection (b)—

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

6 (B) in paragraph (2)—

7 (i) in subparagraph (A)—

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

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

15 (III) by adding at the end the  
16 following:

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

21 (ii) by amending subparagraph (D) to  
22 read as follows:

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



1           “(ii) that demonstrates to the Secretary  
2           that the control program is consistent with ex-  
3           isting State mosquito control plans or policies,  
4           or other applicable State preparedness plans.”;

5           (C) in paragraph (4)(C), by striking “that  
6           extraordinary” and all that follows through the  
7           period at the end and inserting the following:

8           “that—

9                   “(i) extraordinary economic conditions  
10                   in the political subdivision or consortium of  
11                   political subdivisions involved justify the  
12                   waiver; or

13                   “(ii) the geographical area covered by  
14                   a political subdivision or consortium for a  
15                   grant under paragraph (1) has an extreme  
16                   mosquito control need due to—

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

19                           “(II) the size or density of a  
20                           mosquito population that requires  
21                           heightened control; or

22                           “(III) the severity of the mos-  
23                           quito-borne disease, such that ex-  
24                           pected serious adverse health out-

1 comes for the human population jus-  
2 tify the waiver.”; and

3 (D) by amending paragraph (6) to read as  
4 follows:

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

9 (3) in subsection (f)—

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

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

20 (C) in paragraph (3)—

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

23 (ii) by striking “2004” and inserting  
24 “2019”.

1 (b) EPIDEMIOLOGY-LABORATORY CAPACITY  
2 GRANTS.—Section 2821 of the Public Health Service Act  
3 (42 U.S.C. 300hh–31) is amended—

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

7 (2) by amending subsection (b) to read as fol-  
8 lows:

9 “(b) AUTHORIZATION OF APPROPRIATIONS.—There  
10 are authorized to be appropriated to carry out this section  
11 \$40,000,000 for each of fiscal years 2019 through 2023.”.

## 12 **TITLE VII—MISCELLANEOUS** 13 **PROVISIONS**

### 14 **SEC. 701. REAUTHORIZATIONS AND EXTENSIONS.**

15 (a) VACCINE TRACKING AND DISTRIBUTION.—Sec-  
16 tion 319A(e) of the Public Health Service Act (42 U.S.C.  
17 247d–1(e)) is amended by striking “2014 through 2018”  
18 and inserting “2019 through 2023”.

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

22 (c) STRATEGIC INNOVATION PARTNER.—Section  
23 319L(c)(4)(E)(ix) of the Public Health Service Act (42  
24 U.S.C. 247d–7e(c)(4)(E)(ix)) is amended by striking  
25 “2022” and inserting “2023”.

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

11 (C) in subsection (a)(1)(A)—

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”;

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

5           (e) INAPPLICABILITY OF CERTAIN PROVISIONS.—  
6 Subsection (e)(1) of section 319L of the Public Health  
7 Service Act (42 U.S.C. 247d–7e) is amended—

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

10                   “(A) NON-DISCLOSURE OF INFORMA-  
11 TION.—

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

16                           “(ii) INFORMATION DESCRIBED.—The  
17 information described in this clause is in-  
18 formation relevant to programs of the De-  
19 partment of Health and Human Services  
20 that could compromise national security  
21 and reveal significant and not otherwise  
22 publicly known vulnerabilities of existing  
23 medical or public health defenses against  
24 chemical, biological, radiological, or nuclear  
25 threats, and is comprised of—

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

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

15          “(III) security and vulnerability  
16          assessments.”;

17               (2) by redesignating subparagraph (C) as sub-  
18          paragraph (D);

19               (3) by inserting after subparagraph (B) the fol-  
20          lowing:

21               “(C) REPORTING.—One year after the  
22          date of enactment of the Pandemic and All-  
23          Hazards Preparedness and Advancing Innova-  
24          tion Act of 2018, and annually thereafter, the  
25          Secretary shall report to the Committee on

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

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

13 Subsection (d) of section 319F–2 of the Public  
14 Health Service Act (42 U.S.C. 247d–6b) is amended to  
15 read as follows:

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

23 **SEC. 703. CYBERSECURITY.**

24 (a) STRATEGY FOR PUBLIC HEALTH PREPAREDNESS  
25 AND RESPONSE TO CYBERSECURITY THREATS.—

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

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

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

20                   (C) strategies to address identified gaps  
21 and strengthen public health emergency pre-  
22 paredness and response capabilities to address  
23 such cybersecurity threats.

24           (2) PROTECTION OF NATIONAL SECURITY.—  
25 The Secretary shall make such strategy available to



1 the Committee on Health, Education, Labor, and  
2 Pensions of the Senate, the Committee on Energy  
3 and Commerce of the House of Representatives, and  
4 other congressional committees of jurisdiction, in a  
5 manner that does not compromise national security.

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

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

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

5 **SEC. 704. TECHNICAL AMENDMENTS.**

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

9 (1) in paragraphs (1) and (5) of section 319F–  
10 1(a) (42 U.S.C. 247d–6a(a)), by striking “section  
11 319F(h)” each place such term appears and insert-  
12 ing “section 319F(e)”; and

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

16 (b) PUBLIC HEALTH SECURITY GRANTS.—Section  
17 319C–1(b)(2) of the Public Health Service Act (42 U.S.C.  
18 247d–3a(b)(2)) is amended—

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

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

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

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

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

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

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

16 (1) by striking “Nothing in” and inserting the  
17 following:

18 “(A) IN GENERAL.—Nothing in”;

19 (2) by striking “disclose any” and inserting  
20 “disclose or direct—

21 “(i) any”;

22 (3) by striking the period and inserting “; or”;

23 and

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

1           “(ii) in the case of a drug develop-  
2           ment tool that may be used to support the  
3           development of a qualified countermeasure,  
4           security countermeasure, or qualified pan-  
5           demic or epidemic product, as defined in  
6           sections 319F-1, 319F-2, and 319F-3,  
7           respectively, of the Public Health Service  
8           Act, any information that the Secretary  
9           determines has a significant potential to  
10          affect national security.

11          “(B) PUBLIC ACKNOWLEDGMENT.—In the  
12          case that the Secretary, pursuant to subpara-  
13          graph (A), does not make information publicly  
14          available, the Secretary shall provide on the  
15          internet website of the Food and Drug Admin-  
16          istration an acknowledgement of the informa-  
17          tion that has not been disclosed, pursuant to  
18          subparagraph (A).”.

19 **SEC. 705. FORMAL STRATEGY RELATING TO CHILDREN**  
20                   **SEPARATED FROM PARENTS AND GUARD-**  
21                   **IANAS AS A RESULT OF ZERO TOLERANCE POL-**  
22                   **ICY.**

23          Not later than 14 days after the date of enactment  
24          of this Act, the Assistant Secretary for Preparedness and  
25          Response and the Assistant Secretary for the Administra-

1 tion on Children and Families shall submit to the Com-  
2 mittee on Energy and Commerce of the House of Rep-  
3 resentatives and the Committee on Health, Education,  
4 Labor, and Pensions of the Senate a formal strategy to  
5 reunify with their parent or guardian, if the parent or  
6 guardian chooses such reunification, each child who—

7           (1) as a result of the initiative announced on  
8           April 6, 2018, and due to prosecution under section  
9           1325(a) of title 8, United States Code;

10           (2) was separated from their parent or guard-  
11           ian and placed into a facility funded by the Depart-  
12           ment of Health and Human Services; and

13           (3) can be safely reunited with such parent or  
14           guardian.

15 **SEC. 706. REPORTING RELATING TO CHILDREN SEPARATED**  
16 **FROM PARENTS AND GUARDIANS AS A RE-**  
17 **SULT OF ZERO TOLERANCE POLICY.**

18           Beginning on the date of enactment of this Act, the  
19 Assistant Secretary for Preparedness and Response and  
20 the Assistant Secretary for the Administration on Chil-  
21 dren and Families shall submit to the Committee on En-  
22 ergy and Commerce of the House of Representatives and  
23 the Committee on Health, Education, Labor, and Pen-  
24 sions of the Senate weekly reports on the status and wel-  
25 fare of the children who, as a result of the “zero toler-

1 ance” policy, were separated from their parent or guard-  
2 ian and are awaiting reunification with their parent or  
3 guardian, as well as the number of such children in facili-  
4 ties funded by the Department of Health and Human  
5 Services.

6 **SEC. 707. TECHNICAL CORRECTION.**

7 Section 801(e)(4)(E)(iii) of the Federal Food, Drug,  
8 and Cosmetic Act (21 U.S.C. 381(e)(4)(E)(iii)) is amend-  
9 ed by striking “subparagraph” both places it appears in  
10 subclause (I) and subclause (II) and inserting “para-  
11 graph”.

12 **SEC. 708. SAVINGS CLAUSE.**

13 Nothing in this Act shall be construed as reducing  
14 or limiting the authorities vested in any other Federal  
15 agency by any other Federal law.

Passed the House of Representatives September 25,  
2018.

Attest:

*Clerk.*



115<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

**H. R. 6378**

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**AN ACT**

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