

118TH CONGRESS  
1ST SESSION

# S. 2333

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

---

## IN THE SENATE OF THE UNITED STATES

JULY 18, 2023

Mr. CASEY (for himself, Mr. ROMNEY, Mr. SANDERS, and Mr. CASSIDY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

## A BILL

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

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

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

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

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

Sec. 1. Short title; table of contents.

#### TITLE I—STATE AND LOCAL READINESS AND RESPONSE

- Sec. 101. Temporary reassignment of State and local personnel during a public health emergency.
- Sec. 102. Public Health Emergency Preparedness program.
- Sec. 103. Improving and enhancing participation of EMS organizations in the hospital preparedness program.
- Sec. 104. Improving medical readiness and response capabilities.
- Sec. 105. Pilot program to support State medical stockpiles.
- Sec. 106. Enhancing domestic wastewater surveillance for pathogen detection.
- Sec. 107. Reauthorization of Mosquito Abatement for Safety and Health program.

#### TITLE II—FEDERAL PLANNING AND COORDINATION

- Sec. 201. All-Hazards Emergency Preparedness and Response.
- Sec. 202. National Health Security Strategy.
- Sec. 203. Improving development and distribution of diagnostic tests.
- Sec. 204. Pilot program for public health data availability.
- Sec. 205. Combating antimicrobial resistance.
- Sec. 206. Strategic National Stockpile and material threats.
- Sec. 207. Medical countermeasures for viral threats with pandemic potential.
- Sec. 208. Public Health Emergency Medical Countermeasures Enterprise.
- Sec. 209. Strengthening public health communication.
- Sec. 210. Fellowship and training programs.
- Sec. 211. Assessment of COVID-19 mitigation policies.

#### TITLE III—ADDRESSING THE NEEDS OF ALL INDIVIDUALS

- Sec. 301. Transition of certain countermeasures between compensation programs.
- Sec. 302. Accelerating injury compensation program administration and ensuring program integrity.
- Sec. 303. Compensation for injuries relating to the public health emergency caused by SARS-CoV-2.
- Sec. 304. Review of regulations.
- Sec. 305. Supporting individuals with disabilities, older adults, and other at-risk individuals during emergency responses.
- Sec. 306. National advisory committees.
- Sec. 307. Research and coordination of activities concerning the long-term health effects of SARS-CoV-2 infection.
- Sec. 308. National Academies study on prizes.

#### TITLE IV—STRENGTHENING BIOSECURITY

- Sec. 401. Treatment of genetic variants and synthetic products of select agents and toxins.
- Sec. 402. Establishment of no-fault reporting system.
- Sec. 403. Evaluation of the Federal Select Agent Program and related policies.
- Sec. 404. Supporting research and laboratory surge capacity.
- Sec. 405. Gene synthesis.
- Sec. 406. Limitation related to countries of concern conducting certain research.
- Sec. 407. Assessment of artificial intelligence threats to health security.

## TITLE V—PREVENTING DRUG SHORTAGES

- Sec. 501. Improving notification procedures in case of increased demand for critical drugs.
- Sec. 502. Reporting on supply chains.
- Sec. 503. Reporting on use of new authorities and requirements with respect to drug shortages.

## TITLE VI—ADDITIONAL REAUTHORIZATIONS AND TECHNICAL AMENDMENTS

- Sec. 601. Medical countermeasure priority review voucher.
- Sec. 602. Epidemic Intelligence Service loan repayment program.
- Sec. 603. Vaccine tracking and distribution.
- Sec. 604. Regional health care emergency preparedness and response systems.
- Sec. 605. Emergency system for advance registration of volunteer health professional.
- Sec. 606. Limited antitrust exemption.
- Sec. 607. Trauma care.
- Sec. 608. Military and civilian partnership for trauma readiness.
- Sec. 609. National Disaster Medical System.
- Sec. 610. Volunteer Medical Reserve Corps.
- Sec. 611. Epidemiology-laboratory capacity grants.
- Sec. 612. Veterans Affairs.
- Sec. 613. Technical amendments.

1       **TITLE I—STATE AND LOCAL**  
 2       **READINESS AND RESPONSE**

3       **SEC. 101. TEMPORARY REASSIGNMENT OF STATE AND**  
 4                   **LOCAL PERSONNEL DURING A PUBLIC**  
 5                   **HEALTH EMERGENCY.**

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

8                   (1) in paragraph (1), by striking “such Gov-  
 9                   ernor or tribal organization’s designee” and insert-  
 10                   ing “the designee of the Governor or Tribal organi-  
 11                   zation, or the State or Tribal health official”;

12                   (2) in paragraph (2)(B)—

13                   (A) in the matter preceding clause (i), by  
 14                   striking “tribal organization” and inserting

1 “Tribal organization, or the State or Tribal  
2 health official”; and

3 (B) in clause (v), by striking “tribal orga-  
4 nization” and inserting “Tribal organization or  
5 State or Tribal health official”;

6 (3) in paragraph (6)—

7 (A) in the matter preceding subparagraph

8 (A)—

9 (i) by striking “Reauthorization Act  
10 of 2013” and inserting “and Response  
11 Act”; and

12 (ii) by striking “appropriate commit-  
13 tees of the Congress” and inserting “Com-  
14 mittee on Health, Education, Labor, and  
15 Pensions of the Senate and the Committee  
16 on Energy and Commerce of the House of  
17 Representatives”; and

18 (B) in subparagraph (A), by inserting “,  
19 including requests from State or Tribal health  
20 officials” before the semicolon;

21 (4) in paragraph (7)(A), by striking “tribal or-  
22 ganization” and inserting “Tribal organization”; and

23 (5) in paragraph (8), by striking “2023” and  
24 inserting “2028”.

1 **SEC. 102. PUBLIC HEALTH EMERGENCY PREPAREDNESS**  
2 **PROGRAM.**

3 Section 319C–1 of the Public Health Service Act (42  
4 U.S.C. 247d–3a) is amended—

5 (1) in subsection (b)(2)—

6 (A) in subparagraph (A)(ii), by striking  
7 “influenza” and inserting “response planning”;  
8 and

9 (B) in subparagraph (H), by inserting “,  
10 such as community-based organizations, includ-  
11 ing faith-based organizations, and other public  
12 and private entities” after “stakeholders”;

13 (2) in subsection (g)—

14 (A) in paragraph (1), in the matter pre-  
15 ceding subparagraph (A), by inserting “and the  
16 ability of each entity receiving an award under  
17 subsection (a) to respond to all-hazards  
18 threats” before the period at the end of the  
19 first sentence;

20 (B) in paragraph (2)—

21 (i) in the paragraph heading, by strik-  
22 ing “INFLUENZA” and inserting “RE-  
23 SPONSE”; and

24 (ii) in subparagraph (A)—

25 (I) by striking “to pandemic in-  
26 fluenza” and inserting “to a pathogen

1 causing a pandemic, including pan-  
2 demic influenza”; and

3 (II) by striking “such pandemic  
4 influenza” and inserting “such pan-  
5 demic response”;

6 (C) in paragraph (5)—

7 (i) in the paragraph heading, by strik-  
8 ing “INFLUENZA” and inserting “PAN-  
9 DEMIC RESPONSE”;

10 (ii) in the matter preceding subpara-  
11 graph (A), by striking “2019” and insert-  
12 ing “2025”;

13 (iii) in clause (i), by striking “2018”  
14 and inserting “2024”; and

15 (iv) in subparagraph (B), by striking  
16 “pandemic influenza” and inserting “a  
17 pathogen causing a pandemic”; and

18 (D) in paragraph (6)—

19 (i) in subparagraph (A), in the matter  
20 preceding clause (i), by striking “The  
21 amounts described in this paragraph are  
22 the following amounts that are payable to  
23 an entity for activities described in this  
24 section of section 319C–2” and inserting  
25 “The Secretary shall withhold from an en-

1           tity pursuant to paragraph (5) for non-  
2           compliance with the requirements of this  
3           section or section 319C–2 as follows”; and

4                   (ii) in subparagraph (B), by inserting  
5           “with respect to the requirements of this  
6           section or section 319C–2” after “para-  
7           graph (5)”; and

8           (3) in subsection (h)—

9                   (A) in paragraph (1)(A), by striking  
10           “\$685,000,000 for each of fiscal years 2019  
11           through 2023” and inserting “\$735,000,000  
12           for each of fiscal years 2024 through 2028”;

13                   (B) in paragraph (4)—

14                           (i) in subparagraph (A), by striking  
15           “For fiscal year 2027, the Secretary” and  
16           inserting “The Secretary”; and

17                           (ii) in subparagraph (D), by striking  
18           “for fiscal year 2026”; and

19                   (C) in paragraph (5)(A), by striking “For  
20           fiscal year 2007, the Secretary” and inserting  
21           “The Secretary”.

1 **SEC. 103. IMPROVING AND ENHANCING PARTICIPATION OF**  
 2 **EMS ORGANIZATIONS IN THE HOSPITAL PRE-**  
 3 **PARAREDNESS PROGRAM.**

4 (a) INCREASING PARTICIPATION BY EMS IN THE  
 5 HOSPITAL PREPAREDNESS PROGRAM.—Section 319C-2  
 6 of the Public Health Service Act (42 U.S.C. 247d-3b) is  
 7 amended—

8 (1) in subsection (b)(1)(A)—

9 (A) in clause (iii)(III), by striking “; and”  
 10 and inserting semicolon; and

11 (B) by striking clause (iv) and inserting  
 12 the following:

13 “(iv) one or more emergency medical  
 14 service organizations; and

15 “(v) to the extent practicable, one or  
 16 more emergency management organiza-  
 17 tions; and”;

18 (2) in subsection (g)(1)—

19 (A) by striking the heading and inserting:

20 “(1) LOCAL RESPONSE CAPABILITIES.—

21 “(A) PROGRAM COORDINATION.—”;

22 (B) by striking “extent practicable, en-  
 23 sure” and inserting the following: “extent prac-  
 24 ticable—

25 “(i) ensure”;



1 (C) by striking the period and inserting “;  
2 and”; and

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

4 “(ii) seek to increase participation of  
5 eligible entities described in subsection  
6 (b)(1)(A) with lower participation rates  
7 relative to coalitions of other eligible enti-  
8 ties, such as coalitions that include emer-  
9 gency medical services organizations and  
10 health care facilities in underserved  
11 areas.”.

12 (b) PREFERENCES.—Section 319C–2(d)(1)(A)(iii) of  
13 the Public Health Service Act (42 U.S.C. 247d–  
14 3b(d)(1)(A)(iii)) is amended by striking “subsection  
15 (b)(1)(A)(ii)” and inserting “clauses (ii) and (iv) of sub-  
16 section (b)(1)(A)”.

17 **SEC. 104. IMPROVING MEDICAL READINESS AND RESPONSE**  
18 **CAPABILITIES.**

19 Section 319C–2 of the Public Health Service Act (42  
20 U.S.C. 247d–3b) is amended—

21 (1) in subsection (b)(2)—

22 (A) in subparagraph (A), by striking  
23 “and” at the end;

24 (B) in subparagraph (B), by striking the  
25 period and inserting “; and”; and

1 (C) by inserting at the end the following:

2 “(C) designate a lead entity to administer such  
3 award and support coordination between entities de-  
4 scribed in this subsection.”;

5 (2) in subsection (g)(1), as amended by section  
6 102(a)(2), by adding at the end the following:

7 “(B) REGIONAL OPERATIONS.—An eligible  
8 entity shall establish and maintain, or leverage  
9 an existing, capability to enable coordination of  
10 regional medical operations, which may include  
11 systems to facilitate information sharing and  
12 coordination, within a coalition described under  
13 subsection (b)(1)(A) and, as appropriate, be-  
14 tween multiple coalitions that are in close geo-  
15 graphic proximity to each other.”; and

16 (3) in subsection (j)(1)—

17 (A) in subparagraph (A), by striking  
18 “2019 through 2023” and inserting “2024  
19 through 2028”; and

20 (B) in subparagraph (B)(iii), by striking  
21 “2023” and inserting “2028”.

22 **SEC. 105. PILOT PROGRAM TO SUPPORT STATE MEDICAL**  
23 **STOCKPILES.**

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

1 (1) in paragraph (2)(B)(i)—

2 (A) in subclause (I), by striking “and  
3 2024” and inserting “through 2025”; and

4 (B) in subclause (II), by striking “2025”  
5 and inserting “2026”;

6 (2) in paragraph (4)—

7 (A) in subparagraph (G), by striking “;  
8 and” at the end and inserting a semicolon;

9 (B) by redesignating subparagraph (H) as  
10 subparagraph (I);

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

13 “(H) facilitate the sharing of best practices  
14 between States within a consortia of States in  
15 receipt of funding related to establishing and  
16 maintaining a stockpile of medical products;  
17 and”; and

18 (D) in subparagraph (I), as so redesign-  
19 nated, by striking “State efforts” and inserting  
20 “State or regional efforts”;

21 (3) by redesignating paragraphs (5) through  
22 (9) as paragraphs (6) through (10), respectively;

23 (4) by inserting after paragraph (4) the fol-  
24 lowing:

1           “(5) COORDINATION.—An entity in receipt of  
2           an award under paragraph (1), in carrying out the  
3           activities under this subsection, shall coordinate with  
4           appropriate health care entities, health officials, and  
5           emergency management officials within the jurisdic-  
6           tion of such State or States.”; and

7           (5) in paragraph (10), as so redesignated, by  
8           striking “\$3,500,000,000 for each of fiscal years  
9           2023 and 2024” and inserting “such sums as may  
10          be necessary for each of fiscal years 2024 through  
11          2028”.

12          (b) GAO REPORT.—Section 2409(b) of the PRE-  
13          VENT Pandemics Act (Public Law 117–328) is amend-  
14          ed—

15                 (1) in paragraph (2), by striking “; and” and  
16                 inserting a semicolon;

17                 (2) in paragraph (3), by striking the period and  
18                 inserting “; and”; and

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

20                         “(4) the impact of any regional stockpiling ap-  
21                         proaches carried out under such subsection (i)(1) of  
22                         section 319F–2 of the Public Health Service Act (42  
23                         U.S.C. 247d–6b).”.

1 **SEC. 106. ENHANCING DOMESTIC WASTEWATER SURVEIL-**  
2 **LANCE FOR PATHOGEN DETECTION.**

3 (a) IN GENERAL.—Subtitle C of title XXVIII of the  
4 Public Health Service Act (42 U.S.C. 300hh–31 et seq.)  
5 is amended by adding at the end the following:

6 **“SEC. 2827. WASTEWATER SURVEILLANCE FOR PATHOGEN**  
7 **DETECTION.**

8 “(a) WASTEWATER SURVEILLANCE SYSTEM.—The  
9 Secretary, acting through the Director of the Centers for  
10 Disease Control and Prevention and in coordination with  
11 other Federal departments and agencies, shall award  
12 grants, contracts, or cooperative agreements to eligible en-  
13 tities to establish, maintain, or improve activities related  
14 to the detection and monitoring of infectious diseases  
15 through wastewater for public health emergency prepared-  
16 ness and response purposes.

17 “(b) ELIGIBLE ENTITIES.—To be eligible to receive  
18 an award under this section, an entity shall—

19 “(1) be a State, Tribal, or local health depart-  
20 ment, or a partnership between such a health de-  
21 partment and other public and private entities; and

22 “(2) submit to the Secretary an application at  
23 such time, in such manner, and containing such in-  
24 formation as the Secretary may reasonably require,  
25 which shall include—

1           “(A) a description of activities proposed to  
2           be carried out pursuant to an award under sub-  
3           section (a);

4           “(B) factors such entity proposes to use to  
5           select wastewater sampling sites;

6           “(C) a plan for responding, as appropriate,  
7           to findings from such wastewater sampling,  
8           consistent with applicable plans developed by  
9           such entity pursuant to section 319C-1;

10          “(D) a plan to sustain such wastewater  
11          surveillance activities described in such applica-  
12          tion following the conclusion of the award pe-  
13          riod; and

14          “(E) any additional information the Sec-  
15          retary may require.

16          “(c) CONSIDERATION.—In making awards under sub-  
17          section (a), the Secretary may give priority to eligible enti-  
18          ties that have submitted an application that—

19               “(1) details plans to provide public access to  
20               data generated through such wastewater surveillance  
21               activities in a manner that enables comparison to  
22               such data generated by other recipients of an award  
23               under subsection (a); and

24               “(2) provides an assessment of community  
25               needs related to ongoing infectious disease moni-

1 toring, including burden of infectious diseases that  
2 can be detected in wastewater and availability of  
3 other forms of infectious disease surveillance.

4 “(d) USE OF FUNDS.—An eligible entity shall, as ap-  
5 propriate, use amounts awarded under this section to—

6 “(1) establish, or enhance existing, capacity and  
7 capabilities to conduct wastewater sampling, testing,  
8 and related analysis;

9 “(2) conduct wastewater surveillance, as appro-  
10 priate, at individual facilities, institutions, and loca-  
11 tions in rural areas, in which there is an increased  
12 risk of infectious disease outbreaks, or areas in  
13 which wastewater is not treated through the relevant  
14 local utility of the jurisdiction; and

15 “(3) implement projects that use evidence-based  
16 or promising practices to conduct wastewater sur-  
17 veillance activities.

18 “(e) PARTNERSHIPS.—In carrying out activities  
19 under this section, eligible entities shall identify opportuni-  
20 ties to partner with other public or private entities to le-  
21 verage relevant capabilities maintained by such entities,  
22 as appropriate and consistent with this section.

23 “(f) TECHNICAL ASSISTANCE.—The Secretary, in  
24 consultation with the heads of other applicable Federal  
25 agencies and departments, as appropriate, shall provide

1 technical assistance to recipients of awards under this sec-  
2 tion to facilitate the planning, development, and imple-  
3 mentation of activities described in subsection (d).

4 “(g) AUTHORIZATION OF APPROPRIATIONS.—To  
5 carry out this section, there is authorized to be appro-  
6 priated such sums as may be necessary for each of fiscal  
7 years 2024 through 2028.”.

8 (b) WASTEWATER SURVEILLANCE RESEARCH.—

9 (1) IN GENERAL.—The Secretary of Health and  
10 Human Services (in this subsection referred to as  
11 the “Secretary”) shall continue to conduct or sup-  
12 port research on the use of wastewater surveillance  
13 to detect and monitor emerging infectious diseases,  
14 which may include—

15 (A) research to improve the efficiency of  
16 wastewater sample collection and analysis and  
17 increase the sensitivity and specificity of waste-  
18 water testing methods; and

19 (B) implementation and development of  
20 evidence-based practices to facilitate the esti-  
21 mation of population-level data within a com-  
22 munity.

23 (2) NON-DUPLICATION OF EFFORT.—The Sec-  
24 retary shall ensure that activities carried out under  
25 this subsection do not unnecessarily duplicate efforts



1 of other agencies and offices within the Department  
2 of Health and Human Services related to wastewater  
3 surveillance.

4 **SEC. 107. REAUTHORIZATION OF MOSQUITO ABATEMENT**  
5 **FOR SAFETY AND HEALTH PROGRAM.**

6 Section 317S of the Public Health Service Act (42  
7 U.S.C. 247b–21) is amended—

8 (1) in subsection (a)(3)(A), by striking “sub-  
9 section (b)(3)” and inserting “subsection (b)(4)”;

10 (2) in subsection (b)—

11 (A) by redesignating paragraphs (3)  
12 through (6) as paragraphs (4) through (7), re-  
13 spectively; and

14 (B) by inserting after paragraph (2) the  
15 following:

16 “(3) CONSIDERATIONS.—The Secretary may  
17 consider the use of innovative and novel technology  
18 for mosquito prevention and control in making  
19 grants under paragraph (1).”;

20 (3) by amending subsection (d) to read as fol-  
21 lows:

22 “(d) USES OF FUNDS.—Amounts appropriated under  
23 subsection (f) may be used by the Secretary to provide  
24 training and technical assistance with respect to the plan-  
25 ning, development, and operation of assessments and

1 plans under subsection (a) and control programs under  
 2 subsection (b). The Secretary may provide such training  
 3 and technical assistance directly or through awards of  
 4 grants or contracts to public and private entities.”; and  
 5 (4) in subsection (f)(1), by striking “2019  
 6 through 2023” and inserting “2024 through 2028”.

## 7 **TITLE II—FEDERAL PLANNING** 8 **AND COORDINATION**

### 9 **SEC. 201. ALL-HAZARDS EMERGENCY PREPAREDNESS AND** 10 **RESPONSE.**

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

13 (1) in subsection (b)—

14 (A) in paragraph (3)—

15 (i) by striking “Oversee advanced”  
 16 and inserting the following:

17 “(A) IN GENERAL.—Oversee advanced”;

18 and

19 (ii) by adding at the end following:

20 “(B) DEVELOPMENT OF REQUIRE-  
 21 MENTS.—Lead the development and approval,  
 22 and, on a routine basis, the review and update,  
 23 of requirements for such countermeasures and  
 24 products, including related capabilities, to in-  
 25 form the advanced research, development, pro-

1 curement, and replenishment decisions of the  
2 Department of Health and Human Services.”;

3 (B) in paragraph (4)—

4 (i) in subparagraph (F)—

5 (I) in the matter preceding clause  
6 (i), by striking “and in consultation  
7 with the Secretary of Homeland Secu-  
8 rity,”; and

9 (II) in clause (i), by inserting  
10 “enhance” after “capabilities and”;  
11 and

12 (ii) in subparagraph (G)—

13 (I) in clause (i), by striking  
14 “based on” and inserting “based on—  
15 ”;

16 (II) in clause (ii), by striking “;  
17 and” at the end and inserting a semi-  
18 colon;

19 (III) in clause (iii), by striking  
20 the period and inserting “; and”; and

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

23 “(iv) that include, as appropriate, par-  
24 ticipation by relevant industry, academia,

1 professional societies, and other stake-  
2 holders.”;

3 (iii) in subparagraph (H)—

4 (I) by inserting “and the Direc-  
5 tor of the Office of Pandemic Pre-  
6 paredness and Response” after “Secu-  
7 rity Affairs”; and

8 (II) by inserting “and medical  
9 product and supply capacity planning  
10 pursuant to subparagraph (J), includ-  
11 ing discussion of any relevant identi-  
12 fied supply chain vulnerabilities” be-  
13 fore the period at the end;

14 (iv) in subparagraph (I), by inserting  
15 “the Director of the Office of Pandemic  
16 Preparedness and Response Policy,” after  
17 “Security Affairs,”; and

18 (v) in subparagraph (J)(i), in the  
19 matter preceding subclause (I), by insert-  
20 ing “(including ancillary medical supplies  
21 and components of medical products, such  
22 as active pharmaceutical ingredients, key  
23 starting materials, and medical device com-  
24 ponents)” after “supply needs”; and

25 (C) in paragraph (7)—

1 (i) in the matter preceding subpara-  
2 graph (A), by inserting “and the require-  
3 ments developed pursuant to paragraph  
4 (3)(B)” after “subsection (d)”;

5 (ii) by redesignating subparagraphs  
6 (E) and (F) as subparagraphs (F) and  
7 (G), respectively; and

8 (iii) by inserting after subparagraph  
9 (D) the following:

10 “(E) include a professional judgment of  
11 anticipated budget needs for each future fiscal  
12 year accounted for in such plan to account for  
13 the full range of anticipated medical counter-  
14 measure needs and life-cycle costs to address  
15 such priorities and requirements;”;

16 (2) in subsection (d)—

17 (A) by amending paragraph (1) to read as  
18 follows:

19 “(1) IN GENERAL.—Not later than March 15,  
20 2020, and biennially thereafter, the Assistant Sec-  
21 retary for Preparedness and Response shall develop  
22 and submit to the Committee on Health, Education,  
23 Labor, and Pensions of the Senate and the Com-  
24 mittee on Energy and Commerce of the House of  
25 Representatives a coordinated strategy for medical

1 countermeasures to address chemical, biological, ra-  
2 diological, and nuclear threats, informed by the re-  
3 quirements developed pursuant to subsection  
4 (b)(3)(B). Not later than 180 days after the submis-  
5 sion of such strategy to such committees, the Assist-  
6 ant Secretary for Preparedness and Response shall  
7 submit an accompanying implementation plan to  
8 such committees. In developing such a strategy and  
9 plan, the Assistant Secretary for Preparedness and  
10 Response shall consult with the Public Health Emer-  
11 gency Medical Countermeasures Enterprise estab-  
12 lished under section 2811-1.”; and

13 (B) in paragraph (2), in the matter pre-  
14 ceding subparagraph (A), by inserting “strategy  
15 and” before “plan”; and

16 (3) in subsection (f)—

17 (A) in paragraph (1), in the matter pre-  
18 ceding subparagraph (A), by inserting “, includ-  
19 ing an emerging infectious disease,” after “any  
20 such agent”; and

21 (B) in paragraph (2)(A), by striking  
22 “\$250,000,000 for each of fiscal years 2019  
23 through 2023” and inserting “\$335,000,000  
24 for each of fiscal years 2024 through 2028”.

1 **SEC. 202. NATIONAL HEALTH SECURITY STRATEGY.**

2 Section 2802 of the Public Health Service Act is  
3 amended—

4 (1) in subsection (a)(3)—

5 (A) by striking “In 2022, the” and insert-  
6 ing “The”; and

7 (B) by inserting “, maintaining, and sus-  
8 taining” after “establishing”; and

9 (2) in subsection (b)—

10 (A) in paragraph (2)—

11 (i) in subparagraph (A), by inserting  
12 “that support interagency coordination and  
13 availability of information, as appropriate”  
14 before the period;

15 (ii) in subparagraph (B), by inserting  
16 “rapid testing,” after “and supplies,”;

17 (B) in paragraph (3)—

18 (i) in subparagraph (C), by inserting  
19 “and current capacity of facilities within  
20 such systems, as applicable” before the pe-  
21 riod;

22 (ii) in subparagraph (D), by inserting  
23 “and other medical products and medical  
24 supplies directly related to responding to  
25 chemical, biological, radiological, or nuclear  
26 threats, including emerging infectious dis-

1 eases, and incidents covered by the Na-  
2 tional Response Framework, as applicable  
3 and consistent with the activities carried  
4 out under section 2811(b)(4)(J)” before  
5 the period; and

6 (iii) by adding at the end the fol-  
7 lowing:

8 “(H) Supporting the availability of blood  
9 and blood products with respect to public health  
10 emergencies.”;

11 (C) in paragraph (5), by inserting “appli-  
12 cable federally-funded activities and” after “(in-  
13 cluding”;

14 (D) in paragraph (8)—

15 (i) in subparagraph (A), by inserting  
16 “public health and medical” before “activi-  
17 ties”; and

18 (ii) in subparagraph (B), by striking  
19 “familiarity with” and inserting “under-  
20 standing of, and coordination between,”;

21 (E) by redesignating paragraphs (9) and  
22 (10) as paragraphs (10) and (12), respectively;

23 (F) by inserting after paragraph (8) the  
24 following:



1           “(9) OTHER SETTINGS.—Supporting Federal,  
 2           State, local, and Tribal coordination and planning  
 3           with respect to facilities in which there is an in-  
 4           creased risk of infectious disease outbreaks, includ-  
 5           ing such facilities that address the needs of at-risk  
 6           individuals, in the event of a public health emer-  
 7           gency declared under section 319.”;

8                         (G) by inserting after subparagraph (10),  
 9           as so redesignated, the following:

10           “(11) OTHER HAZARDS.—Assessing current  
 11           and potential health security threats from natural  
 12           disasters or other extreme weather events with re-  
 13           spect to public health and medical preparedness and  
 14           response.”; and

15                         (H) by striking “tribal” each place it ap-  
 16           pears and inserting “Tribal”.

17 **SEC. 203. IMPROVING DEVELOPMENT AND DISTRIBUTION**  
 18 **OF DIAGNOSTIC TESTS.**

19           Section 319B of the Public Health Service Act (42  
 20 U.S.C. 247d–2) is amended to read as follows:

21 **“SEC. 319B. IMPROVING DEVELOPMENT AND DISTRIBUTION**  
 22 **OF DIAGNOSTIC TESTS.**

23           “(a) FRAMEWORK.—The Secretary shall develop,  
 24           make publicly available not later than 1 year after the date  
 25           of enactment of the Pandemic and All-Hazards Prepared-

1 ness and Response Act, and update not less frequently  
2 than every 3 years thereafter, a strategic framework for  
3 the rapid development, validation, authorization, manufac-  
4 ture, procurement, and distribution of diagnostic tests,  
5 and for rapid scaling of testing capacity, in response to  
6 chemical, biological, radiological, or nuclear threats, in-  
7 cluding infectious diseases for which a public health emer-  
8 gency is declared under section 319, or that has signifi-  
9 cant potential to cause such a public health emergency.

10 Such strategic framework shall take into consideration—

11           “(1) domestic capacity, including any such ca-  
12           capacity established through partnerships with public  
13           and private entities pursuant to subsection (c), to  
14           support the development, validation, authorization,  
15           manufacture, procurement, and distribution of tests;

16           “(2) novel technologies and platforms that may  
17           be used to improve testing capabilities, including  
18           high-throughput laboratory diagnostics, and point-  
19           of-care diagnostics, and any such technologies to im-  
20           prove the accessibility of such tests, and facilitate  
21           the development and manufacture of diagnostic  
22           tests;

23           “(3) medical supply needs related to testing, in-  
24           cluding diagnostic testing, equipment, supplies, and  
25           component parts, and any potential vulnerabilities

1 related to the availability of such medical supplies  
2 and related planning, consistent with section  
3 2811(b)(4)(J);

4 “(4) strategies for the rapid and efficient dis-  
5 tribution of tests locally, regionally, or nationwide  
6 and scaling laboratory testing capacity; and

7 “(5) assessing such strategies through drills  
8 and operational exercises carried out under section  
9 2811(b)(4)(G), as appropriate.

10 “(b) COORDINATION.—To inform the development  
11 and update of the framework under subsection (a), and  
12 in carrying out activities to implement such framework,  
13 the Secretary shall coordinate with industry, States, local  
14 governmental entities, Indian Tribes and Tribal organiza-  
15 tions, and other relevant public and private entities.

16 “(c) CAPACITY BUILDING.—The Secretary may con-  
17 tract with public and private entities, as appropriate, to  
18 increase domestic capacity in the rapid development, vali-  
19 dation, authorization, manufacture, procurement, and dis-  
20 tribution of diagnostic tests, as appropriate, to State,  
21 local, and Tribal health departments and other appro-  
22 priate entities for immediate public health response activi-  
23 ties to address an infectious disease with respect to which  
24 a public health emergency is declared under section 319,

1 or that has significant potential to cause such a public  
2 health emergency.”.

3 **SEC. 204. PILOT PROGRAM FOR PUBLIC HEALTH DATA**  
4 **AVAILABILITY.**

5 (a) SITUATIONAL AWARENESS SYSTEM.—Section  
6 319D of the Public Health Service Act (42 U.S.C. 247d–  
7 4) is amended—

8 (1) in subsection (c)—

9 (A) in paragraph (1), by inserting “, and  
10 facilitate the leveraging of relevant public  
11 health data across the Department of Health  
12 and Human Services” after “extent prac-  
13 ticable”; and

14 (B) in paragraph (2)—

15 (i) in subparagraph (A)—

16 (I) by striking “among agencies”  
17 and inserting “among, and direct  
18 communication between, agencies”;

19 (II) by inserting “the sharing of  
20 information from applicable public  
21 health data systems,” after “Tech-  
22 nology),”; and

23 (III) by striking “; and” at the  
24 end and inserting a semicolon;

1 (ii) in subparagraph (B), by striking  
2 the period at the end and inserting “;  
3 and”; and

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

6 “(C) facilitate communication, including  
7 bidirectional communication or other means of  
8 communication, to enable timely information  
9 sharing with State, local, and Tribal public  
10 health officials, between agencies and offices of  
11 the Department of Health and Human Services,  
12 and with health care providers, as applicable  
13 and appropriate.”;

14 (2) in subsection (d)—

15 (A) in paragraph (1)—

16 (i) by striking “, the Secretary may”  
17 and inserting “and support the near real-  
18 time public availability of data, as appro-  
19 priate, pursuant to section 319D–2, the  
20 Secretary shall establish a pilot program  
21 to”; and

22 (ii) by striking “, in collaboration with  
23 appropriate” and inserting “. Such States  
24 or consortia of States shall carry out such  
25 activities in collaboration with appropriate

1 stakeholders, such as health information  
2 exchanges, laboratory information sys-  
3 tems,”;

4 (B) in paragraph (2)(A), by inserting  
5 “pursuant to paragraph (3)” after “may re-  
6 quire”;

7 (C) by striking paragraph (6);

8 (D) by redesignating paragraphs (3)  
9 through (5) as paragraphs (4) through (6), re-  
10 spectively;

11 (E) by inserting after paragraph (2) the  
12 following:

13 “(3) DATA PLAN.—For purposes of this sub-  
14 section, the Secretary shall develop a plan for data  
15 elements to be reported to the Secretary pertaining  
16 to potentially catastrophic infectious disease out-  
17 breaks, in such form and manner and at such timing  
18 and frequency as determined by the Secretary. When  
19 developing the plan under this subsection, the Sec-  
20 retary shall—

21 “(A) align with the standards and imple-  
22 mentation specifications adopted by the Sec-  
23 retary under section 3004, where applicable,  
24 and update, as necessary and consistent with  
25 applicable requirements of subsection (b)(3)

1 and section 2823, uniform standards for appli-  
2 cable entities to report data elements;

3 “(B) consider the use of technologies that  
4 enable fast bulk exchange of data; and

5 “(C) ensure the data elements reported  
6 under this subsection and made publicly avail-  
7 able pursuant to section 319D–2 are made  
8 available consistent with applicable Federal and  
9 State privacy law, at a minimum.”; and

10 (F) in paragraph (4), as so redesignated—

11 (i) in subparagraph (A), by striking  
12 “emergencies;” and inserting “emer-  
13 gencies, including such diseases rec-  
14 ommended by the National Public Health  
15 Data Board established under section  
16 319D–2; and”;

17 (ii) in subparagraph (B), by striking  
18 “; and” and inserting a period; and

19 (iii) by striking subparagraph (C);  
20 and

21 (3) in subsection (h)—

22 (A) in paragraph (1), by striking “2022  
23 and 2023” and inserting “2024 through 2028”;  
24 and

1 (B) in paragraph (2), by striking “2022  
2 and 2023” and inserting “2024 through 2028”.

3 (b) DATA SELECTION AND ACCESS.—Title III of the  
4 Public Health Service Act (42 U.S.C. 241 et seq.) is  
5 amended by inserting after section 319D–1 the following:

6 **“SEC. 319D–2. PUBLIC HEALTH DATA PILOT PROGRAM.**

7 “(a) IN GENERAL.—The Secretary shall—

8 “(1) establish and maintain a near real-time,  
9 open source, public-facing, and publicly available  
10 website to provide deidentified, aggregated data on  
11 potentially catastrophic disease outbreaks, in accord-  
12 ance with subsection (b); and

13 “(2) collect the data elements pertaining to  
14 such diseases recommended pursuant to subsection  
15 (b)(1)(B), using existing processes or any new proc-  
16 esses established pursuant to section 319D(d).

17 “(b) NATIONAL PUBLIC HEALTH DATA BOARD.—

18 “(1) IN GENERAL.—The Secretary shall estab-  
19 lish a National Public Health Data Board to advise,  
20 and make recommendations to the Secretary with re-  
21 spect to potentially catastrophic infectious diseases  
22 appropriate for inclusion in the public health situa-  
23 tional awareness system pilot program established  
24 pursuant to section 319D(d) and the website estab-  
25 lished under subsection (a)(1).



1           “(2) MEMBERSHIP.—The Board established  
2 under paragraph (1) shall consist of the following  
3 members:

4           “(A) FEDERAL MEMBERS.—The following  
5 Federal members:

6           “(i) The Secretary of Health and  
7 Human Services.

8           “(ii) The Secretary of Defense.

9           “(iii) The Secretary of Veterans Af-  
10 fairs.

11           “(iv) The National Coordinator for  
12 Health Information Technology.

13           “(v) The Director of the National In-  
14 stitutes of Health.

15           “(vi) The Director of the Centers for  
16 Disease Control and Prevention.

17           “(vii) The Assistant Secretary for  
18 Preparedness and Response.

19           “(viii) The Director of the Indian  
20 Health Service.

21           “(ix) The Administrator of the Cen-  
22 ters for Medicare & Medicaid Services.

23           “(x) The Commissioner of Food and  
24 Drugs.

1           “(xi) Such other heads of depart-  
2           ments, agencies, and offices as the Sec-  
3           retary determines appropriate.

4           “(B) NON-FEDERAL MEMBERS.—Such  
5           other individuals appointed by the Secretary—

6           “(i) who have relevant public health,  
7           medical, or scientific expertise, including—

8           “(I) individuals with expertise or  
9           experience in—

10           “(aa) State, local, or Tribal  
11           health data systems or practices;  
12           or

13           “(bb) health data standards  
14           and technology systems, which  
15           may include hospital, pharmacy,  
16           laboratory information systems  
17           and health information ex-  
18           changes; and

19           “(II) representatives of national  
20           public health organizations; and

21           “(ii) individuals with such other spe-  
22           cific expertise as the Secretary determines  
23           appropriate.

24           “(c) RULE OF CONSTRUCTION.—Nothing in this sec-  
25           tion shall be construed to alter existing obligations under

1 regulations promulgated under section 264(c) of the  
 2 Health Insurance Portability and Accountability Act of  
 3 1996, and this section shall be applied in a manner that  
 4 is consistent with applicable Federal and State privacy  
 5 law, at a minimum.

6 “(d) NONDUPLICATION OF EFFORTS.—The Sec-  
 7 retary shall ensure that the activities carried out by the  
 8 Board under this section do not duplicate the efforts of  
 9 other Federal advisory committees that advise and make  
 10 recommendations to the Secretary.

11 “(e) SUNSET.—This section shall cease to have force  
 12 or effect on September 30, 2028.”.

13 **SEC. 205. COMBATING ANTIMICROBIAL RESISTANCE.**

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

16 (1) in subsection (a)—

17 (A) in paragraph (1), by inserting “and ac-  
 18 tivities” after “Federal programs”;

19 (B) in paragraph (2)—

20 (i) by striking “public health constitu-  
 21 encies, manufacturers, veterinary and med-  
 22 ical professional societies and others” and  
 23 inserting “the Advisory Council described  
 24 in subsection (b) and relevant public and  
 25 private entities”; and

1 (ii) by inserting “, pursuant to para-  
2 graph (4),” after “comprehensive plan”;

3 (C) by amending paragraph (3) to read as  
4 follow:

5 “(3) AGENDA.—The task force described in  
6 paragraph (1) shall consider factors the Secretary  
7 considers appropriate, including factors to—

8 “(A) slow the emergence of resistant bac-  
9 teria and fungi and prevent the spread of re-  
10 sistant infections;

11 “(B) strengthen activities to combat resist-  
12 ance with respect to zoonotic diseases;

13 “(C) advance development and use of rapid  
14 and innovative capabilities, including diagnostic  
15 tests, for identification and characterization of  
16 resistant bacteria and fungi;

17 “(D) accelerate basic and applied research  
18 and development for new antibiotics,  
19 antifungals, and other related therapeutics and  
20 vaccines; and

21 “(E) support international collaboration  
22 and capacities for antimicrobial-resistance pre-  
23 vention, detection, and control.”;

24 (D) by redesignating paragraph (4) as  
25 paragraph (5); and

1 (E) by inserting after paragraph (3) the  
2 following:

3 “(4) ACTION PLAN.—Not later than October 1,  
4 2025, and every 5 years thereafter, the task force  
5 described in paragraph (1) shall develop and submit  
6 to the Committee on Health, Education, Labor, and  
7 Pensions and the Committee on Appropriations of  
8 the Senate and the Committee on Energy and Com-  
9 merce and the Committee on Appropriations of the  
10 House of Representatives a plan regarding Federal  
11 programs and activities to combat antimicrobial re-  
12 sistance, including measurable outcomes, as appro-  
13 priate, informed by the agenda described in para-  
14 graph (3) and input provided by the Advisory Coun-  
15 cil described in subsection (b) and other relevant  
16 stakeholders provided pursuant to paragraph (2).”;

17 (2) by redesignating subsections (b) through (o)  
18 as subsections (c) through (p), respectively;

19 (3) by inserting after subsection (a) the fol-  
20 lowing:

21 “(b) ADVISORY COUNCIL.—

22 “(1) IN GENERAL.—The Secretary may con-  
23 tinue the Presidential Advisory Council on Com-  
24 bating Antibiotic-Resistant Bacteria, referred to in  
25 this subsection as the ‘Advisory Council’.

1           “(2) DUTIES.—The Advisory Council shall ad-  
2           vise and provide information and recommendations  
3           to the Secretary, acting through the Task Force es-  
4           tablished under subsection (a), regarding Federal  
5           programs and activities intended to reduce or com-  
6           bat antimicrobial-resistant bacteria or fungi that  
7           may present a public health threat and improve ca-  
8           pabilities to prevent, diagnose, mitigate, or treat  
9           such resistance. Such advice, information, and rec-  
10          ommendations may be related to improving Federal  
11          efforts related to factors described in subsection  
12          (a)(3) and other topics related to antimicrobial re-  
13          sistance, as appropriate.

14           “(3) MEETINGS AND COORDINATION.—

15           “(A) MEETINGS.—The Advisory Council  
16           shall meet not less than biannually and, to the  
17           extent practicable, in coordination with meet-  
18           ings of the task force established under sub-  
19           section (a).

20           “(B) COORDINATION.—The Advisory  
21           Council shall, to the greatest extent practicable,  
22           coordinate activities carried out by the Council  
23           with the task force established under subsection  
24           (a).

1           “(4) FACA.—Chapter 10 of title 5, United  
2 States Code, shall apply to the activities and duties  
3 of the Advisory Council.”; and

4           (4) in subsection (n), as so redesignated, by  
5 striking “(f) through (j)” and inserting “(g) through  
6 (k)”.

7 **SEC. 206. STRATEGIC NATIONAL STOCKPILE AND MATE-**  
8 **RIAL THREATS.**

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

11           (1) in subsection (a)—

12           (A) in paragraph (2)(B)(i), by striking  
13 subclause (IV) and inserting the following:

14                   “(IV) the emergency health secu-  
15 rity threat or threats such counter-  
16 measure procurement is intended to  
17 address, including—

18                           “(aa) whether such procure-  
19 ment is consistent with meeting  
20 emergency health security needs  
21 associated with such threat or  
22 threats; and

23                           “(bb) in the case of a coun-  
24 termeasure that addresses a bio-  
25 logical agent, whether such agent

1 has an increased likelihood to be-  
2 come resistant to, more resistant  
3 to, or evade, such counter-  
4 measure relative to other avail-  
5 able medical countermeasures;”;  
6 and

7 (B) in paragraph (3)—

8 (i) in subparagraph (B), by striking  
9 “are followed, regularly reviewed, and up-  
10 dated with respect to such stockpile” and  
11 inserting “with respect to such stockpile  
12 are followed, regularly reviewed, and up-  
13 dated to reflect best practices”;

14 (ii) by redesignating subparagraphs  
15 (H) through (K) as subparagraphs (I)  
16 through (L), respectively; and

17 (iii) by inserting after subparagraph  
18 (G) the following:

19 “(H) utilize tools to enable the timely and  
20 accurate tracking, including the location and  
21 geographic distribution and utilization, of the  
22 contents of the stockpile throughout the deploy-  
23 ment of such contents;”;

24 (2) in subsection (c)(2)(C)—

25 (A) by striking “promptly”; and



1 (B) by inserting “, not later than 60 days  
2 after such determination”;

3 (3) in subsection (f)(1), by striking  
4 “\$610,000,000 for each of fiscal years 2019 through  
5 2021, and \$750,000,000 for each of fiscal years  
6 2022 and 2023” and inserting “\$965,000,000 for  
7 each of fiscal years 2024 through 2028”; and

8 (4) in subsection (g)(1), by striking “2019  
9 through 2028” and inserting “2024 through 2033”.

10 **SEC. 207. MEDICAL COUNTERMEASURES FOR VIRAL**  
11 **THREATS WITH PANDEMIC POTENTIAL.**

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

14 (1) in subsection (c)(4)—

15 (A) in subparagraph (D), by amending  
16 clause (iii) to read as follows:

17 “(iii) conduct research to promote  
18 strategic initiatives, such as—

19 “(I) rapid diagnostics;

20 “(II) broad spectrum  
21 antimicrobials;

22 “(III) medical countermeasures  
23 for virus families that have significant  
24 potential to cause a pandemic, includ-  
25 ing such countermeasures that take

1 either pathogen-specific or broad spec-  
2 trum approaches; and

3 “(IV) technologies to improve the  
4 production and use of medical coun-  
5 termeasures, which may include vac-  
6 cine-manufacturing technologies, dose-  
7 sparing technologies, efficacy-increas-  
8 ing technologies, platform tech-  
9 nologies, technologies to administer  
10 countermeasures, and technologies to  
11 improve storage and transportation of  
12 countermeasures.”; and

13 (B) in subparagraph (F), by amending  
14 clause (ii) to read as follows:

15 “(ii) threats that—

16 “(I)(aa) consistently exist or con-  
17 tinually circulate and have a signifi-  
18 cant potential to become a pandemic,  
19 such as pandemic influenza; or

20 “(bb) include priority virus fami-  
21 lies and other viral pathogens with a  
22 significant potential to cause a pan-  
23 demic; and

24 “(II) may include the advanced  
25 research and development, manufac-

1 turing, and appropriate stockpiling of  
 2 qualified pandemic or epidemic prod-  
 3 ucts, and products, technologies, or  
 4 processes to support the advanced re-  
 5 search and development of such coun-  
 6 termeasures (including multiuse plat-  
 7 form technologies for diagnostics, vac-  
 8 cines, and therapeutics; virus seeds;  
 9 clinical trial lots; novel virus strains;  
 10 and antigen and adjuvant material);”;

11 (2) in subsection (d)(2), by striking  
 12 “\$611,700,000 for each of fiscal years 2019 through  
 13 2023” and inserting “\$950,000,000 for each of fis-  
 14 cal years 2024 through 2028”; and

15 (3) in subsection (e)(1), by amending subpara-  
 16 graph (D) to read as follows:

17 “(D) SUNSET.—This paragraph shall cease  
 18 to have force or effect after September 30,  
 19 2028.”.

20 **SEC. 208. PUBLIC HEALTH EMERGENCY MEDICAL COUN-**  
 21 **TERMEASURES ENTERPRISE.**

22 Section 2811–1(c) of the Public Health Service Act  
 23 (42 U.S.C. 300hh–10a(c)) is amended—

24 (1) in paragraph (1)—

1 (A) by redesignating subparagraph (D) as  
2 subparagraph (E); and

3 (B) by inserting after subparagraph (C)  
4 the following:

5 “(D) Assist the Secretary in developing  
6 strategies for appropriate and evidence-based  
7 allocation and distribution of countermeasures  
8 to jurisdictions, in a manner that supports the  
9 availability and use of such countermeasures,  
10 for public health and medical preparedness and  
11 response needs.”;

12 (2) in paragraph (2), by striking “, as appro-  
13 priate”; and

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

15 “(3) INFORMATION SHARING.—The Secretary  
16 shall, as appropriate and in a manner that does not  
17 compromise national security, share information re-  
18 lated to recommendations made and strategies devel-  
19 oped under subparagraphs (A) and (C) of paragraph  
20 (1) with relevant stakeholders, including industry  
21 and State, local, and Tribal public health depart-  
22 ments.”.

1 **SEC. 209. STRENGTHENING PUBLIC HEALTH COMMUNICA-**  
2 **TION.**

3 (a) PUBLIC HEALTH COMMUNICATIONS ADVISORY  
4 COMMITTEE.—The Secretary of Health and Human Serv-  
5 ices (referred to in this section as the “Secretary”) shall  
6 establish an advisory committee to be known as the Public  
7 Health Communications Advisory Committee (referred to  
8 in this subsection as the “Advisory Committee”).

9 (b) DUTIES.—The Advisory Committee shall make  
10 recommendations to the Secretary and report on—

11 (1) critical aspects of communication and dis-  
12 semination of scientific and evidence-based public  
13 health information during public health emergencies;

14 (2) research from relevant external stakeholders  
15 related to evidence-based or evidence-informed strat-  
16 egies and best practices to effectively communicate  
17 and disseminate such information; and

18 (3) strategies to improve communication and  
19 dissemination of scientific and evidence-based public  
20 health information to the public and to improve com-  
21 munication between Federal, State, local, and Tribal  
22 health officials.

23 (c) COMPOSITION.—The Advisory Committee shall be  
24 composed of—

1           (1) appropriate Federal officials, appointed by  
2           the Secretary, who shall serve as nonvoting mem-  
3           bers; and

4           (2) individuals, appointed by the Secretary, rep-  
5           resenting a variety of States and rural and urban  
6           areas, and each of whom that has—

7                   (A) expertise in public health, including in-  
8                   dividuals with experience in State, local, and  
9                   Tribal health departments, medicine, commu-  
10                  nications, related technology, psychology, men-  
11                  tal health and substance use disorders, national  
12                  security;

13                   (B) experience in leading community out-  
14                  reach; or

15                   (C) expertise in other areas, as the Sec-  
16                  retary determines appropriate.

17           (d) DISSEMINATION.—The Secretary shall review the  
18           recommendations of the Advisory Committee and, not  
19           later than 180 days after receipt of the report under sub-  
20           section (b), shall submit to the Committee on Health,  
21           Education, Labor, and Pensions of the Senate and the  
22           Committee on Energy and Commerce of the House of  
23           Representatives a report describing any actions planned  
24           by the Secretary related to this section.

1 (e) TERMINATION.—The Advisory Committee shall  
2 terminate 2 years after the date of enactment of this Act.

3 **SEC. 210. FELLOWSHIP AND TRAINING PROGRAMS.**

4 Section 317G of the Public Health Service Act (42  
5 U.S.C. 247b–8) is amended—

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

8 “(a) IN GENERAL.—The Secretary,”; and

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

10 “(b) NONCOMPETITIVE CONVERSION.—

11 “(1) IN GENERAL.—The Secretary may non-  
12 competitively convert an individual who has com-  
13 pleted an epidemiology, surveillance, or laboratory  
14 fellowship or training program under subsection (a)  
15 to a career-conditional appointment without regard  
16 to the provisions of subchapter I of chapter 33 of  
17 title 5, United States Code, provided that individual  
18 meets qualification requirements for the appoint-  
19 ment.”.

20 **SEC. 211. ASSESSMENT OF COVID–19 MITIGATION POLICIES.**

21 (a) GAO STUDY.—The Comptroller General of the  
22 United States shall conduct a study on the economic im-  
23 pact and health outcomes associated with the response to  
24 the COVID–19 pandemic in the United States. Such study  
25 shall include—

1           (1) a summary of strategies used by local gov-  
2           ernmental entities, States, and the Federal Govern-  
3           ment to contain and mitigate the spread of COVID-  
4           19 during the public health emergency declared  
5           under section 319 of the Public Health Service Act  
6           (42 U.S.C. 247d) on January 31, 2020, including—

7                   (A) limitations on large gatherings of peo-  
8                   ple;

9                   (B) the closure of schools, businesses,  
10                  houses of worship, and other facilities;

11                  (C) masking policies;

12                  (D) testing policies; and

13                  (E) vaccination policies;

14           (2) an analysis and review of the scientific evi-  
15           dence related to the effectiveness of such strategies  
16           in preventing or mitigating the spread of COVID-  
17           19, including estimates of the burden of disease and  
18           death that were avoided through such interventions;

19           (3) an analysis and review of the economic and  
20           health impacts of such strategies, including impacts  
21           related to mental and physical health and student  
22           learning loss; and

23           (4) an accounting of Federal funding used to  
24           implement such strategies.



1 (b) REPORT.—Not later than 18 months after the  
 2 date of enactment of this Act, the Comptroller General  
 3 of the United States shall submit a report on the study  
 4 under subsection (a) to the Committee on Health, Edu-  
 5 cation, Labor, and Pensions of the Senate and the Com-  
 6 mittee on Energy and Commerce of the House of Rep-  
 7 resentatives. Such report shall include recommendations  
 8 based on the findings of the study conducted under sub-  
 9 section (a) regarding the impact of such strategies during  
 10 the COVID–19 public health emergency, including how to  
 11 improve future responses.

12 **TITLE III—ADDRESSING THE**  
 13 **NEEDS OF ALL INDIVIDUALS**

14 **SEC. 301. TRANSITION OF CERTAIN COUNTERMEASURES**  
 15 **BETWEEN COMPENSATION PROGRAMS.**

16 (a) TREATMENT OF CERTAIN INELIGIBLE REQUESTS  
 17 RELATED TO COVID–19 COUNTERMEASURES.—

18 (1) REQUESTS INITIALLY SUBMITTED UNDER  
 19 CICP.—

20 (A) IN GENERAL.—In the case of a request  
 21 for compensation submitted under section  
 22 319F–4 of the Public Health Service Act (42  
 23 U.S.C. 247d–6e) for an injury or death related  
 24 to a COVID–19 vaccine that the Secretary de-  
 25 termines to be ineligible pursuant to subpara-

1 graph (B) of such section 319F–4(b)(4), as  
2 added by subsection (b)(1), the Secretary shall,  
3 not later than 30 days after such determina-  
4 tion, notify the individual submitting the re-  
5 quest of such determination.

6 (B) SUBMISSION OF PETITION.—An indi-  
7 vidual who receives a notification described in  
8 subparagraph (A) shall be eligible to submit a  
9 petition to the United States Court of Federal  
10 Claims under section 2111 of the Public Health  
11 Service Act (42 U.S.C. 300aa–11) with respect  
12 to the same vaccine administration claimed in  
13 the request submitted under section 319F–4 of  
14 such Act (42 U.S.C. 247d–6e), provided that  
15 such petition is submitted not later than the  
16 later of—

17 (i) 1 year after receiving such notifi-  
18 cation under subparagraph (A); or

19 (ii) the last date on which the indi-  
20 vidual otherwise would be eligible to sub-  
21 mit a petition relating to such injury, as  
22 specified in section 2116 of the Public  
23 Health Service Act (42 U.S.C. 300aa–16).

24 (C) ELIGIBILITY.—To be eligible to submit  
25 a petition in accordance with subparagraph (B),

1 the petitioner shall have submitted the request  
2 for compensation under section 319F–4 of the  
3 Public Health Service Act that was determined  
4 to be ineligible not later than the deadline for  
5 filing a petition under section 2116 of the Pub-  
6 lic Health Service Act (42 U.S.C. 300aa–16)  
7 that applies with respect to the administration  
8 of such vaccine.

9 (2) REQUESTS INITIALLY SUBMITTED UNDER  
10 VICP.—

11 (A) IN GENERAL.—If a special master de-  
12 termines that—

13 (i) a petition submitted under section  
14 2111 of the Public Health Service Act (42  
15 U.S.C. 300aa–11) related to a COVID–19  
16 vaccine is ineligible for the National Vac-  
17 cine Injury Compensation Program under  
18 subtitle 2 of title XXI of the Public Health  
19 Service Act (42 U.S.C. 300aa–10 et seq.)  
20 because it relates to a vaccine administered  
21 at a time when the vaccine was not in-  
22 cluded in the Vaccine Injury Table under  
23 section 2114 of such Act (42 U.S.C.  
24 300aa–14); and

1           (ii) the vaccine was administered  
2           when it was a covered countermeasure sub-  
3           ject to a declaration under section 319F-  
4           3(b) of such Act (42 U.S.C. 247d-6d(b)),  
5           the special master shall, not later than 30 days  
6           after such determination, notify the petitioner  
7           of such determination.

8           (B) SUBMISSION OF REQUEST.—An indi-  
9           vidual who receives a notification described in  
10          subparagraph (A) shall be eligible to submit a  
11          request for compensation under section 319F-  
12          4(b) of the Public Health Service Act (42  
13          U.S.C. 247d-6e) with respect to the same vac-  
14          cine administration claimed in the petition sub-  
15          mitted under section 2111 of such Act—

16               (i) not later than 1 year after receiv-  
17               ing such notification; or

18               (ii) in the case that the notification is  
19               issued after judicial review of the petition  
20               under subsection (e) or (f) of section 2112  
21               of such Act (42 U.S.C. 300aa-12), not  
22               later than 1 year after the decision of the  
23               United States Court of Federal Claim or  
24               the mandate is issued by the United States

1 Court of Appeals for the Federal Circuit  
2 pursuant to such subsection (e) or (f).

3 (C) ELIGIBILITY.—To be eligible to submit  
4 a request for compensation in accordance with  
5 subparagraph (B), the individual submitting the  
6 request shall have submitted the petition under  
7 section 2111 of the Public Health Service Act  
8 (42 U.S.C. 300aa–11) that was determined to  
9 be ineligible not later than one year after the  
10 date of administration of the vaccine.

11 (b) CHANGES TO CERTAIN PROGRAMS.—

12 (1) CICP.—Section 319F–4 of the Public  
13 Health Service Act (42 U.S.C. 247d–6e) is amend-  
14 ed—

15 (A) in subsection (b)(4)—

16 (i) by striking “Except as provided”  
17 and inserting the following:

18 “(A) IN GENERAL.—Except as provided”;

19 and

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

22 “(B) EXCLUSION OF INJURIES CAUSED BY  
23 VACCINES ON THE VACCINE INJURY TABLE.—  
24 Notwithstanding any other provision of this sec-  
25 tion, no individual may be eligible for com-

1           pensation under this section with respect to a  
2           vaccine that, at the time it was administered,  
3           was included in the Vaccine Injury Table under  
4           section 2114.”; and

5                   (B) in subsection (d)(3)—

6                           (i) by striking “This section” and in-  
7                           serting the following:

8                           “(A) IN GENERAL.—This section”; and

9                           (ii) by adding at the end the fol-  
10                          lowing:

11                          “(B) EXHAUSTION OF REMEDIES.—A cov-  
12                          ered individual shall not be considered to have  
13                          exhausted remedies as described in paragraph  
14                          (1), nor be eligible to seek remedy under section  
15                          319F–3(d), unless such individual has provided  
16                          to the Secretary all supporting documentation  
17                          necessary to facilitate the determinations re-  
18                          quired under subsection (b)(4).”.

19           (2) VICP.—Title XXI of the Public Health  
20           Service Act (42 U.S.C. 300aa–1 et seq.) is amend-  
21           ed—

22                          (A) in section 2111(a)(2)(A) (42 U.S.C.  
23                          300aa–11(a)(2)(A)), in the matter preceding  
24                          clause (i), by inserting “containing the informa-

1           tion required under subsection (c)” after “un-  
2           less a petition”;

3           (B) in section 2112(d) (42 U.S.C. 300aa-  
4           12(d))—

5           (i) by adding at the end of paragraph  
6           (1) the following: “Such designation shall  
7           not occur until the petitioner has filed all  
8           materials required under section 2111(c).”;  
9           and

10           (ii) in paragraph (3)(A)(ii), by strik-  
11           ing “the petition was filed” and inserting  
12           “on which the chief special master makes  
13           the designation pursuant to paragraph  
14           (1)”;

15           (C) in section 2114(e) (42 U.S.C. 300aa-  
16           14(e))—

17           (i) in paragraph (2), in the matter  
18           preceding subparagraph (A), by striking  
19           “2 years” and inserting “6 months”; and

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

22           “(4) LICENSURE REQUIREMENT.—Notwith-  
23           standing paragraphs (2) and (3), the Secretary may  
24           not revise the Vaccine Injury Table to include a vac-  
25           cine for which the Centers for Disease Control and

1 Prevention has issued a recommendation for routine  
2 use in children or pregnant women until at least one  
3 application for such vaccine has been approved  
4 under section 351. Upon such revision of the Vac-  
5 cine Injury Table, all vaccines to prevent the same  
6 infectious disease, including vaccines authorized  
7 under emergency use pursuant to section 564 of the  
8 Federal Food, Drug, and Cosmetic Act, shall be con-  
9 sidered included in the Vaccine Injury Table.”; and

10 (D) in section 2116 (42 U.S.C. 300aa–16),

11 by adding at the end the following:

12 “(d) CLARIFICATION.—Notwithstanding subsections  
13 (a) and (b), an injury or death related to a vaccine admin-  
14 istered at a time when the vaccine was a covered counter-  
15 measure subject to a declaration under section 319F–3(b)  
16 shall not be eligible for compensation under the Pro-  
17 gram.”.

18 **SEC. 302. ACCELERATING INJURY COMPENSATION PRO-**  
19 **GRAM ADMINISTRATION AND ENSURING PRO-**  
20 **GRAM INTEGRITY.**

21 (a) IN GENERAL.—Section 2112(c) of the Public  
22 Health Service Act (42 U.S.C. 300aa12(c)) is amended—

23 (1) in paragraph (1), by striking “not more  
24 than 8 special masters” and inserting “not fewer  
25 than 10 special masters”; and



1 (2) in paragraph (4)—

2 (A) by striking “a term of 4 years” and in-  
3 serting “an initial term of 4 years”;

4 (B) by striking the second and third sen-  
5 tences; and

6 (C) by adding at the end the following:  
7 “An individual appointed as special master may  
8 be reappointed to serve one or more additional  
9 terms of up to 8 years each, pursuant to para-  
10 graph (1), and subject to termination under  
11 paragraphs (2) and (3).”.

12 (b) PETITIONS FOR COMPENSATION.—Section  
13 2111(a)(2)(A)(i) of the Public Health Service Act (42  
14 U.S.C. 300aa–11(a)(2)(A)(i)) is amended—

15 (1) in subclause (I), by striking “, and” and in-  
16 serting a semicolon;

17 (2) in subclause (II)—

18 (A) by moving the margin 2 ems to the  
19 right; and

20 (B) by striking “, or” and inserting “;  
21 and”; and

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

23 “(III) the judgment described in subclause  
24 (I) does not result from a petitioner’s motion to  
25 dismiss the case; or”.

1 (c) COMPENSATION.—Section 2115(e)(1) of the Pub-  
2 lic Health Service Act (42 U.S.C. 300aa–15(e)(1)) is  
3 amended by adding at the end the following: “When mak-  
4 ing a determination of good faith under this paragraph,  
5 the special master or court may consider whether the peti-  
6 tioner demonstrated an intention to obtain compensation  
7 on such petition and was not merely seeking to satisfy the  
8 exhaustion requirement under section 2121(b).”.

9 **SEC. 303. COMPENSATION FOR INJURIES RELATING TO THE**  
10 **PUBLIC HEALTH EMERGENCY CAUSED BY**  
11 **SARS-COV-2.**

12 (a) IN GENERAL.—With respect to claims filed under  
13 the Countermeasure Injury Compensation Program (re-  
14 ferred to in this section as “the Program”) under section  
15 319F–4 of the Public Health Service Act (42 U.S.C.  
16 247d–6e) alleging a covered injury caused by the adminis-  
17 tration or use of a covered countermeasure pursuant to  
18 a declaration under section 319F–3(b) of such Act (42  
19 U.S.C. 247d–6d(b)) relating to COVID–19, the following  
20 shall apply:

21 (1) Notwithstanding the filing deadline applica-  
22 ble under section 319F–4, the claim shall be filed  
23 within 3 years of the administration or use of the  
24 covered countermeasure, or one year after enactment  
25 of this section, whichever is later, and, if a claim

1 filed under the Program with respect to such admin-  
2 istration or use was filed before the date of enact-  
3 ment of this Act and denied on the basis of having  
4 not been filed within the time period required under  
5 subsection (b)(4) of such section 319F–4, such claim  
6 may be refiled pursuant to this paragraph.

7 (2) With respect to a claim relating to the ad-  
8 ministration of a COVID–19 vaccine, such a claim  
9 may be filed under the Program only if the adminis-  
10 tration of such vaccine occurred prior to the addition  
11 of the vaccine to the Vaccine Injury Table under sec-  
12 tion 2114 of the Public Health Service Act (42  
13 U.S.C. 300aa–14).

14 (3) Not later than 9 months after the date of  
15 enactment of this section, the Secretary of Health  
16 and Human Services shall promulgate a covered  
17 countermeasure injury table pursuant to subsection  
18 (b)(5) of section 319F–4 of the Public Health Serv-  
19 ice Act (42 U.S.C. 247d–6e(b)(5)).

20 (b) PROFESSIONAL JUDGMENT BUDGET.—

21 (1) IN GENERAL.—The Secretary of Health and  
22 Human Services—

23 (A) in consultation with the Attorney Gen-  
24 eral, shall submit a budget outlining the re-  
25 source needs for each agency for purposes of

1 carrying out the National Vaccine Injury Com-  
2 pensation Program under subtitle 2 of title XXI  
3 of such Act (42 U.S.C. 300aa–10 et seq.) for  
4 fiscal years 2024 through 2028; and

5 (B) shall submit a budget outlining re-  
6 source needs for purposes of carrying out the  
7 Countermeasures Injury Compensation Pro-  
8 gram under section 319F–4 of the Public  
9 Health Service Act (42 U.S.C. 247d–6e) for fis-  
10 cal years 2024 through 2028.

11 (2) INCLUSIONS.—The budgets described in  
12 subparagraphs (A) and (B) of paragraph (1) shall  
13 include estimates of both the resources necessary to  
14 process current backlogs and each program’s ability  
15 to reduce processing times with respect to such pro-  
16 fessional judgments.

17 (c) NASEM REPORT.—The Secretary of Health and  
18 Human Services shall seek to enter into a contract with  
19 the National Academies of Sciences, Engineering, and  
20 Medicine under which such National Academies shall re-  
21 port, not later than 3 years after the date of enactment  
22 of this Act, on the Countermeasure Injury Compensation  
23 Program under section 319F–4 of the Public Health Serv-  
24 ice Act (42 U.S.C. 247d–6e), including recommendations  
25 to improve the administration of such program and wheth-

1 er Congress should adjust the compensation payments  
2 available under such program.

3 **SEC. 304. REVIEW OF REGULATIONS.**

4 The Secretary of Health and Human Services shall  
5 update regulations, as needed for purposes of carrying out  
6 the amendments made by sections 301 and 302.

7 **SEC. 305. SUPPORTING INDIVIDUALS WITH DISABILITIES,  
8 OLDER ADULTS, AND OTHER AT-RISK INDI-  
9 VIDUALS DURING EMERGENCY RESPONSES.**

10 (a) TECHNICAL ASSISTANCE CENTERS ON AT-RISK  
11 INDIVIDUALS AND DISASTERS.—

12 (1) IN GENERAL.—The Secretary of Health and  
13 Human Services (referred to in this section as the  
14 “Secretary”) may, through grants, contracts, or co-  
15 operative agreements to eligible entities, establish  
16 more than one research, training, and technical as-  
17 sistance centers to provide appropriate information,  
18 training, and technical assistance to States, local-  
19 ities, Tribes, and other applicable entities related to  
20 addressing the unique needs and considerations of  
21 at-risk individuals, as defined in section 2802(b)(4)  
22 of the Public Health Service Act (42 U.S.C. 300hh-  
23 1(b)(4)), in the event of a public health emergency  
24 declared by the Secretary pursuant to section 319 of  
25 the Public Health Service Act (42 U.S.C. 247d).

1           (2) RESPONSIBILITIES OF THE CENTERS.—The  
2 centers established under paragraph (1) shall con-  
3 duct activities for the purpose of—

4           (A) developing, identifying, evaluating, and  
5 disseminating evidence-based or evidence-in-  
6 formed strategies to improve health and other  
7 related outcomes for at-risk individuals related  
8 to public health emergencies, including by ad-  
9 dressing such unique needs and considerations  
10 in carrying out public health and medical activi-  
11 ties to prepare for, respond to, and recover  
12 from, such public health emergencies; and

13           (B) assisting applicable entities in the im-  
14 plementation of such evidence-based strategies,  
15 including through sub-grants, contracts, or co-  
16 operative agreements.

17           (3) PRIORITY.—In awarding grants for activi-  
18 ties described in this subsection, the Secretary shall  
19 give priority to eligible entities with demonstrated  
20 expertise in, and ability to carry out, the activities  
21 described in paragraph (2).

22           (4) CONSULTATION.—In carrying out activities  
23 under paragraph (2), the centers established under  
24 paragraph (1) shall take into consideration relevant  
25 findings and recommendations of, and, as appro-

1 appropriate, consult with, the National Advisory Com-  
2 mittee on Individuals with Disabilities and Disasters  
3 established under section 2811C of the Public  
4 Health Service Act (42 U.S.C. 300hh–10d), the Na-  
5 tional Advisory Committee on Children and Disas-  
6 ters under section 2811A of such Act (42 U.S.C.  
7 300hh–10b), and the National Advisory Committee  
8 on Seniors and Disasters under section 2811B of  
9 such Act (42 U.S.C. 300hh–10e).

10 (5) REPORTS.—Not later than 2 years after the  
11 date of enactment of this Act and every 2 years  
12 thereafter, the Secretary shall submit to the Com-  
13 mittee on Health, Education, Labor, and Pensions  
14 of the Senate and the Committee on Energy and  
15 Commerce of the House of Representatives a report  
16 describing the activities carried out under this sub-  
17 section during the preceding 2 fiscal years.

18 (6) SUNSET.—This subsection shall cease to  
19 have force or effect on September 30, 2028.

20 (b) CRISIS STANDARDS OF CARE.—Not later than 2  
21 years after the date of enactment of this Act, the Sec-  
22 retary, acting through the Director of the Office for Civil  
23 Rights of the Department of Health and Human Services,  
24 shall issue guidance to States and localities on the develop-  
25 ment or modification of State and local crisis standards

1 of care for use during the response to a public health  
2 emergency declared by the governor of a State or by the  
3 Secretary under section 319 of the Public Health Service  
4 Act (42 U.S.C. 247d), or a major disaster or emergency  
5 declared by the President under section 401 or 501, re-  
6 spectively, of the Robert T. Stafford Disaster Relief and  
7 Emergency Assistance Act (42 U.S.C. 5170, 5191) to en-  
8 sure that such standards of care are consistent with the  
9 nondiscrimination requirements of section 504 of the Re-  
10 habilitation Act of 1973 (29 U.S.C. 794), title II of the  
11 Americans with Disabilities Act of 1990 (42 U.S.C. 12131  
12 et seq.), and the Age Discrimination Act of 1975 (42  
13 U.S.C. 6101 et seq.).

14 **SEC. 306. NATIONAL ADVISORY COMMITTEES.**

15 (a) NATIONAL ADVISORY COMMITTEE ON CHILDREN  
16 AND DISASTERS.—Section 2811A of the Public Health  
17 Service Act (42 U.S.C. 300hh–10b) is amended—

18 (1) in subsection (c)—

19 (A) by striking “may provide advice” and  
20 inserting the following: “may provide—  
21 “(1) advice”;

22 (B) by striking the period and inserting “;  
23 and”; and

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



1           “(2) recommendations to the Director of the  
2           Office of Pandemic Preparedness and Response Pol-  
3           icy and to Congress with respect to the public health  
4           and emergency preparedness needs of children.”;  
5           and

6           (2) in subsection (g), by striking “2023” and  
7           inserting “2028”.

8           (b) NATIONAL ADVISORY COMMITTEE ON SENIORS  
9           AND DISASTERS.—Section 2811B of the Public Health  
10          Service Act (42 U.S.C. 300hh–10c) is amended—

11           (1) in subsection (c)—

12                   (A) by striking “may provide advice” and  
13                   inserting the following: “may provide—  
14                   “(1) advice”;

15                   (B) by striking the period and inserting “;  
16                   and”; and

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

18                   “(2) recommendations to the Director of the  
19                   Office of Pandemic Preparedness and Response Pol-  
20                   icy and to Congress with respect to the public health  
21                   and emergency preparedness needs of seniors.”;

22           (2) in subsection (d)—

23                   (A) in paragraph (1), by striking “17  
24                   members” and inserting “25 members”; and

25                   (B) in paragraph (2)—

1 (i) in subparagraph (J), by striking  
2 “2” and inserting “3”;

3 (ii) in subparagraph (K), by striking  
4 “2” and inserting “3”;

5 (iii) by redesignating subparagraphs  
6 (K) through (L) as subparagraphs (L)  
7 through (M), respectively; and

8 (iv) by inserting after subparagraph  
9 (J) the following:

10 “(K) At least 2 non-Federal health care  
11 professionals with expertise in gerontology.”;  
12 and

13 (3) by amending subsection (g) to read as fol-  
14 lows:

15 “(g) SUNSET.—The Advisory Committee shall termi-  
16 nate on September 30, 2028.”.

17 (c) NATIONAL ADVISORY COMMITTEE ON INDIVID-  
18 UALS WITH DISABILITIES AND DISASTERS.—Section  
19 2811C of the Public Health Service Act (42 U.S.C.  
20 300hh–10d) is amended—

21 (1) by redesignating subsections (c) through (g)  
22 as subsections (d) through (h), respectively;

23 (2) by inserting after subsection (b) the fol-  
24 lowing:

1       “(c) ADDITIONAL DUTIES.—The Advisory Committee  
2 may provide—

3           “(1) advice and recommendations to the Sec-  
4 retary and to Congress with respect to individuals  
5 with disabilities and the medical and public health  
6 grants and cooperative agreements as applicable to  
7 preparedness and response activities under this title  
8 and title III; and

9           “(2) recommendations to the Director of the  
10 Office of Pandemic Preparedness and Response Pol-  
11 icy and to Congress with respect to the public health  
12 and emergency preparedness needs of individuals  
13 with disabilities.”;

14           (3) in subsection (d), as so redesignated—

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

17           (B) in paragraph (2)—

18           (i) by striking subparagraphs (K)  
19 through (M); and

20           (ii) by inserting after subparagraph  
21 (J) the following:

22           “(K) 15 non-Federal members (at least 4  
23 of whom shall be individuals with disabilities)  
24 from diverse backgrounds, including the fol-  
25 lowing:

1                   “(i) One representative from each of  
2 the following:

3                   “(I) A nongovernmental organi-  
4 zation that provides disaster prepared-  
5 ness and response services.

6                   “(II) A community-based organi-  
7 zation that represents individuals with  
8 multiple types of disabilities.

9                   “(III) A State-based organization  
10 that represents individuals with mul-  
11 tiple types of disabilities.

12                   “(IV) A national organization  
13 that represents individuals with mul-  
14 tiple types of disabilities.

15                   “(V) A national organization that  
16 represents older adults.

17                   “(VI) An organization that pro-  
18 vides relevant housing services, includ-  
19 ing during the response to, and recov-  
20 ery from, disasters.

21                   “(VII) An organization that rep-  
22 represents disabled veterans.

23                   “(ii) Four individuals with geographi-  
24 cally diverse expertise in emergency man-  
25 agement.

1           “(iii) Two non-Federal health care  
 2 professionals with expertise in disability ac-  
 3 cessibility before, during, and after disas-  
 4 ters, medical and mass care disaster plan-  
 5 ning, preparedness, response, or recov-  
 6 ery.”; and

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

8           “(3) CONSIDERATION.—In appointing members,  
 9 including the Chair, to the Committee under this  
 10 subsection, the Secretary may give consideration to  
 11 disability status.”; and

12           (4) by amending subsection (h), as so redesign-  
 13 nated, to read as follows:

14           “(h) SUNSET.—The Advisory Committee shall termi-  
 15 nate on September 30, 2028.”.

16 **SEC. 307. RESEARCH AND COORDINATION OF ACTIVITIES**  
 17 **CONCERNING THE LONG-TERM HEALTH EF-**  
 18 **FECTS OF SARS-COV-2 INFECTION.**

19           (a) IN GENERAL.—The Secretary of Health and  
 20 Human Services (referred to in this section as the “Sec-  
 21 retary”) shall, as appropriate—

22           (1) coordinate activities among relevant Federal  
 23 departments and agencies with respect to addressing  
 24 the long-term health effects of SARS-CoV-2 infec-

1 tion, which may include conditions that arise as a  
2 result of such infection;

3 (2) continue to conduct or support basic, clin-  
4 ical, epidemiological, behavioral, and translational  
5 research and public health surveillance related to the  
6 pathogenesis, prevention, diagnosis, and treatment  
7 of the long-term health effects of SARS-CoV-2 in-  
8 fection and re-infection, which may include condi-  
9 tions and any effects on development, cognition, and  
10 neural structure and function that arise as a result  
11 of such infection; and

12 (3) consistent with the findings of studies and  
13 research under paragraph (1), in consultation with  
14 health and public health professional associations,  
15 scientific and medical researchers, and other rel-  
16 evant experts, develop and inform recommendations,  
17 guidance, and educational materials on the long-  
18 term effects of SARS-CoV-2 infection, which may  
19 include conditions that arise as a result of such in-  
20 fection, and provide such recommendations, guid-  
21 ance, and educational materials to health care pro-  
22 viders and the general public.

23 (b) CONSIDERATIONS.—In conducting or supporting  
24 research under this section, the Secretary shall consider  
25 the diversity of research participants or cohorts to ensure

1 inclusion of a broad range of participants, as applicable  
2 and appropriate.

3 (c) ADDITIONAL ACTIVITIES.—The Secretary may—

4 (1) acting through the Director of the Agency  
5 for Healthcare Research and Quality, conduct or  
6 support research related to—

7 (A) the improvement of health care deliv-  
8 ery for individuals experiencing long-term  
9 health effects of SARS-CoV-2, which may in-  
10 clude conditions that arise as a result of such  
11 infection;

12 (B) the identification of any trends associ-  
13 ated with differences in diagnosis and treat-  
14 ment of the long-term health effects of SARS-  
15 CoV-2 infection and related conditions; and

16 (C) the development or identification of  
17 tools and strategies to help health care entities  
18 and providers care for such populations, which  
19 may include addressing any differences identi-  
20 fied pursuant to subparagraph (B);

21 (2) publicly disseminate the results of such re-  
22 search; and

23 (3) establish a primary care technical assistance  
24 initiative to convene primary care providers and or-  
25 ganizations, which may include support for con-

1 continuing training and education for such providers, as  
2 applicable and appropriate, in order to collect and  
3 disseminate best practices related to the care of indi-  
4 viduals with long-term health effects of SARS-CoV-  
5 2 infection, which may include conditions that arise  
6 as a result of such infection.

7 (d) ANNUAL REPORTS.—Not later than 1 year after  
8 the date of enactment of this Act, and annually thereafter  
9 for the next 4 years, the Secretary shall prepare and sub-  
10 mit a report to the Committee on Health, Education,  
11 Labor, and Pensions of the Senate and the Committee on  
12 Energy and Commerce of the House of Representatives  
13 regarding an overview of the research conducted or sup-  
14 ported under this section and any relevant findings. Such  
15 reports may include information about how the research  
16 and relevant findings under this section relate to other re-  
17 search efforts supported by other public or private entities.

18 (e) PUBLIC AVAILABILITY OF INFORMATION.—In  
19 making information or reports publicly available under  
20 this section, the Secretary shall take into consideration the  
21 delivery of such information in a manner that takes into  
22 account the range of communication needs of the intended  
23 recipients, including at-risk individuals.



1 **SEC. 308. NATIONAL ACADEMIES STUDY ON PRIZES.**

2 (a) IN GENERAL.—Not later than 90 days after the  
3 date of enactment of this Act, the Secretary of Health and  
4 Human Services shall seek to enter into an agreement  
5 with the National Academies of Sciences, Engineering,  
6 and Medicine (referred to in this section as the “National  
7 Academies”) to conduct a study to examine—

8 (1) alternative models for directly funding, or  
9 stimulating investment in, biomedical research and  
10 development that delink research and development  
11 costs from the prices of drugs, including the pro-  
12 gressive replacement of patents and regulatory  
13 exclusivities on new drugs with a combination of ex-  
14 panded support for research and innovation prizes to  
15 reward the successful development of drugs or  
16 achievement of related milestones;

17 (2) the dollar amount of innovation prizes for  
18 different stages of research and development of dif-  
19 ferent classes or types of drugs, and total annual  
20 funding, that would be necessary to stimulate invest-  
21 ment sufficient to achieve such successful drug de-  
22 velopment and related milestones;

23 (3) the relative effectiveness and efficiency of  
24 such alternative models in stimulating innovation,  
25 compared to the status quo that includes patents  
26 and regulatory exclusivities;

1           (4) strategies to implement such alternative  
2 models described in paragraph (1), including a  
3 phased transition over time; and

4           (5) the anticipated economic and societal im-  
5 pacts of such alternative models, including an as-  
6 sessment of impact on—

7                   (A) the number and variety of new drugs  
8 that would be developed, approved, and mar-  
9 keted in the United States, including such new  
10 drugs intended to prevent, diagnose, or treat a  
11 rare disease or condition;

12                   (B) the rate at which new drugs would be  
13 developed, approved, and marketed in the  
14 United States;

15                   (C) access to medication and health out-  
16 comes;

17                   (D) average lifespan and disease burden in  
18 the United States;

19                   (E) the number of manufacturers that  
20 would be seeking approval for a drug or bring-  
21 ing a drug to market for the first time;

22                   (F) Federal discretionary and mandatory  
23 spending; and

24                   (G) public and private insurance markets.

1           (b) AUTHORIZATION OF APPROPRIATIONS.—To carry  
2 out this section, there is authorized to be appropriated  
3 \$3,000,000 for fiscal year 2024.

4           (c) REQUIREMENTS.—In conducting the study pursu-  
5 ant to subsection (a), the National Academies shall hold  
6 not fewer than 2 public listening sessions to solicit feed-  
7 back from interested parties, including representatives of  
8 academia, professional societies, patient advocates, public  
9 health organizations, relevant Federal departments and  
10 agencies, drug developers, representatives of other rel-  
11 evant industries, and subject matter experts.

12          (d) REPORT.—Not later than 2 years after the date  
13 of enactment of this Act, the National Academies shall  
14 submit to the Committee on Health, Education, Labor,  
15 and Pensions and the Committee on Appropriations of the  
16 Senate and the Committee on Energy and Commerce and  
17 the Committee on Appropriations of the House of Rep-  
18 resentatives a report on the study conducted pursuant to  
19 subsection (a).

1           **TITLE IV—STRENGTHENING**  
2                           **BIOSECURITY**

3   **SEC. 401. TREATMENT OF GENETIC VARIANTS AND SYN-**  
4                           **THETIC PRODUCTS OF SELECT AGENTS AND**  
5                           **TOXINS.**

6           Section 351A(a)(1) of the Public Health Service Act  
7 (42 U.S.C. 262a(a)(1)) is amended by adding at the end  
8 the following:

9                           “(C) INCLUSIONS.—

10                           “(i) IN GENERAL.—For purposes of  
11 the list under this paragraph, the following  
12 shall be considered to be a biological agent  
13 or toxin included on the list:

14                           “(I) Any biological agent that in-  
15 corporates nucleic acids coding for a  
16 virulence factor from a listed agent or  
17 toxin.

18                           “(II) Any biological agent or  
19 toxin that is genetically homologous to  
20 a listed agent or toxin with respect to  
21 nucleotides coding for virulence fac-  
22 tors or toxicity.

23                           “(III) Any biological agent or  
24 toxin that is synthetically derived with

1 virulence or toxicity characteristics of  
2 a listed agent or toxin.

3 “(IV) Any nucleic acid that en-  
4 codes for components contributing to  
5 pathogenicity, transmissibility, or tox-  
6 icity of a listed agent or toxin.

7 “(ii) EXEMPTIONS.—The Secretary  
8 may exempt from inclusion on the list  
9 under this paragraph any biological agent,  
10 toxin, or nucleic acid described in clause  
11 (i), if such agent, toxin, or nucleic acid  
12 does not meet the criteria under subpara-  
13 graph (B).”.

14 **SEC. 402. ESTABLISHMENT OF NO-FAULT REPORTING SYS-**  
15 **TEM.**

16 Title III of the Public Health Service Act is amended  
17 by inserting after section 351A (42 U.S.C. 262a) the fol-  
18 lowing:

19 **“SEC. 351B. NO-FAULT REPORTING SYSTEM.**

20 “(a) DEFINITIONS.—In this section:

21 “(1) The term ‘listed agents and toxins’ has the  
22 meaning given the term in section 351A(l).

23 “(2) The term ‘reporting system’ means the re-  
24 porting system established under subsection (b)(1).

25 “(b) ESTABLISHMENT.—

1           “(1) IN GENERAL.—Not later than 3 years  
2 after the date of enactment of the Pandemic and  
3 All-Hazards Preparedness and Response Act, the  
4 Secretary shall establish a confidential, anonymous,  
5 voluntary, no-fault reporting system related to acci-  
6 dents, near-accidents, or other safety incidents in-  
7 volving biological agents and toxins, in order to sup-  
8 port continuous improvement and sharing of lessons  
9 learned related to such incidents.

10           “(2) AVAILABILITY.—The ability to submit re-  
11 ports on a voluntary basis to the reporting system  
12 shall be made available to individuals affiliated with  
13 laboratories located in the United States, or at fed-  
14 erally-funded entities outside the United States, that  
15 conduct research involving biological agents and tox-  
16 ins.

17           “(3) DATA.—Not later than 2 years after the  
18 date of enactment of the Pandemic and All-Hazards  
19 Preparedness and Response Act, the Secretary shall  
20 publish a notice in the Federal Register on plans for  
21 the reporting system, including—

22           “(A) data elements that will be included in  
23 the submission of reports;

24           “(B) procedures and processes for the sub-  
25 mission of reports;

1           “(C) criteria for incidents that may be re-  
2           ported to such system; and

3           “(D) procedures for privacy and  
4           anonymization.

5           “(4) PROTOTYPING AND TESTING.—The Sec-  
6           retary shall test and prototype the reporting system  
7           for not less than 1 year before finalizing the report-  
8           ing system.

9           “(5) EXTERNAL FEEDBACK.—The Secretary  
10          shall seek feedback on development of the reporting  
11          system from external stakeholders, including prior to  
12          publication of the information under paragraph (3)  
13          and prior to introduction of prototypes and finaliza-  
14          tion of such system under paragraph (4).

15          “(c) FOIA.—

16               “(1) IN GENERAL.—Information submitted to,  
17               or derived from, the reporting system shall be ex-  
18               empt from disclosure under section 552 of title 5,  
19               United States Code.

20               “(2) APPLICABILITY.—For purposes of para-  
21               graph (1), this section shall be considered a statute  
22               described in section 552(b)(3)(B) of title 5, United  
23               States Code.

24          “(d) PROHIBITION ON USE AS EVIDENCE.—Informa-  
25          tion submitted to, or derived from, the reporting system

1 shall not be used in any Federal or State enforcement ac-  
2 tion or criminal prosecution.

3 “(e) PRIVACY; DISCIPLINARY ACTION FOR UNAU-  
4 THORIZED DISCLOSURE.—An individual or entity that  
5 submits information to the reporting system under sub-  
6 section (b) shall not be required to provide their name.

7 “(f) RELATIONSHIP TO OTHER REPORTING SYS-  
8 TEMS.—The voluntary reporting system established under  
9 this section shall supplement, and not supplant, any other  
10 requirements to submit reports under any other reporting  
11 system.”.

12 **SEC. 403. EVALUATION OF THE FEDERAL SELECT AGENT**  
13 **PROGRAM AND RELATED POLICIES.**

14 (a) IN GENERAL.—Not later than 4 years after the  
15 date of enactment of this Act, the National Science Advi-  
16 sory Board for Biosecurity (referred to in this section as  
17 the “Board”) established pursuant to section 4040 of the  
18 Public Health Service Act (42 U.S.C. 283r) shall be  
19 charged with assessing the framework for biosafety and  
20 biosecurity oversight, particularly with respect to miti-  
21 gating risks to the United States population with respect  
22 to biological threats. The findings of the Board shall ad-  
23 dress scientific advancements and integration of the Pro-  
24 gram and other related Federal policies and frameworks



1 for biosafety and biosecurity. The findings of the Board  
2 shall be transmitted to the President.

3 (b) FRAMEWORK.—

4 (1) IN GENERAL.—The recommendations devel-  
5 oped under subsection (a) shall include a proposed  
6 framework for an integrated approach to the over-  
7 sight of biological research that raises significant  
8 biosafety and biosecurity concerns, which may in-  
9 clude proposals to harmonize and modernize relevant  
10 Federal policies such as the following:

11 (A) The Federal Select Agent Program.

12 (B) Federal policies relating to dual-use  
13 research of concern.

14 (C) Federal policies related to federally  
15 funded research involving enhanced pathogens  
16 of pandemic potential.

17 (D) The Biosafety in Microbiological and  
18 Biomedical Laboratories Manual of the Depart-  
19 ment of Health and Human Services, and other  
20 related guidance documents.

21 (E) The Guidelines for Research Involving  
22 Recombinant or Synthetic Nucleic Acid Mol-  
23 ecules of the National Institutes of Health.

24 (2) REQUIREMENTS FOR FRAMEWORK.—The  
25 framework proposed under paragraph (1) shall—

1           (A) be developed in consultation with  
2 stakeholders and experts from institutions of  
3 higher education, industry, and other govern-  
4 ment agencies; and

5           (B) make recommendations related to miti-  
6 gating any identified risks associated with exist-  
7 ing gaps in oversight of such research, which  
8 may include research that does not receive Fed-  
9 eral funding, taking into consideration any na-  
10 tional security concerns, the potential benefits  
11 of such research, considerations related to the  
12 research community, transparency, and public  
13 availability of information, and international re-  
14 search collaboration.

15       (c) REORGANIZATION.—In carrying out this section,  
16 the Board may make recommendations related to the clar-  
17 ification of the authorities and responsibilities of relevant  
18 Federal departments and agencies and any necessary reor-  
19 ganization of such authorities and responsibilities among  
20 such departments and agencies.

21       (d) REPORT.—Not later than 1 year after the  
22 issuance of recommendations under subsection (a), the  
23 President shall submit to the Committee on Health, Edu-  
24 cation, Labor, and Pensions of the Senate and the Com-  
25 mittee on Energy and Commerce of the House of Rep-

1 representatives, and, as applicable, other appropriate commit-  
2 tees of Congress, a report that describes plans to consider  
3 and implement such recommendations, including the iden-  
4 tification of—

5 (1) any barriers to implementation; and

6 (2) any areas in which the President disagrees  
7 with the findings or recommendations of the Board.

8 **SEC. 404. SUPPORTING RESEARCH AND LABORATORY**  
9 **SURGE CAPACITY.**

10 (a) IN GENERAL.—The Secretary of Health and  
11 Human Services (referred to in this section as the “Sec-  
12 retary”) shall make awards to establish or maintain, as  
13 applicable, not fewer than 12 regional biocontainment lab-  
14 oratories, for purposes of—

15 (1) conducting biomedical research to support  
16 public health and medical preparedness for, and  
17 rapid response to, biological agents, including emerg-  
18 ing infectious diseases;

19 (2) ensuring the availability of surge capacity  
20 for purposes of responding to such biological agents;

21 (3) supporting information-sharing between,  
22 and the dissemination of findings to, researchers and  
23 other relevant individuals to facilitate collaboration  
24 between industry and academia; and

1           (4) providing, as appropriate and applicable,  
2           technical assistance and training to researchers and  
3           other relevant individuals to support the biomedical  
4           research workforce in improving the management  
5           and mitigation of safety and security risks in the  
6           conduct of research involving such biological agents.

7           (b) REQUIREMENTS.—As a condition of receiving a  
8           grant under this section, a regional biocontainment labora-  
9           tory shall agree—

10           (1) to such oversight activities as the Secretary  
11           determines appropriate, including periodic meetings  
12           with relevant officials of the Department of Health  
13           and Human Services, facility inspections, and other  
14           activities as necessary and appropriate to ensure  
15           compliance with the terms and conditions of such  
16           award; and

17           (2) to report accidents, near-accidents, or other  
18           safety incidents involving biological agents and tox-  
19           ins into the no-fault reporting system established  
20           pursuant to section 351B of the Public Health Serv-  
21           ice Act, as added by section 402.

22           (c) BOARD.—The Secretary shall establish a Board  
23           consisting of a representative from each entity in receipt  
24           of an award under subsection (a), which shall be headed  
25           by an executive committee of 3 members elected upon an

1 affirmative vote from a majority of such representatives.  
2 The Board shall make recommendations to the Secretary  
3 in administering awards under this section, for purposes  
4 of—

5           (1) improving the quality and consistency of ap-  
6           plicable procedures and practices within laboratories  
7           funded pursuant to subsection (a); and

8           (2) ensuring coordination, as appropriate, of  
9           federally funded activities carried out at such labora-  
10          tories.

11          (d) DEFINITION.—In this section, the term “regional  
12 biocontainment laboratory” means a Biosafety or Animal  
13 Biosafety Level-3 and Level-2 facility located at an insti-  
14 tution in the United States that is designated by the Sec-  
15 retary to carry out the activities described in subsection  
16 (a).

17          (e) AUTHORIZATION OF APPROPRIATIONS.—To carry  
18 out this section, there are authorized to be appropriated  
19 \$52,000,000 for each of fiscal years 2024 through 2028.

20          (f) ADMINISTRATIVE EXPENSES.—Of the amount  
21 available to carry out this section for a fiscal year, the  
22 Secretary may use not more than 5 percent for the admin-  
23 istrative expenses of carrying out this section, including  
24 expenses related to carrying out subsection (c).

1 (g) REPORT TO CONGRESS.—Not later than 1 year  
2 after the date of the enactment of this Act, and biannually  
3 thereafter, the Secretary, in consultation with the heads  
4 of applicable Federal departments and agencies shall re-  
5 port to the Committee on Health, Education, Labor, and  
6 Pensions of the Senate and the Committee on Energy and  
7 Commerce of the House of Representatives on—

8 (1) the activities and accomplishments of the  
9 regional biocontainment laboratories;

10 (2) any published or disseminated research  
11 findings based on research conducted in such labora-  
12 tories in the applicable year;

13 (3) oversight activities carried out by the Sec-  
14 retary pursuant to subsection (b);

15 (4) activities undertaken by the Secretary to  
16 take into consideration the capacity and capabilities  
17 of the network of regional biocontainment labora-  
18 tories in activities to prepare for and respond to bio-  
19 logical agents, which may include leveraging such ca-  
20 pacity and capabilities to support the Laboratory  
21 Response Network, as applicable and appropriate;

22 (5) plans for the maintenance and sustainment  
23 of federally funded activities conducted at the re-  
24 gional biocontainment laboratories, consistent with  
25 the strategy required under section 2312 of the

1 PREVENT Pandemics Act (Public Law 117–328);  
2 and

3 (6) activities undertaken by the Secretary to co-  
4 ordinate with applicable agencies to ensure work car-  
5 ried out by such facilities is prioritized and com-  
6 plementary to one another, and avoiding unneces-  
7 sary duplication.

8 **SEC. 405. GENE SYNTHESIS.**

9 (a) GUIDANCE.—Not later than 1 year after the date  
10 of enactment of this Act, the Secretary of Health and  
11 Human Services (referred to in this section as the “Sec-  
12 retary”) shall update the Screening Framework Guidance  
13 for Providers of Synthetic Double-Stranded DNA to ac-  
14 count for scientific and technological advancements with  
15 respect to mitigating risk of unauthorized individuals or  
16 individuals with malicious intent from using nucleic acid  
17 synthesis technologies to obtain biological agents or toxins  
18 of concern. Such guidance shall include recommendations  
19 related to—

20 (1) screening for sequences that the Secretary  
21 determines may contribute to toxicity, pathogenicity,  
22 or virulence;

23 (2) screening and verification of the identity  
24 and legitimacy of customers;

1           (3) the identification, evaluation, and use of ap-  
2           propriate software or other tools to enable the  
3           screening described in paragraphs (1) and (2);

4           (4) ensuring nucleic acid synthesis activities are  
5           carried out in compliance with existing regulations  
6           under part 73 of title 42, Code of Federal Regula-  
7           tions, part 331 of title 7, Code of Federal Regula-  
8           tions, part 121 of title 9, Code of Federal Regula-  
9           tions, and part 774 of title 15 Code of Federal Reg-  
10          ulations (or successor regulations);

11          (5) implementing appropriate safeguards, which  
12          may include the use of such software or other tools,  
13          in gene synthesis equipment to facilitate screening of  
14          nucleic acid sequences and, as applicable, customers;

15          (6) maintaining records of customer orders,  
16          metadata, and screening system or protocol perform-  
17          ance in specified formats, which may include stand-  
18          ardized machine-readable and interoperable data for-  
19          mats; and

20          (7) other recommendations as determined ap-  
21          propriate by the Secretary.

22          (b) SEQUENCES OF CONCERN.—The Secretary shall  
23          maintain a public docket to solicit recommendations on po-  
24          tential sequences of concern and, in consultation with  
25          other Federal departments and agencies and non-Federal



1 experts, as appropriate, review and update, on a regular  
2 basis, a list of sequences of concern to facilitate screening  
3 under subsection (a)(1).

4 (c) LANDSCAPE REVIEW.—The Secretary, in coordi-  
5 nation with other Federal departments and agencies, as  
6 appropriate, shall conduct a landscape review of providers  
7 and manufacturers of gene synthesis equipment, products,  
8 software, and other tools with the purpose of under-  
9 standing the number, types, and capabilities of products  
10 and equipment that exist domestically and to inform the  
11 development of any updates to the guidance under sub-  
12 section (a).

13 (d) TECHNICAL ASSISTANCE.—The Secretary, in  
14 consultation with other Federal departments and agencies,  
15 shall provide technical assistance upon request of a gene  
16 synthesis provider, manufacturer of gene synthesis equip-  
17 ment, or developer of software or other screening tools to  
18 support implementation of the recommendations included  
19 in the guidance under subsection (a).

20 (e) DEFINITIONS.—For purposes of this section:

21 (1) The term “gene synthesis equipment”  
22 means equipment needed to produce gene synthesis  
23 products.

24 (2) The term “gene synthesis product”—

1 (A) means custom single-stranded or dou-  
2 ble-stranded DNA, or single-stranded or double-  
3 stranded RNA, which has been chemically or  
4 enzymatically synthesized or otherwise manu-  
5 factured de novo and is of a length exceeding  
6 the screening threshold, as determined by the  
7 Secretary; and

8 (B) does not include—

9 (i) base chemical subunits, such as in-  
10 dividual nucleotides or nucleosides, or  
11 oligonucleotides shorter than the screening  
12 threshold typically used as polymerase  
13 chain reaction primers, as determined by  
14 the Secretary;

15 (ii) by-products generated during se-  
16 quencing that are not useful for assembly  
17 or cloning, as determined by the Secretary;  
18 or

19 (iii) products generated from cloning  
20 or assembling of existing gene or gene  
21 fragment material, in circumstances in  
22 which the gene synthesis provider has no  
23 access or notice to the sequence design, as  
24 determined by the Secretary.

1           (3) The term “gene synthesis provider” means  
2           an entity that synthesizes and distributes gene syn-  
3           thesis products, including bacteria, viruses, or fungi  
4           containing recombinant or synthetic nucleic acid  
5           molecules, for delivery to a customer.

6           (4) The term “manufacturers of gene synthesis  
7           equipment” means an entity that produces and sells  
8           equipment for synthesizing gene synthesis products.

9   **SEC. 406. LIMITATION RELATED TO COUNTRIES OF CON-**  
10                           **CERN CONDUCTING CERTAIN RESEARCH.**

11           Section 2315(c) of the PREVENT Pandemics Act  
12 (Public Law 117–328) is amended—

13           (1) in paragraph (1)—

14                   (A) by inserting “that may reasonably be  
15                   anticipated to involve the creation, transfer, and  
16                   use of enhanced pathogens of pandemic poten-  
17                   tial or biological agents or toxins listed pursu-  
18                   ant to section 351A(a)(1) if such research is”  
19                   after “not fund research”; and

20                   (B) by striking “, involving pathogens of  
21                   pandemic potential” and all that follows  
22                   through the period at the end and inserting a  
23                   period;

24           (2) in paragraph (2)—

1 (A) in the heading, by striking “CONDI-  
2 TIONS FOR LISTING OR SUSPENDING PROHIBI-  
3 TION” and inserting “LIMITATIONS”; and

4 (B) in the matter preceding subparagraph  
5 (A)—

6 (i) by striking “The Secretary” and  
7 inserting “Beginning 5 years after an ini-  
8 tial determination of a country of concern,  
9 the Director of National Intelligence or the  
10 Secretary”; and

11 (ii) by inserting “with respect to such  
12 country of concern” after “paragraph (1)”;  
13 and

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

15 “(3) CLARIFICATION.—

16 “(A) IN GENERAL.—The requirement of  
17 paragraph (1) may be waived by the President  
18 for the duration of the initial response to an  
19 outbreak of a novel emerging infectious disease  
20 if the President determines that such require-  
21 ment impedes the ability of the Federal Govern-  
22 ment to immediately respond to such outbreak.

23 “(B) NOTIFICATION.—The President shall  
24 notify Congress not later than 48 hours after  
25 exercising the waiver under subparagraph (A),

1           and shall provide updates to Congress related to  
2           the use of such waiver every 15 days there-  
3           after.”.

4 **SEC. 407. ASSESSMENT OF ARTIFICIAL INTELLIGENCE**  
5                                   **THREATS TO HEALTH SECURITY.**

6           (a) **IN GENERAL.**—Not later than 45 days after the  
7           date of enactment of this Act, the Secretary of Health and  
8           Human Services (referred to in this section as the “Sec-  
9           retary”) shall seek to enter into a contract with the Na-  
10          tional Academies of Sciences, Engineering, and Medicine  
11          (referred to in this section as the “National Academies”)  
12          to conduct a study assessing the potential vulnerabilities  
13          to health security presented by the current or prospective  
14          use or misuse of artificial intelligence, including with re-  
15          spect to open-source artificial intelligence models, such as  
16          large language models.

17          (b) **INCLUSIONS.**—The study conducted pursuant to  
18          the contract under subsection (a) shall include—

19                 (1)    an    assessment    of    the    potential  
20                 vulnerabilities posed by technical advancements in  
21                 artificial intelligence to health security, including  
22                 any risks related to the development of, enhance-  
23                 ment of, or protection from, chemical, biological, ra-  
24                 diological, or nuclear threats;

1           (2) a description of roles, responsibilities, and  
2 capabilities of agencies and offices of the Depart-  
3 ment of Health and Human Services, and, as appli-  
4 cable and appropriate, other Federal departments  
5 and agencies, with respect to the identification and  
6 mitigation of such potential vulnerabilities;

7           (3) a summary of any ongoing Federal activi-  
8 ties related to the identification, understanding, and  
9 mitigation of such potential risks;

10           (4) the identification of any potential gaps,  
11 whether current or anticipated, related to such roles,  
12 responsibilities, and capabilities; and

13           (5) recommendations to improve Federal efforts  
14 to identify, prepare for, and mitigate such potential  
15 vulnerabilities.

16 (c) REPORTS.—

17           (1) NATIONAL ACADEMIES REPORT.—Not later  
18 than 2 years after the date of the contract under  
19 subsection (a), the National Academies shall submit  
20 to the Committee on Health, Education, Labor, and  
21 Pensions of the Senate and the Committee on En-  
22 ergy and Commerce of the House of Representatives  
23 a report on the study conducted pursuant to sub-  
24 section (a).

1           (2) HHS REPORT.—Not later than 1 year after  
 2           the issuance of the report required under paragraph  
 3           (1), the Secretary shall submit to the Committee on  
 4           Health, Education, Labor, and Pensions of the Sen-  
 5           ate and the Committee on Energy and Commerce of  
 6           the House of Representatives a report detailing ac-  
 7           tions taken to mitigate and monitor risks to health  
 8           security posed by misuse of artificial intelligence, as  
 9           detailed in the report under paragraph (1).

10           **TITLE V—PREVENTING DRUG**  
 11                                   **SHORTAGES**

12           **SEC. 501. IMPROVING NOTIFICATION PROCEDURES IN**  
 13                                   **CASE OF INCREASED DEMAND FOR CRITICAL**  
 14                                   **DRUGS.**

15           (a) IN GENERAL.—Section 506C of the Federal  
 16           Food, Drug, and Cosmetic Act (21 U.S.C. 356c) is amend-  
 17           ed—

18                           (1) in the section heading, by striking “**DIS-**  
 19                           **CONTINUANCE OR INTERRUPTION IN THE PRO-**  
 20                           **DUCTION OF LIFE-SAVING DRUGS**” and inserting  
 21                           “**NOTIFICATION OF ISSUES AFFECTING DOMES-**  
 22                           **TIC SUPPLY OF CRITICAL DRUGS**”;

23                           (2) by striking subsections (a), (b), and (c), and  
 24                           inserting the following:

25                           “(a) NOTIFICATION REQUIRED.—

1           “(1) IN GENERAL.—A manufacturer of a cov-  
2           ered drug shall notify the Secretary, in accordance  
3           with subsection (b), of—

4                   “(A)(i) a permanent discontinuance in the  
5                   manufacture of the drug or an interruption of  
6                   the manufacture of the drug that is likely to  
7                   lead to a meaningful disruption in the supply of  
8                   such drug in the United States;

9                   “(ii) a permanent discontinuance in the  
10                  manufacture of an active pharmaceutical ingre-  
11                  dient of such drug, or an interruption in the  
12                  manufacture of an active pharmaceutical ingre-  
13                  dient of such drug that is likely to lead to a  
14                  meaningful disruption in the supply of the ac-  
15                  tive pharmaceutical ingredient of such drug; or

16                  “(iii) any other circumstance, such as an  
17                  increase in demand or export restriction, that is  
18                  likely to leave the manufacturer unable to meet  
19                  demand for the drug without a meaningful  
20                  shortfall or delay; and

21                  “(B) the reasons for such discontinuance,  
22                  interruption, or other circumstance, if known.

23           “(2) CONTENTS.—Notification under this sub-  
24           section with respect to a covered drug shall in-  
25           clude—



1           “(A) with respect to the reasons for the  
2           discontinuation, interruption, or other cir-  
3           cumstance described in paragraph (1)(A)(iii), if  
4           an active pharmaceutical ingredient is a reason  
5           for, or risk factor in, such discontinuation,  
6           interruption, or other circumstance, the source  
7           of the active pharmaceutical ingredient and any  
8           alternative sources for the active pharma-  
9           ceutical ingredient known to the manufacturer;

10           “(B) whether any associated device used  
11           for preparation or administration included in  
12           the drug is a reason for, or a risk factor in,  
13           such discontinuation, interruption, or other cir-  
14           cumstance described in paragraph (1)(A)(iii);

15           “(C) the expected duration of the interrup-  
16           tion; and

17           “(D) such other information as the Sec-  
18           retary may require.

19           “(b) TIMING.—A notice required under subsection (a)  
20           shall be submitted to the Secretary—

21           “(1) at least 6 months prior to the date of the  
22           discontinuance or interruption;

23           “(2) in the case of such a notice with respect  
24           to a circumstance described in subsection  
25           (a)(1)(A)(iii), as soon as practicable, or not later

1 than 10 business days after the onset of the cir-  
2 cumstance; or

3 “(3) if compliance with paragraph (1) or (2) is  
4 not possible, as soon as practicable.

5 “(c) DISTRIBUTION.—To the maximum extent prac-  
6 ticable, the Secretary shall distribute, through such means  
7 as the Secretary determines appropriate, information on  
8 the discontinuance or interruption of the manufacture of,  
9 or other circumstance described in subsection  
10 (a)(1)(A)(iii) that is likely to lead to a shortage or mean-  
11 ingful disruption in the supply of, covered drugs to appro-  
12 priate organizations, including physician, health provider,  
13 and patient organizations, as described in section 506E.”;

14 (3) in subsection (g), in the matter preceding  
15 paragraph (1), by striking “drug described in sub-  
16 section (a)” and inserting “covered drug”; and

17 (4) in subsection (j), by striking “drug de-  
18 scribed in subsection (a)” and inserting “covered  
19 drug”.

20 (b) DEFINITIONS.—Paragraph (1) of section 506C(h)  
21 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
22 356c(h)) is amended to read as follows:

23 “(1) the term ‘covered drug’ means a drug that  
24 is intended for human use and that—

25 “(A) is—

1 “(i) life-supporting;  
2 “(ii) life-sustaining; or  
3 “(iii) intended for use in the preven-  
4 tion or treatment of a debilitating disease  
5 or condition, including any such drug used  
6 in emergency medical care or during sur-  
7 gery or any such drug that is critical to  
8 the public health during a public health  
9 emergency declared by the Secretary under  
10 section 319 of the Public Health Service  
11 Act;

12 “(B) is not a radio pharmaceutical drug  
13 product or any other product as designated by  
14 the Secretary; and

15 “(C) is not a biological product (as defined  
16 in section 351(i) of the Public Health Service  
17 Act), unless otherwise provided by the Secretary  
18 in the regulations promulgated under subsection  
19 (i);”.

20 **SEC. 502. REPORTING ON SUPPLY CHAINS.**

21 Section 510(j)(3)(A) of the Federal Food, Drug, and  
22 Cosmetic Act (21 U.S.C. 360(j)(3)(A)) is amended—

23 (1) by inserting “, and the names and unique  
24 facility identifiers of the manufacturers of the active  
25 pharmaceutical ingredients such person used for the

1 manufacture, preparation, propagation,  
2 compounding, or processing of such drug, and the  
3 amount of such drug manufactured, prepared, prop-  
4 agated, compounded, or processed using each such  
5 active pharmaceutical ingredient from each such  
6 manufacturer” before the period at the end of the  
7 first sentence; and

8 (2) by inserting after the first sentence the fol-  
9 lowing: “In addition to the reporting required under  
10 the preceding sentence, the Secretary may receive  
11 voluntary submissions of such information at more  
12 frequent intervals.”.

13 **SEC. 503. REPORTING ON USE OF NEW AUTHORITIES AND**  
14 **REQUIREMENTS WITH RESPECT TO DRUG**  
15 **SHORTAGES.**

16 Not later than 90 days after the date of enactment  
17 of this Act, the Secretary of Health and Human Services  
18 (referred to in this section as the “Secretary”) shall report  
19 to the Committee on Health, Education, Labor, and Pen-  
20 sions of the Senate and the Committee on Energy and  
21 Commerce of the House of Representatives on—

22 (1) the extent to which the Secretary has imple-  
23 mented the authorities and requirements under sec-  
24 tions 506C(g), 506C(j), 506E(d), 510(j)(3), and  
25 704(b)(2) (21 U.S.C. 356c(g), 356c(j), 356e(d),

1 360(j)(3), 374(b)(2)) of the Federal Food, Drug,  
2 and Cosmetic Act, as amended by section 3111 and  
3 3112 of the Coronavirus Aid, Relief, and Economic  
4 Security Act (Public Law 116–136), including—

5 (A) specific examples of uses of such au-  
6 thorities and requirements; and

7 (B) an assessment of the extent to which  
8 such authorities and requirements have helped  
9 mitigate drug shortages; and

10 (2) the status of the guidance documents that  
11 the Secretary intends to issue with respect to report-  
12 ing and risk management plan requirements applica-  
13 ble to manufacturers of drugs and active pharma-  
14 ceutical ingredients, pursuant to the amendments  
15 made to section 506C of the Federal Food, Drug,  
16 and Cosmetic Act (21 U.S.C. 356c) by subsections  
17 (a) and (b) of section 3112 of the Coronavirus Aid,  
18 Relief, and Economic Security Act (Public Law  
19 116–136).

1 **TITLE VI—ADDITIONAL REAU-**  
2 **THORIZATIONS AND TECH-**  
3 **NICAL AMENDMENTS**

4 **SEC. 601. MEDICAL COUNTERMEASURE PRIORITY REVIEW**  
5 **VOUCHER.**

6 Section 565A(g) of the Federal Food, Drug, and Cos-  
7 metic Act (21 U.S.C. 360bbb–4a) is amended by striking  
8 “2023” and inserting “2028”.

9 **SEC. 602. EPIDEMIC INTELLIGENCE SERVICE LOAN REPAY-**  
10 **MENT PROGRAM.**

11 Section 317F(c)(2) of the Public Health Service Act  
12 (42 U.S.C. 247b–7(c)(2)) is amended by striking “2019  
13 through 2023” and inserting “2024 through 2028”.

14 **SEC. 603. VACCINE TRACKING AND DISTRIBUTION.**

15 Section 319A(e) of the Public Health Service Act (42  
16 U.S.C. 247d–1(e)) is amended by striking “2019 through  
17 2023” and inserting “2024 through 2028”.

18 **SEC. 604. REGIONAL HEALTH CARE EMERGENCY PRE-**  
19 **PAREDNESS AND RESPONSE SYSTEMS.**

20 Section 319C–3(e)(2) of the Public Health Service  
21 Act (42 U.S.C. 247d–3c(e)(2)) is amended by striking  
22 “2023” and inserting “2028”.

1 **SEC. 605. EMERGENCY SYSTEM FOR ADVANCE REGISTRA-**  
2 **TION OF VOLUNTEER HEALTH PROFES-**  
3 **SIONAL.**

4 Section 319I(k) of the Public Health Service Act (42  
5 U.S.C. 247d–7b(k)) is amended by striking “2019  
6 through 2023” and inserting “2024 through 2028”.

7 **SEC. 606. LIMITED ANTITRUST EXEMPTION.**

8 Section 319L–1(b) of the Public Health Service Act  
9 (42 U.S.C. 247d–7f(b)) is amended by striking “at the  
10 end of the 17-year period that begins on the date of enact-  
11 ment of this Act” and inserting “on September 30, 2028”.

12 **SEC. 607. TRAUMA CARE.**

13 Section 1232(a) of the Public Health Service Act (42  
14 U.S.C. 300d–32(a)) is amended by striking “\$24,000,000  
15 for each of fiscal years 2023 through 2027” and inserting  
16 “\$39,000,000 for each of fiscal years 2024 through  
17 2028”.

18 **SEC. 608. MILITARY AND CIVILIAN PARTNERSHIP FOR**  
19 **TRAUMA READINESS.**

20 Section 1291(g) of the Public Health Service Act (42  
21 U.S.C. 300d–91(g)) is amended by striking “2019  
22 through 2023” and inserting “2024 through 2028”.

23 **SEC. 609. NATIONAL DISASTER MEDICAL SYSTEM.**

24 (a) IN GENERAL.—Section 2812 of the Public Health  
25 Service Act (42 U.S.C. 300hh–11) is amended—

1 (1) in subsection (c)(4)(B), by striking “2023”  
2 and inserting “2028”; and

3 (2) in subsection (g), by striking “\$57,400,000  
4 for each of fiscal years 2019 through 2023” and in-  
5 serting “\$65,900,000 for each of fiscal years 2024  
6 through 2028”.

7 (b) REPEAL OF SUNSET.—

8 (1) IN GENERAL.—Section 301(d)(3) of the  
9 Pandemic and All-Hazards Preparedness and Ad-  
10 vancing Innovation Act of 2019 (Public Law 116–  
11 22; 34 U.S.C. 10284 note) is repealed.

12 (2) EFFECTIVE DATE.— Paragraph (1) shall  
13 take effect as if enacted on September 30, 2021.

14 **SEC. 610. VOLUNTEER MEDICAL RESERVE CORPS.**

15 Section 2813(i) of the Public Health Service Act (42  
16 U.S.C. 300hh–15(i)) is amended by striking “2019  
17 through 2023” and inserting “2024 through 2028”.

18 **SEC. 611. EPIDEMIOLOGY-LABORATORY CAPACITY GRANTS.**

19 Section 2821(b) of the Public Health Service Act (42  
20 U.S.C. 300hh–31(b)) is amended, in the matter preceding  
21 paragraph (1), by striking “2019 through 2023” and in-  
22 serting “2024 through 2028”.



1 **SEC. 612. VETERANS AFFAIRS.**

2 Section 8117(g) of title 38, United States Code is  
3 amended by striking “2019 through 2023” and inserting  
4 “2024 through 2028”.

5 **SEC. 613. TECHNICAL AMENDMENTS.**

6 (a) Title XXI of the Public Health Service Act (42  
7 U.S.C. 300aa–1 et seq.) is amended—

8 (1) in section 2105(b), by striking “, 2103, and  
9 2104” each place it appears and inserting “and  
10 2103”;

11 (2) in section 2110(b), by striking “the pro-  
12 gram” and inserting “The Program”;

13 (3) in section 2111(a)—

14 (A) in paragraph (6), by striking “1988  
15 for” and inserting “1988, for”; and

16 (B) in paragraph (10), by striking “United  
17 States Claims Court” and inserting “United  
18 States Court of Federal Claims”;

19 (4) in section 2112—

20 (A) in subsection (c)(6)(A), by striking  
21 “United States Claims Courts” and inserting  
22 “United States Court of Federal Claims”; and

23 (B) in subsection (f)—

24 (i) by striking “United States Claims  
25 Court on” and inserting “United States  
26 Court of Federal Claims on”; and

1 (ii) by striking “United States Claims  
2 Court’s judgment” and inserting “judg-  
3 ment of the United States Court of Fed-  
4 eral Claims”;

5 (5) in section 2115(b)(3), by striking “sub-  
6 section (e)” and inserting “subsection (e)”;

7 (6) in section 2117—

8 (A) in the section heading, by striking  
9 “**SUBROGRATION**” and inserting “**SUBROGA-  
10 TION**”; and

11 (B) in subsection (a), by striking  
12 “subrogated” and inserting “subrogated”; and

13 (7) in section 2127—

14 (A) in subsection (b)(1), by inserting “and  
15 Prevention” before the period; and

16 (B) in subsection (c), by striking “Com-  
17 mittee on Labor and Human Resources” and  
18 inserting “Committee on Health, Education,  
19 Labor, and Pensions”.

20 (b) Section 319F–3 of the Public Health Service Act  
21 (42 U.S.C. 247d–6d) is amended—

22 (1) in subsection (c)(5)(B)(ii)(I), by striking  
23 “chapter 5” and inserting “chapter V”; and

24 (2) in subsection (i)(7)—

1 (A) by striking “321(g)(1))” and inserting  
2 “321(g)(1))”; and

3 (B) by striking “321(h))” and inserting  
4 “321(h))”.

5 (c) Section 319F–4 of the Public Health Service Act  
6 (42 U.S.C. 247d–6e) is amended—

7 (1) in subsection (b)(1), by striking “under  
8 319F–3(b)” and inserting “under section 319F–  
9 3(b)”; and

10 (2) in subsection (d)(5), by striking “under  
11 subsection (a) the Secretary determines that a cov-  
12 ered individual qualifies for compensation” and in-  
13 serting “a covered individual is determined under  
14 subsection (a) to be eligible for compensation under  
15 this section”.

16 (d) Part C of title II of the Public Health Service  
17 Act (42 U.S.C. 239 et seq.) is amended—

18 (1) in section 261(a)(2)(A), by striking “speci-  
19 alities” and inserting “specialties”;

20 (2) in section 265(c)(5), by striking “involves”  
21 and inserting “involved”;

22 (3) in section 266(b)(3)(B)(ii), by striking “to  
23 with respect to an eligible” and inserting “with re-  
24 spect to an eligible”; and

1           (4) in section 267(b), by striking “such Act”  
2           and inserting “such part”.

3           (e) Section 351A(e)(7)(B)(ii) is amended by striking  
4 “judical” and inserting “judicial”.

○